Lumos Diagnostics Holdings Limited
Capital Raising

6 June 2022

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Important notice and disclaimer

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Executive Summary

Q3 FY22 trading update	• As announced on 11 April 2022, Lumos Diagnostics Holdings Limited ('Lumos' or the 'Company') initiated a cost reduction program targeting a reduction in Lumos' operating cash burn to under US$1.0 million per month by the end of FY22. This has included:
	  • an approximately 55% reduction in headcount from 124 to 55 FTEs; and
	  • future discretionary expenses and investments will be subjected to detailed review and scrutiny.
	• The cost reduction program is designed to better align Lumos' current resources with its immediate, near-term commercial opportunities and to ensure that future expenditure is closely tied with company growth.

Key management changes	• Lumos is pleased to announce that Doug Ward, an experienced commercial diagnostics executive, has been appointed as CEO and is expected to commence with Lumos as CEO in mid-June 2022. • A range of other leadership changes have also been implemented including the transition of Rob Sambursky to an external consultant role and the rationalisation of staff numbers across all functions within the Company.
Outlook and prospects	• Lumos believes it is on track to receive a decision in the coming months from the FDA on the regulatory clearance and CLIA status of FebriDx®. Refer to slide 10 for detailed process. • Regulatory applications for Lumos' ViraDx™ have been filed in the U.S. and Canada which, if successful, may provide co-marketing opportunities for both ViraDx and FebriDx. • Lumos intends to prudently and selectively invest in targeted business development activities and will continue to review and evaluate its development services and contract manufacturing operations with a focus on building and diversifying its project pipeline and resourcing accordingly. • Potential contracts for the purchase of CoviDx™ are currently under consideration by government departments in Canada and Australia.
Capital Raising	• Lumos is announcing a fully underwritten 1-for-2.55 pro rata accelerated, non-renounceable entitlement offer to raise approximately A$11.2 million (Entitlement Offer). • Participants in the Entitlement Offer will also receive one free option for every new share subscribed for, exercisable at A$0.30 and expiring on 30 November 2022. Lumos will seek quotation of options, subject to satisfaction of the relevant ASX Listing Rules criteria. If the ASX Listing Rules criteria is not satisfied, the Options will still be issued but will not be tradeable on the market conducted by ASX. • The offer price of A$0.19 per share represents a 17.2% discount to the TERP (as at last close Wednesday, 1 June 2022). • The proceeds from the capital raise will be used to progress the current applications for regulatory clearances of FebriDx, ViraDx and CoviDx and, if successful, initiate the commercial launch of these products in the relevant jurisdictions, as well as support the development of Lumos' contract development and manufacturing business. • The capital raising will fully fund the company's activities until the end of CY22. This will align with the expiry of the listed options on 30 November 2022 which would raise a further A$17.7m subject to being fully exercised.

Major shareholder and Board commitment	• Lumos' largest shareholder Planet Innovation has committed for up to A$6.0m of the Entitlement Offer. This consists of:
	  – Take-up of its full pro rata entitlement in the Offer, equating to approximately A$3.0m; and
	  – In addition, Planet Innovation has committed to a total sub-underwriting of A$3.0m of the Entitlement Offer. Planet Innovation's voting power in Lumos may increase from its current holding of ~27% up to a maximum of ~34% following completion of the Entitlement Offer.
	• Lumos' Australian directors who are shareholders in Lumos intend to participate in the Entitlement Offer.

Company Update

Services and Operations

- **Lumos has undertaken a restructure and cost reduction program[1]:**
  - Company had scaled capacity and personnel ahead of near-term requirements;
  - Utilization of new manufacturing capacity has been modest – client projects have not transitioned as expected due to changing demands for different COVID-19 products;
  - Service business impacted by under-investment in business development, client project delays and changing market conditions.
- **The recent cost management, business development and alignment of resourcing decisions were based on:**
  - An in-depth review of pipeline and facilities undertaken by Sam Lanyon (Interim CEO) and Barrie Lambert (CFO)
  - An assessment of Lumos' ongoing facility requirements that has taken into consideration:
    - The outcome of pending regulatory applications; and
    - The pipeline of commercial development and manufacturing contracts with clients.
  - Facility rationalisation which has been completed in CA. Options for FL facility are currently under evaluation.
  - A desire to diversify composition of Lumos' client projects to minimise uncertainty associated with high-volume/high commercial-risk COVID-19 opportunities.

SARASOTA, FL USA

CARLSBAD, CA USA

1. Refer to ASX Announcement dated 11 April 2022. Lumos Operational Review and Management Changes

Company Restructure – Update and Impact

- **Organisational Restructure Completed in May 2022**
  - Recent key C-suite appointments: Sam Lanyon as interim CEO and Barrie Lambert as CFO;
  - Headcount reduced by 55% from 124 to 55 FTEs:
    - This provides sufficient personnel to support Lumos' anticipated, near-term commercial activities for the launch of its own diagnostic tests, subject to receiving the necessary regulatory clearances, and the provision of its contract development and manufacturing services to its commercial clients.
    - All internal R&D programs now focused on supporting current product range.
  - After serving his notice period (4th August 2022), Rob Sambursky will become an external consultant on Lumos' Medical Advisory Board, which will provide Lumos with access to his networks, product know-how and knowledge of corporate history
  - Future discretionary expenses and investments will be subjected to detailed review and scrutiny.
  - Manufacturing facility rationalisation project underway to eliminate capability duplication and reduce leasing costs.

- **Cost Reduction Impact**
  - Targeting monthly cash burn of less than US $1.0M per calendar month by the end of FY22, including:
    - Completion of current severance payments and termination obligations;
    - Implementation of cost reductions identified in initial organisational review.[1]
  - Finalisation of operating expenditure and commitments related to restructure to be completed prior to end of FY22, including impact of anticipated cost reductions related to facility rationalisation to be realised throughout FY23.

Function	FTEs
Sales and Marketing	9
Commercial Services	19
Manufacturing	7
Supply Chain	3
Quality & Regulatory	6
Medical Affairs	3
Corp/Finance/Admin	8
Total (9 May 22)	**55**

1. Refer to ASX Announcement dated 11th April 2022.

Highly Experienced Diagnostics Executive Appointed as CEO

- **Background**
  - Extensive industry-wide executive search by Egon Zhender which included candidates from Board and advisors networks.
- **Introducing Doug Ward**
  - 30+ year career in Diagnostics and Life Sciences industries across a range of commercial and operational roles.
  - Senior executive commercial roles with Roche/Ventana Medical, GE, Siemens, Bayer, Chiron and Hologic.
  - Led Ventana's international expansion of companion diagnostics growing revenue to US$50M+ over 2 years.
  - CEO of PGDx, responsible for establishing key genomic IVD assets e.g. PGDx elio Tissue Complete. PGDx subsequently acquired by LabCorp in 2022 for US$450 million upfront and US$125 million in performance based milestones.
  - Extensive experience in securing regulatory clearances and commercially launching new diagnostic products.
  - Most recent role as VP of Strategy and Business Development for Hologic (client of Lumos Diagnostics).

- **Appointment**
  - Contracted on 6 June 2022. Expected to commence as CEO in mid-June 2022.
  - Initial base-compensation of US$415k p.a. with a cash-based incentive package focused on delivery of commercial outcomes.
  - Options package of 7.5M options each over 1 ordinary share, time based vesting with 40% at 2 years and remainder 100% vested pro-rata at 4 years. Exercise price of A$0.30. Unexercised outstanding options to expire 7 years post issue date.

Focused Business Plan

FebriDx® – U.S. Regulatory Update

- **Regulatory clearance for FebriDx in the U.S. by the FDA has taken much longer than the Company expected:**
  - Clinical and performance data requirements for the FDA have changed over the course of the pandemic;
  - Lumos has responded to these evolving requirements, but this has resulted in delays to the process.

- **Expecting final decision on U.S. clearance from the FDA for FebriDx in the coming months:**
  - Recent considerations by the FDA appear to be primarily focused on the appropriate CLIA categorisation for FebriDx[1].
  - Formal supplementary response filed by Lumos and acknowledged by the FDA on 9 May 2022.
  - The FDA is expected to provide Lumos with an indicative clearance decision within 58 days of filing this formal response (i.e. 6 July 2022)[2].
  - If Lumos receives an indicative clearance decision from the FDA for FebriDx, there may be a short period of additional time required to refine the label claims and package insert before a final clearance is issued.
  - The decision from the FDA will cover CLIA usage (waiver, or use in moderate complexity settings) as well as clearance.
  - If FebriDx receives final clearance, Lumos will be allowed to commence marketing activities for FebriDx in the U.S.

NOTES:

[1] CLIA refers to the Clinical Laboratory Improvement Amendments. The FDA categorises diagnostic tests on the complexity of the setting in which they they can be used in. Tests that are classified as 'waived' tests are simple tests with a low-risk for incorrect result. Waived tests can be used in all primary care and outpatient settings.

[2] FebriDx clearance from the FDA within the current timetable is not guaranteed. Refer to Risks on page 24.

FebriDx – U.S. Commercial Launch Plans

- **Lumos is prepared and ready for the U.S. commercial launch of FebriDx subject to receiving clearance from the FDA:**
  - Key initial target primary and urgent care sites already identified:
    - All initial target sites are 'moderate complexity'[1] settings so should not require CLIA waiver to use FebriDx;
    - Existing reimbursement codes[2] for diagnostic tests using CRP and MxA markers may provide coverage for FebriDx[3];
    - Initial target sites can use FebriDx while the potential to use these existing reimbursement codes is verified; and
    - Lumos intends to apply for specific reimbursement code to provide long-term reimbursement coverage for FebriDx.
  - Lumos has established a Medical Advisory Board that will seek to provide awareness and access to these early adopter customers.

- **Bacterial vs Viral differentiation – momentum for use of host immune response approach is increasing[4]:**
  - Lumos is in active discussion with potential partners for commercialisation of FebriDx in the U.S. through:
    - Distribution partnerships; and
    - Licensing of commercial rights for FebriDx.

1. Refer to note on CLIA on page 12.
2. Medical products covered by reimbursement have lower out-of-pocked costs to the user which encourages their use.
3. CRP means C-reactive protein. MxA means myxovirus resistance protein A. These are the two markers that are used in Lumos' FebriDx test.
4. Host immune response approach refers to biomarkers which detect natural immune response to infection. Refer to recent announcements from Cepheid (GeneExpert™), MeMed (MeMed BV™), Inflammatix (BacVerity™) for example.

FebriDx Recap: Essential Diagnostics Tool

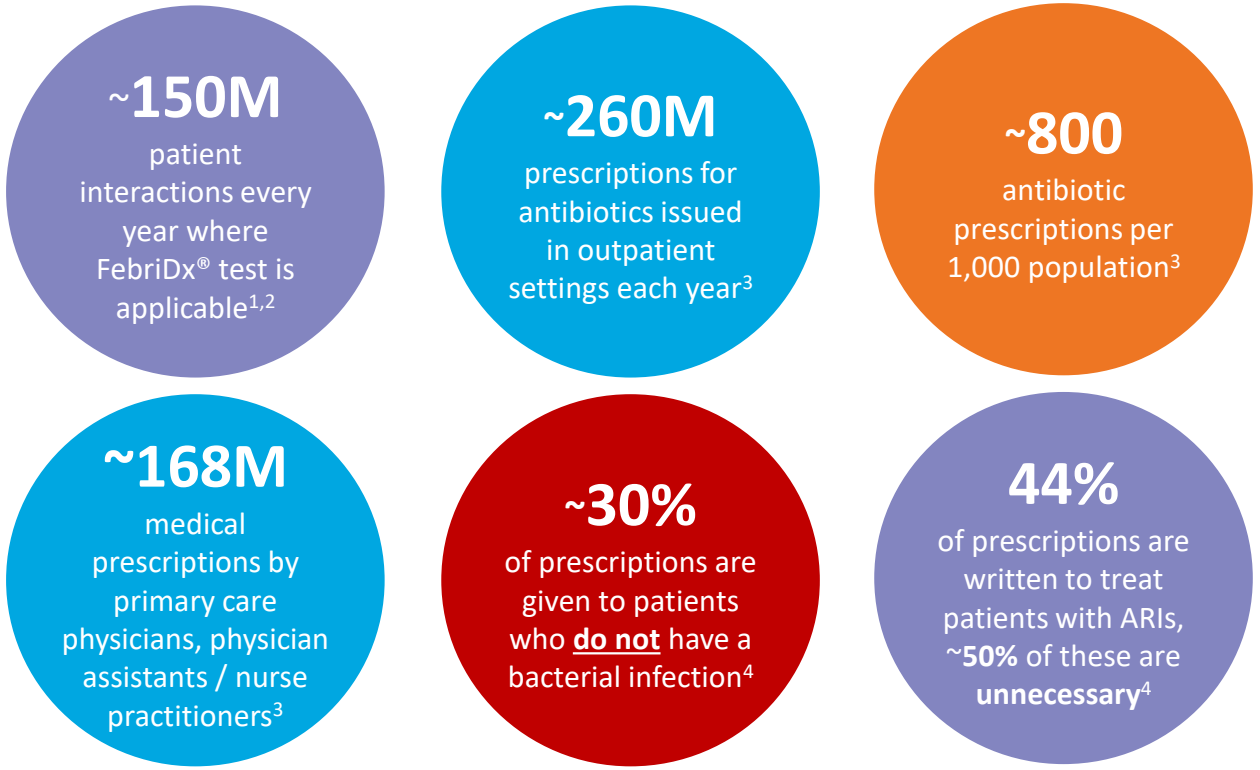
Clinicians cannot readily differentiate between bacterial and viral infections based on patient symptoms alone.

FebriDx has the potential to become an essential part of a doctor's diagnostics toolkit.

Unmet diagnostic requirement

- Clinicians cannot readily differentiate between bacterial or viral infections based on patient symptoms alone.
- FebriDx provides a rapid, objective way to establish if a patient has a bacterial or viral infection.
- FebriDx also can improve patient workflow - administered by nurse or medical assistant while patient waits to see the clinician (similar to rapid Strep and Flu tests).
- Total addressable market of >US$2.5B p.a. in the US across primary care, urgent care and hospitals.[5]

Antibiotic Prescriptions in the US



1. https://www.jucm.com/improving-appropriate-antibiotic-use-common-clinical-conditions-urgent-care. 2. Unnecessary Antibiotics for Acute Respiratory Tract Infections: Associations with Care Setting and Patient Demographics,(2016). 3. Centers for Disease Control and Prevention. Outpatient antibiotic prescriptions — United States, 2017. 4. https://www.pewtrusts.org/en/research-and-analysis/reports/2016/05/antibiotic-use-in-outpatient-settings. 5. Based on an estimated 154 million patient interactions where FebriDx would be applicable annually (approximately 58 million from ARI visits for primary care and approximately 96 million from emergency room and hospitals for retail health and standalone urgent care), and the applicable reimbursement of US$16.71 per test.

ViraDx™ North American Opportunities

- **Regulatory applications for ViraDx under review in the U.S. and Canada:**
  - ViraDx is a three-in-one COVID-19/Flu A/Flu B test for use by healthcare professionals.
  - Applications for Emergency Use Authorisation (EUA) in the U.S. and Interim Order Authorisation in Canada have been submitted and are under review by the FDA and Health Canada respectively.
  - Active application review with FDA with last correspondence received on 20th May 2022.
  - US target launch by September 2022 in anticipation of Northern Hemisphere influenza season.

- **U.S. represents the key North American market opportunity:**
  - Pre-qualified customers and reference laboratories expected to facilitate early initial sales (subject to timing of approval with respect to the timing of the U.S. flu season).
  - Existing billing codes expected to provide U.S. $31 reimbursement coverage to doctors using the test in the U.S. (referencing U.S. Medicare CPT Code 87428).
  - Strong potential synergies with FebriDx in terms of sales channel, customers, and patient workflow.
  - Lumos has been provided with non-binding, indicative commitments for initial stocking orders worth approximately U.S. $800,000 from regional distributors.

CoviDx™ potential opportunities in the wings

- **Lumos has the potential to capitalise on specific opportunities in the Canadian market using existing inventory:**
  - minimal investment in sales effort – using distributors or direct sales to a few, select potential customers;
  - potential to supply CoviDx for self-test subject to completion of US clinical trial (funded via 3rd party); and
  - in discussion with media companies regarding supply of CoviDx for testing on production sets.

- **Supply contracts under consideration with government departments in Australia and Canada:**
  - **Victorian State Government** – CoviDx purchase commitment from HealthShare Victoria subject to TGA approval of CoviDx for OTC use and post-clearance testing by VIDRL[1]:
    - Response to first round questions from TGA submitted on 13th of May; and
    - Potential support extends beyond CoviDx procurement: i.e. establishment of a local manufacturing capability for rapid diagnostic tests in Victoria which may include partial onshoring of Lumos' manufacturing capacity[1]
  - **Canadian Federal Government** - Standing Offer with the Canadian Federal Government in place;
    - Potential to progress to a binding purchase order, with recent request for Lumos to confirm capacity and delivery capability. A response to a request for supply/shipping requirements from Health Canada was provided by Lumos on 13th May.

[1] Refer to ASX announcement dated 2 February 2022. VIDRL refers to the Victorian Infectious Disease Reference Laboratory

Near term opportunities and potential value drivers

Core Assets / Key Focus

FebriDx

- Outcome of FDA 510(k) application expected in coming months (clearance and CLIA status)
- Initial launch customers identified (primary and urgent care) – reimbursement and CLIA independent

ViraDx

- Regulatory clearances: Emergency Use Authorization (U.S.) & Interim Order Authorization (Canada)
- Focus on US as primary market with potential to co-market alongside FebriDx if cleared

Commercial Services

- Modest investment in Business Development personnel to actively build commercial project pipeline
- Focus on quality opportunities and diversification of partner projects beyond COVID tests

Legacy Initiatives

CoviDx

- Targeted government supply contracts in Canada and Australia under active consideration
- Potential to establish permanent rapid diagnostic manufacturing capability in Victoria

Capital Raising

Capital Raising Details

Structure	• Equity raising of a fully underwritten 1 for 2.55 pro rata accelerated non-renounceable entitlement offer to eligible existing shareholders of approximately 59.1m New Shares to raise approximately A$11.2m (Entitlement Offer), (together with the offer of options below, the Offer); • The Entitlement Offer is non-renounceable and entitlements will not be tradeable or otherwise transferable.
Offer Price	• Offer Price of A$0.19 per New Share under the Offer, which represents: – 17.2% discount to the TERP[1] of A$0.230[2]; and – 22.4% discount to the last close of A$0.245[2].
Options	• Participants will receive 1 free attaching option for every 1 share subscribed for under the Entitlement Offer with an exercise price of A$0.30 per option and an expiry date of 30 November 2022; – The option exercise price represents a 2.8% premium to the 30-day VWAP of A$0.292[2] • Lumos will seek quotation of options, subject to satisfaction of the relevant ASX Listing Rules criteria. • The option exercise price of A$0.30 aligns with the exercise price of the employee share options to incoming CEO, Doug Ward and other employees[3]
Ranking	• The New Shares issued under the Offer (including on exercise of options) will rank equally with existing Lumos shares on issue on the relevant issue date

[1] The Theoretical Ex rights Price (TERP) is calculated by reference to Lumos' share price on Wednesday, 1 June 2022 of A$0.245 per share, being the last trading date prior to the announcement of the Offer. TERP is a theoretical calculation only and the actual price at which Lumos' shares trade immediately after the ex date of the Offer will depend on many factors and may not approximate TERP.
[2] Based on the last close price of Lumos shares on Wednesday, 1 June 2022.
[3] 7.5m options being issued to Doug Ward under the Employee Share Option Plan and exercise price of the current Employee Share Option Plan being adjusted to A$0.30.

Capital Raising Details (cont..)

Institutional Entitlement Offer	• The Institutional Entitlement Offer will be open on Monday, 6 June 2022 and closes at 12pm on Tuesday, 7 June 2022 • The Institutional Entitlement Offer will be open to eligible institutional holders in Australia, New Zealand, the United Kingdom, Singapore, Hong Kong. Eligible institutional shareholders will have the opportunity to subscribe for 1 New Share for every 2.55 existing Lumos shares held as at the Record Date (7.00pm on Wednesday, 8 June 2022) • Entitlements not taken up under the Institutional Entitlement Offer will be offered to new and existing eligible institutions in the above jurisdictions at the Offer Price via a shortfall bookbuild to be conducted concurrently with the Institutional Entitlement Offer
Retail Entitlement Offer	• The Retail Entitlement Offer is expected to open on Friday, 10 June 2022 and close on Thursday, 23 June 2022. Eligible retail shareholders will have the opportunity to subscribe for 1 New Share for every 2.55 existing Lumos shares held as at the Record Date (7.00pm on Wednesday, 8 June 2022) • Eligible retail shareholders, who must have a registered address in Australia or New Zealand, will have the ability to subscribe for shares over and above their entitlement, subject to the level of uptake of the Retail Entitlement Offer, under a Top Up Facility. There is no guarantee that those Shareholders will receive the number of New Shares applied for under the Top Up Facility, or any. The number of New Shares available under the Top Up Facility will not exceed the shortfall from the Retail Entitlement Offer. The Directors, after consultation with the Joint Lead Managers, reserve the right to allot and issue New Shares under the Top Up Facility at their discretion. • Further details will be provided to eligible retail shareholders in the Prospectus lodged with ASIC
Underwriting	• Bell Potter Securities Limited and Wilsons Corporate Finance Limited are Joint Lead Managers and Underwriters to Entitlement Offer.
Major Shareholder Intentions	• Lumos' largest shareholder Planet Innovation has committed for up to A$6.0m of the Entitlement Offer. This consists of: – Take-up of its full pro rata entitlement in the Offer, equating to approximately A$3.0m; and – In addition, Planet Innovation has committed to a total sub-underwriting of A$3.0m of the Entitlement Offer. Planet Innovation's voting power in Lumos may increase from its current holding of ~27% up to a maximum of ~34% following completion of the Entitlement Offer. • Lumos' Australian directors who are shareholders intend to participate in the Entitlement Offer

Expected use of funds

- Lumos expects to have pro-forma net cash as at 30 April 2022 of approximately US$12.4 million[1,2] post completion of the Entitlement Offer, after paying the costs of the offer.
- The capital raising will fully fund the company's activities until the end of CY22. This will align with the expiry of the listed options on 30 November 2022 which would raise a further A$17.7 million subject to being fully exercised
- The proceeds from the capital raise will be used to:
  - progress the current applications for regulatory clearances of FebriDx, ViraDx and CoviDx;
  - initiate the commercial launch of these products in the relevant jurisdictions, if applications for regulatory clearances are successful;
  - support the development of Lumos' contract development and manufacturing business; and
  - working capital purposes.

Sources of funds[1,2]	(US$ million)
Proceeds of Entitlement Offer	7.9
Cash at bank (as at 30 April 2022)	5.0
Total Sources	**12.9**

Expected Uses of funds[1]	(US$ million)
Infrastructure and Capacity Expansion	0.1
Sales and Marketing	3.1
Regulatory, Clinical and Quality	2.3
Development of Test Pipeline	1.0
Technology Platform Development	0.5
Working Capital	5.5
Offer Costs	0.4
Total Uses	**12.9**

[1] Assumes AUD / USD exchange rate of 0.7. [2] Assumes the Entitlement Offer is fully subscribed
Note: The above represents a statement of the Company's current intentions as at the date of this Presentation. Investors should note that this may change depending on a number of factors, including the changes in the competitive environment, business performance, strategic and operational considerations, regulatory developments, and market and general economic conditions. Any proceeds from the exercise of options offered under the Offer are intended to be used to support commercial sales and marketing activities for Lumos' cleared products in relevant markets, business development activities to support the growth of Lumos' services business, and as working capital to support the Company's operations.

Timetable

Event[1]	2022
Announcement of the Entitlement Offer	Monday, 6 June
Institutional Entitlement Offer	Monday, 6 June – Tuesday, 7 June
Announcement of results of Institutional Entitlement Offer	Wednesday, 8 June
Trading halt lifted and Shares recommence trading	Wednesday, 8 June
Entitlement Offer Record Date (7pm AEST)	Wednesday, 8 June
Retail Entitlement Offer opens (9am AEST) and Prospectus dispatched	Friday, 10 June
Settlement of the Institutional Entitlement Offer	Friday, 10 June
Issue of Shares issued under the Institutional Entitlement Offer	Tuesday, 14 June
Trading of securities issued under the Institutional Entitlement Offer	Wednesday, 15 June
Retail Entitlement Offer closes (5pm AEST)	Thursday, 23 June
Announcement of results of Retail Entitlement Offer	Tuesday, 28 June
Issue of Shares under the Retail Entitlement Offer and intended Issue of Options under the Retail and Institutional Offer	Thursday, 30 June
Normal trading of New Shares issued under the Retail Entitlement Offer and, if quoted, Options under the Retail and Institutional Offer[2]	Friday, 1 July
Holding statements in respect of New Shares issued under the Retail Entitlement Offer, and, if quoted, Options under the Retail and Institutional Offer dispatched[2]	Monday, 4 July

[1] The above timetable is indicative only and subject to change. Subject to the requirements of the Corporations Act, the ASX Listing Rules and any other applicable laws, Lumos in consultation with the Joint Lead Managers, reserves the right to amend this timetable and withdraw the offer at any time. [2] Lumos will seek quotation and trading of options will be subject to satisfaction of the relevant ASX Listing Rules criteria.

Summary pro-forma balance sheet

Summary pro-forma balance sheet

US$m	30-Apr-22 (Unaudited)	Impact of equity raising[1,2]	30-Apr-22 Pro-forma
Cash and cash equivalents	5.0	7.4	12.4
Other current assets	13.6		13.6
Total Current Assets	18.6	7.4	26.0
Total Non-Current Assets	42.4		42.4
Total Assets	61.0	7.4	68.4
Total Current Liabilities	14.1		14.1
Total Non-Current Liabilities	7.0		7.0
Total Liabilities	21.1		21.1
Equity	39.9	7.4	47.3

[1] Assumes AUD / USD exchange rate of 0.70.
[2] Illustrates the post transaction costs impact of Entitlement Offer to raise up to approximately A$11.2m.

Key Risks

Key risks

This section discloses some of the key risks attaching to an investment in Lumos. Before investing or increasing your investment in Lumos, you should consider whether this investment is suitable for you having regard to publicly available information and your personal circumstances and following consultation with your professional advisors. The risks in this section are not, and should not be considered to be or relied on as, an exhaustive list of the risks relevant to an investment in Lumos. The risks are general in nature and regard has not been had to the investment objectives, financial situation, tax position or particular needs of any investor. Refer to the Prospectus risk section for further information.

- **Regulatory Approvals and Responsibilities:** For each country in which Lumos wishes to distribute its products, Lumos will be required to obtain product clearances or approvals prior to marketing the product and is required to maintain an up-to-date product registration with appropriate governmental authorities and regulatory bodies. Lumos' manufacturing facilities are also required to hold certification and compliance with regulatory and notified bodies (including for example registration of manufacturing facilities under the FDCA) in order to produce Lumos' products, and commercial services client products. Lumos' manufacturing facilities are MDSAP certified and ISO13485 compliant. Lumos cannot accurately predict product clearance or approval timelines, cost or other requirements that may be imposed by regulators (e.g. clinical trials or other requirements proving effectiveness of its new products). Any delay in the receipt of regulatory approval or clearance (including for example in obtaining FDA clearance for FebriDx®) may result in a delay to the intended launch date of certain new products. Delays may also affect Lumos' ability to achieve its growth objectives by geographic expansion of sales into new markets. There is also no guarantee that Lumos will receive all necessary regulatory approvals for FebriDx® or other products and the success of earlier clearance or approvals may not necessarily be predictive of the success of subsequent product clearance or approval applications.

- **Reliance on Distributors:** The success of Lumos' products relies on its ability to attract, retain, support and motivate distributors. The loss of, or any significant decrease in business from these distributors may negatively impact Lumos' financial performance. Lumos is also intending to appoint distribution partners to distribute FebriDx® in North America which will increase Lumos' reliance on distribution partners for its revenue. If product distributors or end customers do not continue to purchase Lumos' products, terminate the existing contracts or do not increase their usage over time, the growth in Lumos' revenue may slow or decline, which will have an adverse impact on Lumos' operating and financial performance.

- **Reliance on Clients:** A significant portion of Lumos' revenues come from the provision of contract services for the development and manufacture of POC diagnostic tests. Lumos must ensure that any product it develops is aligned to the client's needs and specifications, otherwise the client may not be willing to pay for the services provided or continue to contract with Lumos. The loss of, or a significant decrease in, the business from Lumos' commercial services clients could adversely impact Lumos' revenues. Any factors that impact on the ability of commercial services clients to obtain and retain regulatory approval, any significant delays in obtaining such approvals, or any impact on their ability to launch a finished diagnostic product into the market, may impact the client's customer's purchase volumes and consequently negatively impact Lumos' financial performance.

- **Reliance on Suppliers:** Lumos is reliant on third party suppliers for the development and manufacture of outsourced clients' products and the manufacture of components within Lumos' own product portfolio, including some specific single source parts. Many of these suppliers are located outside of the United States, whilst the raw materials Lumos requires may be in high demand globally. A number of single source parts may be difficult to replace with alternative parts and may require significant development, time and effort to remediate. Any disruption to third party businesses or supply chains or in the supply of single source parts that Lumos relies on for its development and manufacturing activities could have a material impact on the availability of Lumos' products for distribution.

- **Sufficiency of Funding:** Lumos' financial resources are limited and there is a risk that Lumos may never achieve profitability. Accordingly, Lumos may be required to raise additional funds from time to time to finance the development of its products and support its commercial services division, for example additional funds may be raised through an issue of equity or other convertible security or through debt financing. Further, Lumos expects that it may need to raise more funds to expand business in accordance with its business plan. The ability to raise additional funding is subject to factors beyond Lumos' control and Lumos can give no assurance that it will be able to secure future funding on favourable terms, or at all or that any amount raised will be sufficient to meet the Company's financing requirements.

Key risks cont.

- **Production / Manufacturing Risks:** Lumos' manufacturing facilities in Sarasota, Florida and Carlsbad, California are exposed to risks of harm, including those caused by man-made or natural disasters like earthquakes or fires, or human error, which may result in manufacturing disruptions or an inability to manufacture and produce its products for an unknown period of time. This has the potential to limit, delay or prevent supply of Lumos' products and may have an adverse impact on the availability of Lumos' products, which would affect contractual obligations, particularly with respect to failure to supply.

- **Inventory / Materials Risks:** Lumos manufactures products which embody a range for raw materials including biological and organic components which may be susceptible to degradation over time which may also be accelerated when exposed to certain environmental conditions such as increased temperature or humidity. Consequently, some raw materials and supplier components which Lumos relies on to produce its products may have a limited shelf-life or be susceptible to unexpected degradation in performance due to improper shipping or storage conditions and therefore may result in manufacturing disruptions, inventory write-offs or product recalls.

- **Timing of Orders or Services:** Lumos is expected to supply products to distributors and services clients in a timely manner. There can be long lead times to develop products and Lumos' ability to deliver products within certain time frames (or at all) may be affected by events outside of Lumos' control, for example impacts on supply chains by COVID-19. If delays occur and Lumos is unable to meet expected production and delivery timeframes, Lumos' revenues may be deferred or reduced, or those delays may adversely impact Lumos' relationship with distributors and services clients.

- **Intellectual Property:** The value of Lumos' own products depends in part on its success in obtaining and maintaining issued patents, trademarks and other intellectual property rights and protecting Lumos' proprietary technology. If Lumos' intellectual property and proprietary technology are not adequately protected, competitors may be able to use the technologies and replicate Lumos' products or commercial services offering and consequently erode or negate any competitive advantage Lumos may have, which could harm Lumos' commercial position and viability. The issue of a patent is not conclusive as to its validity or its enforceability and it may not provide Lumos with adequate proprietary protection or competitive advantages against competitors with similar products. Lumos cannot predict whether any patent applications that it is currently pursuing will be issued as patents, or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. There is a risk that Lumos may be subjected to infringement claims or litigation arising out of patents and pending applications for additional proceedings initiated by third parties. The defence and prosecution of intellectual property rights lawsuits, proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is often uncertain. If Lumos infringes the rights of third parties, Lumos could be prevented from selling its products and may be forced to defend litigation proceedings and pay damages. In addition to its patent activities, Lumos also relies on protecting its trade secrets, especially with regard to its manufacturing processes. Although Lumos implements reasonable endeavours to protect its trade secrets, these measures may not always be sufficient and Lumos may not be able to meaningfully protect its trade secrets and unpatented know-how in order to keep them secret.

- **Business execution** - Lumos operates in a highly dynamic and evolving industry whose structure and commercial attractiveness is significantly influenced by competition, regulations, reimbursement, public policy, and healthcare needs, all of which can change rapidly. Lumos' strategic vision and long-term strategic decisions are based on its awareness, understanding and interpretation on how these factors are likely to impact on the present and future industry in which it operates. If these factors change, or Lumos operates under a business plan that does not appropriately incorporate the industry dynamics, it may fail to, or may not be in a position to, successfully compete or take advantage of commercial opportunities as they emerge. There is also a risk that the cost reductions initiated by Lumos will not be successful or may not be sustainable in the long term.

Key risks cont.

- **Reimbursement and Coverage:** The significant adoption of tests (including those offered by Lumos) requires either government payment or third-party reimbursement payments including governmental payers (such as the Medicare and Medicaid programs in the U.S.), managed care organisations and private health insurers, particularly for example the U.S., Switzerland and Germany. In other countries with national health services, a material cost saving may be required in order for the tests to be readily adopted. There is a risk that Lumos will not be able to secure reimbursement for new products, or that reimbursement entitlements for existing entitlements are reduced or eliminated as a result of existing or new laws, regulations or policies. The absence of third party or governmental reimbursement could limit the amount of revenue opportunities available to Lumos, as clients would be required to pay, out of pocket, the full price of its products at the time of sale.

- **Ability to Attract and Retain Key Personnel:** Lumos relies on its senior leadership team who have intimate knowledge of the business and its products. If a member of Lumos' senior leadership team were to resign or leave the business there is no certainty that Lumos could attract a suitable replacement, or how long it may take to do so. As Lumos relies on the technical expertise of its employees to maintain and develop intellectual property, the loss of any key personnel may lead to a loss of operational knowledge, technology capabilities, key customer relationships, as well as delays in the development, launch and commercialisation of new products. Further, Lumos operates in a competitive and specialised industry where talent can be difficult to identify and retain. Lumos has included non-competition and non-solicitation clauses in certain employee's contracts where the applicable jurisdictions permit such restrictive covenants, however these may not always be enforceable.

- **Product Acceptance:** Lumos' growth and the commercial success of Lumos' own products is reliant on their acceptance as reliable, cost-effective and clinically proven by individual users and healthcare professionals. While Lumos has had success in the past with the adoption of its products for use by healthcare professionals, the degree of market acceptance and continued adoption of Lumos' products will depend on a number of factors, including the potential and perceived advantages of Lumos' products over competing products and Lumos' products performing to expected standards and quality. Furthermore, changes in the healthcare delivery system have resulted in major consolidation among reference laboratories and in the formation of multi-hospital alliances, reducing the number of institutional customers for POC diagnostic test products. Due to such consolidation, Lumos may not be able to enter into and/or sustain contractual or other marketing or distribution arrangements on a satisfactory commercial basis with institutional clients. Further, there is no guarantee that the adoption of Lumos' products will be sufficient enough to meet Lumos' sales objectives.

- **Reduction in Demand Post COVID-19 Pandemic:** Demand for Lumos' services and products in the past has, in part, been driven by increased investment in the healthcare sector due to the COVID-19 pandemic and the need to rapidly develop diagnostic tests to assist with managing the crisis. While FebriDx®'s primary use case is not specific to COVID-19 and CoviDx is not a COVID-19 detection test (but an antigen test), demand for these products for these settings is driven by infection rates for COVID-19 which are volatile depending on new and emerging variants and vaccine coverage and effectiveness. In addition, there are a number of alternative POC diagnostic tests and technologies that third parties are developing or commercializing for COVID-19, which could adversely impact demand for Lumos' products or services and as a result, its operations and financial performance.

- **Competition:** Lumos operates in a competitive market against a number of other diagnostic technology companies, with the market being further disrupted by new technologies and products introduced as a result of the COVID-19 pandemic and the increased demand for diagnostic tests. Many of Lumos' existing competitors have significantly more resources and greater market access than Lumos. These competitors may use aggressive marketing campaigns, new product formats, product improvements, acquisitions or price discounting to secure market share which could impact on Lumos' revenue and margins. Lumos is continually investing in research and development activities in order to generate new products to license, partner or sell. However, the medical device industry is characterised by rapid and significant change including in technology, industry standards, opportunities or customer needs. Lumos' competitors or new market entrants may develop or market devices and products that are more effective than Lumos' products and which could render Lumos' products obsolete or non-competitive. Additionally, new therapies or diagnostic devices could be developed that replace or reduce the need for Lumos' products.

Key risks cont.

- **New Product Development Pipeline:** Lumos' commercial success is dependent on the continued advancement of existing products and the generation and acceptance of new products that utilise Lumos' technology through its investment in research and development. Developing new products is expensive and often involves an extended period of time to achieve a return on investment, if a return is achieved at all. The success of new products depends on several factors, including Lumos' ability to properly identify and predict clinician and patient needs and preferences; innovate and develop new technologies and products in a timely manner; manufacture and supply new products that meet quality requirements, are cost effective, and can be produced in a timely manner; and obtain the necessary regulatory clearances or approvals.

- **Product Liability:** Any defects in products manufactured by Lumos may harm Lumos and its clients' reputation and business. Lumos may also be subject to warranty and liability claims for damages related to defects in its products. In addition, the products may be subject to a recall, withdrawal or other regulatory action. This risk exists even if a product is cleared or approved for commercial sale regulatory authorities and manufactured in facilities licensed and regulated by regulatory authorities. There may also be adverse events reported from the use, misuse or defect of Lumos' own products which could expose Lumos to product liability claims or litigation. The industry in which Lumos operates has historically been subject to extensive litigation over product liability claims, especially in the United States. Product liability claims may result in substantial litigation costs, product recalls or market withdrawals, decreased sales and demand for Lumos' products and damage to Lumos' reputation, regardless of merit or eventual outcome. If this were to occur it would adversely impact Lumos' operating and financial performance and potentially create significant customer relations issues.

- **Early Termination of Contracts:** A number of Lumos' direct contracts with its clients allow for termination based on a specified notice period. While Lumos has established relationships with many of these clients, should a client decide to terminate its contract with Lumos for convenience (i.e. by providing the requisite prior notice), Lumos will suffer a loss of the client revenue associated with that contract, and would need to sign up additional clients to replace that revenue. The loss of clients would have an adverse impact on Lumos' financial performance.

- **Privacy Risk:** Security measures and risk management systems in place to maintain the confidentiality and privacy of information collected by Lumos in relation to its clients, employees and other sources of personal information are subject to various risks including computer viruses, electronic theft, physical damage resulting in a loss or corruption of data, operating system failures, third party provider failures or similar disruptions. Lumos' efforts to combat these risks may not be successful and there is a risk that a data breach may occur, or a third party may gain access to confidential information of Lumos' clients or employees. Although Lumos does not obtain individualised medical information for any end-user patients, it may obtain generalised medical information (particularly during a clinical trial study) or billing information for its clients which may be the subject of potential breaches. The failure of Lumos to maintain the confidentiality of this information could result in a breach of law and cause significant operational, financial and reputational damage (such as claims from Lumos' clients or end-user patients) or the imposition of penalties if regulatory action is taken against Lumos.

- **Workplace Health and Safety:** There is a risk of worker fatality or injury while working at Lumos' sites, including manufacturing facilities. The occurrence of an accident resulting in injury or death to a worker could materially affect Lumos' reputation and expose Lumos to claims and regulatory enquiries. Further, Lumos may have difficultly retaining or employing employees if there are perceived safety concerns in working at Lumos' facilities.

- **Country Specific Risks:** Lumos' manufacturing facilities are based in the United States and so Lumos must comply with a range of different U.S. legal and regulatory regimes in the development and manufacture of its products. As Lumos sells its products internationally, it must also comply with a number of different laws and regulations in facilitating the sale and distribution of its products in different countries. There is a risk that policies and procedures designed to comply with laws and regulations of a particular subject matter established by Lumos are not sufficient to prevent Lumos from contravening the laws and regulations of all jurisdictions in which Lumos operates and sells its products. A contravention of laws could result in fines or penalties, the payment of compensation or the cancellation or suspension of Lumos' ability to carry on certain activities or product offerings.

Appendix – Foreign Selling Restrictions

Offer jurisdiction & disclaimers

Hong Kong

- WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the "SFO"). Accordingly, this document may not be distributed, and neither the New Shares nor the Options may be offered or sold, in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance). No advertisement, invitation or document relating to the New Shares or the Options has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to such securities that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares or Options may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities. The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

New Zealand

- This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the "FMC Act"). The New Shares and the Options are not being offered to the public within New Zealand other than to existing shareholders of the Company with registered addresses in New Zealand to whom the offer of these securities is being made in reliance on the Financial Markets Conduct (Incidental Offers) Exemption Notice 2021. Other than in the entitlement offer, the New Shares and the Options may only be offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) to a person who:
  - is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
  - meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
  - is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
  - is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
  - is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

Singapore

- This document and any other materials relating to the New Shares or the Options have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of such securities, may not be issued, circulated or distributed, nor may such securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the Securities and Futures Act 2001 of Singapore (the "SFA") or another exemption under the SFA. This document has been given to you on the basis that you are an "institutional investor" or an "accredited investor" (as such terms are defined in the SFA). If you are not such an investor, please return this document immediately. You may not forward or circulate this document to any other person in Singapore. Any offer is not made to you with a view to the New Shares or the Options being subsequently offered for sale to any other party. There are on-sale restrictions in Singapore that may be applicable to investors who acquire such securities. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

United Kingdom

- Neither this document nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the New Shares or the Options. The New Shares and the Options may not be offered or sold in the United Kingdom by means of this document or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This document is issued on a confidential basis in the United Kingdom to "qualified investors" within the meaning of Article 2(e) of the UK Prospectus Regulation. This document may not be distributed or reproduced, in whole or in part, nor may its contents be disclosed by recipients, to any other person in the United Kingdom. Any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received in connection with the issue or sale of the New Shares and the Options has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of the FSMA does not apply to the Company. In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investment to which this document relates is available only to relevant persons. Any person who is not a relevant person should not act or rely on this document.

Glossary

Glossary

- **ASIC** means the Australian Securities and Investments Commission.
- **ASX** means ASX Limited ACN 008 624 691 or the financial market known as the 'Australian Securities Exchange' operated by it, as the context requires.
- **ASX Listing Rules** means the official listing rules of the ASX as amended or waived.
- **CLIA** means the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations which include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease.
- **Company** or **Lumos** means Lumos Diagnostics Holdings Limited ACN 630 476 970.
- **CPT Codes** means Current Procedural Terminology, being a medical code set that is used to report medical, surgical, and diagnostic procedures and services.
- **CRP** means C-reactive protein.
- **Eligible Institutional Shareholder** means a shareholder who is an Institutional Investor and who the Company determines may receive an offer under the Institutional Entitlement Offer.
- **Eligible Retail Shareholder** means a person who: was registered as the holder of Shares as at 7.00pm (Sydney time) on the Record Date; has a registered address in Australia or New Zealand; is not in the U.S. nor acting for the account or benefit of a person in the U.S. or elsewhere outside Australia and New Zealand; and does not hold Shares on behalf of another person who resides outside Australia or New Zealand (unless they hold Shares in another eligible capacity).
- **FDA** means the U.S. Food and Drug Administration.
- **FDCA** means the Federal Food, Drug, and Cosmetic Act.
- **FebriDx** means Lumos' POC diagnostic test that is able to rapidly identify patients with a microbial infection and, if positive, determine if that infection is caused by a virus or bacteria.
- **Institutional Entitlement Offer** means the the offer of New Shares and Options to Eligible Institutional Shareholders under the Prospectus.
- **IVD** means in vitro diagnostics.
- **MDSAP** means Medical Devise Single Audit Program.
- **MxA** means Myxovirus resistance protein A.
- **New Shares** means the new Shares offered under the Entitlement Offer.
- **Option** means the right of the holder to be issued one New Share on payment of the applicable exercise price.
- **Options** means means the right of the holder to be issued one New Share on payment of the applicable exercise price, on the terms and conditions set out in the Prospectus.
- **OTC** mean over the counter.
- **POC** means point of care.
- **Prospectus** means a prospectus dated 6 June 2022 and lodged with ASIC on that date, including any supplementary or replacement prospectus in relation to the prospectus.
- **Retail Entitlement Offer** means the the offer of New Shares and Options to Eligible Retail Shareholders under the Prospectus.
- **Share** means a fully paid ordinary share in the capital of the Company**.**
- **TGA** means the Therapeutic Goods Administration.
- **Top Up Facility** means the facility under which Eligible Retail Shareholders may apply for additional New Shares if there is a shortfall under the Retail Entitlement Offer.
- **U.S.** means the United States of America.
- **VIDRL** means Victorian Infectious Diseases Reference Laboratory.

www.lumosdiagnostics.com