NeuralDx Ltd

SHAREHOLDER

INFORMATION MEMORANDUM

DECEMBER 2022

PROTOTYPING EVESTG™ SYSTEMS

(FOR CLINICIANS and SPECIALISTS USE)

SCREENING, MONITORING AND DIAGNOSING

DEPRESSION – BIPOLAR – CONCUSSION - ALZHEIMER'S.

Registered Office:

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Refer to the 'Risks' section included in Section 10 of this Document for a summary of general and specific risk factors that may affect the Company.

Chairman's Letter

Dear Shareholder

NeuralDx Ltd (NDx) is seeking to advance the commercialisation of its break-through technology for rapidly and accurately diagnosing patients suffering from Central Nervous System Disorders (CNS). The prevalence of such conditions impacts more than 45% of the global population in their lifetime and carry a cost burden predicted to exceed $16 trillion per year by 2030, including over $500 million per day of lost productive output in Australia alone.

The NDx technology, called electrovestibulography and trademarked as EVestG™, uses verified objective biomarkers to screen and diagnose patients for CNS disorders, as described in the peer-reviewed papers listed in Annexure Two. EVestG™ biomarkers are obtained by the recording of deep brain function using electrodes placed non-invasively close to the peripheral balance organs, via the ear-canal, and recording and analysing the resulting signal. This EVestG™ service can be provided to clinicians to determine their patient's probability of experiencing a specific CNS Disorder with greater accuracy and more quickly when compared to the use of current subjective clinical assessment rating scales alone.

Over several years, NDx has established that its EVestG™ proprietary technology can identify a range of CNS Disorders in patients, including Major Depression, Bipolar, Alzheimer's, Post-Concussion Syndrome, Parkinson's, and Vertiginous disorders, including differentiating between similar or closely related disorders. The science behind the EVestG™ technology is supported by the analysis of the evoked neural bio-features extracted from the datasets obtained from 600 subjects, with evidence published in over 24 peer reviewed non-predatory international journal articles. (Annexure One)

There are several areas of EVestG™ application for which great market opportunities exist, and for which clinicians have confirmed a need. NDx's immediate priority applications, as discussed in Section 3 of this IM, are:

- Differential diagnosis of Major Depression from the depressive phase of Bipolar Disorder. Present diagnostic accuracies by GP's are less than 50% [a coin-toss), and a correct Bipolar diagnosis can take up to 9 years to achieve
- Monitoring head trauma in Concussion and emergence of Post Concussive Syndrome (PCS) with or without the comorbidity of Major Depression (MDD). Test data has established that EVestG™ can diagnose both the initial presence of PCS, as well as its further progression where cognitive impairment is present.
- Differential diagnosis of Alzheimer's disease from etiologically Mixed Dementias, and monitoring those suitable for benefiting from physical Therapy, rTMS.
  (See Glossary, Annexure One)

Commercial development of the EVestG™ technology for these and other applications requires several tasks to be undertaken. Of major significance are the design and fabrication of a commercial wireless headset measuring system, the preparation of a formal business case and marketing study, and generation of a revenue model.

Further details of the budget for achieving these tasks can be found in Section 4 of this IM.

VICTORIAN "BREAKTHROUGH" FUND

The Victorian Government has recently announced a new funding mechanism for Start Up companies such as NDx – the **"VICTORIA BREAKTHROUGH FUND"** – to provide up to $2,000,000 non-diluting funds, on a $-for$ basis, with Applicants being required to submit a formal independent Business Case/Market Analysis of the path to market.

Such an Analysis will assist NDx to determine the most appropriate means of establishing the EVestG™ diagnostic system in the marketplace, and to progress the means for obtaining long-term funding to achieve this objective.

Funding is therefore now being sought to:

A. Commission a Business Case and Market Analysis to assist submission for a Victorian Government "Breakthrough" Grant

B. Design and fabricate a commercial prototype Headset (a *Vestibular Signal Acquisition and Transmission Device [VSAD]*) and electrode sets,

C. Initiate discussions with the Therapeutic Goods Administration (TGA), the Food and Drug Administration (FDA), and the European Medicine Agency (EMA) to determine requirements for gaining regulatory approval for commercial use and applying for Breakthrough Device Designation.

D. Develop re-imbursement strategy in respective Health Care subsidised systems.

Yours sincerely

Lou Panaccio

Chairman,

NeuralDx Limited

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1. Commercialisation Strategy

A. Commission a Market Study of the integration of EVestG™ technology into Clinician's and Mental Healthcare Specialist's clinics.

B. Design and fabrication of the Commercial EVestG™ Headset (*a Vestibular Signal Acquisition and Transmission Device* [VSAD]) for use by Clinicians and mental health care specialists.,

C. Formalise the analysis of EVestG™ static test data for submission to a peer-reviewed journal.

D. Commence discussions with regulatory Australian, USA, and European Authorities (TGA, FDA and EMA) as to registration requirements for EVestG™.

E. Undertake a commercialisation pathway by:

- ❖ The promotion of the application and use of the EVestG™ System as a Diagnostic Decision Support Service by Clinicians and Mental Healthcare workers.

Concurrently seek collaboration with:

- ❖ Neuroscience research institutions
- ❖ Pharmaceutical companies for use in drug trials
- ❖ Manufacturing and Distribution Medical Device companies

F. Plan reimbursement strategy

G. Protection of Intellectual Property (patents and trademarks).

H. Corporate overheads and consultants.

2. Business Update

2.1. Background

Over several years, NDx has established Proof-of-Concept evidence that its "EVestG™" proprietary technology can identify a range of CNS Disorders in patients such as Major Depression, Bipolar Disorder, Parkinson's, Alzheimer's, Vertiginous disorders, Post-Concussion Syndrome and can also differentiate between the different Disorders at first diagnostic interview with greater accuracy and speed than current clinical practice.

Professor Brian Lithgow and his team at Monash Alfred Psychiatric Research Centre, and the University of Manitoba and Riverview Hospital Winnipeg have undertaken ethically approved trials in clinical research settings to measure and analyse the neural signals of over 600 subjects. The scientific evidence from such EVestG™ trials has been presented in over 24 peer reviewed journal articles (referenced in Annexure Two and www.neuraldx.com/research).

This past data was obtained with the patient either seated or supine (on-back) in a specialist chair capable of a range of tilt movements (swell, pitch, yaw, roll), as well as being held stationary, to painlessly and non-invasively capture the spontaneously evoked stream of asynchronous field potentials created in the peripheral balance organ emanating from signals in the brain. On analysis of the recorded signal, using its proprietary and patented software NEER (Neural Event Extraction Routine), electrophysiological biomarker signature profiles of each disorder have been identified. Such biomarker patterns have been confirmed in recording of measurements taken while the subject is stationary / still, as well as while in motion (dynamically tilted).

Clinical application and use of the EVESTG™ Headset System.

While most published data from EVestG™ measurements have come from data recorded during both dynamic and static time segments, Proof-of-Concept evidence has also been established using ONLY data from static time segments. This has enabled the classifying of Major Depression from the depressive phase of Bipolar Disorder from Healthy Controls at a diagnostic accuracy of 80% that is significantly greater than that achieved by a general practitioner applying current qualitative assessment methods alone**.** Thus, an MDD/BP diagnosis can be achieved without the need or cost of an integrated tilt-chair

NDx has therefore commenced the design of an EVestG™ Measurement System incorporated into a Headset (VSAD) suitable for use in clinical screening/triaging circumstances without the need for a multi-axis tilt-chair to stimulate dynamic responses. This System will be conveniently available to the patient's Clinician to enable clinical use for early screening and diagnosis as well as monitoring treatment efficacy, progress, or relapse.

In progressing to commercialise its EVestG™ proprietary technology, it has been necessary for NDx to focus on those CNS disorders that it believes will have a major impact on improving current diagnostic methods and where each application provides significant market opportunities.

For this purpose, the Company has elected to focus on the following in **priority order**:

1. **The differential diagnosis of Major Depression (MDD) from depressive phase of Bipolar Disorder (BPAD).**

2. **Monitoring recovery from Mild Traumatic Brian Injury (mTBI) and/or relapse to Post-Concussion Syndrome (PCS), with or without the comorbidity of Major Depression (MDD).**
3. **Diagnosing Alzheimer's Disease (AD) from other dementias (MxD), and monitoring the benefits of pharmaceutical, psychological, or physical therapy, particularly rTMS.**

Each of these Clinical Opportunities are discussed in the following Sections 3.3-3.5.

2.2. EVestG™ and the Balance System (Vestibular)

The EVestG™ proprietary advanced digital signal software and hardware are designed to record and analyse the naturally and continuously asynchronous neural firing of the hair-cell structures of both the left and right peripheral balance organs, sited 5mm behind each eardrum. These structures have a random beat or spike rate of around 90 to 300 firings per second (much faster and smaller in magnitude than the heart), that changes in firing rate, firing pattern and waveform shape when stimulated, in the vestibular case, through movement. These Vestibular structures have bi-directional neural pathways to the brainstem, and onwards to deep and cortical brain structures associated with cognition, emotions, behaviours, and movement, which are also linked to mental and neurological disorders.

Over 10 Masters, 10 PhD's and 4 Post- Doctoral Studies have been successfully examined and undertaken at two leading international universities in Australia and Canada, which resulted in over 24 peer-reviewed paper published on EVestG™ and its performance. These publications provide evidence that the analysed vestibular signal contains biomarker signature patterns that correlate with specific CNS Disorders studies. This correlation/finding is a world first discovery and is seen as a potential breakthrough for the early objective diagnosis of many mental and neurological disorders.

Published EVestG™ results have demonstrated that diagnostic accuracies of >80% have been achieved for approximately 8 common disorders following a 40-minute measurement session, with results possible to be delivered to the treating clinician's desktop within minutes of the session ending.

This accuracy is to be compared with literature that reports GPs achieving less than 50% accuracy for first diagnosis of Major Depression, and only 31% accuracy for correct first time diagnosing of Bipolar Disorder. Further the time to a correct diagnosis of Bipolar Disorder can be over 9 years with more than 3 misdiagnoses in that time. **Achieving 80% accuracy within an hour of measurement is therefore considered a paradigm changing breakthrough**.

2.3. Diagnosing and differentiating MDD from BPAD

Depression is a disease with major personal, social, and economic impacts in Australia and worldwide. Globally depression is the single largest contributor to years lived with disability (World Bank brief on Mental Health, 2017), with over 300 million people affected worldwide (WHO Depression Fact Sheet, 2017). Best estimates are that between 4% and 10% of all people will experience major depression at some point in their lifetime, with lifetime prevalence of depression in Australia reported to be even higher than this, at 16.6%, and similar rates in the United States (16.1%).

Field trials for the Diagnostic and Statistical Manual version 5 (DSM-5-TR), the latest version of the American Psychiatric Associations classification of mental disorders, found only 'questionable' agreement between clinicians in the diagnosis of several psychiatric disorders, including major depressive disorder (Freedman et al. 2013, Regier et al. 2013).

This was between clinicians with at least 2 years or more of specialist psychiatric training (Clarke et al. 2013).

In essence, trained clinicians regularly fail to reach consensus in relation to MDD diagnoses.

Further concern is that the majority (perhaps 80%) of initial diagnosis and treatment decisions in respect of MDD and BPAD are made by GPs.

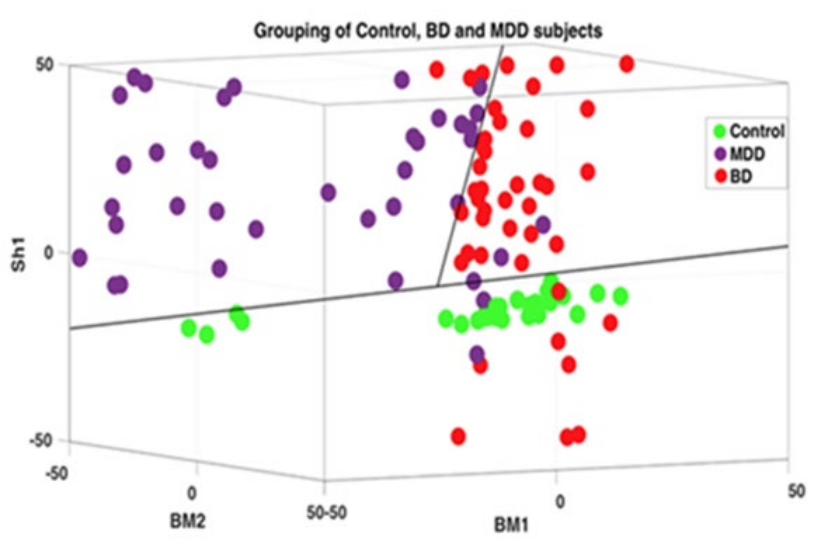
As well as the substantial personal and social burdens to the sufferer, including a 4x higher suicide risk, depression also has significant economic cost, with worldwide lost economic output due to depression estimated to be at least US$800 billion in 2010, and expected to more than double this by 2030 (World Bank Brief on Mental Health, 2017). Depression is estimated to cost the United States US$210 billion a year, with the cost in Australia estimated as high as A$12.6 billion annually.

The Table below sets out the separation of control (normal) subjects from patients with Major Depression (MDD) from those suffering the depressive phase of bipolar disorder (BPAD) by utilising only three different EVestG™-measured biomarkers. The data were obtained from patients undergoing evoked responses resulting from both static and dynamic stimulation.

CLASSIFICATION	EVestG Biomarker Features		
	Combined* STATIC and DYNAMIC	STATIC Only	Accuracy Difference
MDD from Control	78% to 87%	76%*	2% to 11%
Bipolar from Control	75% to 79%	75%	0% to 4%
MDD from Bipolar	84%	82%	2%

The close agreement in diagnostic accuracy between the dynamic and static measurements supports the use of static testing without the need for a specialist chair to generate the evoked response for a fast-screening service.

That said, the scatterplot below demonstrates the higher classification accuracy from use of both static and dynamic EVestG Biomarkers for diagnostically separating Bipolar Disorder from Major Depression.



2.4. Diagnosing and differentiating recovery from mild-Traumatic Brain Injury (mTBI) and emergence of Post Concussive Syndrome (PCS)

Current diagnosis of PCS and its severity following an mTBI event is difficult, slow, and inaccurate, and made more complex by the "all too often" comorbidity of Major Depression, with its inherent risk of suicide, and Chronic Traumatic Encephalography emerging after multiple injuries over a sporting career.

Consequently, in the absence of any other diagnostic technology for such conditions and comorbidities, there is a need for an accurate and objective technology, such as EVestG™, capable of objectively measuring brain function and symptoms associated with confusion, balance, cognition, and depression, for monitoring the immediate severity of a concussion, and any relapse and possible emergence of PCS, or recovery and fitness to "return-to-play".

Public focus and concern as to long term harm occurring in contact sports such as Australian Rules, Rugby, Soccer, Boxing, Cycling and now Cricket, is rapidly growing.

A 5-year study by Dr Stuart McDonald at Monash University published in January 2021 has confirmed that physiological consequences of concussion last much longer than previously believed. Dr McDonald stated, *"It's very difficult to actually establish when a player has recovered from concussion and it's completely reliant on self-reporting of symptoms."*

In addition, the revelations in early December 2020 that a group of former rugby players in the UK have been diagnosed with dementia and probable chronic traumatic encephalopathy (CTE) and consequently intend to take legal action against World Rugby and the Rugby Football Union in England, is only the latest in a very long line of similar litigation.

The NFL in the US has already paid out damages well over $1 billion to thousands of former players, as well as faced damning evidence about the prevalence of traumatic brain injury and long-term neurological damage sustained by them.

In Australian Rules Football, the recent insurance payment to former AFL player Shaun Smith for "total and permanent disablement" due to head knocks sustained during his playing career follows revelations earlier that former greats Graham "Polly" Farmer and Danny Frawley were both found to have had CTE after their deaths in the past year.

2.4.1. EVestG™ and mTBI/PCS

In Ontario, Canada, "Rowan's Law" – instigated in 2016 after the sports concussion-related death of a teenager, Rowan Stringer – mandates that annual concussion education be given to all who participate in contact sport.

In 2015, Professors Lithgow and Moussavi and one of their Post-Doctoral Fellows at the University of Manitoba realised that this Rowan's Law situation could become more universal and needed appropriate and convenient technology, such as the EVestG™ Headset VDAS System, for on-going routine monitoring of participants and those injured.

In late 2019, they published data in a series of articles in Nature Scientific Reports of EVestG™'s ability to accurately detect and monitor recovery from concussions and the emergence of Post-Concussion Syndrome (PCS), as well as the beneficial effectiveness of using Trans Cranial Magnetic Stimulation (TMS) to assist in the treatment of PCS.

One of these Papers is titled ***"mild Traumatic Brain Trauma (mTBI) and the emergence of Post-Concussive Syndrome (PCS) with and without moderate /severe MDD"***

(See www.neuraldx.com/research).

Concussion and Static Response Biomarker Feature Test Data

Data analysis from patients using static stimulation to assess concussion provided the following calculated accuracies of assessments:

- Control from all Concussion patients – 84%
- Control from short-term Concussion patients – 95%
- Control from long-term Concussion patients – 77%
- Short-term Concussion patients from long-term Concussion patients – 79%

The data give confirmation of the value of EVestG™ technology for application in assessing concussion, which can be applied in a number of areas of social and sporting activity.

2.5. EVestG™ and Alzheimer's Disease and Other Dementias

Based on autopsy, about 1 in 5 Alzheimer's disease (AD) diagnoses can be incorrect, and AD makes up approximately 66% of dementia cases. Other dementia types (such as Cerebral Vascular Dementia – (cvad), Lewy body, Parkinsonian, frontotemporal, etc.) often confound both conventional diagnosis and result in ineffective/suboptimal treatment.

The most common form of mixed dementia (MxD) diagnosis is a mix of AD plus vascular symptomatology (cognitive problems stemming from insufficient blood flow to portions of the brain creating areas of dead tissue), and to date, literature references confirm that there is no consensus for the diagnosis of MxD.

Significantly, recent published works in 2021 by Professor Lithgow and colleagues has demonstrated that EVestG™ can achieve an over 90% diagnostic classification between AD and AD + Cardio-vascular disorder.

2.6. EVestG™ and rTMS Therapy

Repetitive Transcranial Magnetic Stimulation (rTMS) is a non-invasive brain stimulation therapy that uses repetitive electromagnetic pulses to stimulate nerve cells and has been demonstrated to improve symptoms of neurological or mental health disorders in approximately 50% of those with Treatment Resistant Depression (TRD).

rTMS has successfully provided an alternate therapy to pharmaceutical resistant depression for both MDD and BPAD, as well as to treat cognitive decline in dementia patients, and in treating concussed sports people.

Noting that many dementia and concussed sufferers also experience severe depression, there is a need to objectively evaluate these symptoms before effectively addressing their underlying disorder or trauma.

Regardless of severity and the type of disorder suffered, it is known that about 50% of patients are non-responders to rTMS therapy. Therefore, rapidly, and accurately identifying these non-responders will save wastage of scarce clinical resource as well as costly and time consuming rTMS Therapy.

Again, EVestG™ has peer-reviewed published evidence of it being able to identify non-responders for all of its prioritised disorders (AD/MDD/BPAD/mTBI/PCS) discussed above, as well as to predict those who will benefit from rTMS Therapy.

The saving from such an EVestG™ Headset VDAS System to the healthcare system will be significant. For example, in November 2021, the Australian Government provided a budget of $288 million over 4 years to the MBS to reimburse users of rTMS therapy for the treatment of MDD and BPAD alone, of which there is the probability that 50% will be wasted by being applied to non-responders. Incorporating a low-cost EVestG™ Screening test at $300, to identify non-responders prior to them undertaking a costly rTMS Program at >$3000, would provide an excellent cost effectiveness proposition for the community.

3.0 EVestG™ Patents and Intellectual Property

Three (3) Patents are registered in 7 countries, with one pending.

Exclusive exploitation rights across several jurisdictions, including the United States, Canada, United Kingdom, Europe, Australia, China, India, and Japan.

A Neural Event Process ***WO 2006/024102***

This patent family covers details of the algorithm used to extract the electrical signal from the electrically noisy recording.

A Neural Response Process ***WO 2008/144840***

This patent family covers specifically the extraction of signals in response to a tilt stimulus and subsequent processing to produce biomarkers.

A Neural Analysis System ***WO 2010/148452***

This patent family covers details involved in extracting biomarkers from the obtained signals and in providing an assessment of a diagnosis related to such biomarkers.

Vestibulo-Acoustic Signal Processing **PCT/AU2018/050477**

This patent was lodged in May 2017 and extends the understanding of the neurophysiological components of the EVestG™ signal. It also expands upon the ways that this signal is analysed to obtain the diagnostic biomarkers for classifying a sufferer with either Major Depression or Bipolar Disorder or other disorders.

4. NDx Development Plan

4.1 Market Analysis

4.1.1 The Challenge of Mental Health Diagnosis

Mental Illness is recognized as a 'National Health Priority' by the Australian Government and other Governments World-wide. However, globally, the continued reliance on **SUBJECTIVE** assessment rating scales and checklists set out in Gold Standard Diagnostic Manuals, such as the DSM-5 (and conversely the absence of an efficient, **OBJECTIVE** diagnostic technology) results in unacceptable levels of misdiagnosis of mental and neurological disorders and delays in delivering effective interventions for sufferers.

The focus of NDx is on screening, classification, diagnosis and monitoring of Major Depression (MDD), Bipolar Disorder (BPAD), Concussion (mTBI/PCS), and Alzheimer's AD and other Dementias (MxD).

Best estimates of the most common mental disorder (Major Depression) are that between 4% and 10% of the population will suffer at some stage in their lifetime, with lifetime prevalence of depression in Australia reported to be even higher than this, at 16.6%, and similar rates in the United States (16.1%).

Field trials for the Diagnostic and Statistical Manual version 5 (DSM-5), the GOLD Standard Manual for classification of mental disorders, found only 'questionable' agreement between clinicians in the diagnosis of a number of psychiatric disorders, including MDD (Freedman et al. 2013, Regier et al. 2013).

Indeed, the Lancet reports that GPs, (who deliver over 80% of mental healthcare services), only achieve a 50% accuracy for Major Depression at first consultation, and other literature indicates that sufferers of Bipolar Disorder can expect to be mis-diagnosed 69% of the time at first consultation and can expect over 3 further misdiagnoses over 10 years before a correct intervention is achieved. (Hirschfeld, 2006). Similar delayed and inaccurate diagnoses occur for many other brain disorders.

NDx internal studies confirm that the annual global cost burden of neurological and mental disorders will exceed $16 trillion per year by 2030, which in turn creates global market opportunities for medical technologies which improve the speed and accuracy of diagnosis of these brain disorders, as well as reduce the overall cost burden on the community. Considerable value will be placed on technologies, available at Clinics, Hospitals and at home or sports grounds, that can provide an objective, accurate, quick, and affordable diagnosis, or screening of a patient to ascertain whether or not that patient is suffering from a mental illness or concussion.

While NDx has assembled the following information on the potential for NDx to market its EVestG™ technology, the Company proposes to commission independent market analyses and business case development to better define and quantify the pathway into the "mental Illness" market.

In particular, better definition of distribution routes and the drivers of adoption rates in the specified market segments will assist in planning and achieving faster roll-out.

4.2 Commercial Opportunities

NDX has identified 6 market segments as potential clients for EVestG™ Product and Services.

Priority will be given to Major Depression and Bipolar.

4.2.1 Neuroscience Research Institutions

Clinical Research Institutes, as the innovators in early technology adoption, will provide the early market entry opportunity, using a CE-Certified EVestG™ System marketed for R&D Measurement purposes ONLY. Regulatory approval is not required.

NDx understands that in the absence of a low cost, objective and sensitive measurement instrument of brain function, and the scarcity of research grants, neuroscientists around Australia and globally struggle to find funds to undertake the necessary large-scale projects to solve many of today's brain-related research challenges. They are forced to rely upon the use of slow, subjective, and inaccurate assessment rating scales as well as meeting the costs of accessing expensive imaging devices for use in generating objective data for publications. We see this large sector as a natural early client and partner for the EVestG™ Technology, as well as a source for future practitioners of EVestG™.

4.2.2 Direct Clinical Use

Once validated by future registered Clinical Trials, EVestG™ Headset VDAS System can provide a Diagnostic Decision Support Service to Clinicians and mental healthcare professionals.

The patient's GP/psychiatrist would have available in the clinic (e.g. comparable to an ECG unit) an EVestG™ Headset (VSAD) to quickly and objectively screen/diagnose the patient's neural signals to assist in the clinician's diagnosis of MDD, BPAD or PCS (and possibly other co-morbidities).

TGA and FDA Regulatory Approvals will be required for the EVestG™ Headset VDAS system as a Medical Device before a commercial service can be delivered.

Such approvals require Validation Data obtained from Randomised and Blinded Clinical Trials of sufficient size to allow for high statistically confident separation of one cohort from another, and would initially, be centred upon diagnosing MDD and BPAD and distinguishing one from the other.

The proposed Market Analysis to be commissioned to support this approach would include a clinical study of Psychiatrists and GPs involving:

- workshops with GPs and Psychiatrists focussing on the methodology of integration of the EVestG™ Diagnostic Decision Support Technology into clinical practice, hospitals, and other locations.
- qualitative research in one-on-one in-depth interviews of the needs and expectations of GPs and Mental Health care professionals in the modern digital age.
- quantitative research survey of Australian GPs and Psychiatrists
- gathering of information on the unmet need for diagnostic support and how EVestG™ technology may meet this need.

The results from such a study would set the basis for the development pathway and enable more precise estimates to be made of future revenues.

4.3 Potential Revenue

Whilst an independent business and market analysis will be undertaken, the following general information is indicative of revenue potential.

In Australia, there are 3,615 Psychiatrists, 540 Neurologists, 16,700 Clinical Psychologists and 43,400 GPs dealing with patients suffering from Mental and/or Neurological Disorders. There is a recognised shortage of all mental healthcare clinical professionals where over-work and burn-out are commonly reported, particularly in time of COVID-19, hence a validated and objective Diagnostic Decision Support Services is expected to be willingly accepted.

More than 10% of the Australian population received specific Medical Benefit Scheme (MBS) supported mental health care in 2019–20, almost doubling the rate from the previous 10 years. The majority of these services (82%) were provided by a GP. (Royal Australian College of GPs 2021).

In relation to the USA (population of >330 million), as of September 2020 there were 30,451 practicing psychiatrists, a ratio of 9 physicians per 100,000 people, with an estimated workforce deficit of 6.4%. By 2025, this deficit is projected to escalate to 25%, with Key Opinion Leaders predicting that the demand for psychiatry in the USA will outstrip supply by 15,600 psychiatrists.

For both countries (Australia and USA), it is evident that with the pressure on clinicians, access to a validated EVestG™ technology that provided a more accurate, and timely method of patient assessment and diagnosis will be welcomed.

Supply Side Analysis

Initial NDx's target geographic markets include the following nations Australia / New Zealand / USA / Canada / UK / France / Germany / Austria / Netherlands / Italy / Japan / South Korea, which create a population approaching 1 Billion people of whom 10% (a conservative estimate) will suffer from a mental illness in any year.

They are serviced by approximately 12 Psychiatrists and 250 General Practitioners per 100,000. For Australia, this figure is similar at 14 psychiatrists per 100,000 (3,615 in total), and for all target clinicians the figure is 247 per 100,000 (64,255 in total).

A Cogentum Market Research study undertaken in the USA for NDx indicated that about 2.5% of professionals in a particular field could be classified as "innovators/early adopters" of a new technology, taking it up in the first year. If this figure is applied to Australian clinicians, it indicates that about 1,600 clinicians would be early adaptors, with about 100 of these being psychiatrists. These would provide the basis for early introduction of EVestG™ technology into the clinical market. Royal Australasian College of General Practice accepts that the range and frequency of problems managed in primary care is similar between Australia, the USA, and the UK.

In Australia, > 80% Mental Healthcare is delivered by GPs (representing an estimated 12-20% of their patients) and only 20% by psychiatrists, the former tending to mostly deal with Depression/Depressive Symptom and Anxiety and refer on more complex cases to specialists for management. In 2019, there were MBS subsidised 37,626 Diagnosis and Management Plans prescribed by Australian-registered Psychiatrists. The scope for reimbursement of EVestG™ technology within the MBS system is evident.

NDx would initially, whilst the market was established, consider providing the Headset free conditional upon a minimum of 50 tests undertaken per annum. Thereafter the Clinician would either lease or buy an EVestG™ Point-of-Care System, anticipated to cost less than $6,000.

For an EVestG™ test, a Medicare item reimbursement subsidy like that for extra-tympanic Electrocochleography would be anticipated, i.e., approximately $200 per service for ECochG or $335 for EEG. (See Medical Benefits Scheme (MBS) Item Numbers 11000, 11003,11005, and 11303). NDx would charge $125 - $160 for supplying a Diagnostic Decision Support Analytical Report and single-use electrode set to the Clinician. The balance of the patient fee payable to the Clinician plus any "gap".

Note: In comparison to current best practice, a recognised standard Service fee for MBS Item No 291 - Psychiatric diagnosis is $485.

Demand Side Analysis

An internal initial conservative estimate of potential revenue for NDx in Australia alone, once the Technology has been approved for clinical use, is based on the following assumptions:

- Australian population 26 million
- 10% will suffer from a brain disorder in any year, and of those 10% are estimated to likely seek to gain access to EVestG™ analysis at (say) $125 per assessment and report.

These assumptions lead to an estimated 260,000 EVestG™ measurements in Australia per year, with a total revenue of $70.8m of which approx. $32m would flow to NDx. Revenue flows would of course be substantially increased by maximising uptake and application of the technology in much larger markets internationally.

4.5 Anticipated Budget - Stage One of Commercialisation

NOTE - R&D cash rebate is an estimate only. All expenses are informed estimates.

• **Design and fabrication of Vestibular Signal Acquisition Device (VSAD) Headset and Electrode CE-Marked prototypes**	**$ 360,000**
• **MAPrc Clinical Performance Verification Testing of Prototype**	**$ 185,000**
• **Business cases for Clinical Market Access GP/Specialist Clinics (Aust. Only)**	**$ 150,000**
• **Regulatory, Reimbursement Pathway Analyses**	**$ 50,000**
• **R&D Clinical Study (at Manitoba) – extend Static Data Analysis And submit Static Biomarker Paper**	**$ 150,000**
• **Progress new electrode design concepts + Anxiety Biomarker Research**	**$ 25,000**
• **IP Management**	**$ 80,000**
• **NDx Overheads, Project Management, Office, IT, Phone**	**$ 200,000**
• **Contingencies**	**$ 200,000**
TOTAL	**$1,400,000**
Less R & D Rebate (estimate)	**$ 400,000**
TOTAL	**$1,000,000**

No provision for additional revenue (if any) from Government Grants such as the Victorian "Breakthrough" programme.

5. Competitive Advantages of EVestG

TECHNOLOGY	DESCRIPTION / COMMENT ✓ Strength – x – Weakness • - Feature
EVestG™/NEER™* (see Annexure One – Glossary)	• Objective Analysis of vestibular system naturally evoked responses. • The subject is passively relaxed with eyes closed in a quiet darkened room. ✓ Accurate results can be obtained within an hour. ✓ The procedure uses six minimally invasive electrodes painlessly applied. ✓ EVestG™ is inexpensive, and cognitively, linguistically, and culturally neutral.
Electroencephalography (EEG/ ERP) – • **Total Brain Ltd** • **Elminda Inc.**	• After 100 years since invention, EEG is mostly used for epilepsy, determining brain death and depth of Anaesthesia. • EEG requires subject to be cognitively alert during most testing. × To date, EEG has not been validated for either MDD or BPAD. × Requires >64 electrodes – slow to administer, × Complex analysis due to many ERP feature correlations. × Inconvenient and time–consuming to undertake and clean-up. [>2 hours]
Blood and Cerebral Spinal Fluid tests	• Commercially available **MD score** multi assay based on 9 blood markers. × Invasive tests with an often-variable turn-around time and requiring specialist processing facilities.
fMRI / PET / SPECT / MEG Imaging	× Costly and are generally used to exclude other disorders causing symptoms. × PET can detect Amyloidβ and Tau in Alzheimer's and assist with other dementias. × PET uses radio-nucleotides
Psychiatric diagnosis [DSM-5; ICD-10] Standardised Subjective Criteria	× Prolonged hour consultations (generally >2) applied by a trained clinician using a structured qualitative assessment rating scale and checklist. × It can often be expensive, and there is questionable agreement as to symptoms between clinicians when examining the same patient, as objective measurements are not used. × Accessing a psychiatrist can often involve long wait times, long travel time, and high costs, due to Psychiatrists being concentrated in major metropolitan locations.
GP Diagnosis	• Use DSM-5 /ICD-10 diagnostic manuals / checklists subjective approach • >80% of depressed patients are diagnosed by GPs, who also regularly treat patients they suspect are suffering from mental and neurological disorders. × When assessing a patient who is suffering from depression, a correct diagnosis is only achieved 50% at first or second interview.
Medibio ID	• Diagnosis of depression based on circadian heart rate variability during sleep and wake. Measured over a minimum 24hr period. • Claims to diagnose Depression from Anxiety, × No recent peer-reviewed publications of note. × This product has not been validated and is only promoted as an aid, along with general health monitoring.

6. Early-Stage Innovation Company [ESIC]

The Company qualifies as an **Early-Stage Innovation Company [ESIC]** meeting the defined Early-Stage Tests and is thus able under the "**Tax incentives for innovation**" scheme [Scheme] (as it is involved in innovation), to self-assess eligibility on the 100 points based "Gateway" test.

Because of the company's eligibility under the Scheme, a subscriber to shares in this company will qualify as an investor able to claim under the "Tax Incentives for Early Investors" section of the above Tax Incentive for Innovation Scheme.

A "Sophisticated Investor" under section 708 of the Corporations Act may claim a non-refundable carry forward tax offset equal to 20% of the amount paid for the qualifying investments. This is capped at a maximum tax offset amount of $200,000. If not a Sophisticated Investor, the subscriber can invest up to $50,000 in that year and claim a 20% offset ($10,000).

Also, a modified capital gains tax (CGT) treatment exists, under which capital gains on qualifying shares that are continuously held for at least 12 months and less than ten years may be disregarded. Capital losses on shares held less than ten years must be disregarded. The modified CGT treatment is not limited to the shares which can claim the tax offset.

The above statement is made in good faith based on independent expert advice. However, investors who intend to take advantage of this Scheme are advised to seek independent advice as to their personal eligibility.

See https:/www.ato.gov.au/Business/Tax-incentives-for-innovation/in-detail/Tax-incentives-for-early-stage-investors. Shareholders should seek their own advice before taking up this Offer.

FOR MORE COMPANY INFORMATION VISIT THE WEB SITE – www.neuraldx.com

7. Material Contracts

7.1 Asset Sale Agreement

- On 1st June 2017, NeuralDx Ltd acquired the EVestG™ technology from Neural Diagnostics Pty Ltd (NDPL) for consideration of A$500,000.
- NDPL had been exclusively licensed by Monash University to commercialise the technology.
- Payment of this sum has been deferred by agreement until NDx has achieved an ASX Listing.

7.2 Monash IP Royalty

- The EVestG™ technology was initially developed in collaboration with Monash University, which is a shareholder in NeuralDx Ltd.
- The technology has now been transferred to NeuralDx Ltd subject to a royalty of 1% of gross sales revenue and 5% of sublicense income received by NeuralDx Ltd from commercialization of the technology.

7.3 Consultancy Agreement with Prof B. Lithgow (Inventor)

- Prof. Lithgow is to receive an annual salary of $120,000 commencing upon ASX Listing. Until any such listing, the salary is $108,000 p.a. based on three days a week.
- All IP and R&D knowledge accrue to NeuralDx Ltd.
- Fees approximating $400,000 have been accumulated but by agreement have been deferred until Listing.

7.4 R&D Agreement with University of Manitoba, Canada.

- The Agreement commenced 13 December 2016 (transferred from NDPL).
- It expires in 2023. It is intended to extend this License.
- The benefit of all IP and R&D knowledge accrues to NeuralDx Ltd.
- The University of Manitoba is responsible for ethics approval and recruiting of test subjects.

7.5 Multi-Centre Clinical Trial Service Agreement

- This in principle agreement with Monash Alfred Psychiatry Research Centre (MAPrc) provides for the testing of 480 subjects as part of achieving TGA/FDA Regulatory approval.

8. Directors and Management

Mr Lou Panaccio **Non-Executive Chairman**

Lou is a Chartered Accountant with extensive executive management experience in business and healthcare services.

He is currently on the boards of ASX listed companies Genera Biosystems Limited (non-executive Chairman from July 2011, non-executive Director from November 2010), Avita Medical Limited (non-executive Chairman from July 2014) and Rhythm Biosciences Limited (non-executive Director from August 2017). Lou has more than 30 years of executive leadership experience in healthcare services.

Mr Charles Hider LL B (Melbourne) **Executive Director**

Charles is formerly Chairman of Partners of Rigby Cooke, Solicitors, Melbourne. He has practised as a Barrister and Solicitor of the Supreme Court of Victoria since 1970, and has gained extensive international legal, commercial, and negotiating experience in respect of Technology and Resources. For 10 years, he was a member of the Victorian Parliament. Charles was formerly a Director and Chairman of several ASX listed resource companies.

Associate Professor Harry Minas MBBS, FRANZCP **Non-Executive Director**

Harry graduated in medicine and surgery, and medical science, from the University of Melbourne [UoM]. During his BMedSci studies, he contributed to the early scientific work that resulted in the Cochlear implant. He was foundation director of the Victorian Transcultural Psychiatry Unit.

Since 1995, he has also been Director of the UoM Centre for International Mental Health, Melbourne School of Population and Global Health.

He has served as a member of the Executive of the Mental Health Council of Australia and on numerous state, national and international boards, and committees, including ministerial advisory groups. He has led the development of research, teaching and service development activities around transcultural mental health and in the field of international mental healthcare service development.

Dr Len Walker, B.Eng. (Melb), Ph.D. [Cantab], MBA (Melb.) **Non-Executive Director**

Len has two degrees in engineering from Melbourne University. He graduated with a Doctor of Philosophy from Cambridge University in 1967, and Master of Business Administration from Melbourne University in 1973. From 1967 to 1985, Len practiced as a consulting engineer, and for ten years was Managing Director of one of Australia's leading geotechnical and mining engineering consulting companies.

Since 1985, Len has initiated and invested in the development of several resource companies, both private and publicly listed on the Australian Stock Exchange, involving the acquisition of assets, management of staff and raising of capital for project development. His professional activities have been undertaken in a range of countries in Europe, America, and Asia.

Management

Dr Roger Edwards, B.Sc. (Hons) Mech Eng., (Surrey), Ph.D. (Strathclyde) **CEO**

Roger is a biomedical engineer and has worked in senior executive roles in therapeutic device regulation, R&D, and manufacturing of medical devices, as well as other industry sectors. As

Executive Director of the Food and Packaging CRC, Roger was instrumental in creating 4 spin-offs, licensing two technologies internationally, and raising over $5m in investment capital and other grants.

Associate Professor Brian Lithgow BSc, MSc (Monash)(Inventor) Chief Research Officer (CRO)

Brian was until recently the Director of Teaching for the Monash University Centre for Biomedical Engineering and the Leader of the Monash University Diagnostic and Neuro-signal Processing Research Group. He is now Assoc. Professor at the University of Manitoba. In the past he has worked for Defence and in Industry in positions including Chief Electronic Design Engineer and Deputy Director of Clinical Engineering.

His research interests focus on Vestibular (Meniere's Disease) and Neurological (Depression and Parkinson's Disease) Diagnostics and include modelling of the auditory and vestibular systems, Tinnitus suppression, cochlear implant signal processing, and the application of time-frequency and statistical signal processing techniques to speech.

His publications include over 75 refereed publications (8 peer reviewed journal articles), 4 patents, 6 books, 2 chapters and 3 reports.

Dr Chris Green PhD. **1983. (Lancaster University, UK). MIET. CEng**. **Consultant Electronics Engineer**

Chris was previously Director and Manager of Texas Instruments Australia Pty Ltd. And spent 38 years working in various operational areas of the international semiconductor electronics business including research, product design, product engineering, manufacturing, marketing, business development, technical sales, account management and general management. His recent focus has been deep technical and commercial support for some major medical Players to assist their growth within their markets.

Prof Zahra Moussavi Canadian Chair; Professor of Biomedical Engineering (University of Manitoba).

Zahra has led the establishment of an EVestG™ facility in her University Department at the University of Manitoba and the Riverview Hospital.

She has initiated a longitudinal study to determine if EVestG™ can discover and validate electrophysiological biomarkers for some Dementias [e.g., Alzheimer's] and the monitoring the effectiveness of physical rTMS Therapy.

8.1. NDx Organisational structure for Pre IPO activities

NeuralDx Ltd currently has three full-time consultants and several part-time consultants and contractors, which are adequate to undertake the Budgeted programme outline in this IM.

Funds raised will be used to hire additional Australian resources if required Pre IPO raise.

8.2 Management Post ASX Listing

During this period and conditional upon ASX Listing, a search will be undertaken for an experienced CEO and support staff to carry NDx forward and to obtain ISO 13485 Accreditation for NDx, and appropriate consideration given to restructuring the Board

8.3 Scientific Advisory Committee

Post this Pre-IPO Raising a number of highly qualified experts in mental health will be invited to join a Scientific Advisory Committee chaired by Professor Harry Minas utilising Harry's national and international networks in mental healthcare.

9 Investment Risks

General

Investment in NeuralDx involves various risks and should be considered speculative. Neural*Dx*'s business activities are subject to risk factors both specific to its business activities and of a general nature. While some of these risks can be mitigated using appropriate safeguards and systems, many are outside the control of Neural*Dx* and cannot be mitigated.

Before deciding whether to invest in Shares, prospective investors should carefully consider the risk factors described below. If any of these risks and uncertainties, together with the possible additional risks and uncertainties of which the Directors are currently unaware or which they consider not to be material in relation to **NeuralDx** 's business, actually occur, **NeuralDx** 's business, financial position or operating results could be materially and adversely affected.

It should be noted that the list is not exhaustive and that certain other risk factors may apply.

You should also seek your own professional advice in relation to the risks associated with an investment in **NeuralDx** and should make your own assessment as to whether to invest.

Key Risks to an Investment in NeuralDx

The key risks which the Directors consider are associated with an investment in the Company are identified below.

i. Limited operating history

NeuralDx has a limited operating history, and the potential of its business model is unproven.

No assurances can be given that **NeuralDx** will achieve commercial viability through the successful implementation of its business plans. There is no guarantee that the proposed marketing and pricing strategies will be successful to achieve a sizeable take up rate by users of its diagnostic products and/ or market share.

ii. Funding requirements

Operating costs, net losses and negative cash flow from Company operations may increase for the foreseeable future, due primarily to increases in expenses for clinical trials, further product development, and increased staff costs should the research prove successful. The time required for the Company to reach or sustain profitability is highly uncertain and the Company may not be able to achieve or maintain profitability. Also, if the Company does achieve profitability, the level of any profitability cannot be predicted and may vary significantly.

The Company is likely to need additional funds in the future to continue to develop and fund its business. However, to the extent that the Company's capital resources are insufficient to meet future capital requirements, the Company may have to raise additional funds to continue the development of its technology. The success or otherwise of fund raising from time to time will depend upon market conditions.

The Company may not be able to raise funds on favourable terms or at all. The Company's current operating plan could change because of many factors and the Company may require additional funding sooner than anticipated.

The Company's requirements for additional capital may be substantial and will depend on many factors, some of which are beyond the Company's control, including:

- Slower than anticipated progress in research.
- Requirement to undertake additional research.
- Adverse clinical trial results.
- Competing technological and market developments.
- The cost of protection of patent and other intellectual property rights; and
- Progress with commercialisation.
    - Technology development is inherently high risk, and the above risks are not exhaustive.
    - Other risks may become evident with further development of the technology and commercial relationships.

iii. Uncertainty of Research

The success of the Company is dependent on the quality of the pilot research it has under development, its results, and its acceptance in the market. There are risks related to the successful research and development of any technology and ensuing commercialisation. Product development involves lengthy processes and is subject to evaluations by external groups such as the United States Food and Drug Administration (FDA) and Australian Therapeutic Goods Administration (TGA). There is a risk inherent in activities of this nature that obtaining approvals may be affected by factors outside the control of the Company and its partners, including but not only that government agencies may not process applications in a timely manner or that their activities may be interrupted or delayed due to government policy changes or funding not being available.

Additionally, new products must also find acceptance in a competitive marketplace. Market acceptance will depend on many factors, including convincing potential customers and alliance partners that the Company's product is more attractive than other alternative products and the ability to manufacture products in sufficient quantities with acceptable quality at an acceptable cost. Because of these and other factors, our technology may not gain market acceptance; where that is the case it will mean that it is unlikely that the Company will become profitable.

To continue the Company's research and development of its projects and investments, the Company may from time to time enter new business initiatives. Such arrangements will expose the Company to risks commonly associated with such ventures including amongst others assimilation of the new operations and personnel into the Company.

There can be no assurance that any potential venture will not have a material adverse effect on the Company's business, financial conditions, and operations.

iv. Commercialisation

The commercialisation of technology developed by the Company might require the licensing of technology to or from other entities. The Company cannot give an assurance that such licences will be obtained or, if obtainable, will be on commercially acceptable terms. Further, there is always the risk that licensing arrangements, once negotiated, could be terminated for reasons that may be beyond the Company's control.

Other Risks Specific to the Company

v. Intellectual Property

Obtaining, securing, and maintaining rights to technology and patents are an integral part of securing potential product value in the Company's activities. Competition in retaining and sustaining protection of technology and the complex nature of technologies can lead to patent disputes.

The Company's success depends, in part, on its ability to continue to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of third parties.

Additionally, success may depend on the Company enforcing and defending its intellectual property against third-party challengers.

Because the patent positions of biotechnology and pharmaceutical companies can be highly uncertain and frequently involve complex legal and factual questions, neither the breadth of claims allowed in biotechnology and pharmaceutical patents, nor their enforceability can be predicted. There can be no assurance that any patents which the Company may own, access or control will afford the Company commercially significant protection of its technology or its products or have commercial application, or that access to these patents will mean that the Company will be free to commercialise its technology.

vi. Competition risk

While the Company is currently of the opinion that there are limited competitors in the market, it is a constant risk that the Company may face unexpected competition in the industry in which it operates.

The biotechnology and medical technology industries are characterised by rapid and continuous technology innovation.

Consequently, the Company may face high competition as new companies enter the market and advances in research and new technologies become available. The Company's technology, services and expertise may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by the Company or one or more of its competitors.

Competition could adversely impact the Company's market share and cause downward price pressure on the Company's margins and revenue. Existing and new providers of neurological diagnostic services may respond aggressively to the Company's products and services and seek to regain market share and revenue, which could also impact adversely the Company's margins and revenue.

vii. Reliance on core information technology and other systems

The availability and success of **NeuralDx**'s EVestG™ platform is dependent upon the performance, reliability and availability of its IT and communication systems, as well as its diagnostic algorithms. This includes its core technologies such as computer servers, and back-end processing systems.

These systems may be adversely affected by several factors including major events such as acts of terrorism or war, a breakdown in utilities such as electricity and fibre-optic cabling and even pandemics. Events of that nature may cause one or more of those core technologies to become unavailable.

There are also internal and external factors that may adversely affect those systems and technologies such as natural disasters, misuse by employees or contractors or other technical issues.

The Company's disaster recovery plans may not adequately address every potential event and its insurance policies may not cover loss or damage suffered because of a system failure.

Any damage to, or failure of, the Company's key systems can result in disruptions in the Company's ability to operate its platform. Such disruptions have the potential to reduce the Company's ability to generate revenue, attract and/or retain clients, impact service levels, and damage the Company's brand. This could adversely affect the Company's ability to generate new business and cause it to suffer financial loss.

The business of NeuralDx relies significantly on the contribution of certain key employees and management personnel. The departure of the Chief Executive Officer and/or other senior management personnel could impact the ability of the Company to perform.

viii. Customer's take-up

There is no guarantee that prospective clients will take up all or some of the product and service offerings on a long-term basis or that customers will renew their contracts or expand their product uptake. Similarly, the Company must maintain its service quality and close relationships with its customers and prospective clients to maintain and secure their ongoing patronage. Failure to maintain, expand and secure additional clients could have a material negative impact on the Company's revenue and operating results.

ix. Security breaches

A malicious attack on the Company's systems, processes, or people from external or internal sources could put the integrity and privacy of customers' data and business systems used to run the platform at risk. The impact of loss or leakage of customer or business data could include costs for rebates, potential service disruption, litigation and brand damage resulting in reduced or falling revenues. The Company will ensure best practice in relation to security policies, procedures, automated and manual protections, encryption systems and staff screening to minimise this risk. If the Company's efforts to combat any malicious attack are unsuccessful or if the platform has actual or perceived vulnerabilities, the Company's business reputation and brand name may be harmed, potentially having a material adverse effect on the Company's operations and financial position.

x. Unlisted, illiquid shares

The Company and its securities are not currently listed or quoted on ASX or any other securities exchange. Accordingly, there is no liquid market for the Company's Shares or other securities, and shareholders would be entirely reliant on off-market buyers being able to be identified and private arrangements for sales to be made if they wish to trade their Shares.

Should the market for the Company's securities become entirely illiquid Shareholders will be unable to realise their investment in the Company.

Prospective investors should be aware that the price (if any) they may be able to sell Shares at may be less than the Offer price. There is no guarantee that Shares will be able to be traded or in respect of profitability, dividends, return of capital or the price at which the Shares may be able to be traded.

External factors such as general economic outlook, movements in interest or inflation rates, currency fluctuations, commodity prices, investor confidence and other factors may affect the Share sale price.

General Investment Risks

xi. Government policies and legislation

The Company's businesses and performance are affected generally by the policies (including taxation) that are adopted by government both in Australia and in the other jurisdictions in which the Company operates. Any change in regulation or policy may adversely affect the performance or financial position of the Company, either on a short-term or long-term basis. The Company may also be adversely affected by the pace or extent of such change.

xii. General Economic conditions

The Company's business is affected by general economic conditions. Deterioration in economic conditions could lead to reductions in personal and business spending and other potential revenues which could be expected to have a corresponding adverse impact on the Company's operating and financial performance.

xiii. Market risk and interest rate volatility

From time to time, the Company may borrow money and accordingly will be subject to interest rates which may be fixed or floating. A change in interest rates would be expected to result in a change in the interest cost to the Company and, hence, may affect its financial performance.

xiv. Risk of Shareholder dilution

In the future, the Company may elect to issue Shares to engage in fundraisings and to fund, or raise proceeds, for acquisitions the Company may decide to make. Shareholders may be diluted because of such issues of Shares and fundraisings or by any capital reduction.

xv. Litigation

Litigation brought by third parties including but not limited to customers, partners, suppliers, business partners or employees could negatively impact the business, particularly in the case where the impact of such litigation is greater than or outside the scope of the Company's insurance.

xvi. Investment Speculative

The above list of risk factors ought not to be taken as exhaustive of the risks faced by the Company or by investors in the Company. The above factors, and others not specifically referred to above may, in the future, materially affect the financial performance of the Company and the value of the Company's securities.

xvii. Taxation

A. Whilst the Directors are advised that the Company qualifies as an Early-Stage Innovation Company [ESIC] under the ATO's "Tax incentives for innovation" scheme it does not warrant or represent the correctness of that advice. The Investor should therefore make its own enquiries and seek its own advice.

B. Changes to the rate of taxes imposed on **Neural*Dx*** are likely to affect Shareholder returns. In addition, an interpretation of Australian taxation laws by the Australian Taxation Office that differs to **Neural*Dx***'s interpretation may lead to an increase in **Neural*Dx***'s taxation liabilities.

xviii. Impact of hostilities, terrorism, pandemics, or other force majeure events

War, other hostilities, terrorism, pandemics, or major catastrophes can adversely affect global and Australian market conditions. Such events can have direct and indirect impacts on the **Neural*Dx***'s business and earnings.

ANNEXURE ONE GLOSSARY

ASIC	The Australian Securities and Investments Commission, Australia's integrated corporate, markets, financial services, and consumer credit regulator.
A Neural Analysis System	The patent family titled 'A Neural Analysis System', reference WO 2010/148452. This patent family covers details involved in extracting biomarkers from the obtained signals and in providing an assessment of a diagnosis related to such biomarkers.
A Neural Event Extraction Process, **or NEER**	The patent family titled 'A Neural Event Process', reference WO 2006/024102. This patent family covers details of the algorithm used to extract the electrical signal from the electrically noisy recording.
A Neural Response Process	The patent family titled 'A Neural Response Process' reference WO 2008/144840. This patent family covers specifically the extraction of signals in response to a tilt stimulus, and subsequent processing to produce biomarkers.
AD	Alzheimer's Disease, the most common type of Dementia.
Biomarker	Defined by the FDA as a characteristic that is measured as an indicator of normal biological processes, pathogenic processes (or responses to an exposure or intervention, including therapeutic interventions. https://www.fda.gov/files/BIOMARKER-TERMINOLOGY--SPEAKING-THE-SAME-LANGUAGE.pdf
BPD	Bipolar Affective Disorder.
CE marking	A certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area. CE stands for Conformité Européenne.
CNS disorders	Central Nervous System (CNS) disorders, covering psychiatric and neurological disorders.
Company	NeuralDx Ltd ACN 619 270 709.
Cooling-off Period	The period ending five business days after an application is made under this Offer, during which an investor has a right to withdraw their application and be repaid their application money
CSF	Crowd-sourced funding under Part 6D.3A of the Corporations Act
CT Scan	An X-Ray computed tomography scan.

CI – Confidence Level	A statistical term for a measure of the reliability of a result. A confidence level of 95 per cent means that there is a probability of at least 95 per cent that the result is reliable/reproducible to a given value or range.
DEM	Dementia.
DSM Criteria	The current diagnostic criteria by which depression is diagnosed, by the Diagnostic and Statistical Manual of Mental Disorder 5th Version of the American Psychiatrists Association, since 2013 known as DSM-5.
EEG	An electroencephalogram. 0 Hz to 100 Hz from Brain surface
EMI	Electro-magnetic Interference (electronic noise of biological and environmental origin).
EVestG™	The diagnostic technology owned by NDx, specifically, electrovestibulography. 300 Hz to >5000 Hz from Deep Brain Structures and neural function
EVestG™ Technology	Knowhow, methodology, and other intellectual property relating to NEER™ and EVestG™, including the facilitating hardware, firm- and soft-ware.
FDA	the Food and Drug Administration as a Federal Agency of the United States Department of Health and Human Services, responsible for regulating the safety and efficacy of Medical Devices and Pharmaceuticals
ICD-10 or 11	The WHO "International Classification of Diseases 10th or 11th Edition (2019)", the EU and Rest of World alternate DSM-5.
Large Proprietary Company	means a company that is not a Small Proprietary Company as defined below and in s45A of the Corporations Act.
Limbic System	A set of deep brain structures that support a variety of functions, including emotion, behaviour, motivation, long-term memory, and smell.
MAPrc	The Monash Alfred Psychiatry Research Centre, located at Level 4, 607 St Kilda Road, Melbourne VIC 3004.
Subscription	The amount specified in this IM offer document as the amount sought to be raised by the Offer
MD	Meniere's Disease.
MDD	Major Depressive Disorder.
Mental or Neurological Disorder	CNS conditions that affect the Brain and Central Nervous System, and includes Major Depressive Disorder, Bipolar Affective Disorder, Schizophrenia, Parkinson's Disease, Alzheimer's Disease, Dementia, mild-traumatic brain injury (mTBI), and post-concussive syndrome (PCS).
MRI	Magnetic resonance imaging.

MEG	Magnetoencephalography
MBS	The Australian Medical Benefits Service Scheme administered by MSAC.
MSAC	The Australian Medical Services Advisory Committee.
NDPL	Neural Diagnostics Pty Ltd ACN 115 788 068.
NeuralDx or NDx	NeuralDx Ltd ACN 619 270 709.
Offer	The Offer for New Shares in the Company, as detailed in this Crowd Funding Source Document.
Offer Close Date	**2 September 2022**
Offer Open Date	**10 August 2022**.
Patents	The patents (granted and applied for) owned by NeuralDx, being Neural Analysis System, A Neural Event Process, a Neural Response Process and Vestibulo-Acoustic Signal Processing
PD	Parkinson's Disease.
SCZ	Schizophrenia
Small Proprietary Company	means, as defined in s45A of the Corporations Act, a company which satisfies at least two of the following: • the annual consolidated revenue of your company and any entities it controls is less than $50 million; • the value of the consolidated gross assets of your company and any entities it controls is less than $12.5 million; and • your company and any entities that it controls have less than 50 employees at the end of the financial year.
TGA	The Therapeutic Goods Administration, the Commonwealth Agency of Australia's Department of Health and Human Services, responsible to regulating the safety and efficacy of Medical Devices and Pharmaceuticals.
UNIT	The commercial EVestG™ measurement and analysis unit.
VSAD	Vestibular Signal Acquisition Device
Vestibulo-Acoustic Signal Processing	PCT Au/35284718 Application of this title lodged in May 2018. This patent extends the understanding of the Neurophysiological components of the EVestG Signal and expands upon the ways it can be measured to obtain the diagnostic biomarkers for classifying a sufferer.

ANNEXURE TWO - EVestG™ Peer Reviewed Publications

(as at 1st December 2022)

PUBLISHED EVIDENCE on EVestG™ APPLICATIONS

The Inventor of the EVestG™ Technology and NeuralDx's Chief Scientific Officer and Head of Research is Associate Professor Brian Lithgow.

He is also the lead or corresponding Author of most of the Published Evidence on EVestG™'s Applications.

As at 1st July 2022, there are over 24 Peer-reviewed publications on EVestG™ and its clinical applications in international scientific journals as follows:

EVestG TECHNOLOGY and BIOLOGICAL BASIS

1. Gurvich C, Maller J, Lithgow B, Haghgooie S, and Kulkarni J. *Vestibular Insights into Cognition and Psychiatry.* Brain Research (2013); 1537: 244–59. doi: 10.1016/j.brainres.2013.08.058.
2. Lithgow, B., *A Methodology for Detecting Field Potentials from the External Ear Canal - NEER and EVestG.* Annals of Biomedical Engineering (2012), 40(8), (: 1835– 1850; DOI:0.1007/s10439-012-0526-3
3. Blakley B, Suleiman A, Rutherford G, Moussavi Z, Lithgow B. *EVestG Recordings are Vestibuloacoustic Signals.* J Medical and Biological Engineering; (2019),39(2):213-217 DOI:10.1007/s40846-018-0398-6
4. : Blakley B, Ashiri M, Moussavi Z, Lithgow B. *Verification EVestG recordings are vestibuloacoustic signals.* Laryngoscope Investigative Otolaryngology. 2022;1-7. doi:10.1002/lio2.862
5. Ashiri M, Lithgow B, Suleiman A, Blakley B, Mansouri B, and Moussavi Z. *Differences Between Physical vs. Virtual Evoked Vestibular Responses.* Ann. Biomed. Eng. (2020), 48(4):1241-55. DOI: 10.1007/s10439-019-02446-3.
6. Ashiri M, Lithgow B, Suleiman A, Mansouri B, and Moussavi Z. *Quantitative measures of the visually evoked sensation of body movement in space (Vection) using Electrovestibulography (EVestG),* Virtual Reality, 2020, DOI: 10.1007/s10055-020-00488-w.
7. Ashiri M, Lithgow B, Suleiman A, Mansouri B, and Moussavi Z. *Electrovestibulography (EVestG) application for measuring vestibular response to horizontal pursuit and saccadic eye movements.* Biocybernetics and Biomed. Eng. (2021): 41: 527-539.

APPLICATIONS AND NEUROPSYCHIATRIC CONDITIONS

Mood Disorders - Major Depression and Bipolar Affective Disorder

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