prospectus

Initial public offering of shares in
Lumos Diagnostics Holdings Limited

ACN 630 476 970

LUMOS DIAGNOSTICS

Joint Lead Managers and Underwriter

WILSONS BELL POTTER

Australian Legal Adviser

CLAYTON UTZ

Financial adviser

blackpeak capital

Important Notices

The Offer

The Offer contained in this Prospectus is an invitation for you to apply for fully paid ordinary shares (**Shares**) in Lumos Diagnostics Holdings Limited ACN 630 476 970 (the **Company** or **Lumos**). This Prospectus is issued by the Company and Lumos Diagnostics SaleCo Limited ACN 650 279 511 (**SaleCo**). See Section 7.1 for further information on the Offer, including as to details of the securities that will be issued and transferred under this Prospectus.

Lodgement and Listing

This Prospectus is dated Monday, 7 June 2021 and copy was lodged with the Australian Securities and Investments Commission (**ASIC**) on that date (**Prospectus Date**).

Lumos will apply to the ASX within seven days after the Prospectus Date for admission of the Company to the Official List and quotation of the Shares on the ASX (**Listing**).

None of ASIC, the ASX or their respective officers take any responsibility for the content of this Prospectus or for the merits of the investment to which this Prospectus relates.

Lumos, SaleCo, each of their respective directors and officers, Computershare Investor Services Pty Limited (**Share Registry**) and Bell Potter Securities Limited and Wilsons Corporate Finance Limited (the **Joint Lead Managers**) disclaim all liability, whether in negligence or otherwise, to persons who trade Shares before receiving their holding statement.

Expiry Date

This Prospectus expires on the date that is 13 months after the Prospectus Date (**Expiry Date**). No Shares will be issued or transferred on the basis of this Prospectus after the Expiry Date.

Exposure Period

The Corporations Act prohibits Lumos from processing applications to subscribe for, or acquire, Shares offered under this Prospectus (**Applications**) in the seven day period after lodgement of this Prospectus with ASIC (**Exposure Period**). This Exposure Period may be extended by ASIC by up to a further seven days.

The purpose of the Exposure Period is to enable this Prospectus to be examined by market participants prior to the raising of funds. The examination may result in the identification of deficiencies in this Prospectus, in which case any Application may need to be dealt with in accordance with section 724 of the Corporations Act.

Applications received during the Exposure Period will not be processed until after the expiry of the Exposure Period. No preference will be conferred on any Applications received during the Exposure Period.

Not investment advice

The information contained in this Prospectus is not financial product advice and does not take into account the investment objectives, financial situation or particular needs (including financial and tax issues) of any prospective investor.

It is important that you read this Prospectus carefully and in its entirety before deciding whether to invest in Lumos. In particular, in considering the prospects of Lumos, you should consider the risk factors that could affect the performance of Lumos. You should carefully consider these risks in light of your investment objectives, financial situation and particular needs (including financial and tax issues) and seek professional guidance from your stockbroker, solicitor, accountant, financial adviser or other independent professional adviser before deciding whether to invest in the Shares. Some of the key risk factors that should be considered by prospective investors are set out in Section 5. There may be risk factors in addition to these that should be considered in light of your personal circumstances.

You should also consider the assumptions underlying the Forecast Financial Information set out in Section 4 and the risk factors set out in Section 5 that could affect Lumos' business, financial condition and results of operations.

No person named in this Prospectus, nor any other person, guarantees the performance of Lumos, the repayment of capital by Lumos or the payment of a return on the Shares.

No person is authorised to give any information or make any representation in connection with the Offer which is not contained in this Prospectus. Any information or representation not so contained may not be relied on as having been authorised by Lumos or SaleCo, any of either of their Directors, officers, employees, advisers, agents, partners, consultants, representatives, the Joint Lead Managers, any other Lead Manager Parties (defined below) or any other person in connection with the Offer.

Statements of past performance

This Prospectus includes information regarding the past performance of Lumos. Past performance information given in this Prospectus is given for illustrative purposes only. Investors should be aware that past performance does not represent, and should not be relied upon as being indicative of, future performance. Actual results could differ materially from the past performance information contained in this Prospectus.

Forward-looking statements

No person is authorised to give any information or make any representation in connection with the Offer which is not contained in this Prospectus. Any information or representation not so contained may not be relied on as having been authorised by Lumos, SaleCo, the Directors, the SaleCo Directors, the Joint Lead Managers or any other person in connection with the Offer. You should rely only on information in this Prospectus when deciding whether to invest in Shares. Except as required by law, and only to the extent so required, neither the Company nor any other person warrants or guarantees the future performance of Lumos, or any return on any investment made pursuant to this Prospectus.

This Prospectus contains forward-looking statements which are statements that may be identified by words such as "may", "will", "would", "should", "could", "believes", "estimates", "expects", "intends", "plans", "anticipates", "predicts", "outlook", "forecasts", "guidance" and other similar words that involve risks and uncertainties. The Forecast Financial Information is an example of forward-looking statements. These statements are based on an assessment of present economic and operating conditions and on a number of best estimate assumptions regarding future events and actions that, at the Prospectus Date, are expected to take place (including the key assumptions set out in Section 4).

No person who has made any forward-looking statements in this Prospectus (including Lumos) has any intention to update or revise forward-looking statements, or to publish prospective financial information in the future, regardless of whether new information, future events or any other factors affect the information contained in this Prospectus, other than to the extent required by law.

Such forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of Lumos, the directors and management of Lumos and SaleCo. Forward-looking statements should therefore be read in conjunction with, and are qualified by reference to, Sections 4 and 5,

and other information in this Prospectus. Lumos and SaleCo cannot and do not give any assurance that the results, performance or achievements expressed or implied by the forward-looking statements contained in this Prospectus will actually occur and investors are cautioned not to place undue reliance on these forward-looking statements.

Rounding

A number of figures, amounts, percentages, estimates, calculations of value and fractions in this Prospectus are subject to the effect of rounding. Accordingly, the actual calculation of these figures may differ from the figures set out in this Prospectus.

No offering where offering would be illegal

This Prospectus does not constitute an offer or invitation in any place in which, or to any person to whom, it would not be lawful to make such an offer or invitation. No action has been taken to register or qualify the Shares or the Offer, or to otherwise permit a public offering of the Shares in any jurisdiction outside Australia. The distribution of this Prospectus (including in electronic form) outside Australia may be restricted by law and persons who come into possession of this Prospectus outside Australia should seek advice on and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws.

The Offer is not being extended to any investor outside Australia, other than to certain Institutional Investors as part of the Institutional Offer. In particular, this Prospectus may not be distributed to, or relied upon by, any person in the United States.

The Shares have not been, and will not be, registered under the U.S. Securities Act of 1933, as amended (**U.S. Securities Act**), or the securities laws of any state or other jurisdiction of the United States, and may not be offered or sold, directly or indirectly, in the United States unless the Shares have been registered under the U.S. Securities Act or are offered and sold, in a transaction exempt from or not subject to, the registration requirements of the U.S. Securities Act or the securities laws of any state or any other jurisdiction in the United States.

See Appendix B for more detail on selling restrictions that apply to the Offer and sale of Shares in jurisdictions outside Australia.

Disclaimer

The Joint Lead Managers have acted as joint lead managers and underwriters to the Offer. The Joint Lead Managers, together with their respective related bodies corporate, shareholders and affiliates and their respective officers, directors, employees, partners, affiliates, agents and advisers (each a Lead Manager Party) have not authorised, permitted or caused the issue or lodgement, submission, dispatch or provision of this Prospectus, and do not make or purport to make any statement in this Prospectus, and there is no statement in this Prospectus which is based on any statement made by a Lead Manager Party. To the maximum extent permitted by law, each Lead Manager Party expressly disclaims any and all liabilities (including, without limitation, any liability arising out of fault or negligence for any direct, indirect, consequential or contingent loss or damage) in respect of, and makes no representations or warranties (express or implied) regarding, and takes no responsibility for, and has not independently verified, any part of this Prospectus or the Offer (other than references to their name) and makes no representation or warranty as to the currency, accuracy, reliability, completeness or fairness of this Prospectus. The Lead Manager Parties make no recommendations as to whether you or your related parties should participate in the Offer nor do they make any representations or warranties to you concerning the Offer, and you represent, warrant and agree that you have not relied on any statements made by a Lead Manager Party in relation to the Offer and you further expressly disclaim that you are in a fiduciary relationship with any of them.

The Lead Manager Parties are involved in, or in the provision of, a wide range of financial services and businesses including (without limitation) securities trading and brokerage activities and providing retail, private banking, commercial and investment banking, investment management, corporate finance, securities issuing, credit and derivative, trading and research products and services, including (without limitation) to, or in connection with, persons directly or indirectly involved with the Offer (such as Existing Securityholders and members of the Board) or interests associated with such persons, out of which conflicting interests or duties may arise. In the ordinary course of these activities, each of the Lead Manager Parties may at any time hold long or short positions, and may trade or otherwise effect transactions, for its own account or the accounts of customers, including (without limitation) in debt or equity securities, loans, financing arrangements, or other financial accommodation, financial products or services, in connection with, or which rely on the performance of obligations by, interests associated with the Existing Securityholders, members of the Board or other persons that may be involved in the Offer.

Prospectus availability

This Prospectus is available in electronic form to Australian residents on the Lumos' offer website, lumosdiagnostics.com/investors. The Offer constituted by this Prospectus in electronic form is available only to Australian residents accessing the website within Australia and is not available to persons in any other jurisdictions, including the United States.

A hard copy of the Prospectus is available free of charge during the Offer Period to any person in Australia by calling the Lumos Offer Information Line on 1300 040 690 (toll free within Australia) between 8:30am and 5.00pm (Sydney time), Monday to Friday.

Applications and Privacy

Applications for Shares may only be made on the Application Form attached to, or accompanying, this Prospectus in its hard copy form, or in its soft copy form available online at lumosdiagnostics.com/investors, together with an electronic copy of this Prospectus. By making an Application, you declare that you were given access to the Prospectus, together with an Application Form.

The Corporations Act prohibits any person from passing the Application Form on to another person unless it is attached to, or accompanied by, this Prospectus in its paper copy form or the complete and unaltered electronic version of this Prospectus.

By completing an Application Form, you are providing personal information to Lumos and SaleCo through the Share Registry, which is contracted by Lumos to manage Applications. Lumos and SaleCo, and the Share Registry on their behalf, and their agents and service providers may collect, hold, disclose and use that personal information to process your Application, service your needs as a Shareholder, provide facilities and services that you request and carry out appropriate administration, and for other purposes related to your investment listed below.

If you do not provide the information requested in the Application Form, Lumos, SaleCo and the Share Registry may not be able to process or accept your Application.

Once you become a Shareholder, the Corporations Act and Australian taxation legislation require information about you (including your name, address and details of the Shares you hold) to be included on the Share register. In accordance with the requirements of the Corporations Act, information on the Share register will be accessible by members of the public. The information must continue to be included on the Share register if you cease to be a Shareholder.

Important Notices

Lumos and the Share Registry may disclose your personal information for purposes related to your investment to their agents and service providers including those listed below or as otherwise authorised under the *Privacy Act 1988* (Cth):

- the Share Registry for ongoing administration of the Share register;
- the Joint Lead Managers to assess your Application;
- printers and other companies for the purposes of preparation and distribution of documents and for handling mail;
- market research companies for analysing Lumos' shareholder base; and
- legal and accounting firms, auditors, management consultants and other advisers for administering, and advising on, the Shares and for associated actions.

Lumos' agents and service providers may be located outside Australia where your personal information may not receive the same level of protection as that afforded under Australian law.

You may request access to your personal information held by or on behalf of Lumos and SaleCo. You may be required to pay a reasonable charge to the Share Registry in order to access your personal information.

You can request access to your personal information or obtain further information about Lumos' privacy practices by contacting the Share Registry as follows:

- Telephone:
  - Telephone: 1300 850 505
- Address:
  - Yarra Falls, Computershare Investor Services Pty Ltd, 452 Johnston Street, Abbotsford VIC 3067

Lumos aims to ensure that the personal information it retains about you is accurate, complete and up-to-date. To assist with this, please contact Lumos or the Share Registry if any of the details you have provided change.

No cooling-off rights

Cooling-off rights do not apply to an investment in Shares pursuant to the Offer. This means that, in most circumstances, you cannot withdraw your Application once it has been accepted.

Defined terms and abbreviations

Defined terms and abbreviations used in this Prospectus, unless specified otherwise, have the meaning given in the glossary. Unless otherwise stated or implied, references to times in this Prospectus are to (Sydney time).

Unless otherwise stated or implied, references to dates or years are calendar year references.

Photographs and diagrams

Photographs and diagrams used in this Prospectus that do not have descriptions are for illustration only and should not be interpreted to mean that any person shown in them endorses this Prospectus or its contents or that the assets shown in them are owned by Lumos. Diagrams used in this Prospectus are illustrative only and may not be drawn to scale or accurately represent the technical aspects of the products.

Market and industry data

This Prospectus (and in particular Section 2) contains data relating to the industries, segments, sectors and channels in which Lumos operates.

Investors should note that industry and sector data and statistics are inherently predictive and subject to uncertainty and not necessarily reflective of actual industry or market conditions.

Third Party Reports

Any statements, data or other contents referenced or attributed to reports by a third party (each a Third Party Report) in this Prospectus represent research opinions or viewpoints only of that third party, and are in no way to be construed as statements of fact. No third party author makes any representation or guarantee as to the accuracy or completeness of any information upon which a view, opinion or forecast or information contained in any Third Party Report is based. Any views, opinions or predictions contained in a Third Party Report is subject to inherent risks and uncertainties, and third parties do not accept responsibility for actual results or future events. Any statement made in a Third Party Report is made as at the date of or as specified in that Third Party Report and any forecasts or expressions of opinion are subject to future change without notice by any respective third party author of such reports. As such, investors are cautioned not to place undue reliance on such information. A third party is not obliged to, and will not, update or revise any content of a Third Party Report irrespective of any changes, events, conditions, availability of new information or other factors which may occur subsequent to the date of that Third Party Report. The Third Party Reports do not represent investment advice nor do they provide an opinion regarding the merits of the Offer.

Consent not sought for certain statements

Unless specifically noted in Section 10.7, statements made by, attributed to or based on statements by third parties have not been consented to for the purpose of section 729 of the Corporations Act and are included in this Prospectus on the basis of ASIC Corporations (Consents to Statements) Instrument 2016/72 relief from the Corporations Act for statements used from books, journals or comparable publications.

Investigating Accountant's Report and Financial Services Guide

The provider of the Investigating Accountant's Report on the Financial Information is required to provide Australian retail clients with a Financial Services Guide in relation to that review under the Corporations Act. The Investigating Accountant's Report and accompanying Financial Services Guide is provided in Section 8.

Intellectual Property

This Prospectus may contain trademarks of third parties, which are the property of their respective owners. Third-party trademarks used in this Prospectus belong to the relevant owners and use is not intended to represent sponsorship, approval or association by or with us.

Website

Any references to documents included on Lumos' website (https://lumosdiagnostics.com) are provided for convenience only, and none of the documents or other information on Lumos' website, or any other website referred in this Prospectus, is incorporated in this Prospectus by reference.

Questions

If you have any questions in relation to the Offer, contact the Lumos Offer Information Line on 1300 040 690 between 8:30 am and 5:00 pm (Sydney time), Monday to Friday.

This document is important and should be read in its entirety.

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Key Offer Details

Key Offer Statistics

Offer Price	$1.25 per Share
Total proceeds of the Offer	$63.0m
Primary proceeds of the Offer to be paid to Lumos	$38.0m
Proceeds of the Offer to be paid to the Selling Shareholders	$25.0m
Total number of Shares to be issued under the Offer	30.4m
Total number of Shares to be sold under the Offer	20.0m
Number of Shares to be held by Existing Securityholders on Completion[2,3]	99.8m
Total number of Shares on issue at Completion[3]	150.2m
Indicative market capitalisation at the Offer Price[4]	$187.7m
Pro forma net cash as at 31 December 2020	$47.2m
Enterprise value at the Offer Price[5]	$140.5m
Enterprise value/pro forma FY21F revenue[6]	5.9x

Notes:

1. This table contains Forecast Financial Information and information derived from the Forecast Financial Information. The Forecast Financial Information is based on certain assumptions as discussed in Section 4 and should be read in conjunction with the discussion of the Pro Forma Financial Information in Section 4, the sensitivities set out in Section 4.7, the significant accounting policies summarised in Appendix A, and is subject to the key risks set out in Section 5. Certain financial information in this Prospectus is described as pro forma for the reasons described in Section 4.2. Forecasts have been included in this Prospectus for FY21F. There is no guarantee that the forecasts will be achieved.
2. Existing Securityholders may acquire additional Shares under the Offer.
3. The exact number of Shares to be on issue (or held by particular Existing Securityholders) at Completion will depend on the date Completion occurs. This is because the number of Shares that Pre-IPO Convertible Notes convert into is determined by reference to the aggregate face value and interest accrued in respect of those notes at the date the number of those Shares is calculated. For this purpose, the Prospectus assumes that Completion occurs on the date indicated in the Important Dates table below. If Completion occurs on a different date, and the number of Shares to be on issue at Completion varies from that indicated in this Prospectus, Lumos will publish that number of Shares to ASX at the time of Listing.
4. Indicative market capitalisation at the Offer Price is defined as the Offer Price multiplied by the total number of Shares on issue at Completion.
5. Enterprise value at the Offer Price is defined as the indicative market capitalisation at the Offer Price, less pro forma cash of $47.2m as at 31 December 2020.
6. Enterprise value/pro forma FY21F revenue is calculated as the enterprise value at the Offer Price divided by pro forma FY21F revenue of $23.8m.

This Prospectus assumes all forward looking forecast financial tables are stated at the exchange rate of AUD0.78/USD1.00.

Important Dates

Prospectus Date	Monday, 7 June 2021
Opening date of the Broker Firm Offer and Priority Offer	Tuesday, 15 June 2021
Closing date of the Broker Firm Offer and Priority Offer	Wednesday, 23 June 2021
Settlement of the Offer	Monday, 28 June 2021
Completion of the Offer	Tuesday, 29 June 2021
Expected dispatch of holding statements	Wednesday, 30 June 2021
Expected commencement of trading on the ASX	Monday, 5 July 2021

Note: This timetable is indicative only and may change without notice. Unless otherwise indicated, all references to time are to the time in Sydney, NSW. The Company and SaleCo, in consultation with the Joint Lead Managers, reserves the right to vary any and all of the above dates and times without notice (including, subject to ASX Listing Rules and the Corporations Act, to close the Offer early, to extend the Closing Date, to accept late Applications or bids, either generally or in particular cases, or to cancel or withdraw the Offer, in each case without notifying any recipient of this Prospectus or any applicants). If the Offer is cancelled or withdrawn, then all application monies will be refunded in full (without interest) as soon as possible in accordance with the requirements of the Corporations Act. Investors are encouraged to submit their Applications as early as possible after the Offer opens.

How to invest

Applications for Shares can only be made by completing and lodging the Application Form attached to or accompanying this Prospectus.

Instructions on how to apply for Shares are set out in Section 7 of this Prospectus and on the back of the Application Form.

Letter from the Chair

Dear investor,

On behalf of the board, it is my pleasure to offer you the opportunity to become a shareholder in Lumos Diagnostics Holdings Limited (**Lumos**).

Lumos is a fully integrated developer and manufacturer of point-of-care (**POC**) diagnostic tests, with corporate headquarters in Melbourne Australia, and manufacturing facilities in California and Florida in the United States. The business was founded in 2015 by Planet Innovation (located in Melbourne, Australia) and merged with Florida-based Rapid Pathogen Screening, Inc. in 2019.

Lumos develops and manufactures proprietary and in-licensed POC diagnostic tests for commercial sale through distributors under its Products division, and develops and manufactures POC diagnostic tests for clients under fee-based commercial contracts, under its Commercial Services division. Lumos' Products and Commercial Services divisions are underpinned by its technology platform, which includes Lumos' patents, know-how, expertise, skills and capabilities for developing lateral flow POC diagnostic tests for different commercial applications and markets, in addition to a range of customisable digital reader formats and digital applications (hardware and software tools) developed by Lumos.

In FY20, Lumos launched FebriDx®, a 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. Lumos has already appointed distributors and commenced initial commercial sales of FebriDx® in target markets including the United Kingdom, Germany and Canada. An initial 510(k) submission for regulatory clearance for FebriDx® in the United States is currently under review with the US Food and Drug Administration (**FDA**) for the use of FebriDx® to differentiate viral from bacterial infection in patients with acute respiratory infections. Subject to approval from the FDA for FebriDx®, Lumos intends to launch the product into the United States market.

Lumos is led by an experienced senior leadership team and has a track record of achieving revenue growth. For example, in 1H21 Lumos' Commercial Services division generated revenue of $9.8m compared to revenue of $3.3m in 1H20, while its Products division generated 1H21 revenue of $1.7m compared to revenue of $0.1m for 1H20. Lumos made a pro-forma EBITDA loss of $17.7m in FY20, reflecting continued investment in sales and marketing, clinical trials, facilities expansion, manufacturing scale-up, research & development and building out the senior leadership team and is not expected to be profitable in the prospectus forecast period.

The purpose of the offer is to provide funding and financial flexibility to support Lumos' growth strategy and future growth opportunities; broaden Lumos' shareholder base and provide a liquid market for shares; provide Lumos with the benefits of an increased brand profile that may arise from being a publicly listed entity; and provide existing securityholders with an opportunity to realise a portion of their investment in Lumos.

The offer will raise $63.0m at $1.25 per share, comprising the offer of $38.0m of new shares by Lumos, and $25.0m of existing shares allowing existing securityholders an opportunity to realise part of their investment in Lumos. Upon completion of the offer, new shareholders are expected to hold approximately 33.6% of Lumos shares. Existing securityholders will retain approximately 66.4% of Lumos shares, of which approximately 75.6% of those shares will be escrowed voluntarily following the completion of the offer, with a staged release.

This prospectus contains detailed information about the offer, the industry in which Lumos operates, Lumos' growth strategies, and its financial and operating performance. Risk factors that could affect Lumos' business, including its financial position, performance and prospects, include risks in relation to regulatory approvals and responsibilities; product acceptance; reliance on distributors and clients and suppliers; timing of orders and services; and risks in investing in shares generally. These and other risk factors are described in further detail in section 5 and should be considered in detail before making any investment decision. It is important that you read this prospectus in its entirety, and if you have any queries consult with your accountant, financial adviser, stockbroker, lawyer or other professional adviser before making any investment decision.

On behalf of my fellow directors, I look forward to welcoming you as a shareholder in Lumos.

Yours sincerely,

Sam Lanyon
Executive Chair, Lumos Diagnostics Holdings Limited

Section 1

Investment Highlights

1.1. Introduction

Topic	Summary	For more information
Who is Lumos and what does it do?	Lumos Diagnostics (**Lumos**) is a fully integrated developer and manufacturer of rapid, point-of-care (**POC**) diagnostic solutions. Lumos' capabilities and technologies allow it to take a POC diagnostic test from the early stage of developing an initial product concept, through development, clinical validation and verification, and then to manufacture of the test at commercial scale. Lumos develops and manufactures proprietary and in-licensed POC diagnostic tests for commercial sale through distributors under its Products division, and develops and manufactures POC diagnostic tests on behalf of clients under fee-based commercial contracts under its Commercial Services division.	Section 3
What is the history of Lumos?	The Lumos business was founded in 2015 by Planet Innovation (located in Melbourne, Australia) following the acquisition of Nplex Pty Ltd, which owned proprietary technologies for electronic readers of diagnostic tests. In 2017, the business acquired Kestrel Biosciences, Inc, further expanding the business' technology platform and bringing with it a rapid diagnostic assay development capability. The "Lumos Diagnostics" name was adopted in 2017. In 2019, Lumos merged with Florida-based Rapid Pathogen Screening, Inc. (**RPS**) which was primarily focused on the development and commercialisation of the POC diagnostic test FebriDx®.	Section 3.1.2
What is POC diagnostic testing?	POC diagnostic testing is an area of testing in which analysis is performed, and healthcare is provided to the patient, without requiring access to a laboratory or specialist testing facility. POC diagnostic tests are typically simple to conduct and can provide rapid results while the patient is still present. POC diagnostic tests have numerous applications including testing for infectious diseases, glucose levels, fertility and pregnancy, cancers and cholesterol levels. Testing for infectious diseases, Lumos' primary focus, includes testing for bacterial versus viral infections, influenza, HIV, hepatitis, tuberculosis, sexually transmitted diseases, healthcare-associated infections, and tropical diseases and lately COVID-19. POC diagnostic testing can be carried our using different technologies in different settings or environments.	Section 2.2
What is the industry in which Lumos operates?	Lumos participates in the POC diagnostic testing market with a focus on the development and commercialisation of POC diagnostic tests for infectious diseases. Global sales for POC diagnostic tests were approximately US$29.6 billion in 2020.[1] POC diagnostic tests for infectious diseases accounted for approximately 9.8% of the total global sales of all POC diagnostic tests in 2020.[2] Lumos' is currently focused on the North American and European markets which collectively make up approximately 64% of the global market for POC diagnostic tests.[2] The total addressable market for POC diagnostic tests for the purpose of identifying infectious diseases in North America and Europe per annum is currently estimated to be approximately US$1.8 billion (approximately 6% of the total POC diagnostic market).[2]	Section 2.1 and 2.3

1. MarketsandMarkets, Point of Care / Rapid Diagnostics Market - Global Forecast to 2025, published on February 2021 ("MarketsandMarkets Report, 2021").
2. MarketsandMarkets Report 2021.

1.2. Key features of Lumos' business model

Topic	Summary	For more information
How does Lumos generate revenue?	Lumos generates revenue from its two complementary business divisions: • **Products**: develops and manufactures proprietary and in-licensed POC diagnostic tests for commercial sale by Lumos; and • **Commercial Services**: develops and manufactures POC diagnostic tests on behalf of clients under fee-based commercial contracts. Lumos uses third-party distributors to sell its POC diagnostic tests to its end customers.	Section 3.2.1
What is Lumos' technology platform?	Both Lumos' Products and Commercial Services divisions are underpinned by a technology platform that includes intellectual property covering the technology used in Lumos' POC diagnostic tests and its range of digital reader formats and digital applications. Lumos uses its technology platform and other capabilities (such as designs, in-house expertise and facilities) to develop and manufacture POC diagnostic tests which can be customised for specific applications and end user settings. Lumos' technology platform encompasses: • **POC diagnostic tests**: rapid tests, comprising of test strips encased in a cassette, with associated technologies that analyse, interpret, display and, for some products, transmit the result of the diagnostic test electronically; • **Digital reader formats**: Lumos has developed a range of digital reader formats that can be customised to work with specific POC diagnostic tests; and • **Digital applications**: hardware and software tools that can enhance the functionality of a test and its connectivity across a range of different user settings, for example in-patient, out-patient and over-the-counter (**OTC**) settings.	Section 3.3
What does Lumos' Products division provide?	Lumos' Products division uses its capabilities (such as design, in-house expertise and facilities) to develop and manufacture proprietary and in-licensed POC diagnostic tests for commercial sale. Lumos' Product portfolio currently comprises of two POC diagnostic tests that are available for sale in certain markets: • **FebriDx®**: a POC diagnostic test able to rapidly identify microbial infections in patients with acute respiratory infection (**ARI**) symptoms and, if positive, determine if that infection is caused by a virus or bacteria. FebriDx® has regulatory approval in several markets including Europe, Canada, the United Kingdom and Australia. A 510(k) submission with the United States Food and Drug Administration (**FDA**) is currently under review for the use of FebriDx® to differentiate viral from bacterial infection in the United States. Lumos will also need to obtain or identify applicable reimbursement codes if it wishes to obtain reimbursement (for example from governments) for FebriDx® in a particular jurisdiction or jurisdictions. • **CoviDx™**: a POC diagnostic test which detects antigens present on the COVID-19 virus and may be used to test subject for an active COVID-19 infection. CoviDx™ has been granted a CE Mark for sale in Europe, and Lumos has applied for country-specific regulatory clearances to allow sales of CoviDx™ in the United States and Canada (which are currently under review by the FDA and Health Canada). Lumos' Products division is seeking to expand its sales of POC diagnostic tests and Lumos has a pipeline of new proprietary diagnostic POC tests currently under development.	Section 3.1, 3.4 and 3.5

Topic	Summary	For more information
What Commercial Services does Lumos provide?	Under the Commercial Services division, Lumos develops and manufactures POC diagnostic tests for clients by providing a comprehensive range of services across three key areas: • **Strategic innovation**: developing a POC diagnostic test product concept, including evaluating its commercial potential, developing an assay, undertaking initial studies and clinical trials; • **Development and manufacturing**: developing the POC diagnostic test (including the integration of a digital reader) into a commercial-ready form and developing the manufacturing process; and • **Validation and commercial manufacturing**: supporting applications for regulatory clearance (the compiling of clinical and quality data) and undertaking commercial manufacturing.	Section 3.1
Who are Lumos' Commercial Services clients?	Lumos' clients represent a combination of established multi-national companies and well-funded early stage healthcare companies seeking to develop one or more POC diagnostic tests which, if successful, may lead to on-going manufacturing contracts. Lumos has a diverse client base and has undertaken various degrees of contracted development work for over 20 different clients since its inception. Clients that Lumos has worked with are spread across various complementary industries to Lumos, including: • Human diagnostics and wellbeing; • Food safety and quality; • Animal health; and • Pharmaceuticals and clinical trials. Lumos recently added a manufacturing capability to provide a more comprehensive Commercial Services offering for its clients and to provide the option to continue the commercial relationship with its clients beyond the development of the POC diagnostic tests and digital readers. Lumos has already commenced production under its first Commercial Services manufacturing contract, and is in the process of transferring other POC diagnostic tests that it has developed for clients into commercial manufacturing.	Section 3.6.3
What is Lumos' sales strategy for its Products division?	Lumos' Products are developed for use by end customers in a variety of setting, including hospitals and critical care centres and outpatient facilities. Lumos sells its Products using one or more distributors in each region or country-defined market. Lumos provides marketing resources including local managers who support the in-country distributors. Lumos has already appointed distributors and commenced initial commercial sales of FebriDx® in the United Kingdom, Germany and Canada. The distributors focus on local marketing initiatives, local pricing, order fulfillment, inventory management and customer support. Lumos' staff focus on overseeing and managing the distributor relationships and on securing country-specific clinical data, regulatory clearances and reimbursement in each market. In addition to the existing appointed distributors, Lumos intends to appoint three to four national and regional distributors in the United States once FDA regulatory clearance for FebriDx® is obtained.	Section 3.4.8

Section 1
Investment Highlights

Topic	Summary	For more information
What is Lumos' growth strategy?	**Products** Lumos is seeking to grow its Products division by securing regulatory approvals for its existing and new products and commencing sales of those products in its target markets. Lumos is directing its initial commercial efforts for FebriDx® to settings where doctors and clinical staff require a diagnostic test to help determine if a patient has a bacterial or viral infection in order to determine if prescribing an antibiotic is appropriate. Lumos is also currently developing new test formats for FebriDx® that will use multi-use disposable and desktop readers and new POC diagnostic tests for three different infectious diseases, being: • **ViraDx**™: a rapid, lateral-flow test for simultaneously detecting infection by either influenza A or B (being two strains of the influenza virus) and COVID-19; • **UriDx**™: a rapid, lateral-flow test for patients who potentially have a urinary tract infection; and • **SepsiDx**™: a rapid, lateral-flow test for patients who potentially have a bloodstream infection (sepsis). The development and successful commercialisation of each of Lumos' pipeline tests is subject to uncertainties, including successful clinical validation that supports regulatory clearances in Lumos' target markets and obtaining those regulatory approvals, and is not guaranteed. **Commercial Services** Lumos aims to grow its Commercial Services business by seeking long-term strategic collaborations with clients and engaging in comprehensive projects and activities with longer-term revenue potential. This includes converting development projects into multi-year contract manufacturing agreements. Lumos' strategy with its Commercial Services division is to: • Streamline the core service business to focus on assay development, digital reader customisation, and manufacturing for pharmaceutical and medical device companies who target non-infectious medical conditions; • Partner with companies with novel reagents that seek assay development as well as with existing assay providers to develop or translate commercially viable tests on to a digital platform; • Translate development services into long-term supply relationships (e.g. test strips, digital readers); and • Limit COVID-19 projects to be a minority of the base business.	Section 3.6.6, 3.5 and 3.4.10

Topic	Summary	For more information
What key impacts has COVID-19 had on Lumos?	The COVID-19 pandemic resulted in a number of changes to Lumos' operations but had minimal impact on Lumos' overall productivity. The COVID-19 pandemic has provided opportunities for companies developing or selling POC diagnostic tests, including Lumos, through an increased awareness of the need for rapid and accurate diagnostic tests for infectious diseases. For Lumos specifically, the COVID-19 pandemic led to: • **FebriDx® sales growth in inpatient/hospital settings in the United Kingdom, Canada and Germany**: Healthcare professionals need to rapidly assess the risk of suspected COVID-19 infected patients when they present at hospitals. FebriDx® could be used in the triaging process by providing a means to rapidly identify high risk patients (namely, those patients with an active, viral infection) for isolation while a COVID-19 specific confirmatory test was conducted. • **The development of new infectious disease POC diagnostic tests**: Lumos was able to leverage its technology platform to develop an antigen POC diagnostic test for COVID-19 testing (CoviDx™) for sale via Lumos' distribution channels and its existing Commercial Services relationships for the distribution of these products, such as with DiaSorin; and • **Increased demand for Lumos' Commercial Services**: industry response to the COVID-19 pandemic has resulted in new agreements between Lumos and large healthcare businesses (e.g. DiaSorin).	Section 3.2.4
What is Lumos' Intellectual Property portfolio?	Both Lumos' Products and Commercial Services divisions are underpinned by a technology platform that includes intellectual property covering the technology used in Lumos' POC diagnostic tests and its range of digital reader formats and digital applications. Lumos' proprietary Products and Commercial Services products utilise Lumos' intellectual property in their production which may include: • Patents that cover the test strip components, specific biomarkers and combination thereof, and the use of an electronic reader • Trademarks; • Specialised and novel external controls; and • Software code, applications and test procedures.	Section 9
Where are Lumos and its employees located?	Lumos has established two manufacturing facilities located in Sarasota, Florida and Carlsbad, California which include manufacturing facilities, research and development laboratories and offices for sales, marketing, product support and general administration support in the United States. As at 1 May 2021, the two United States facilities cover 42,000 square feet (3,900 square metres) and have a combined manufacturing capacity of approximately 10m tests per month. Lumos' United States facilities are MDSAP certified and ISO13485 compliant. As at 1 May 2021, Sarasota has approximately 63 FTEs and Carlsbad has 42 FTEs. Two FTEs are located in the United Kingdom, and three FTEs are located in Melbourne.	Section 3.7

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Investment Highlights

1.3. Key characteristics of the industry in which Lumos operates

Topic	Summary	For more information
What is the POC diagnostic testing competitive landscape?	The POC diagnostic test industry is highly fragmented with a large number of participants offering POC diagnostic tests. These companies typically fall into three broad categories: • Multi-disciplinary healthcare companies; • Specialist diagnostic companies; and • Emerging diagnostic companies. Lumos classifies itself as an emerging diagnostic company, being a type of company that is usually in the early stages of development or commercialisation and typically has a few specialised diagnostic products focused on a particular diagnostic marker, therapeutic area or testing platform.	Section 2.6
What are the regulatory regimes that apply to Lumos?	The use, supply and manufacturing of POC diagnostic tests is subject to extensive regulation across jurisdictions. 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. The first format of Lumos' FebriDx® test is a standalone, disposable, qualitative product that has received regulatory clearance in several markets, including Europe, Australia, and Canada. An initial 510(k) submission for regulatory clearance for FebriDx® in the United States is currently under review with the FDA for the use of FebriDx® to differentiate viral from bacterial infection.	Section 2.7
What are the industry growth drivers?	The use of POC diagnostic tests is expected to increase from 2020 to 2025 due to their ability to provide non-specialist users with results in a short time frame without needing to access a testing laboratory, and a growing trend towards decentralisation of healthcare services.[3] There are a number of key trends supporting growth in the POC diagnostic testing market, including: • Technological developments; • Decentralisation of healthcare services; • Growing incidence and prevalence of healthcare conditions that benefit from regular monitoring; • Operational efficiencies and healthcare economics; • Shortage of skilled laboratory technicians; • Onshoring of manufacturing – security of domestic supply; • Rapid diagnostic benefits becoming mainstream; and • Emerging markets increased use of POC diagnostics tests.	Section 2.5.1 and 2.5.2

3. Markets and Markets Report, 2021.

Topic	Summary	For more information
What key considerations may limit growth of the POC diagnostic testing market?	Key growth considerations in the POC diagnostic testing market that may limit adoption and/or production include: • Higher price points than laboratory-based tests; • Resistance to change existing testing procedures; • Lack of alignment with results from central laboratories; and • More complex regulatory and reimbursement paths.	Section 2.5.2
Has COVID-19 impacted the POC diagnostic testing market?	COVID-19 has highlighted several benefits of POC diagnostic tests, including convenient and rapid results and immediate patient management which has driven demand for COVID-19 related POC diagnostic testing. These tests have also allowed for the diagnosis of patients in a range of different user settings, including at home. With calls for continued COVID-19 testing as international travel resumes, the demand for POC diagnostic testing is expected to continue.[4] In addition, adoption of COVID-19 specific POC diagnostic tests has brought greater awareness to the POC diagnostics testing market in general.	Section 2.5.3
What is the global issue of overuse and misuse of antibiotics?	When patients present with acute ARI symptoms, it is often difficult to distinguish between a bacterial or viral ARI as they often have similar symptoms. As a result, patients may be prescribed antibiotics out of caution so as not to accidently miss a possible bacterial infection. The United States Center for Disease Control and Prevention (**CDC**) estimates that at least 30% of antibiotics prescribed in outpatient settings are unnecessary, meaning the patient does not have a bacterial infection to treat. The unnecessary prescribing of antibiotics has two major healthcare implications: • **Immediate side effects**: numerous patients experience side-effects or allergic reactions to antibiotics, some of which can be serious and require additional medical interventions or even hospitalisation; and • **Antibiotic drug resistance (antimicrobial resistance)**: unnecessary and inappropriate use of antibiotics contributes to the emergence of antibiotic resistant strains that no longer respond to these drugs In 2019, the World Health Organization (**WHO**) identified antimicrobial resistance as one of the 10 greatest public health threats facing humanity. It has been estimated that if no steps are taken to reduce their emergence, antibiotic-resistant bacteria may be responsible for up to 10m deaths worldwide by 2050. Lumos' FebriDx® test can be used by healthcare providers to rule out patients that do not have a bacterial infection and therefore make an informed decision not to treat the patient with antibiotics.	Section 2.4.2, 2.5.4 and 3.4

4. Christopher Price and Andrew John, Will COVID-19 be the coming of age for point-of-care testing?, BMJ Innovations 2021 vol. 7, published on December 2020.

1.4. Investment highlights

Topic	Summary	For more information
Strong financials	Lumos' Commercial Services business has grown rapidly delivering $9.8M in revenue in 1H21 ($3.3M in 1H20) as a result of a contribution from development services, with revenue from recently added manufacturing capability commencing in 2H21.	Section 4
Proprietary products	Lumos' Products division uses its capabilities (such as design, in-house expertise and facilities) to develop and manufacture proprietary and in-licensed POC diagnostic tests for commercial sale. Lumos' first proprietary POC diagnostic product, FebriDx®, which distinguishes between viral and bacterial infections for ARIs, has commenced sales in UK, Germany and Canada. Lumos has also submitted a 510(k) application with the FDA for the use of FebriDx® to differentiate viral from bacterial infection.	Section 3.2.2, 3.4 and 3.5
FebriDx® is a new disruptive technology	The use of POC diagnostic tests for rapid bacterial versus viral detection like FebriDx® is a new, disruptive technology. The FebriDx® test can be used by healthcare providers in these interactions to rule out patients that do not have a bacterial infection and therefore make an informed decision not to treat the patient with antibiotics. This can provide immediate beneficial outcomes to patients and physicians through providing more diagnostic certainty and confidence around the most effective treatment for the patient.	Section 2.4.2 and 3.4
Products and Commercial Services divisions are underpinned by its technology platform	Lumos' technology platform includes its patents, know-how, expertise, skills and capabilities for developing lateral flow POC diagnostic tests and the digital readers that are used with those tests. In addition to the core, underlying technology, the technology platform may also include: • **Components**: ready access to key components that are used in the different products; • **Processes**: established design, development, production and delivery processes; • **Knowledge**: experience, skills and methods for developing products; and • **People**: team and organisational structure, supplier networks, established partnerships. One of the key features of a technology platform is that it can be used to develop multiple products that have different applications for different commercial markets. As a consequence, product development using a technology platform is generally faster, cheaper, and less risky compared to creating each new product from scratch.	Section 3.3.1
End-to-end provider of POC diagnostic tests and development services	As a fully integrated developer and manufacturer of rapid POC diagnostic tests, Lumos is able to provide its clients with services that span all stages of the development for a new POC diagnostic product, from the early stage of initial product concept, through development, clinical validation and verification, and finally to the manufacturing of the test at commercial scale.	Section 3.2.3
Established client base	Lumos' clients represent a combination of established multi-national companies and well-funded early stage healthcare companies seeking to develop one or more POC diagnostic tests. Lumos has a diverse client base and has undertaken various degrees of contracted development work for over 20 different clients who operate in various complementary industries to Lumos.	Section 3.6.3

Topic	Summary	For more information
Large addressable market	Lumos operates in the POC diagnostic testing market, estimated to be worth approximately US$29.6 billion in 2020. The total addressable market for POC diagnostic tests in North America and Europe per annum for the purpose of identifying infectious diseases (which is Lumos primary focus market) is currently estimated to be approximately US$1.8 billion (approximately 6% of the total POC diagnostic market). In the United States, approximately 150m patients present to inpatient and outpatient settings with ARI symptoms per year.[5] The FebriDx® test can be used by healthcare providers to rule out patients that do not have a bacterial infection and therefore make an informed decision not to treat the patient with antibiotics.	Section 2.3.1
Pipeline of additional proprietary POC diagnostics tests and new test formats for FebriDx®	In addition to FebriDx® and CoviDx™, Lumos has a pipeline of tests it is developing for other infectious disease applications. Lumos is also currently developing new test formats for FebriDx® that will use multi-use disposable and desktop readers.	Section 3.5
Board and Senior Leadership Team with a depth of experience in the medical technology industry	Lumos' Board and Senior Leadership Team are highly experienced in the medical technology and diagnostics industry both in the Unites States and in Australia. Lumos is led by a Senior Leadership Team with strong technical and commercial experience and who have extensive knowledge of the Lumos business and the industry in which the Group operates.	Sections 6.1 and 6.2

5. Tamar Barlam et al, Unnecessary Antibiotics for Acute Respiratory Tract Infections: Association With Care Setting and Patient Demographics, Open forum infectious diseases vol. 3(1), published on February 2016; Patricia Sweeney, Improving Appropriate Antibiotic Use For Common Clinical Conditions in Urgent Care, The Journal of Urgent Care Medicine, published on June 2017.

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1.5. Key risks (see also Section 5)

Topic	Summary	For more 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 required to maintain certification and compliance with regulatory and notified bodies in order to produce Lumos' Products, and Commercial Services client products. Lumos' failure to comply with ongoing regulatory responsibilities or requirements could jeopardise Lumos' ability to produce or sell its products and result in enforcement action by the FDA, the European Union or the applicable regulatory authorities in other markets in which Lumos sells/markets its products. Such enforcement actions may include recalls or seizures of products, fines, total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current approvals, resulting in prohibitions on sales of Lumos' products; and in the most serious cases, criminal penalties. Any of the above actions could negatively impact Lumos' reputation and have an adverse effect on Lumos' operating and financial performance.	*Section 5.1.1*
Reliance on Distributors	The success of Lumos' Products division relies on its ability to attract, retain, support and motivate distributors. The loss of, or any significant decrease in business from distributors may negatively impact Lumos' financial performance. If product distributors or end clients 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. Lumos is also reliant on the success of its distributors' sales and marketing teams to adequately promote Lumos' Products, and for the distributors to promote the Products in accordance with the relevant regulatory requirements governing advertising including labelling and promotional materials. If distributors do not expend sufficient resources to promote the marketing and sales of Lumos' Products, or do not promote the Products in accordance with the relevant regulatory requirements, Lumos' operating and financial performance may be adversely affected.	Section 5.1.2
Reliance on Commercial Services 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. Lumos' Commercial Services clients and partners rely on having regulatory approved products and the sale of these products relies on obtaining or maintaining regulatory approvals or other clearances. The Commercial Services clients are responsible for obtaining and maintaining the regulatory approvals for finished products and Lumos is therefore dependent on these parties to do so. Commercial Services clients are also reliant on the performance of their distributors to sell their products to end clients. The loss of, or a significant decrease in, the business from Lumos' Commercial Services clients could adversely impact Lumos' revenues.	Section 5.1.3

Topic	Summary	For more information
Reliance on suppliers	Lumos is reliant on third party suppliers for the development and manufacture of outsourced Commercial Services 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.	Section 5.1.4
Timing of orders and services	Lumos is expected to supply products to distributors and Commercial 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 if a client requires a change to product labelling). 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 Commercial Services clients and may adversely impact Lumos' operating and financial performance within a specific period or in general.	Section 5.1.5
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 Commercial Services divisions. 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.	Section 5.1.6
Loss making	Lumos has operated at a loss since its incorporation. Lumos had a statutory net loss after tax of $13.5m and $18.3m on a pro forma basis in FY20 (please to Section 4.3.1 and 4.3.2). Lumos anticipates that its operating expenses will continue to rise as it expands its operations and continues to invest in developing its product pipeline. These expenses may prove more costly than Lumos' budgets and Lumos' revenue may not increase sufficiently to turn an operating profit and become cash flow positive. Should these extra expenses occur, Lumos will continue to incur losses, or it may have to reduce its product development expenditure, either of which may have a negative impact on Lumos' financial performance.	Section 5.1.7

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Topic	Summary	For more information
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 (see Section 9 for an overview of Lumos' intellectual property rights). 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. The granting of a patent does not guarantee that competitors will not develop competing intellectual property that misappropriates, circumvents or works around the patent. 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. There is also a risk that effective intellectual property protection, including patents, trademark, copyright and trade secrets, may not be available in every country in which Lumos' Products are available. 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.	Section 5.1.8
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, managed care organisations and private health insurers. 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. This could have a material impact on the viability of new Products or demand for existing Products and have an adverse impact on Lumos' financial performance.	Section 5.1.9
Ability to attract and retain key personnel	Lumos relies heavily on existing key management personnel who have intimate knowledge of the business and its Products. If a member of Lumos' key management 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.	Section 5.1.10

Topic	Summary	For more information
Repayment of monies advanced under the PPP	In 2020, Lumos' two U.S. subsidiaries applied for and obtained an aggregate of US$1.88m in loans under the U.S. Small Business Administration's Paycheck Protection Program (PPP), which were made available to U.S. companies to help retain employees through the COVID-19 pandemic. Under the PPP, loans made to eligible borrowers qualify for full loan forgiveness subject to satisfying certain conditions. When applying for the PPP loans, Lumos' subsidiaries expected to apply for and receive forgiveness on all monies provided under the PPP. Based on a recent review of monies provided under the PPP, Lumos has determined that, although its subsidiaries' applications under the PPP were made in good faith, Lumos' subsidiaries mistakenly received proceeds in excess of the amounts permitted under PPP program requirements as a result of an error in the initial calculation of the amount it was entitled to receive. Lumos' subsidiaries repaid the excess amount to the PPP lenders together with any accrued interest on 27 May 2021. While Lumos' believes it has complied with necessary requirements to receive forgiveness of the amount it was entitled to receive, there is a risk that Lumos may not be able to receive forgiveness for this amount, or that its PPP bank lenders will seek to accelerate and demand the immediate repayment of the amount, or Lumos may be subject to material criminal, civil and/or administrative penalties for failure to comply with the PPP laws.	Section 5.1.11
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, including hospitals and critical care centres. The adoption of Lumos' own Products may take longer or have lower market penetration due to difficulty in securing market acceptance by healthcare professionals. Further, there is no guarantee that the adoption of Lumos' Products will be sufficient enough to meet Lumos' sales objectives. Insufficient market acceptance would likely impact Lumos' operating and financial performance.	Section 5.1.12
Reduction in demand for Lumos' products currently being used in relation to COVID-19	Demand for Lumos' services in the last 12 months 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. There is a risk that the demand for these products could decline as the impact of the COVID-19 pandemic is reduced. 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.	Section 5.1.13

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Topic	Summary	For more information
Other risks	There are a number of other risks that may impact an investment in Lumos relating to the below: • Competition • Product pipeline and development of new product • Product liability • Manufacturing/production risks • Early termination of customer contracts • Management of growth • Currency movements may be unfavourable • Privacy risk • Execution of strategic vision • Future acquisitions • Work health and safety • Country/region specific risks In addition, Section 5.2 outlines some general investment risks. Investors should review all these risks carefully before making an investment decision	Section 5.1.13 to 5.1.25 and Section 5.2

1.6 Summary of key financial information

Topic	Summary	For more information
On what basis has the Financial Information been prepared?	The Financial Information included in this Prospectus is intended to present potential investors with information to assist them in understanding the underlying historical financial performance, cash flows and financial position of Lumos, together with its forecast financial performance and cash flows. Lumos is responsible for the preparation and presentation of the Financial Information. The Financial Information presented in this Prospectus has been reviewed by BDO Corporate Finance (East Coast) Pty Ltd (BDO) in accordance with the Australian Standard on Assurance Engagements (ASAE) 3450 Assurance Engagements involving Corporate Fundraisings and/or Prospective Financial Information as stated in its Independent Limited Assurance Report. Investors should note the scope and limitations of the Independent Limited Assurance Report (refer to Section 9). Lumos operates on a financial year ended 30 June. All amounts disclosed in Section 4 are presented in Australian Dollars and, unless otherwise noted, are rounded to the nearest $1,000. Rounding in the Financial Information may result in some discrepancies between the sum of components and the totals outlined within the tables and percentage calculations. As with the rest of this Prospectus, this Section assumes all forward looking forecast financial tables are stated at AUD0.78/USD1.00.	Section 4.2

Topic	Summary	For more information
What is Lumos' historical and forecast financial performance and pro forma financial position?	Condensed versions of the Pro Forma Historical Results, Statutory Historical Results, Pro Forma Forecast Results and Pro Forma Statutory Results is set out below.	Section 4

	Pro Forma Historical		Pro Forma Forecast	Pro Forma Historical	
A$'000s	**FY19**	**FY20**	**FY21**	**1H20**	**1H21**
Revenue	6,474	8,396	23,765	3,409	11,557
EBITDA before non-operating items	(10,991)	(17,697)	(14,570)	(6,530)	(4,696)
EBITDA	(10,885)	(17,683)	(14,711)	(6,515)	(4,545)
EBIT	(11,677)	(18,368)	(15,816)	(6,956)	(4,809)
Net profit/(loss) after tax	(11,691)	(18,295)	(15,972)	(6,918)	(4,980)
Total comprehensive income	**(11,593)**	**(18,369)**	**(15,972)**	**(6,970)**	**(5,977)**

	Statutory Historical		Statutory Forecast	Statutory Historical	
A$'000s	**FY19**	**FY20**	**FY21**	**1H20**	**1H21**
Revenue	6,382	8,396	23,765	3,409	11,557
EBITDA before non-operating items	(3,518)	(14,872)	(13,673)	(5,134)	(3,348)
EBITDA	(6,591)	(12,136)	(15,358)	(5,118)	(3,198)
EBIT	(7,268)	(12,798)	(16,463)	(5,544)	(3,462)
Net profit/(loss) after tax	(6,546)	(13,447)	(20,466)	(6,232)	(4,637)
Total comprehensive income	**(6,448)**	**(13,521)**	**(20,466)**	**(6,284)**	**(5,634)**

A summary of Lumos' Pro Forma Statement of Financial Position, (as at 31 December 2020) is set out below.

Pro forma 31 December 2020	**A$'000s**
Cash	47,198
Net tangible assets	53,365
Net assets	85,994

The information presented above contains measures which are not recognised under IFRS or Australian Accounting Standards and should be read in conjunction with the more detailed financial overview set out in Section 4, including the assumptions, management discussion and analysis and sensitivity analysis, as well as the key risks set out in Section 5. Detail on the reconciliation of the pro forma historical and forecast results to the statutory historical and forecast results is provided in Sections 4.3.2 and 4.4.2.

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<table>
<tr><th>Topic</th><th>Summary</th><th>For more information</th></tr>
<tr><td>What is the sensitivity of the Pro Forma Forecast Revenue and Gross Profit?</td><td>The Forecast Financial Information is based on a number of specific and general assumptions, as described in Sections 4.6.1 and 4.6.2. These specific and general assumptions are subject to business, economic and competitive uncertainties and contingencies, many of which are beyond the control of Lumos, the Directors and management, and upon assumptions with respect to future business decisions, which are subject to change.

<table>
<tr><th></th><th>Increase/ Decrease</th><th colspan="2">Revenue</th><th colspan="2">Gross Profit</th></tr>
<tr><th>A$'000s</th><th></th><th>+</th><th>–</th><th>+</th><th>–</th></tr>
<tr><td rowspan="2">Change in AUD/USD FX Rate[1]</td><td>+/-5%</td><td>$643</td><td>$581</td><td>$286</td><td>$259</td></tr>
<tr><td>+/-10%</td><td>$1,357</td><td>$1,110</td><td>$603</td><td>$494</td></tr>
<tr><td rowspan="2">Change in contract manufacturing volumes[2]</td><td>+/-5%</td><td>$178</td><td>$178</td><td>$82</td><td>$82</td></tr>
<tr><td>+/-10%</td><td>$357</td><td>$357</td><td>$163</td><td>$163</td></tr>
</table>
Notes: Sensitivities have been applied to 2H21F only.
1. FX sensitivities applied to the AUD0.78/USD1.00 used in the Forecast Financial Information
2. Contract manufacturing volumes commenced in 2H21F.</td><td>Section 4.7</td></tr>
<tr><td>How does Lumos intend to fund its operations?</td><td>Lumos believes that from Completion it will have sufficient funds available from the proceeds of the Offer and from its operations to fulfil the purposes of the Offer and meet Lumos' stated business objectives during the Forecast Period.</td><td>Section 7.1.8</td></tr>
<tr><td>What is Lumos' dividend policy?</td><td>The Directors do not provide any assurance of the future level of dividends paid by Lumos. Lumos intends to retain future earnings to fund the development and growth of the business. Lumos does not anticipate paying dividends to shareholders for the foreseeable future.</td><td>Section 4.9</td></tr>
</table>

1.7. Directors and Management

Topic	Summary	For more information
Who are the Directors of Lumos?	The Directors of Lumos are: • Samuel Lanyon, Executive Chair; • Lawrence Mehren, Non-executive Director and Deputy Chair; • Robert Samburksy, Chief Executive Offer and Executive Director; • Bronwyn Le Grice, Non-executive Director; and • Catherine Robson, Non-executive Director.	Section 6.1
Who are the Senior Leadership Team of Lumos?	The Senior Leadership Team of Lumos are: • Robert Samburksy, Chief Executive Offer and Executive Director; • Melanie Leydin, Chief Financial Officer and Company Secretary; • Tracey Weimar, Company Secretary; • Jill Thomson, Senior VP of Corporate Strategy and Development; • Sacha Dopheide, Chief Technology Officer; • Jeffrey Bishop, Senior VP of Research and Development; • Aaron Erlandson, Senior VP of Finance; • Kurt Phinney, Senior Director of Operations; • Annie Bell, Director of Medical Affairs; • Sue Hibbeln, Senior Director of Regulatory Affairs; • Paul Kase, Vice President of North American Sales; • Jeff Bauer; Vice President of Product and Business Development; • Sarah Glubka, Senior Director of Human Resources; and • Huan Tran, Director of Quality.	Section 6.2

1.8. Significant interests of key people and related party transactions

Topic	Summary	For more information
Who are the Existing Securityholders and what will their interest be in Lumos at Completions of the Offer?	**Securityholdings as at Prospectus Date and Completion**	Section 6.3

	Prospectus Date				Sold under the Offer	Completion			
	Shares[1]		Options[2]	Fully diluted[3]	Shares	Shares[1]		Options[2]	Fully diluted[3]
Shareholder	**Number**	**%**	**Number**	**%**	**Number**	**Number**	**%**	**Number**	**%**
Planet Innovation[4]	59,822,600[5]	50.0%	–	45.3%	19,697,685	40,124,915	26.7%	–	24.7%
RPS Diagnostics[6]	15,647,189	13.1%	–	11.9%	–	15,647,189	10.4%	–	9.6%
Other security -holders[7]	44,282,624	37.0%	–	33.6%	302,315[8]	43,980,309	29.3%	–	27.1%
Option-holders[8]	–	–	12,203,663	9.2%	–	–	0.0%	12,203,663	7.5%
Investors in the Offer	–	–	–	0.0%	–	50,400,000[9]	33.6%	–	31.0%
Total	**119,752,413**	**100.0%**	**12,203,663**	**100.0%**	**20,000,000**	**150,152,413**	**100.0%**	**12,203,663**	**100.0%**

Notes:

1. **Shares on the Prospectus Date** comprises Shares (ie ordinary shares), Preference Shares (each of which will convert into 1 Share on Completion) and the number of Shares which will be issued in respect of the conversion of Pre-IPO Convertible Notes on Completion. Shares on the Prospectus Date includes the Shares to be issued to Robert Sambursky prior to Completion (see note 8 below). **Shares on Completion** comprises only Shares. The exact number of Shares to be on issue (or held by particular Existing Securityholders) at Completion will depend on the date Completion occurs (refer to Section 6.3 for a further information). The Prospectus assumes that Completion occurs on 29 June 2021. No Preference Shares or Pre-IPO Convertible Notes will remain on issue on Completion.
2. **Options** comprises the Options (each over 1 Share) on issue at the Prospectus Date and on Completion (as referred to in Section 6.4.6). Includes 5,498,515 Options held by Robert Sambursky as referred to in Section 6.4.6. Refer also to Notes 6 and 7 below.
3. **Fully diluted:** refers to the number of Shares on the Prospectus Date (or Shares on Completion) as described in Note 1 above, plus the number of Shares which would be issued on exercise of Options (each in respect of one Share).
4. Sam Lanyon does not hold any securities in Lumos at the Prospectus Date, however he holds 10.98% of Planet Innovation directly (in the form of options and restricted shares), and a trust held in his wife's name holds 256,417 Preference Shares in Lumos, resulting in an indirect economic interest in Lumos of approximately 5.7% on the Prospectus Date and 3.1% on Completion (each on an undiluted basis).
5. Represents Planet Innovation's 10,359,587 Shares and 49,463,013 Preference Shares in Lumos as at the Prospectus Date.
6. Robert Sambursky holds shares and warrants over shares in RPS Diagnostics, a Shareholder of Lumos (and 5,498,515Options in Lumos excluding the Options referred to in Note 7) at the Prospectus Date, resulting in a potential indirect economic interest in Lumos of approximately 5.1% on the Prospectus Date and, after taking into account Rob's sell-down referred to in Note 8 below, 3.9% on Completion. These percentages are calculated on an undiluted basis.
7. **Other securityholders** comprises (i) holders of 11,459,323 Preference Shares as at the Prospectus Date (excluding Planet Innovation) which will convert into 11,459,323 Shares on Completion;(ii) holders of Pre-IPO Convertible Notes which will convert into 32,561,467 Shares on Completion; and (iii) 261,834 Shares to be issued to Robert Sambursky prior to Completion pursuant to his exercise of 261,834 Options prior to the Prospectus Date. Catherine Robson's interest in Preference Shares and Pre-IPO Convertible Notes is described in Section 6.4.2.7.

Topic	Summary	For more information
Who are the Existing Securityholders and what will their interest be in Lumos at Completions of the Offer? *continued*	8. Robert Sambursky will sell 261,834 Shares (referred to in Note 7) s at the Offer Price per Share through SaleCo under the Offer to receive $327,292.50 in aggregate. These Shares will be issued with disclosure under this Prospectus. Also includes the sale by an unrelated other Securityholder of 40,481 Shares at the Offer Price per Share through SaleCo. 9. Includes 208,800 Shares expected to be applied for by Directors (directly and indirectly) under the Offer at the Offer Price as referred to in Section 6.4.2.7.	
What significant benefits and interests are held by or payable to Directors connected with Lumos or the Offer?	Directors are not required by the Constitution to hold any Shares. It is expected that the following Directors will personally (or through entities with which they are associated) hold the following Shares on Completion. **Director** / **Shares on Completion** / **Options on Completion** Sam Lanyon[1] – – Robert Sambursky[2] – 5,498,515 Catherine Robson[3] 278,839 – Bronwyn Le Grice[4] 28,400 – Lawrence Mehren[4] 80,000 – **Notes:** 1. Sam Lanyon does not hold any securities in Lumos at the Prospectus Date, however he holds 10.98% of Planet Innovation directly (in the form of options and restricted shares) and a trust held in his wife's name holds 256,417 Preference Shares in Lumos, resulting in an indirect economic interest in Lumos of approximately 5.7% on the Prospectus Date and 3.1% on Completion (each on an undiluted basis). 2. Robert Sambursky holds shares and warrants over shares in RPS Diagnostics a Shareholder in Lumos (and 5,760,349 Options in Lumos) at the Prospectus Date, resulting in a potential indirect economic interest in Lumos of approximately 5.1% on the Prospectus Date (on an undiluted basis). Robert Sambursky exercised 261,834 Options prior the Prospectus Date and will receive 261,834 Shares prior to Completion and will sell those Shares at the Offer Price per Share through SaleCo under the Offer to receive $327,292.50 in aggregate). This will give him approximately 3.9% indirect economic interest in Lumos on Completion (on an undiluted basis). These Shares will be issued with disclosure under this Prospectus. 3. Catherine's holding comprises 128,209 Shares to be issued upon conversion of Preference Shares, 90,230 Shares to be issued on conversion of Pre-IPO Convertible Notes, and 60,400 to be applied for under the Offer at the Offer Price per Share. These holdings may be held by Catherine or through an entity associated with her. 4. To be applied for under the Offer at the Offer Price per Share. These holdings may be held by the Director or through an entity associated with them.	Section 6.4.2.7
Will any Shares be subject to restrictions on disposal following Completion?	At Completion, approximately 50.2% of the Shares will be subject to voluntary escrow. In relation to the Shares held by Existing Securityholders at Completion, approximately 75.6% of those Shares will be subject to voluntary escrow arrangements. Each Escrowed Shareholder has entered into an escrow deed in respect of their Shareholding at Completion which restricts them in dealing with their respective Escrowed Shares for the applicable Escrow Periods as described in Section 6.5 subject to the terms of their escrow deeds. Certain Existing Shareholders who are allocated Shares under the Priority Offer may agree with the Company to enter into voluntary escrow deeds on equivalent terms to those entered into by Other Existing Securityholders as described in Section 6.5. Details of any such escrow arrangements will be advised to ASX by Listing.	Section 6.5

Section 1
Investment Highlights

Topic	Summary	For more information
Will there be a controlling interest in the Company?	On Completion, no Shareholder will have a controlling interest (as defined by section 50AA of the Corporations Act) in the Company.	Section 7.1.7
Are there any other related party arrangements in place?	Lumos does not anticipate that it will be party to any material related party arrangements with its Directors, officers or shareholders (or affiliates from them) from Completion other than as set out in this Prospectus. Refer to arrangements with Directors described in Section 6.3 and Section 6.4, and Section 6.7 which contains a description of the Planet Innovation MSAs between Lumos and entities associated with Planet Innovation (which will hold approximately 26.7% of the Shares on Completion, on an undiluted basis).	Sections 6.3, 6.4 and 6.7

1.9. Key terms and conditions of the Offer

Topic	Summary	For more information
Who are the Issuers of this Prospectus?	Lumos Diagnostics Holdings Limited (ACN 630 476 970) and Lumos Diagnostics SaleCo Limited (ACN 650 279 511)	Section 10
What is SaleCo?	SaleCo is a special purpose vehicle established to facilitate the sale of Existing Shares by the Selling Shareholders.	Section 10.4
What is the Offer?	This Prospectus relates to an initial public offering of 30,400,000 Shares at the Offer Price of $1.25 per Share and the sale of 20,000,000 Shares held by SaleCo. The Shares offered under this Prospectus will represent approximately 33.6% of the Shares on issue at Completion. The Offer is expected to raise $63,000,000. The total number of Shares on issue at Completion will be approximately 150,152,413 and all Shares will, once issued, rank equally with each other. A summary of the rights attaching to the Shares is set out in Section 7.11. The Offer is made on the terms, and is subject to the conditions, set out in this Prospectus.	*Section 7.1*
What is the purpose of the Offer?	The purpose of the Offer is to: • provide funding and financial flexibility to support Lumos' growth strategy and future growth opportunities; • provide Lumos with the benefits of an increased brand profile that may arise from being a publicly listed entity; • broaden Lumos' shareholder base and provide a liquid market for Shares; and • provide existing securityholders with an opportunity to realise a portion of their investment in Lumos.	*Section 7.1.2*

Topic	Summary	For more information
What is the proposed use of funds raised under the Offer?	The Offer proceeds received by the Company and SaleCo will be applied as described in Section 7.1.3.	*Section 7.1.3*

Sources of funds	A$ million	Uses of funds[1]	A$ million
The Company			
Cash proceeds received by the Company under the Offer from the issue of Shares	38.0	Infrastructure and capacity expansion[2]	5.8
		Sales and Marketing[3]	8.4
		Regulatory, Clinical and Quality[4]	3.7
		Development of test pipeline[5]	3.1
		Technology platform development[6]	5.4
		Working capital[7]	7.0
		Offer costs	4.6
SaleCo			
Cash proceeds received by SaleCo from the sale of Shares by SaleCo	25.0	Payments to Selling Shareholders for Shares in the Company	25.0
Total sources	**63.0**	**Total uses**	**63.0**

Notes:

1. This represents a statement of the Company's current intentions as at the Prospectus Date. 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. In addition, as the proceeds of the Offer will be received in Australian dollars and, as the expenditure will predominantly be in US dollars, the actual amount of the proceeds used for each of the items above will depend on the AUD:USD exchange rate at the time that the funds are converted to US dollars.
2. Infrastructure and capacity expansion related to Carlsbad facility including fit-out and manufacturing equipment for capacity increase.
3. Sales and marketing relates to increase in sales headcount and expenses for product division & commercial services divisions and establishment of commercial manufacturing e.g. pre-launch/product demonstration costs.
4. Regulatory, Clinical and Quality relates to headcount, compliance and clinical trials costs associated with Lumos branded products.
5. Development of test pipeline related to investment in new POC diagnostic tests.
6. Technology platform development related to investment in technology platform related assets e.g. digital readers and associated software applications.
7. Working capital includes general and administrative (corporate, finance, travel and general expenses) and changes in working capital in line with revenue growth.

The Board retains the right to vary these uses of funds, acting in the best interests of Shareholders and as circumstances require.

Section 1
Investment Highlights

Topic	Summary	For more information
Will the Shares be quoted on the ASX?	Lumos will apply to the ASX within seven days after the Prospectus Date for admission to the Official List and quotation of Shares on the ASX (which is expected to be under the code LDX). Completion is conditional on ASX approving this application. If approval is not given within three months after such application is made (or any longer period permitted by law), the Offer will be withdrawn and all application monies received will be refunded (without interest) as soon as practicable in accordance with the requirements of the Corporations Act. The ASX takes no responsibility for this Prospectus or the investment to which it relates. The fact that ASX may admit the Company to the Official List is not to be taken as an indication of the merits of an investment in the Company.	
How is the Offer Structured?	The Offer comprises: • the Broker Firm Offer, which is open to Australian retail clients of Brokers who have received a firm allocation from their Broker; and • the Priority Offer, which is open to investors who have received an invitation to participate in the Offer from the Company and who have a registered address in Australia; and • the Institutional Offer, which consisted of an invitation to bid for Shares made to Institutional Investors in Australia and certain other eligible jurisdictions. No general public offer of Shares will be made under the Offer	Section 7.1.1
Is the Offer underwritten?	Yes. The Joint Lead Managers have fully underwritten the Offer pursuant to the Underwriting Agreement.	Section 10.6
What is the allocation policy?	The allocation of Shares between the Broker Firm Offer, the Priority Offer and the Institutional Offer was determined by the Joint Lead Managers, the Company and SaleCo, having regard to the results of the Bookbuild and the allocation policies outlined in Sections 7.3, 7.4 and 7.5 (as applicable). For Broker Firm Offer participants, the relevant Broker will decide as to how they allocate Shares among their retail clients. The Joint Lead Managers and the Company have absolute discretion regarding the allocation of Shares to applicants under the Offer and may reject an Application, or allocate a lesser number of Shares than applied for. The Joint Lead Managers and the Company also reserve the right to aggregate any Applications that they believe may be multiple Applications from the same person.	Section 7.3, 7.4 and 7.5
Are there any escrow arrangements?	Yes. Details are provided in Section 6.5.	Section 6.5.
Has any ASIC relief or ASX waiver been sought or obtained?	Yes. Details are provided in Section 10.9.	Section 10.9.
Are there any brokerage, commission or stamp duty considerations?	No brokerage, commission or stamp duty is payable by applicants on the acquisition of Shares under the Offer. Refer to Section 6.4.1 for details of the fees payable by the Company to the Joint Lead Managers.	Section 7.2
Are there any taxation considerations?	The tax consequences of any investment in the Shares will depend upon an investor's particular circumstances. Applicants should obtain their own tax advice prior to deciding whether to invest. Refer to Section 10.11 for general Australian taxation considerations.	Section 10.11

Section 2

Industry Overview

Section 2
Industry Overview

2.1. Introduction

Lumos Diagnostics (**Lumos**) is a fully integrated developer and manufacturer of rapid, point-of-care (**POC**) diagnostic solutions. Lumos develops and manufactures proprietary and in-licensed POC diagnostic tests for commercial sale through distributors under its Products division, and develops and manufactures POC diagnostic tests on behalf of clients under fee-based commercial contracts under its Commercial Services division. Refer to Section 3 for further information on Lumos' two business divisions.

Lumos participates in the POC diagnostic testing market, with a focus on the development and commercialisation of POC diagnostic tests for infectious diseases, which accounted for approximately 9.8% of the total global sales of POC diagnostic tests by healthcare application in 2020.[1] Lumos' current principal sales efforts are directed towards the North American and European markets which collectively make up approximately 64% of the market with combined POC diagnostic test sales of approximately US$18.8 billion in 2020.[1]

Lumos has launched its primary product, FebriDx®, a POC diagnostic test for rapid bacterial versus viral detection in acute respiratory infections (**ARIs**), in the United Kingdom, Germany, and Canada. An initial 510(k) submission for regulatory clearance for FebriDx® in the United States is currently under review with the U.S. Food and Drug Administration (**FDA**) for the use of FebriDx® to differentiate viral from bacterial infection.

As described in Section 2.4, the total addressable market for POC diagnostic tests for the purpose of identifying infectious diseases in North America and Europe per annum is currently estimated to be approximately US$1.8 billion (approximately 6% of the total POC diagnostic market)[1] and for bacterial versus viral detection in the United States alone is estimated to be approximately US$2.4 billion per annum.[2]

2.2. Point-of-care diagnostic testing market

2.2.1. Overview

POC diagnostic testing is an area of testing in which analysis is performed, and healthcare is provided to the patient, without requiring access to a laboratory or specialist testing facility.[3] POC diagnostic tests are typically simple to conduct[3] and can be used in settings where access to centralised testing laboratories is limited, such as in community and primary care settings, rural and remote communities, or in developing countries.[3]

The underlying objective of POC diagnostic testing is to facilitate immediate and convenient testing. This means that results can be provided to both the patient and physician faster, which allows for more immediate clinical treatment and management decisions to be made.[3]

1. MarketsandMarkets Report, 2021.
2. This is incremental to the total addressable market for POC diagnostic tests for infectious diseases, described in Section 2.4.1.
3. Australian Department of Health, Definitions – Point-of-care testing, published on May 2013.

2.2.2. POC diagnostic testing market characteristics

The POC diagnostic testing market is a global market that can be characterised by clinical application, by technology platform, and by user setting, as outlined in Table 2.1 below:

Table 2.1: POC diagnostic testing market characteristics[4]

	Clinical application	Technology platform	User setting
Description	What is being tested	Technologies that are often used in POC diagnostic tests	The settings/environments where POC diagnostic testing is used
Examples	• Glucose • Cardiac • Infectious diseases • Fertility and pregnancy • Fecal occult • Cancer markers • Urinalysis • Cholesterol	• Lateral flow assays (**LFAs**) • Immunoassays • Microfluidics (sometimes referred to as "lab-on-a-chip") • Molecular diagnostics (for the detection of specific DNA or RNA sequences) • Dipsticks	• Hospitals and critical care centres • Outpatient and ambulatory care • At-home testing • Other community sites
Focus of Lumos' products	Lumos' own products, and many of the products Lumos develops for its clients are primarily focused on POC diagnostic tests for infectious disease	The tests that Lumos develops, both for itself and for its clients, are primarily based on lateral flow assays or immunoassays	Lumos' products are developed for a range of user environments including hospitals and critical care centres, home care settings and outpatient facilities
Further information	Refer to Section 2.2.2.1	Refer to Section 2.2.2.2	Refer to Section 2.2.2.3

2.2.2.1 POC diagnostic testing market by clinical application

POC diagnostic testing can include a wide variety of testing applications, as outlined in Figure 2.1 below. The largest share of the POC diagnostic testing market globally comes from glucose monitoring products that are regularly used by patients with diabetes.[4] The glucose testing market is mature, highly competitive, and dominated by large, multinational pharmaceutical and healthcare companies.[4] The infectious disease testing products market, which is the focus of Lumos' Products division and many of its Commercial Services projects, includes testing for bacterial versus viral infections, influenza, HIV, hepatitis, tuberculosis, sexually transmitted diseases, healthcare-associated infections, tropical diseases,[4] and more recently COVID-19. Other key market segments for POC diagnostic tests include cardiac health, coagulation testing for patients using blood thinners, and fertility and pregnancy testing.[4]

4. MarketsandMarkets Report, 2021.

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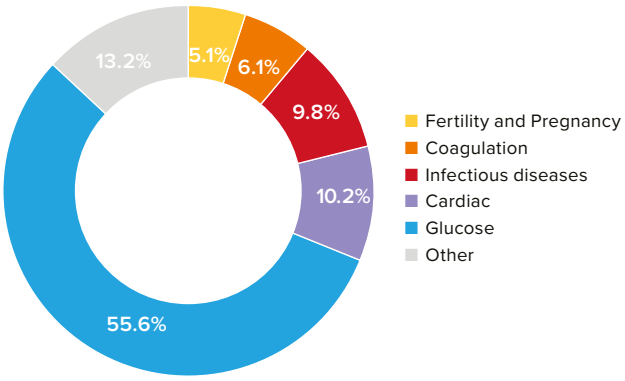
Industry Overview

Figure 2.1: POC global sales by healthcare application, 2020[5]



Note: Other applications include fecal occult, hematology, cancer markers, urinalysis, drug-of-abuse, cholesterol and other POC diagnostic tests.

Lumos focuses on the infectious diseases segment of the POC diagnostic testing market, which accounted for 9.8% of the total global sales of POC diagnostic tests by healthcare application in 2020.[5] Within infectious diseases, Lumos is a key participant in bacterial versus viral detection using POC diagnostic tests. Lumos' primary product FebriDx® accurately rules out bacterial infections in ARIs, which is important in determining whether antibiotics should be prescribed, as discussed further in Sections 2.4.2 and 3.4.

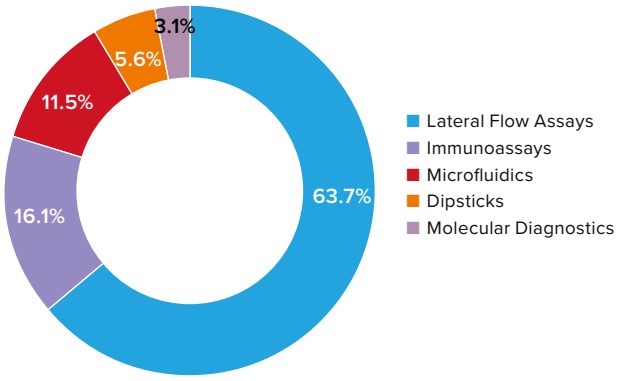
2.2.2.2 POC diagnostic testing market by technology platform

POC diagnostic tests can also be characterised by the technology platform with which they operate, shown in Figure 2.2 below. The majority of global POC diagnostic test sales in 2020 were generated from tests based on lateral flow assays (approximately 64%) or immunoassays (approximately 16%).[5] Lateral flow assays are simple devices used to detect and quantify target analytes in complex mixture samples whereas immunoassays are chemical tests used to detect and quantify analyte in the blood and body fluid samples.[5] These POC diagnostic tests use antibodies to detect the presence or absence of diagnostic markers or analytes in a liquid sample that is applied to, and allowed to diffuse through, a test strip.[5] For example, many of the at-home pregnancy tests are based on a lateral flow assay format[5], whilst a common immunoassay test is the testing of insulin to measure hypoglycemia.

Both lateral flow assays and immunoassays can be used in simple devices to detect the presence or absence of target analytes or antigens in liquid test samples such as whole blood, saliva, or urine.[5] These tests can often replace lengthy conventional laboratory procedures and are expected to continue to be the basis for the majority of POC diagnostic tests for the next five to ten years.[5] The tests developed by Lumos, both for itself and for its clients, are primarily based on lateral flow assays or immunoassays.

5. MarketsandMarkets Report, 2021.

Figure 2.2: POC diagnostic testing market by technology platform, 2020[6]

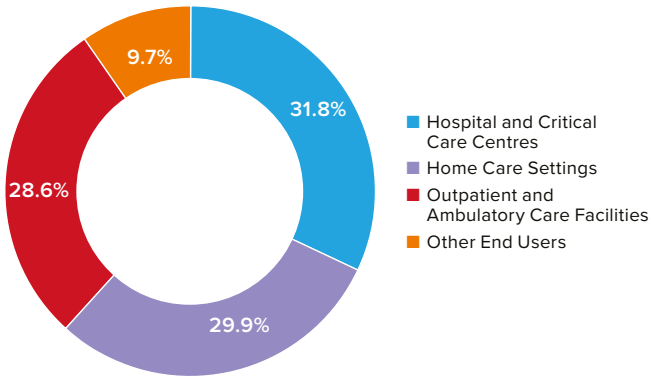


Note: Lateral flow assays and immunoassays are described above in this Section 2.2.2.2. Microfluidics is the science that studies fluid behaviour flowing through technologically advanced microminiaturised devices. Molecular diagnostics uses a technique for the analysis of biological markers to help detect specific sequences in DNA or RNA samples. Dipsticks or test trips are basic diagnostics tools that determine pathological changes in a patient's urine.[6]

2.2.2.3 POC diagnostic testing market by user setting

POC diagnostic tests can further be characterised by the end user, as outlined in Figure 2.3 below. The main settings where POC diagnostic tests are currently used are in hospitals and critical care centres, outpatient settings, at-home testing and at other community sites.[6]

Figure 2.3: POC diagnostic testing market, by end user, 2020[6]



Note: End users are described below. Other end users include rehabilitation centres, sports studios, pharmacies, old-age homes, research institutes, and blood banks.

6. MarketsandMarkets Report, 2021.

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Industry Overview

Hospitals and critical care centres are estimated to have accounted for approximately 32% of global POC diagnostic test sales in 2020.[7] A key driver for hospitals and critical care centres to use POC diagnostic tests is their ability to deliver fast results within a clinical setting.[7] While many hospitals have access to centralised testing laboratories, POC diagnostic tests are often used for the regular monitoring of patients, or in situations where a rapid result is required to enable a faster diagnosis or to allow a more timely treatment decision to be made.[7]

Home care settings (for example POC diagnostic tests used by consumers in the home) are estimated to have accounted for approximately 30% of POC diagnostic test sales in 2020.[7] Home POC diagnostic tests include blood glucose tests for patients with diabetes, pregnancy tests, and HIV test kits.[7] A key reason that home POC diagnostic tests are used is to allow testing to be conducted outside of a healthcare setting, providing consumers with easier access to tests and with greater privacy.[7] Growth in this sector is likely to be driven by an ongoing increase in consumer monitoring of health metrics, a shift towards home healthcare (telemedicine and in-home care), and an increase in the range of consumer-focused POC diagnostic tests that are available.[7]

Outpatient and ambulatory care facilities (such as general practitioner practices, urgent care clinics, hospital outpatient departments, ambulances, and specialist healthcare clinics) are estimated to have accounted for approximately 29% of POC diagnostic test sales in 2020.[7] POC diagnostic tests are often used in these settings because they are able to provide rapid results while the patient is still present, enabling more timely treatment decisions and interventions.[7] For example, in ambulances, cardiac monitoring kits are used to help with the early diagnosis of acute myocardial infarction (heart attack) while the patient is being transported.[7] In primary care settings, such as general practice clinics, POC diagnostic tests can be used to assist with the diagnosis of acute conditions, such as influenza or urinary tract infections, which can aid in prescribing the appropriate medicine or treatment while the patient is still present.[7]

In addition to the above user settings, POC diagnostic tests are also used in community settings such as rehabilitation centres, aged care homes and blood banks where there is not easy access to a testing laboratory or when a rapid result is required, for example when the tests are being used for infection control.[7]

Lumos' products are developed for a range of these user environments including hospitals and critical care centres, home care settings and outpatient facilities.

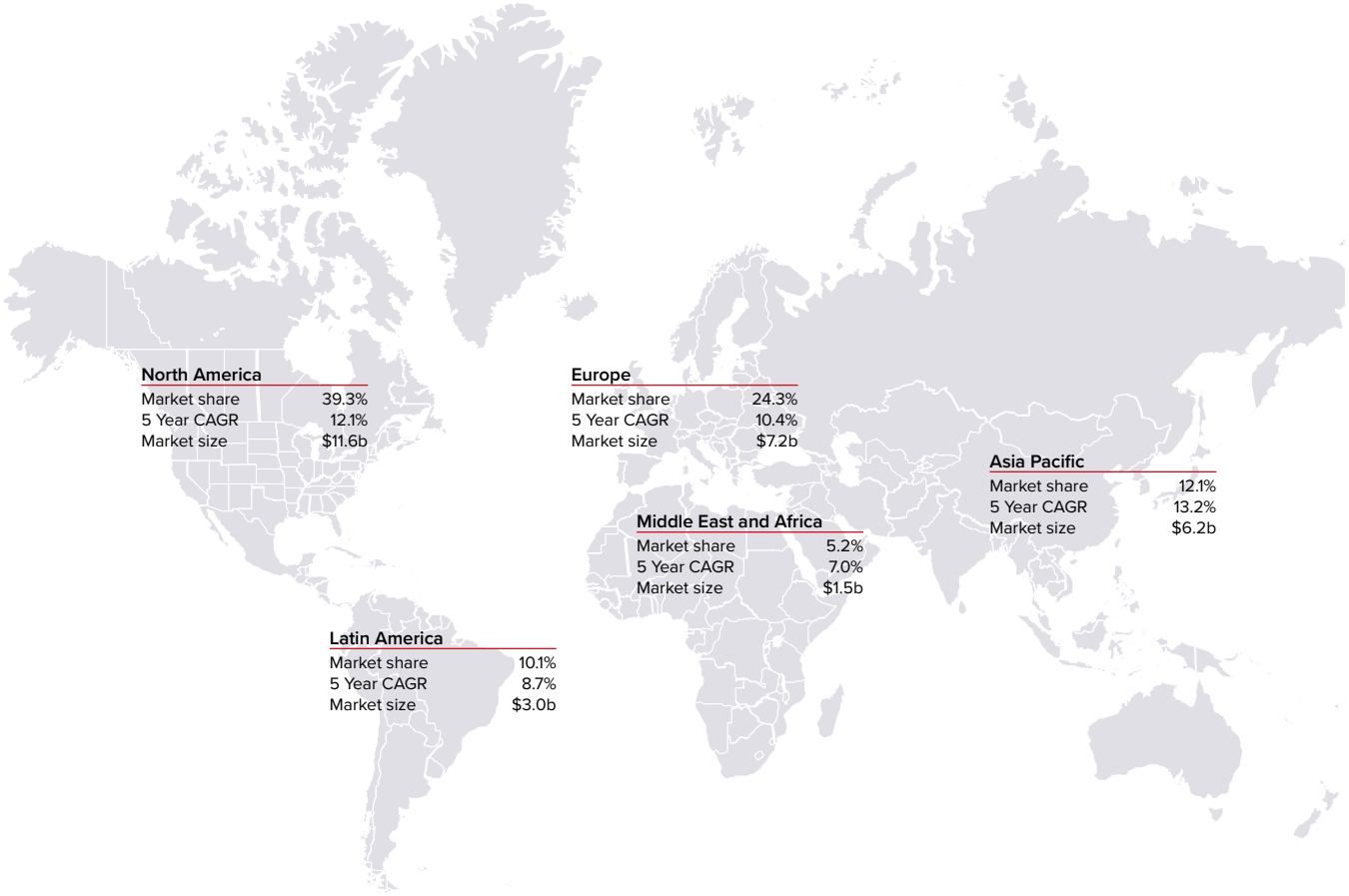
7. MarketsandMarkets Report, 2021.

2.3. Market size and growth

2.3.1. Market size

Global sales of POC diagnostic tests in 2020 are estimated to have been US$29.6 billion, with the largest sales generated out of North America (US$11.6 billion).[8] POC diagnostic test sales by region are displayed in Figure 2.4 below.

Figure 2.4: POC diagnostic global test sales (2020)[8]



The North American and European markets are a strategic focus of Lumos given they are the largest markets globally (for POC diagnostic test sales),[8] have advanced healthcare systems that can adopt new healthcare technologies, and are projected to experience rapid growth.[9] Factors driving growth in POC diagnostic testing in North America include the existence of major manufacturers and distributors, supportive government conditions for product development and patient adoption, high product quality due to widespread regulatory compliance, early uptake of novel technologies, growing awareness of reimbursement and high patient awareness of self-testing and home care.[8] Europe is also expected to experience significant growth driven by an increasing number of POC diagnostic testing conferences being held, a significant volume of ongoing clinical trials, the rising prevalence of lifestyle diseases, and the launch of several new and advanced POC diagnostic products.[8]

8. MarketsandMarkets Report, 2021.
9. European Commission, Digital health technologies addressing the pandemic, accessed on April 2021; MarketsandMarkets Report, 2021.

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The United States was estimated to account for 88.6% of the North American market in 2020.[10] In the United States, the adoption of POC diagnostic tests has been driven by an increase in the incidence and prevalence of healthcare conditions that can be tested using POC diagnostic tests (such as diabetes, hematology disorders, cancer and cardiac disorders), combined with a trend towards the decentralisation of healthcare services.[10] In the United States there has been an increasing number of healthcare services that are being provided at non-hospital locations such as community centres, local primary care practices, outpatient clinics, specialist clinics, and in patients' homes[10] as there has been a greater acceptance of POC diagnostic testing at doctor's offices, compared to hospitals.[10] Furthermore, POC diagnostic tests in the United States are covered by nation-wide regulatory and reimbursement frameworks which has facilitated their adoption in both hospital and non-hospital locations.[10]

Europe, which was estimated to account for 24.3% of the POC diagnostic market in 2020,[10] is expected to experience significant growth, with Germany, the United Kingdom, France, Italy and Spain being major contributors to the market. Germany accounts for the largest share of the European market, and has demonstrated a high demand for novel, accurate, and low-cost products and an increasing emphasis on R&D into POC testing devices.[10] In the United Kingdom, growth is driven by increased awareness of the benefits offered by POC diagnostics (such as through conferences), product development and R&D, and growing Government support to develop innovative technologies (for example through grants).[10]

In most European countries, the majority of healthcare services are state funded, universal health care single-payer systems.[11] Accordingly, in order for POC diagnostic testing to be more widely adopted throughout Europe, it must be demonstrated to governments that these tests improve workflow or deliver significant cost savings for their country. The majority of non-consumer diagnostic testing is conducted by centralised testing laboratories rather than in doctor's offices or outpatient clinics.[10] Furthermore, while the CE Mark process[12] provides a regulatory path that allows POC diagnostic tests to be marketed in most European countries, reimbursement of the tests varies throughout Europe, with the level of reimbursement determined on a country-by-country basis.[11] For countries such as France, reimbursement for several POC diagnostic tests has contributed to wider adoption of these tests.[10]

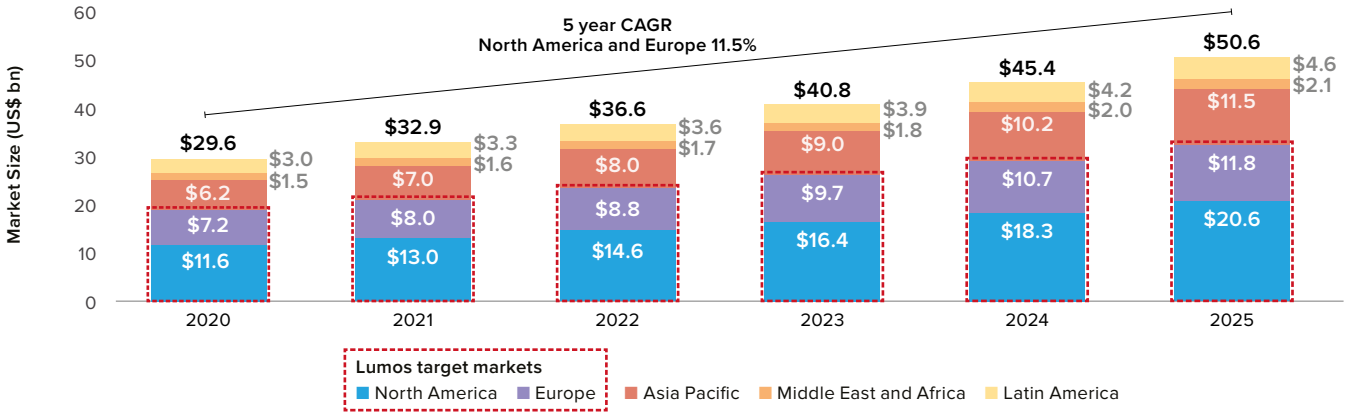
POC diagnostic tests also have strong potential utility in developing countries where access to centralised testing laboratories is often not readily available.[13] However, the prices that POC diagnostic tests typically command, combined with lower budgets for healthcare, has slowed or constrained their initial adoption in these markets.[10] It is forecast that developing countries, China and India, will collectively account for more than half (52.8%) of the Asia Pacific region POC test sales by 2025, with China being the largest contributor (37.9%), followed by Japan (35.2%) and India (14.8%). The current regulations, guidelines and operational requirements for implementing a national POC healthcare network in China are not yet developed and lab-based POC tests or home-based rapid testing is not reimbursed by the Chinese central government.[10] Given developing countries form a majority share of the Asia Pacific region, Lumos is not currently targeting this market, including Australia, which is forecast to account for 2.5% of the Asia Pacific region market by 2025.[10]

10. MarketsandMarkets Report, 2021.
11. WHO, Medicines reimbursement policies in Europe, published on March 2018.
12. CE marking is an administrative marking that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA). Source: European Commission, CE marking, published on April 2021.
13. Belinda Hengel et al, A decentralised point-of-care testing model to address inequities in the COVID-19 response, published on December 2020.

2.3.2. Market growth by region

The global market for POC diagnostic tests is expected to grow from US$29.6 billion in 2020 to US$50.6 billion by 2025, at an average growth rate of 11.4% per annum.[14] The highest growth is expected to come from emerging markets in the Asia Pacific region, projected to grow at over 13.2% CAGR from 2020 to 2025. This is followed by the more mature markets, North America and Europe, which are projected to grow at over 12.1% CAGR and 10.4% CAGR from 2020 to 2025, respectively (11.5% collectively).[14] POC diagnostic test sales by region, from 2020 to 2025, are shown in Figure 2.5 below.

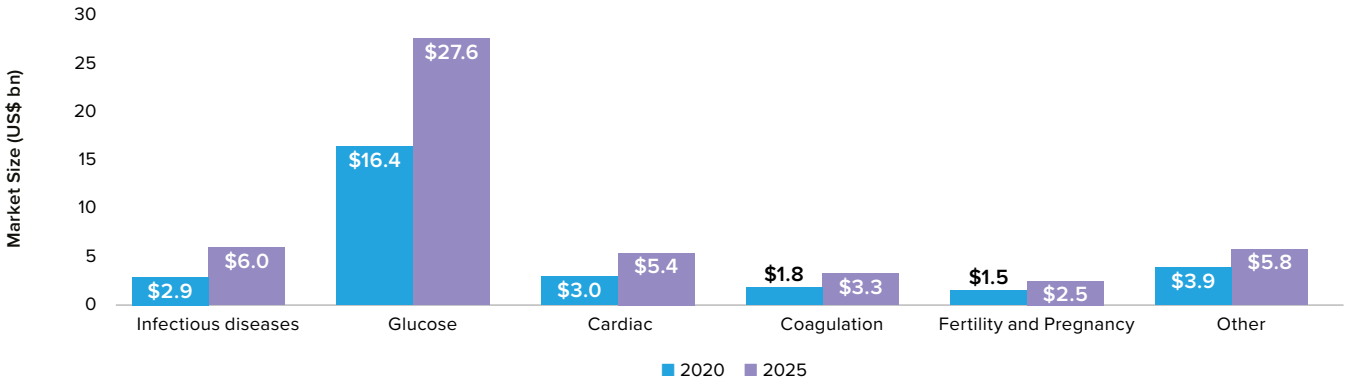
Figure 2.5: Forecast POC diagnostic tests global sales, 2020 to 2025[14]



2.3.3. Estimated market growth by application

The global market for POC diagnostic tests is expected to grow across all applications from 2020 to 2025, with glucose monitoring products continuing to be the dominant segment.[14] The highest growth is expected to come from the infectious disease testing products segment, forecast to grow from $2.9 billion in 2020 to $6.0 billion in 2025, at an average growth rate of 15.7% per annum.[14] As mentioned in section 2.2.2.1, both Lumos' Products and Commercial Services divisions focus on the infectious disease market. POC diagnostic test sales by application in 2020 and forecast sales in 2025 are shown in Figure 2.6 below.

Figure 2.6: POC diagnostic tests global sales by Application, 2020 vs. 2025[14]



14. MarketsandMarkets Report, 2021.

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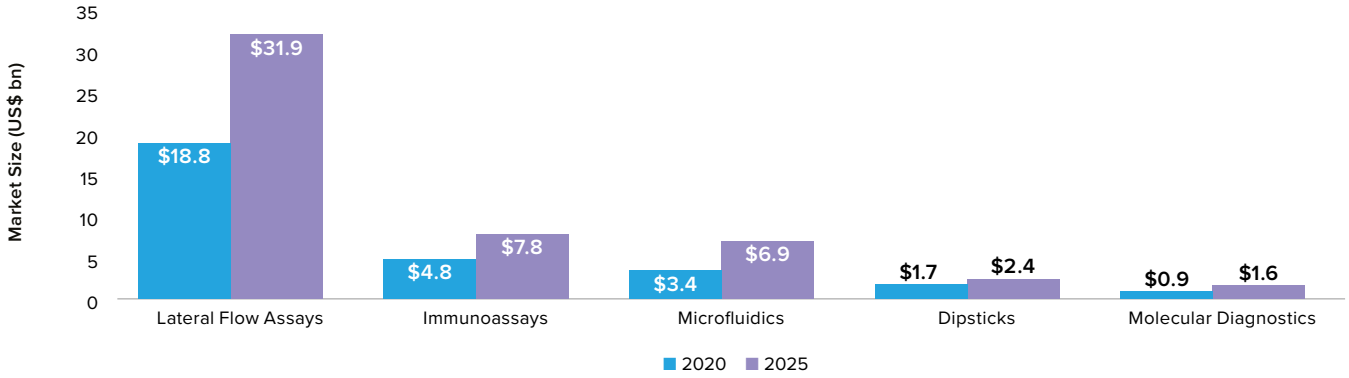
2.3.4. Estimated market growth by platform

POC diagnostic tests global sales are expected to grow across all platform types, from 2020 to 2025, with increased adoption of lateral flow assay testing in replacement of conventional, lengthy laboratory procedures.[15] The tests that Lumos produces for itself and for its clients, are primarily based on lateral flow assays or immunoassays. POC diagnostic test sales for lateral flow assay testing is forecast to grow from $18.8 billion in 2020 to $31.9 billion in 2025, at an average growth rate of 11.1% per annum.[15] The highest growth is expected to come from the microfluidics segment, forecast to grow at 15.3% per annum.[15] POC diagnostic test sales by platform in 2020 and forecast sales in 2025 are shown in Figure 2.7 below.

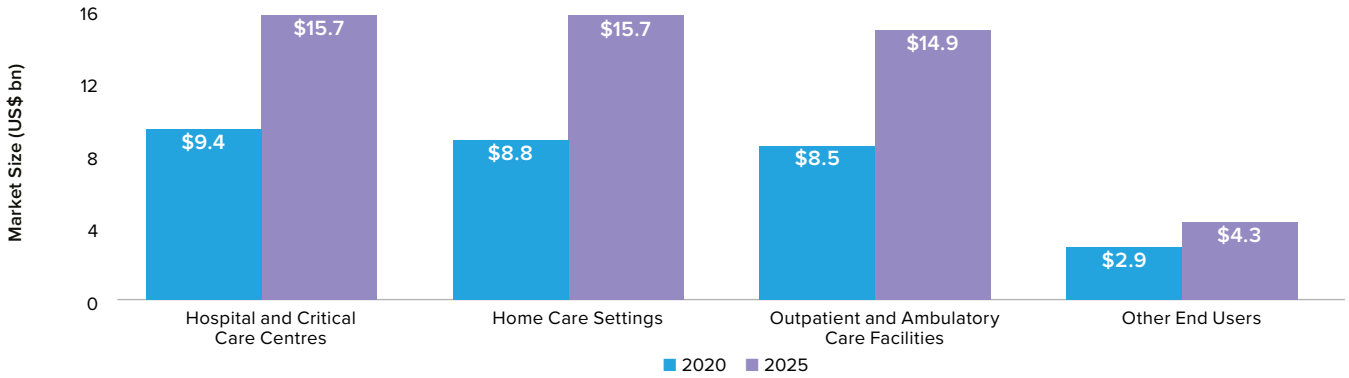
Figure 2.7: POC diagnostic tests global sales by Platform, 2020 vs. 2025[15]



2.3.5. Estimated market growth by end user

The global market for POC diagnostic tests is expected to be relatively evenly spread between the three core end-user segments by 2025: hospital and critical care centres ($15.7 billion by 2025), home care settings ($15.7 billion by 2025) and outpatient and ambulatory care facilities ($14.9 billion by 2025).[15] The largest growth is expected to be from the home care setting, with an average growth rate of 12.2% per annum, driven by an increased preference for home and remote monitoring and rapid tests.[15] Lumos' products are applicable across all the end user settings set out below, with POC diagnostic test sales by end user in 2020 and forecast sales in 2025 shown in Figure 2.8.

Figure 2.8: POC diagnostic tests global sales by End User, 2020 vs. 2025[15]



15. MarketsandMarkets Report, 2021.

2.4. Lumos' addressable market

2.4.1. POC diagnostic testing market – general

As noted in Section 2.3.1, Lumos operates in the POC diagnostic testing market, estimated to be approximately US$29.6 billion in 2020.[16] Lumos is focusing its sales efforts on the European and North American market (referred to as its target markets) which collectively make up approximately 64% of the POC diagnostic test market with combined sales of US$18.8 billion.[16] The largest of these markets is North America, comprising of the United States and Canada, with global POC diagnostic test sales of US$11.6 billion in 2020 (39.3% of the total market).[16] This is followed by Europe, with Germany, the United Kingdom, France, Italy, and Spain being major contributors to the European POC diagnostic test sales market, estimated to be US$7.2 billion (24.4% of the total market).[16] Further, as noted in Section 2.3.3, within the POC diagnostic testing market, Lumos is focused on the development and commercialisation of POC diagnostic tests for infectious diseases, which accounted for 9.8% of the total global sales of POC diagnostic tests by healthcare application in 2020.[16]

Based on the above figures, the total addressable market for POC diagnostic tests in North America and Europe per annum for the purpose of identifying infectious diseases is currently estimated to be approximately US$1.8 billion (approximately 6% of the total POC diagnostic test market).[16]

2.4.2. POC diagnostic testing market – bacterial versus viral detection

The use of POC diagnostic tests for rapid bacterial versus viral detection like FebriDx® is a new, disruptive technology[17] as further explained in Section 3.4. A test of this nature is particularly relevant when patients present with ARI symptoms, as it is difficult to distinguish between a bacterial or viral ARI given they often have similar symptoms. FebriDx® has received regulatory approval in the United Kingdom, Germany, Australia and Canada and has been submitted for FDA approval in the United States. Refer to Section 2.7 for more information on regulatory approvals. Other current and potential key participants in the POC diagnostic tests for bacterial versus viral detection are described in Section 2.6.2.

Given this technology is new (and in the case of FebriDx® currently only approved in the jurisdictions referred to above), the addressable market or estimated market opportunity for these tests has not yet been defined. In developing FebriDx®, Lumos approached the product's addressable market through an examination of annual patient interactions where FebriDx® tests would be applicable, that is, instances where FebriDx® would give healthcare providers greater diagnostic certainty as to the patient's condition. Lumos concluded that the primary interaction where FebriDx® would be applicable is for patients presenting with ARI symptoms, which includes acute respiratory tract infections (**ARTI**), such as the common cold, influenza and COVID-19.

In the United States, approximately 150m patients present to inpatient and outpatient settings with ARI symptoms per year.[18] The majority (approximately 62%) are patients visiting urgent care centres presenting with symptoms of ARIs,[19] and the remaining (approximately 38%) are patients visiting community-based office practices, hospital-based outpatients practices and emergency rooms presenting with ARTI symptoms.[20] The FebriDx® test can be used by healthcare providers in these interactions to rule out patients that do not have a bacterial infection and therefore make an informed decision not to treat the patient with antibiotics. This can provide immediate beneficial outcomes to patients and physicians through providing more diagnostic certainty and confidence around the most effective treatment for the patient.

16. MarketsandMarkets Report, 2021.
17. National Institute for Health and Care Excellence, FebriDx for C-reactive protein and myxovirus resistance protein A testing, published on August 2020.
18. Tamar Barlam et al, Unnecessary Antibiotics for Acute Respiratory Tract Infections: Association With Care Setting and Patient Demographics, Open forum infectious diseases vol. 3(1), published on February 2016; Patricia Sweeney, Improving Appropriate Antibiotic Use For Common Clinical Conditions in Urgent Care, The Journal of Urgent Care Medicine, published on June 2017.
19. Patricia Sweeney, Improving Appropriate Antibiotic Use For Common Clinical Conditions in Urgent Care, The Journal of Urgent Care Medicine, published on June 2017.
20. Tamar Barlam et al, Unnecessary Antibiotics for Acute Respiratory Tract Infections: Association With Care Setting and Patient Demographics, Open forum infectious diseases vol. 3(1), published on February 2016.

There are also financial benefits to insurers and governments as result of reduced antibiotic intake amongst the population, given the financial costs of anti-microbial resistance (**AMR**) on the healthcare system (refer to Section 2.5.4). Antibiotic-resistant infections, which often occur in hospitals, require significant and expensive healthcare resources to treat and commonly result in longer recoveries, or in some cases death.[21] According to the United States Centers for Diseases Control and Prevention (**CDC**), antibiotic resistance in the United States can add approximately US$1,400 to a patient's hospital bill for the treatment of bacterial infections. According to different studies, AMR is projected to cost from $300 billion to more than $1 trillion annually by 2050 globally, driven by direct treatment costs and lost productivity.[21]

Reimbursement models influence both the use, and wholesale price, of POC diagnostic tests. In the United States, Medicare pays for physician services, including a range of diagnostic services, based on the Medicare physician fee schedule, which lists more than 10,000 unique codes and their payments rates.[22] There is no specific code for FebriDx®, however there is a potential that existing reimbursement codes may apply (refer to Section 3.4.7), assuming approval is ultimately obtained from the FDA for use of the product in the United States. The wholesale price of the FebriDx® test in the United States would be equivalent to the test's reimbursement price so healthcare providers would not be out-of-pocket when purchasing the product, in order to incentivise widespread use. Management expects that healthcare providers would charge patients a retail price above the wholesale cost, with any additional margin covered by health insurers. This would mean that patients with health insurance would not incur any out-of-pocket expenses for using FebriDx®.

In the US, there are an estimated 150m inpatient and outpatient interactions each year for patients with ARI for whom FebriDx® could be used. Assuming reimbursement coverage of approximately US$16 per FebriDx® test (an estimate based on existing reimbursement codes for C-reactive protein (**CRP**) and infectious disease immunoassays), the total addressable market for bacterial versus viral detection in the United States would be US$2.4 billion per year.[23] The figure represents only an estimated market opportunity and does not imply that Lumos would achieve 100% or any other particular percentage penetration of this market with FebriDx®. Lumos' capacity to penetrate this market in the United States will be contingent on a number of factors, including: FDA approval, availability of applicable Medicare codes for reimbursement, a willingness of doctors and patients to use FebriDx®, and Lumos' ability to manufacture and distribute the product in required quantities. Refer to Section 3.4 and risk factors in Section 5 for further information.

2.5. Growth drivers and considerations for POC diagnostic testing market

2.5.1. Overview

The use of POC diagnostic tests is expected to increase from 2020 to 2025 due to their ability to provide non-specialist users with results in a short time frame without needing to access a testing laboratory, and a growing trend towards decentralisation of healthcare services.[21] However, the adoption of POC diagnostic testing has been constrained by the typically higher cost of reagents and components used in POC diagnostic tests, their lack of integration with electronic patient medical record systems,[21] a lack of alignment between POC and testing laboratory results, as well as a reluctance by practitioners to change from established diagnostic testing practices.

21. MarketsandMarkets Report, 2021.
22. Medical Learning Network, Medicare Physician Fee Schedule (MPFS) Booklet, published on March 2021.
23. This is incremental to the total addressable market for POC diagnostic tests for infectious diseases described in Section 2.4.1.

2.5.2. Growth drivers and considerations

There are a number of key trends supporting growth in the POC diagnostic testing market, principally those described below in Table 2.2.

Table 2.2: Key Trends supporting growth in the POC diagnostic testing market

Key Trends	Description
Technological developments	New or improved technologies are making POC diagnostic testing an option for a greater range of healthcare applications.[24] These can arise from the development of new diagnostic tests or the development of new technology platforms of test formats that are able to be used in a POC setting.[25] For example, in 2018, researchers from the Institute of Pancreatic Cancer Research at the Lustgarten Foundation and the National Research Foundation of Korea developed a new POC integrated biosensor system for the rapid identification of early Sepsis, a common medical condition with a high mortality rate (60%).[26] In addition, many tests are being developed that use digital readers and software applications that are able to interface with the cloud and electronic medical record systems, making them easier to integrate into primary care or outpatient workflows.[27] Further, through technological innovation, such as developments in fluid handling, microchip and miniaturisation technology, POC diagnostic testing devices are becoming more robust and less prone to error than previous generations.[28]
Decentralisation of healthcare services	In the United States, and several other developed and developing countries, an increasing number of healthcare services are being provided at non-hospital locations such as outpatient clinics, specialist clinics and in patients' homes.[29] POC diagnostic tests are suited to these non-hospital settings as they are able to provide a rapid test result and do not require access to a testing laboratory.[29] The trend towards the decentralisation of healthcare services is expected to continue, given the potential benefits which include a reduction in overall healthcare costs, increased efficiency in the treatment of patients, opportunities for citizen's to have greater participation in their healthcare and improved access to healthcare services at a regional level.[29]
Growing incidence and prevalence of healthcare conditions that benefit from regular monitoring	Conditions such as diabetes, hematology disorders, and cardiac diseases require continuous monitoring making them well suited to POC diagnostic testing.[29] As noted in section 2.2.2.1, the largest share of the POC diagnostic testing market globally comes from glucose monitoring products used by patients with diabetes. There were 463m people living with diabetes in 2019 globally, and the IDF Diabetes Atlas estimates this number to significantly increase to 700mn by 2045.[29] The growing incidence and prevalence of conditions, like diabetes, combined with increasing patient participation in the measurement and monitoring of health metrics is expected to contribute to a growing demand for POC diagnostic tests.[29]

24. Peter Luppa, Point-of-care testing at the interface of emerging technologies and new clinical applications, Journal of Laboratory Medicine vol. 44(2), published on April 2020.
25. Peter Luppa, Point-of-care testing at the interface of emerging technologies and new clinical applications, Journal of Laboratory Medicine vol. 44(2), published on April 2020; Reed Sutton et al, An overview of clinical decision support systems: benefits, risks, and strategies for success, Nature Partner Journals vol. 3, published on February 2020.
26. M2M market report, 2021.
27. Reed Sutton et al, An overview of clinical decision support systems: benefits, risks, and strategies for success, Nature Partner Journals vol. 3, published on February 2020.
28. Shashank Patil, POCTED: Use of Point of care Test Devices in Emergency Department, ICU Management & Practice vol. 16(3), published 2016.
29. MarketsandMarkets Report, 2021.

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Key Trends	Description
Operational efficiencies and healthcare economics	Rapid POC diagnostic tests that provide immediate actionable results to guide patient treatment decisions in physician's office and clinics lead to improved patient care through increased efficiency in the treatment process. The introduction of POC diagnostic tests for new target areas which could not previously be tested in the POC setting (such as additional infectious diseases and other new analytes) are now available. Likewise, the growth of personalised healthcare and personalised medicine, and the need for rapid tests to support the diagnosis of therapies associated with these is expected to support demand for POC diagnostic testing. Further, cost effective solutions that impact long term outcomes such as antimicrobial complications or the development of drug resistance have been shown to save significant costs.[30]
Shortage of skilled laboratory technicians	There is currently a shortage of lab technicians and pathologists in both developed and developing nations.[31] This has been driven by both the retirement of aging laboratory staff and declining numbers of new graduates as colleges with limited funds close their clinical lab programs.[31] This can lead to longer turnaround times for tests conducted in centralised laboratories due to capacity constraints, batch processing, and longer transport times as the number of testing laboratories becomes rationalised.[31]
Onshoring of manufacturing – security of domestic supply	The trend towards manufacturing domestically was driven by COVID-19, which caused global supply chain disruptions for POC diagnostic test manufacturers.[32] Further, many COVID-19 tests were lacking sufficient quality and performance. Accordingly, the United States and many other countries are evaluating programs to develop and manufacture diagnostic tests in-country, which will also insulate against future supply chain interruptions.[32] Until recently, many companies in the United States were importing devices from countries with lower manufacturing costs.[32] There has also been strong support for business strategies that create jobs in the United States and strengthen the economy, further supporting onshore manufacturing in the United States.[32]
Rapid diagnostics benefits becoming mainstream	There is growing adoption of POC diagnostic testing being driven by the global acknowledgement and awareness of the benefits amongst healthcare professionals and patients, which include rapid result generation, ease of diagnosis, immediate patient management, the potential to reduce cost and time per test, increased patient convenience and overall greater efficiency.[31] Part of this growing awareness is attributable to an increasing number of conferences and events aimed at spreading awareness about POC diagnostic developments and benefits, including the United Kingdom Diagnostic Summit in 2019, the POC Diagnostics Global World Congress in the Unites States in 2019 and the National Institutes of Health conference in 2017 on POC technologies in the United States.[31]
Emerging markets increased use of POC diagnostic tests	Emerging markets, such as China, India, Brazil and Mexico have a high and growing prevalence of infectious and lifestyle diseases.[31] For example, China had 114m people living with diabetes in 2017, the highest of any country, and more than a quarter of total cases globally.[31] As awareness of POC diagnostic testing grows in emerging markets, the management and treatment of infectious diseases, including through POC diagnostic testing is expected to be a major healthcare focus.[31] All of the factors listed above are also relevant to emerging markets and are expected to contribute to a growing demand for POC diagnostic testing in these markets.[31]

Conversely, there are a number of key growth considerations in the POC diagnostic testing market which may limit adoption and/or production, as described in Table 2.3 below.

Table 2.3:

30. J.E. Schneider et al, Application of a simple point of care test to reduce UK healthcare costs and adverse events in outpatient acute respiratory infections, Journal of Medical Economics vol. 23(7), published on April 2020.
31. MarketsandMarkets Report, 2021.
32. Kevin Young and Ralph Tricomi, LFI Rapid Diagnostics: Onshoring Strategies for Supply-Chain Stability, published on December 2020.

Table 2.4: Key Growth Considerations in the POC diagnostic testing market

Key Trends	Description
Higher price points	POC diagnostic tests typically have higher per-test price points than laboratory-based tests due to their higher manufacturing costs and their capital-intensive pathway for regulatory approval.[33] For POC diagnostic tests to be readily adopted, the higher per-test price point of POC diagnostic tests need to be covered by a higher reimbursement or justified by the health economic benefit generated from use of the test, for example the ability to conduct the test in a rapid timeframe which allows the diagnosis and potential therapeutic decisions to be made while the patient is still present.[33]
Resistance to change existing testing procedures	A reluctance to change established medical practices and business models, such as highly organised and complex central laboratory systems (found in the United Kingdom and France), have constrained the adoption and growth of POC diagnostic testing.[33] In addition, there may be a misalignment of stakeholder interests, for example between healthcare providers focused on providing rapid results and patient efficiency versus owners or operators of centralised testing laboratories.[33] Further doctors may believe that the best quality testing is performed in laboratories by skilled lab technicians rather than by using POC diagnostic tests.[33]
Lack of alignment with results from central laboratories	Results from POC diagnostic tests may differ from those generated using a centralised testing laboratory due to a number of pre and post-clinical analytical errors that may be made by the operator in conducting a POC diagnostic test or interpreting its visual readouts.[33] These may relate to inappropriate test selection, inappropriate sample collection, inadequate sample validation, and poor reading and recording of results.[33] While these errors may arise due to factors unrelated to the test itself, such as being conducted by non-trained operators, in high-volume or busy community settings, or in time-critical emergency situations, they can act as a barrier to the acceptance of POC diagnostic testing.[33]
More complex regulatory and reimbursement paths	POC diagnostic tests typically have more complex regulatory paths to approval for use due to their potential for use by non-professional or untrained operators.[33] For a POC diagnostic test to be approved, it often needs to be demonstrated that a POC diagnostic test is able to reliably provide the same result as an equivalent laboratory test in a variety of settings and when conducted by personnel with different levels of skills and training.[33] Furthermore, the higher price point of POC diagnostic tests, combined with their use in specific settings, often requires new reimbursement codes to be secured.[33]

2.5.3. Impact of COVID-19

COVID-19 has highlighted several benefits of POC diagnostic tests, including convenient and rapid results and immediate patient management, which has led to an increased adoption of portable diagnostic tests globally.[34] The ability for POC diagnostic tests to provide healthcare workers with fast results that allow them to make timely decisions, including those around patient triaging, has driven demand for COVID-19 related POC diagnostic testing.[34] These tests have also allowed for the diagnosis of patients in a range of different user settings, including at home, supporting decisions to isolate patients or refer them to hospitals.[34] With calls for continued COVID-19 testing as international travel resumes, the demand for POC diagnostic testing is expected to continue.[34] In addition, adoption of COVID-19 specific POC diagnostic tests has brought greater awareness to the POC diagnostics testing market in general.

33. MarketsandMarkets Report, 2021.
34. Christopher Price and Andrew John, Will COVID-19 be the coming of age for point-of-care testing?, BMJ Innovations 2021 vol. 7, published on December 2020.

2.5.4. Global overuse and misuse of antibiotics

As noted in Section 2.3, Lumos is focused on the development and commercialisation of POC diagnostic tests for infectious disease, within the POC diagnostic testing market. Lumos' primary product, FebriDx®, is a POC diagnostic test that is able to rapidly identify whether patients have a microbial infection[35] and, if positive, determine if that infection is caused by a viral or bacterial pathogen. Lumos believes FebriDx® can assist a reduction in global antibiotic use through healthcare professionals prescribing less antibiotics as a precautionary measure (as discussed further in Section 3.4) given the test can reliably rule out bacterial infections and the requirement for antibiotics as a treatment. Increased consumption of antibiotics, particularly inappropriate use (overuse and misuse) is an issue which has gained increasing governmental and public concern due to the consequential adverse side effects linked to taking antibiotics (as discussed in Section 2.5.4.1).[36]

Antibiotics are a class of antimicrobial drugs that are specifically designed to kill bacteria. They do not work against other microbial pathogens, such as viruses, fungi or parasites which require other drugs (namely antiviral, antifungal, and antiparasitic drugs) specifically targeting that class of microbe.[37]

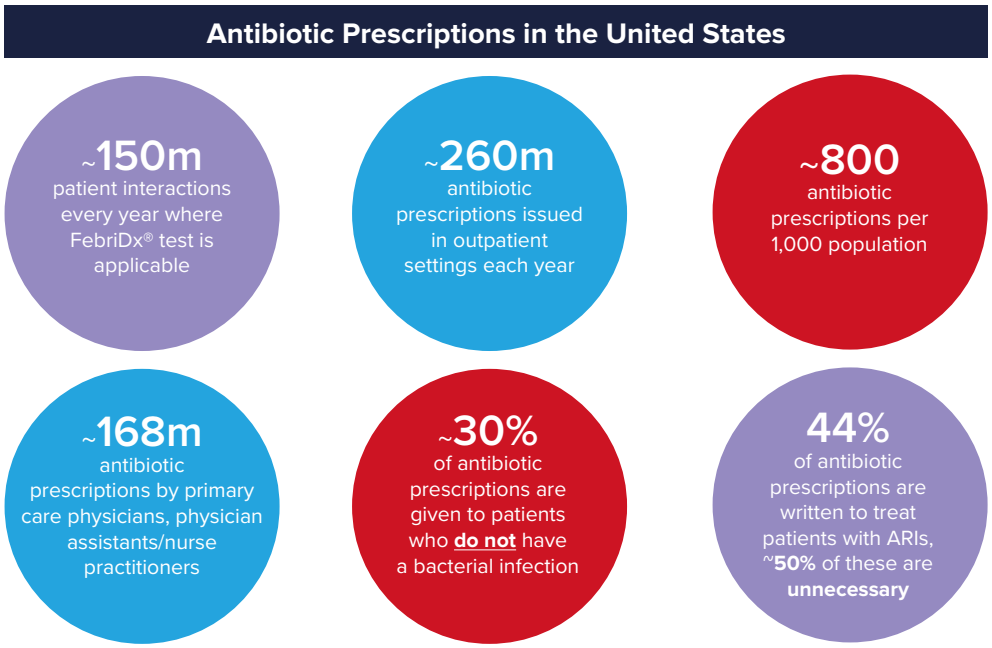
The discovery of the first antibiotic, penicillin, in 1928 by Sir Alexander Fleming is considered one of the major breakthroughs of modern medicine.[38] Before this time, few treatments were available for patients with a bacterial infection and, consequently, infectious diseases were a leading cause of death around the world.[39] The discovery of antibiotics dramatically changed this, and several new classes of antibiotic drugs were subsequently discovered in the period between the 1950s and 1970s. Since the 1970s however, only a limited number of new antibiotic drugs have been developed and approved.[39]

It is often difficult to distinguish between a bacterial or viral ARI as they often have similar symptoms. As a result, patients may be prescribed antibiotics out of caution so as not to accidently miss a possible bacterial infection.[40] The CDC estimates that at least 30% of antibiotics prescribed in outpatient settings are unnecessary, meaning the patient does not have a bacterial infection to treat.[41] Prior to the COVID-19 pandemic, approximately 50% of patients with an ARI received a prescription for antibiotics even though bacteria are only responsible for 10%-15% of ARIs.[42] Due to the COVID-19 pandemic, the prescription of antibiotics has increased and may be accelerating the rate of AMR (discussed below).[43]

35. Microbial infection is the invasion of infectious agents into the organism, their multiplication and the reaction of host tissue against these agents. Infectious agents include bacteria, virus, parasite and fungi. Source: National Institutes of Health (US), Understanding Emerging and Re-emerging Infectious Diseases.
36. Martin Blaser et al, Accounting for variation in and overuse of antibiotics among humans, BioEssays, published on October 2020.
37. HealthyChildren.org, Tips For Treating Viruses, Fungi, and Parasites, published on November 2015.
38. Katie Kalvaitis, Penicillin: An accidental discovery changed the course of medicine, Penicillin: An accidental discovery changed the course of medicine, published on August 2008.
39. W.A. Adedeji, THE TREASURE CALLED ANTIBIOTICS, Annals of Ibadan postgraduate medicine vol. 14(2), published December 2016.
40. Chief Public Health Officer of Canada, Preserving Antibiotics, Spotlight Report, published on June 2019.
41. Centers for Disease Control and Prevention, 1 in 3 antibiotic prescriptions unnecessary, published on May 2016.
42. Onrubia and Gonzelez, A pilot evaluation of the FebriDx test, Clin Med Invest vol. 5, published on March 2020.
43. Ajit Singh, How covid-19 is accelerating the threat of antimicrobial resistance, The BMJ, published on May 2020.

Figure 2.9 below outlines a number of statistics surrounding the prescription of antibiotics in the United States.

Figure 2.9: Prescriptions of precautionary antibiotics in the United States[44]



The unnecessary prescribing of antibiotics to patients who do not have a bacterial infection, and therefore are unlikely to receive any benefit from them, has two major healthcare implications:

1. **Immediate side effects**: numerous patients experience side-effects or allergic reactions to antibiotics, some of which can be serious and require additional medical interventions or even hospitalisation;[45] and
2. **Antibiotic drug resistance (antimicrobial resistance)**: unnecessary and inappropriate use of antibiotics contributes to the emergence of antibiotic resistant strains that no longer respond to these drugs.[46]

In contrast, where a bacterial infection requires antibiotics but is left untreated, this can result in several health complications, including potentially progressing to a bloodstream infection (sepsis).[47]

2.5.4.1 Immediate side effects from antibiotics

The United Kingdom's National Health Service (**NHS**) estimates that 1-in-10 patients experience side-effects from taking antibiotics, and 1-in-15 experience an allergic reaction.[45] The side-effects from taking an antibiotic are usually relatively mild and pass once the treatment is completed.[45] The most common side-effects of antibiotics are those affecting the digestive system resulting in bloating, indigestion and stomach pain reactions.[45] However, antibiotics can result in sensitivity to light, fever and, very occasionally, more serious side-effects including disabling, long-lasting permanent side effects affecting the joints, muscles and nervous system and for those who are at risk of heart valve problems, swollen limbs, heart palpitations and shortness of breath can occur.[45]

44. Patricia Sweeney, Improving Appropriate Antibiotic Use For Common Clinical Conditions in Urgent Care, The Journal of Urgent Care Medicine, published on June 2017; Tamar Barlam et al, Unnecessary Antibiotics for Acute Respiratory Tract Infections: Association With Care Setting and Patient Demographics, Open forum infectious diseases vol. 3(1), published on February 2016; Centres for Disease Control and Prevention, Outpatient Antibiotic Prescriptions — United States, published 2017; The Pew Charitable Trusts, Antibiotic Use in Outpatient Settings, published on May 2016.
45. NHS, Antibiotics side effects, published on May 2019.
46. Centres for Disease Control and Prevention, Antibiotic resistance threats in the United States, published on December 2019.
47. M.L. Martinez et al, An approach to antibiotic treatment in patients with sepsis, Journal of thoracic disease vol. 13(3), published on March 2020.

Patients may also experience an allergic reaction to antibiotics such as a rash, especially from antibiotics that belong to the commonly used penicillin or cyclosporin drug families.[48] Occasionally, patients can develop an anaphylactic reaction to an antibiotic drug which is usually severe and may be life threatening.[48] Antibiotic-related events are a common cause of both hospitalisations and emergency department visits, accounting for over 14% of all outpatient adverse drug event visits.[49] Further, antibiotics also may lead to secondary infections such as C.dificile colitis (a bacterium that causes severe diarrhea) and colitis (an inflammation of the colon) which can have significant morbidity.[50]

2.5.4.2 Antibiotic drug resistance

In 2019, the World Health Organization (**WHO**) identified antimicrobial resistance as one of the 10 greatest public health threats facing humanity.[51] A person with resistant bacteria will double their chances of developing serious health issues and triple their chances of death.[52] According to the CDC, more than 2.8m antibiotic-resistant infections occur in the United States each year, resulting in over 35,000 deaths.[53] It has been estimated that if no steps are taken to reduce their emergence, antibiotic-resistant bacteria may be responsible for up to 10m deaths worldwide by 2050.[54]

There are many factors that are likely to contribute to the emergence of antibiotic resistant bacterial strains. One well-recognised factor is the widespread use of antibiotics by patients who do not have a bacterial infection and thus do not need to take them.[55] Patients taking antibiotics can create an environment in which bacteria that are sensitive to the drug are killed, but those that are resistant are able to grow.[55] These resistant bacteria can then be transmitted to other members of the community, and consequently spread.[55] Limiting the use of antibiotics to only patients who need them could reduce the number of people taking these drugs by up to 30% and thus reduce the emergence of resistant strains by this mechanism.[56]

One of the main reasons the WHO considers antibacterial drug resistance to be such a great public health threat is that relatively few new antibiotics have been developed since the 1970s.[57] Historically, antibiotics have not been considered an attractive investment by pharmaceutical companies due to their high cost to develop and low revenue potential.[58] As such, if bacterial pathogens develop widespread resistance to the current antibiotics, there may be limited options available to treat bacterial infections, potentially resulting in a significant increase in deaths.[54]

2.5.4.3 Public health initiatives to reduce antibiotic use

Antibiotic misuse is a significant economic burden on the healthcare system, driven by the direct cost of treating antibiotic-resistant infections and lost productivity. These infections often occur in hospitals, due to the vulnerability of patients, invasive procedures and high rates of antibiotic use.[59] In most cases, patients with resistant infections require a lengthier recovery, with significantly longer hospital stays and more doctor visits, and experience a higher incidence of long-term disability.[59] It is estimated that the total economic burden placed on the United States economy by antibiotic-resistant infections is as high as $55 billion, consisting of $20 billion in health care costs and $35 billion a year in lost productivity.[59]

48. NHS, Antibiotics side effects, published on May 2019.
49. National Estimates of Emergency Department Visits for Antibiotic Adverse Events Among Adults—United States, 2011–2015.
50. Benjamin Mullish and Horace Williams, Clostridium difficile infection and antibiotic-associated diarrhoea, Clinical Medicine (London, England) vol. 18(3), published on June 2018.
51. Martin Chenal, The other pandemic: Once-treatable diseases are growing resistant to antibiotics, published on January 2021.
52. Porooshat Dadgostar, Antimicrobial Resistance: Implications and Costs, Infection and drug resistance vol. 12 3903-3910, published on December 2019.
53. Centres for Disease Control and Prevention, Antibiotic resistance threats in the United States, published on December 2019.
54. Jim O'Neill, Antimicrobial Resistance: tackling a crisis for the health and wealth of nations/the Review on Antimicrobial Resistance, Welcome Collection, published on December 2014.
55. Victorian State Government Department of Health, Antibiotics resistant bacteria, published on March 2017.
56. Centers for Disease Control and Prevention, 1 in 3 antibiotic prescriptions unnecessary, published on May 2016.
57. W.A. Adedeji, THE TREASURE CALLED ANTIBIOTICS, Annals of Ibadan postgraduate medicine vol. 14(2), published December 2016.
58. Benjamin Plackett, No money for new drugs, Nature vol. 586, published October 2020.
59. C.L. Ventola, The antibiotic resistance crisis: part 1: causes and threats, P & T : a peer-reviewed journal for formulary management vol. 40(4), published on April 2015.

Due to the potential impact increasing antibiotic resistant bacteria could have on public health, many countries have developed, or are developing initiatives to reduce antibiotic use. A survey conducted in 2017 by the Transatlantic Taskforce on Antimicrobial Resistance identified nine countries with established targets to reduce antimicrobial use in humans, and 17 further respondents were working towards establishing such targets.[60] The U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria (2020-2025) has the reduction and more appropriate use of antibiotics as key objectives.[61] Likewise, the United Kingdom's five-year national action plan is targeting a 15% reduction in the number of antibiotic prescriptions by 2024.[62] Furthermore, the United Kingdom's NHS includes specific targets for reducing antibiotic use in its current standard contract.[62]

Lumos believes the use of FebriDx® can assist healthcare professionals to better identify patients with a bacterial infection and thus help reduce the unnecessary prescribing of antibiotics (as discussed further in Section 3.4).

2.6. COMPETITIVE LANDSCAPE

2.6.1. POC test industry overview

The POC diagnostic test industry is highly fragmented with a large number of participants offering POC diagnostic tests. These companies typically fall into three broad categories:

- Multi-disciplinary healthcare companies;
- Specialist diagnostic companies; and
- Emerging diagnostic companies.

From a corporate perspective, the industry is quite active with company acquisitions being a common mechanism for participants to access new tests, new technologies or broaden their range of diagnostic tests.[63]

2.6.1.1 Multi-disciplinary healthcare companies

Many of the multinational, multi-disciplinary healthcare and pharmaceutical companies have business units focused on diagnostic tests which include POC diagnostic tests. Typically, the diagnostic business units have products that are relevant to therapeutic areas for which the company has pharmaceuticals or other healthcare products. Multi-disciplinary healthcare companies include those outlined in Table 2.4 below.

Table 2.5: Multi-disciplinary healthcare companies

Company	Headquarters	Description
Abbott Laboratories	United States	Develops, manufactures and markets a range of healthcare products and significantly expanded its diagnostics division with the US$5.3 billion acquisition of diagnostic specialist Alere. Abbott's diagnostics business unit accounted for approximately 24% of its revenue in 2019.[643]
Becton Dickinson	United States	Leading player in medical technology including medical devices, laboratory equipment and diagnostic products and reagents. Its diagnostic systems, primarily focused on infectious diseases, generated 36% of group revenue in 2019.[63]
Johnson&Johnson	United States	Multinational healthcare and pharmaceutical company which has been one of the leading players in consumer products for blood-glucose monitoring for patients with diabetes.[63]

60. Fablo D'Arti et al, Targets for the reduction of antibiotic use in humans in the TATFAR partner countries, Euro Serveill vol. 24(28), published on July 2019.
61. U.S. Department of Health & Human Services, U.S. National Action Plan for Combating Antibiotic – Resistant Bacteria (National Action Plan), published October 2020.
62. UK Government, The UK's five-year national action plan, published January 2019.
63. MarketsandMarkets Report, 2021.

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Company	Headquarters	Description
Roche Diagnostics	Switzerland	Diagnostics subsidiary of Hoffman-La Roche which also develops and markets new pharmaceuticals. Roche Diagnostics specialises in molecular tests, blood-glucose, blood-coagulation and infectious diseases and generated revenue of US$13 billion in 2019.[64]
Siemens	Germany	Core business is based on devices and instruments used in healthcare. In 2019 its diagnostics division accounted for 28% of group revenue with a key focus on blood and cardiovascular tests and blood-gas analysis systems.[64]

2.6.1.2 Specialist diagnostic companies

A number of companies have their primary business focus on the development and marketing of diagnostic tests. These companies aim to leverage expertise in one or more key therapeutic areas, different diagnostic testing platforms (molecular, lateral flow, microfluidics etc) and their established sales channels and commercial relationships. Specialist diagnostic companies include those outlined in Table 2.5 below.

Table 2.6: Specialist diagnostic companies

Company	Headquarters	Description
ChemBio Diagnostics	United States	Develops and commercialises rapid POC diagnostic tests with major focus on infectious, tropical and respiratory diseases using lateral flow assays that generated US$34.5m in revenue in 2019.[64]
Orasure	United States	Specialises in rapid diagnostic tests, sample collection devices and molecular testing services which generated US$155m in revenue in 2019.[65]
Qiagen	Germany	Provider of sample and assay technologies for molecular diagnostics that has expanded significantly through a series of acquisitions since 2004. Qiagen recorded revenues of US$1.5 billion in 2019.[66]
Quidel	United States	Focused on POC diagnostic tests and generated US$535m in revenue in 2019 from its products that are focused on cardiovascular, immunoassays and molecular testing.[64]
Trinity Biotech	Ireland	Leading developer and manufacturer of diagnostic products for the POC and laboratory markets which generated US$90.4m revenue in 2019.[64]

64. MarketsandMarkets Report, 2021.
65. OraSure, 2019 Annual Report.
66. Qiagen, Financial Report 2019 – Performance Review.

2.6.1.3 Emerging diagnostic companies

There are a large number of emerging diagnostic companies that typically have a few specialised diagnostic products focused on a particular diagnostic marker, therapeutic area or testing platform. These companies are usually in the early stages of development or commercialisation and often are private. Management would classify Lumos as an emerging diagnostic company, based on this description. Successful products from emerging diagnostic companies, or the companies themselves, may be acquired by multi-disciplinary healthcare companies or specialist diagnostic companies looking to expand their POC diagnostic product range. Emerging diagnostic companies include those outlined in Table 2.6 below.

Table 2.7: Emerging diagnostic companies

Company	Headquarters	Description
Biosensis	Australia	Developing qualitative (positive of negative) and quantitative (specific measurement) POC diagnostic tests using fluorescence detection with a disposable assay cartridge and a small, desktop instrument.[67]
Ellume	Australia	Developing and marketing cartridge-based products for COVID-19 and influenza testing in partnership with Qiagen.[68]
Lumira	United States	Focused on the development of connected diagnostics and diagnostic-led care solutions that are able to interface with electronic medical record systems.[69]
LightDeck Diagnostics[70]	United States	Developing a range of cartridge-formatted diagnostic products based on its proprietary planar waveguide technology detection system.[71]
MeMed	Israel	Developing and commercialising a cartridge and reader based POC diagnostic test to assist with determining whether patients have a viral or bacterial infection.[72]
Oxford Immunotec	United Kingdom	Primarily focused on the sale and marketing of its FDA approved T-SPOT.TB test for the detection of tuberculosis infection.[73]

67. Biosensis homepage.
68. Ellume, Covid-19 Response.
69. Lumira Ventures homepage.
70. Formerly MBio Diagnostics.
71. LightDeck, Mbio Diagnostics Announces Rebrand to LightDeck Diagnostics, published on October 2020.
72. MeMed, What is MeMed BV.
73. Oxford Ummunotec, Oxford Immunotec Announces Food and Drug Administration (FDA) Clearance of the T-SPOT®.TB Test for Use in Pediatrics Over the Age of Two, published on September 2020.

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2.6.2. FebriDx® competitive environment: bacterial versus viral detection

Figure 2.10 is an overview of the key current POC diagnostic test technologies that compete with FebriDx® in the detection of bacterial or viral infections.

Figure 2.10: Bacterial versus viral detection key players[74, 75, 76]

Test name	FebriDx®	MeMed BV™	Virabac™
Company name	**Lumos Diagnostics FebriDx® Platform**	**MeMed Key™ Platform**	**Inflammatix Platform**
Ancillary equipment	 Highly portable, all-in-one, simple blood test	 Desktop reader + cartridge platform (future menu expansion)	 Desktop reader + cartridge platform (fingerstick collection)
Sample type	Blood sample	Blood sample	Blood sample
Result and accuracy	99% NPV for bacterial infection	96% NPV for bacterial infection	>95% NPV for bacterial infection
Time to results	10 minutes	15 minutes	<30 minutes
Throughput[3]	High	Low	Low
Commercial Status	• Clinically validated (ARIs and COVID-19) • In-market • Regulatory cleared in Canada (Health Canada), Europe Economic Area and United Kingdom (CE mark), Australia (TGA)	• Clinically validated • Recently launched (June 2020) • Regulatory cleared in Europe Economic Area and UK (CE mark)	• Clinically validated • All products are in development • Not FDA cleared (not yet lodged for regulatory clearance)
End User suitability	• Hospitals and critical care centres • Outpatient facilities • Home care settings	• Outpatient facilities	• Critical care centres • Outpatient clinics
Cost	Low complexity, low COGs test format	Total cost of ownership includes capital + consumables	Equipment costs

74. MeMed, What is MeMed BV; BioWorld, MeMed secures CE mark for new POC blood test, published on June 2020.
75. High throughput testing can be defined as testing hundreds of different patient samples simultaneously and/or obtaining very rapid results. Source: Arun Wiita and Iris Schrijver et al, Clinical application of high throughput molecular screening techniques for pharmacogenomics 2011.
76. Inflammatix, Pipelin.

2.6.3. Competitive advantages for existing manufacturers

This market that Lumos operates in can favour more developed manufacturers over new entrants as a result of the potentially significant costs, time and resources required to develop new products that comply with the complex set of regulations. Factors which may advantage existing manufacturers can therefore include:

- The requirements associated with obtaining and maintaining the requisite regulatory clearances for products and services;
- Obtaining patent and other relevant intellectual property approvals in jurisdictions;
- In-market adoption of products for new clinical applications and new applications, as well as greater adoption in existing markets; and
- Access to sufficient capital and human know-how to allow development and scale up of a business to drive sales and enter new markets.

There are a number of global participants operating in the industry that have significant resources that may be put toward developing competing products to Lumos.

2.7. Regulation

The use, supply and manufacturing of POC diagnostic tests is subject to extensive regulation across jurisdictions. The first format of Lumos' FebriDx® test is a standalone, disposable, qualitative product that has received regulatory clearance in several markets, including Europe, Australia, and Canada. An initial 510(k) submission for regulatory clearance for FebriDx® in the United States is currently under review with the FDA for the use of FebriDx® to differentiate viral from bacterial infection.

Key regional regulations and standards relevant to POC diagnostic tests are summarised in Table 2.7 below.

Table 2.8: Regulations and standards for POC diagnostic tests

Region	Regulation	Status of FebriDx® approvals
United States	In the United States, POC diagnostic tests, including Lumos' products, are regulated by the FDA and are subject to the Federal Food, Drug, and Cosmetic Act (**FDCA**). Under the FDCA, medical devices are classified into one of three classes, either Class I, II or III. Regulatory control increases from Class I to Class III. Most Class I devices are exempt from premarket notification or approval by the FDA; most Class II devices require Premarket Notification under section 510(k) of the FDCA; and most Class III devices require Premarket Approval based on FDA review of detailed information on product safety, effectiveness, and manufacturing controls. A 510(k) clearance will be granted if the submitted data establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device or to a Class III medical device for which the FDA has not required pre-market approval (a "predicate device"). A device is substantially equivalent if, in comparison to a predicate device it: has the same intended use as the predicate; and has the same technological characteristics as the predicate; or has the same intended use as the predicate; and has different technological characteristics and does not raise different questions of safety and effectiveness; and the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device. A device may not be marketed in the U.S. until the submitter receives a letter from the FDA finding that the device substantially equivalent, typically within 90 days after submission.	Lumos has filed a 510(k) submission with the FDA for the use of FebriDx® to differentiate viral from bacterial infection (under review[196] Lumos intends to file additional regulatory submissions of its multi-use disposable and re-useable desktop formats of FebriDx® over the ensuing 12-24 months[197]

Region	Regulation	Status of FebriDx® approvals
United States ***continued***	Lumos' products must receive either an emergency use authorization (**EUA**), which provides an expedited pathway to commercialization in the U.S. market but which is only effective for as long as the public health emergency under which the EUA was issued remains in effect, or a 510(k) clearance from the FDA for commercialisation.[77] During a public health emergency, as declared by the Secretary of the Department of Health and Human Services, the FDA can use its EUA authority to authorise the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. *In vitro* diagnostic (**IVD**) devices (Class I and Class II IVD), including POC tests that are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them are subject to IVD-specific criteria under the FDA Modernization Act of 1997.[78] As a result, manufacturers are required to obtain FDA clearances when launching their products in different user settings, such as for traditional clinical laboratory use, for at-home use and over the counter sales.[78] Laboratory Developed Tests, a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory, including POC diagnostic tests, are regulated under the Clinical Laboratory Improvement Amendments 1988 (**CLIA**) which requires all clinical laboratories to be certified by the Centers for Medicare and Medicaid Services (**CMS**) prior to conducting diagnostic tests on human samples.[78] Tests which are simple and have a low risk for an incorrect result may be waived from CLIA requirements. Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria.[79]	Lumos has filed a 510(k) submission with the FDA for the use of FebriDx® to differentiate viral from bacterial infection (under review)[80] Lumos intends to file additional regulatory submissions of its multi-use disposable and re-useable desktop formats of FebriDx® over the ensuing 12-24 months[81]
Canada	In Canada POC diagnostic tests are regulated under the Food and Drugs Act and Health Canada. Health Canada refers to guidance published by the FDA for POC diagnostic testing and self-testing kits. Health Canada also looks for guidance from Canada's National Microbiology Lab, the Canadian Public Health Laboratory Network and the WHO.[82]	Regulatory clearance granted (Health Canada)

77. U.S. Food & Drug Administration, Premarket Notification 510(k), published March 2020.
78. MarketsandMarkets Report, 2021.
79. Centres for Disease Control and Prevention, Waived Testing, 2021, Waived Tests, published January 2021.
80. Lumos is completing a prospective, multi-centre clinical trial with approximately 673 subjects (approximately 503 symptomatic and approximately 170 asymptomatic), in the United States to leverage the pending 510(k) clearance to support an intended use for FebriDx® to test that patients for both viral and bacterial infections. Lumos expects to complete this trial in May 2021 and this data will be combined with the 221 patient pilot data along with real world COVID-19 specific clinical studies conducted in the United Kingdom, as described in section 3.3.3.2, per the requirements under FDA clearance.
81. Regulatory submissions for its multi-use disposable and re-useable desktop formats of FebriDx® would represent enhancements of a cleared product and would require a combination of prospective studies and archived sample testing, but with a reduced sample size and Lumos would seek to leverage off the existing regulatory clearance for the qualitative FebriDx® product. Lumos is targeting filing for the first of these regulatory clearances in 2022.
82. Government of Canada, Testing devices for COVID-19, published February 2021.

Region	Regulation	Status of FebriDx® approvals
Europe (excluding United Kingdom)	The medical devices sector in the EU is supported by a regulatory framework which governs over 500,000 types of medical devices and IVDs on the EU market.[83] Examples of medical devices are X-ray machines, pacemakers and software apps, while IVDs are used to perform tests on samples with examples including HIV blood tests, pregnancy tests and glucose tests.[83] New legislation regulating medical devices within the EU entered into force on 25 May 2017, with a staggered transition period of four years for new medical devices, and up to seven years for IVDs.[83] The new framework regulating medical devices consists of two Regulations, which will replace the existing Medical Device Directives (**MDD**): 1. **(EU) 2017/745 of the European Parliament and of the Council on medical devices regulation (MDR):** amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; and 2. **(EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices regulation (IVDR)**: repealing Directive 98/79/EC and Commission Decision 2010/227/EU.[83] To market medical devices in the European Union, the current regulatory environment requires CE Marking, which demonstrates a medical device conforms to the 'essential requirements' set forth in the product's applicable Directives (mentioned above). A medical device must be evaluated and certified by a Notified Body (for example MDC Medical Device Certification GMBH, in Germany) in order to obtain CE Mark certification. The role of a Notified Body is to conduct conformity assessments of medical devices under the relevant EU framework.[83] The international medical device quality system standard ISO 13485:2016 is aligned with the current MDD, meaning its standards are fulfilled by a medical device which has obtained CE certification.[84] New IVDs will be required to be CE Marked under the IVDR by 26 May 2022 in order to be sold in Europe (excluding the United Kingdom).[85] For IVDs that are already certified by a Notified Body under the current Directive (this applies to FebriDx®), the IVDR will be fully applicable on 26 May 2024.[85]	Regulatory clearance granted in Germany (CE Mark)

83. European Commission, Medical Device – Sector.
84. ISO 13485:2016: The Logical Route to CE Marking for Medical Devices and In Vitro Diagnostics Medical Devices, UL White Paper, published 202.
85. MedTech Europe, The transition to a new regulatory framework for in vitro diagnostic medical devices in the EU; European Commission, Medical Device Sector, published May 2018.

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Region	Regulation	Status of FebriDx® approvals
United Kingdom	In order for an IVD to be approved in the United Kingdom, it must first meet the requirements of the United Kingdom Medical Devices Regulations 2002 (S1 2002 No 618, as amended) (UK MDR 2002). Part IV of the UK MDR 2002 details regulatory requirements for manufacturers of IVDs, dealing with the safety, quality and performance of IVDs. It lists various essential requirements with which IVDs must comply, prior to being placed on the market or put into service. It is for the manufacturer to asses which requirements are relevant to the particular product, as not all essential requirements will be applicable to all devices.[86] The UK MDR 2002 is intended to ensure IVDs do not compromise the health and safety of users when used for their intended purpose, are designed and manufactured to be suitable for the purpose specified by the manufacturer, and achieve the performances stated by the manufacturer.[87] From 1 January 2021, all medical devices, including IVDs, placed on the Great Britain market are required to be registered with the Medicines and Healthcare products Regulatory Agency (**MHRA**).[87] Lumos' UK Responsible Person[88] will register FebriDx in Great Britain within the grace period applicable to FebriDx®. Following legislative changes related to Brexit, the UKCA (United Kingdom Conformity Assessed) marking was introduced on 1 January 2021 to replace the CE Mark for goods being marketed in Great Britain (England, Wales and Scotland).[86] For medical devices, the UKCA mark demonstrates that the device conforms to the requirements in the UK MDR 2002. The UKCA mark covers most goods which previously required the CE Marking and has largely the same essential requirements, conformity assessment processes and standards as the CE Marking.[89] The CE Mark will be valid in Great Britain market until 30 June 2023 for general IVDs which have obtained the CE Mark through self-certification (applies to FebriDx®), pursuant to existing Directive 98/79/EC covering IVD medical devices (EU IVDD).[90] From 1 July 2023, new devices placed on the Great Britain market will need to conform with UKCA marking requirements. The Northern Ireland market requires the CE Marking or UKNI marking and not the UKCA marking.[90]	Regulatory clearance granted (CE Mark, effective till 30 June 2023, FebriDx® will be re-submitted for MHRA approval in order to obtain a UKCA Mark)
Australia/ New Zealand	To obtain approval and authorisation for sale in Australia, products must be entered on the Australian Register of Therapeutic Goods (**ARTG**) and be approved by the Therapeutic Goods Association (**TGA**). Products are entered on the ARTG when medicines, biological or medical device applications have been validated, or when higher risk products have been assessed as meeting prescribed quality and safety requirements.[91] The New Zealand Government is currently working on a new and comprehensive regulatory regime to regulate therapeutic products in New Zealand, following cessation of the Australia New Zealand Therapeutic Products Agency project. This regime will replace and modernise the existing regulatory arrangements under the Medicines Act 1981.[92]	Regulatory clearance granted in Australia (TGA) only

86. UK Government, Regulating medical devices in the UK, published on December 2020.
87. Medicines and Healthcare products Regulatory Agency, In vitro diagnostic medical devices: guidance on legislation, published on January 2021.
88. A UK Responsible Person is a person or body established in the United Kingdom that acts on behalf of a manufacturer, based outside of the United Kingdom, in relation to the manufacturer meeting their obligations under United Kingdom regulations. Source: UK Government, Regulating medical devices in the UK, published on December 2020.
89. UK Government, Using the UKCA marking, published on February 2021.
90. UK Government, Using the UKCA marking, published on February 2021; UK Government, Regulating medical devices in the UK, published on December 2020.
91. Australian Government Department of Health, Overview of supplying therapeutic goods in Australia, published on August 2020.
92. Ministry of Health NZ, Therapeutic products regulatory regime, published on December 2019.

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3.1. Company Introduction

3.1.1. Introduction

Lumos is a fully integrated developer and manufacturer of POC diagnostic tests. This means that Lumos has capabilities and technologies that allow it to take a POC diagnostic test from the early stage of developing an initial product concept, through development, clinical validation and verification, and then to manufacture of the test at commercial scale.

Lumos generates revenue from its two complementary business divisions:

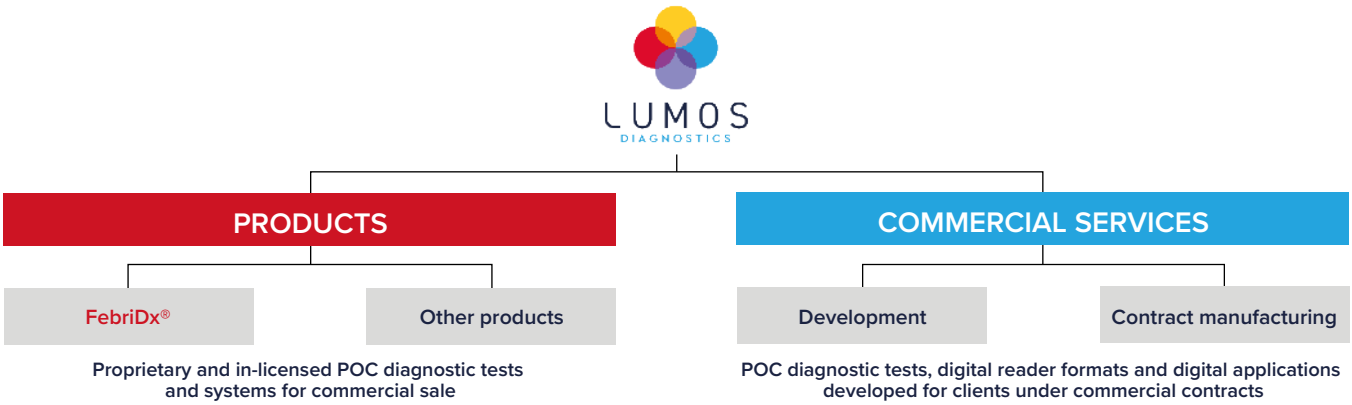
- **Products:** develops and manufactures proprietary and in-licensed POC diagnostic tests for commercial sale by Lumos[1]; and
- **Commercial Services:** develops and manufactures POC diagnostic tests on behalf of clients under fee-based commercial contracts.

Both Lumos' Products and Commercial Services divisions are underpinned by a technology platform that includes intellectual property covering the technology used in Lumos' POC diagnostic tests and its range of digital reader formats and digital applications. Lumos uses its technology platform and other capabilities (such as designs, in-house expertise and facilities) to develop and manufacture POC diagnostic tests which can be customised for specific applications and end user settings. Lumos' technology platform encompasses:

- **POC diagnostic tests:** rapid tests, comprising of test strips encased in a cassette, with associated technologies that analyse, interpret, display and, for some products, transmit the result of the diagnostic test electronically;
- **Digital reader formats:** Lumos has developed a range of digital reader formats that can be customised to work with specific POC diagnostic tests[2]; and
- **Digital applications:** hardware and software tools that can enhance the functionality of a test and its connectivity across a range of different user settings, for example in-patient, out-patient and over-the-counter (**OTC**) settings.

Figure 3.1 below illustrates Lumos' two business divisions, its key products and activities undertaken by those divisions which are described further in Section 3.4, Section 3.5 and Section 3.6. Section 3.3 provides further details on Lumos' digital reader technologies and digital applications. Lumos' target markets for sales are North America and Europe.

Figure 3.1: Overview of Lumos' business divisions



1. A proprietary test is one which has been developed inhouse and branded as a Lumos product. An in-licenced test is one which contains in-licensed components developed by a third party licensor that also contains Lumos intellectual property and is manufactured and distributed by Lumos.
2. Single-use disposables contain a digital electronic reader and single-use fully integrated test strip; multi-use disposables are supplied in kit form and contain a reusable digital electronic reader for 20 to 50 disposable test strips; and reusable desktop readers are digital electronic readers that are able to analyse and interpret the results of multiple tests, and may include a digital interface which allows test results to be transferred (eg uploaded) to third party systems including patient Electronic Medical Record (EMR) systems.

Products

Lumos' product portfolio currently comprises of two POC diagnostic tests that are available for sale:

- **FebriDx®:** a test that can differentiate between bacterial and viral respiratory infections with regulatory approval in several markets including Europe, Canada and Australia. A 510(k) submission with the FDA is currently under review for the use of FebriDx® to differentiate viral from bacterial infection in the United States. Further detail on the 510(k) submission that Lumos has filed with the FDA is in Section 2.7 and Section 3.4.5; and
- **CoviDx™:** an antigen test for COVID-19 which has been granted a CE Mark for sale in Europe. Lumos has applied for country-specific regulatory clearances to allow sales of CoviDx™ in the United States and Canada which are currently under review by the FDA and Health Canada, respectively.

Lumos' Products division is seeking to expand its sales of POC diagnostic tests and has a pipeline of new proprietary diagnostic POC tests currently under development:

- **Pipeline tests in development:** a combination test for two common respiratory viral pathogens (influenza and COVID-19) (ViraDx™), a sepsis (blood stream infection) test (SepsiDx™), and a urinary tract infection test (UriDx™); and
- **Pipeline test formats:** the existing FebriDx® test, formatted for use in combination with digital readers (being a multi-use re-useable digital reader and desktop digital reader) that can be used in different user settings.

Further information regarding Lumos' existing POC diagnostic tests and those under development is set out in Sections 3.4 and 3.5.

Commercial Services

Lumos develops and manufactures POC diagnostic tests for clients by providing a comprehensive range of services across three key areas:

- **Strategic innovation:** initial evaluation of a POC diagnostic test product concept and the development of new diagnostic test assays;
- **Development and manufacturing transfer:** development of new POC diagnostic test products, including use of Lumos' technology platform and the customisation and integration of Lumos' digital reader technology where required and requested by Lumos' clients; and
- **Validation and commercial manufacturing:** clinical and product validation and commercial-scale manufacture of test strips and readers.

The significant majority of Lumos' FY20 revenue (approximately 94%) was generated from Lumos' Commercial Services division, with the remaining revenue (approximately 6%) generated by its Products division. Lumos is seeking to increase its Products revenue, in absolute terms and as a percentage of overall revenue, as it obtains regulatory approvals for its existing and new products and commences sales of those products in Lumos' target markets.

3.1.2. Company History and Structure

The business was founded in 2015 by Planet Innovation (located in Melbourne, Australia) following the acquisition of Nplex Pty Ltd (**Nplex**), which owned proprietary technologies for electronic readers of diagnostic tests. Its initial commercial focus was the contracted development of products for diagnostic tests on behalf of clients (now conducted in its Commercial Services division). In 2017, the business acquired Kestrel Biosciences, Inc (**Kestrel**). The Kestrel acquisition further expanded the business' technology platform and brought with it a rapid diagnostic assay development capability. The "Lumos Diagnostics" name (or "Lumos") was adopted in 2017.

In 2019, Lumos merged with Florida-based Rapid Pathogen Screening Inc (**RPS**) which was primarily focused on the development and commercialisation of POC diagnostic test FebriDx®. Lumos gained access to FebriDx®, and the majority of RPS's staff and facilities through this merger. RPS had a track record of successfully securing United States regulatory clearances and generating commercial sales for its ophthalmology focused rapid diagnostic tests. RPS divested its ophthalmology business in 2017 prior to its merger with Lumos. Rob Sambursky, the founder and CEO of RPS, joined Lumos with the merger in 2019 and is now Lumos' CEO.

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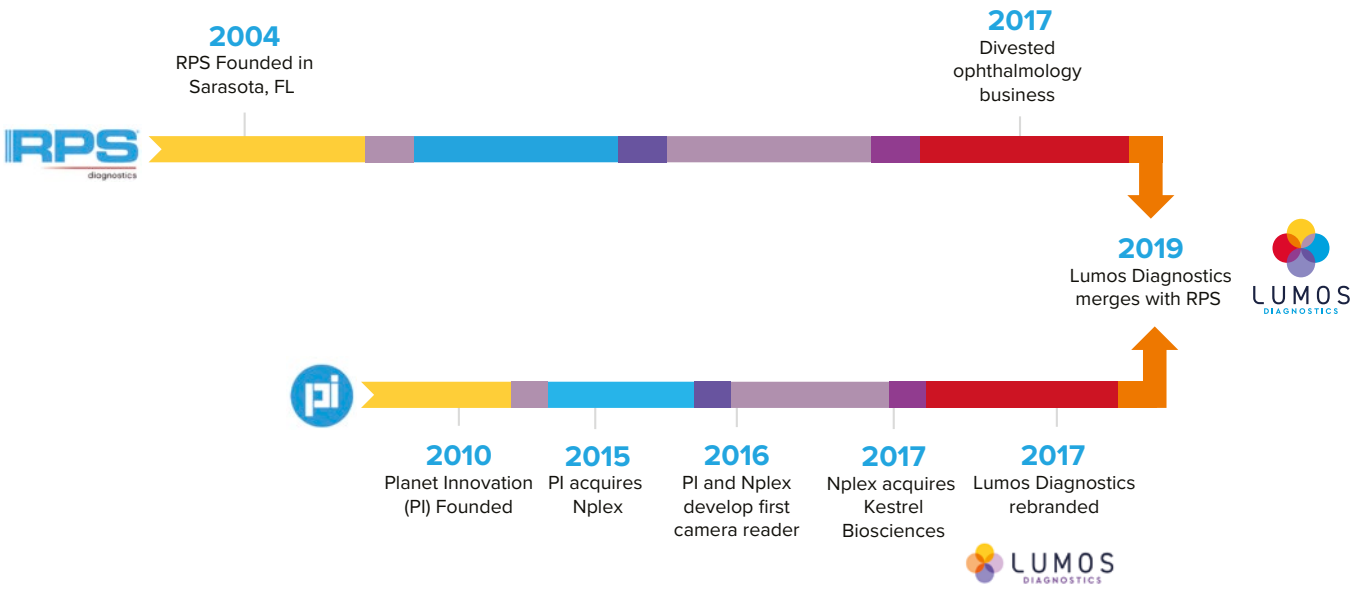
Figure 3.2: Timeline of Lumos' history



3.1.3. Company Operations

Lumos' head office is located in Melbourne, Australia. Lumos has two operating sites in the United States which include manufacturing facilities, research and development laboratories and offices for sales, marketing, product support and general administration. Lumos' main operating site is located in Sarasota, Florida, where it has established a high-throughput manufacturing facility for the manufacture, warehousing and global distribution of POC diagnostic tests. Lumos also has a facility in Carlsbad, California which conducts internal and client research and development activities and pilot-scale manufacturing services.[3]

Lumos moved to and commenced operations at its new Sarasota facility in April 2021. The area of the new facility is 32,000 square feet. Lumos has the option to increase its warehouse space by an additional 40,000 square feet.[4] Currently the two United States facilities cover 42,000 square feet (3,900 square metres) and have a combined manufacturing capacity of approximately 10m tests per month. Lumos' manufacturing facilities currently combine manual and semi-automated manufacturing equipment and processes, but will shortly employ automated packaging and labeling processes.

As at 1 May 2021, Lumos' employed 110 full time equivalents across the business, which are both Medical Device Single Audit Program (**MDSAP**) certified and ISO13485 compliant.[5] Further information on Lumos' facilities and employees is described in Sections 3.7.1 and 3.7.2.

3. Pilot-scale manufacturing services is the manufacture of rapid diagnostic tests for clients for the purpose of clinical trials and first commercial sales where batches are manually assembled due to the limited quantity of tests per batch.
4. This option is exercisable before 31 December 2023.
5. Medical Device Single Audit Program (MDSAP) certified is a program established by a consortium of regulatory bodies and covers the US (FDA), Canada (Health Canada), Australia (TGA), Brazil (ANVISA) and Japan (MLHW/PMDA) and allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory jurisdictions. ISO13485 is an International Organization for Standardization (ISO) standard which establishes essential requirements for a comprehensive quality management system for the design and manufacture of medical devices.

3.2. Lumos' Business Model

3.2.1. Revenue generation

Lumos currently generates revenue from its two divisions:

- **Products**: through the sale, by its distributors, of POC diagnostic tests developed and manufactured by Lumos; and
- **Commercial Services**: by providing outsourced services (for example development and manufacturing) relating to POC diagnostic tests for Lumos' clients.

In FY20 Lumos reported revenues of $8.4m, of which $7.9m was generated by its Commercial Services division and $0.5m was generated by its Products division. In 1H21, Lumos' Commercial Services division generated revenues of $9.8m compared to revenue of $3.3m for 1H20 (and $7.9m for the full year FY20). Its Products division generated 1H21 revenues of $1.7m compared to revenue of $0.1m for 1H20 (and $0.5m for the full year FY20), predominantly from the sale of its FebriDx® POC diagnostic test ($1.6m).

Lumos has generated revenue from the provision of contracted Commercial Services since FY17. Since this time, Lumos' Commercial Services revenues have grown significantly as a consequence of developing a more comprehensive offering for its clients and from undertaking more projects for them. Many of these clients have engaged Lumos to conduct multiple projects (discussed further in Section 3.6.3). Lumos currently has multi-year contract manufacturing agreements in place which are expected to provide revenue in future years based on committed minimum order quantities.

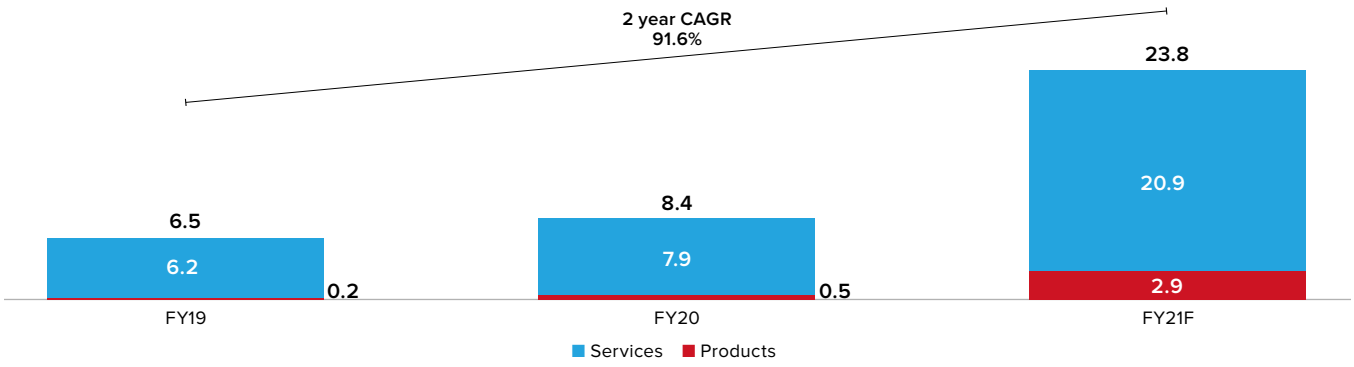
Lumos' Products division experienced significant growth with the commencement of FebriDx® product sales in FY20 and other product sales in 1H21. Lumos is seeking to drive further growth in its Products division through:

- sales of FebriDx® in the United States, subject to securing regulatory clearance for FebriDx® from the FDA; and
- sales from ViraDx™ (targeted launch date in 1H FY22) and other pipeline products (for example SepsiDx™ and UriDx™), subject to their successful development and securing the regulatory clearances required to allow their sale in Lumos' target markets,

and if successful in doing so expects its Products division revenue to contribute to a higher percentage of total revenue over time.

Since July 2020, sales for both Lumos' Products and Commercial Services divisions have benefitted from an increase in demand which has, in part, been driven by the COVID-19 pandemic. This increase in demand has provided Lumos with opportunities to increase its sales and the range of products and services offered by both its divisions. Lumos expects the growth in demand for its Products and Commercial Services offerings is likely to return to pre-pandemic levels as the COVID-19 pandemic becomes better managed through initiatives, such as the vaccination programs being conducted by the majority of countries over the next two years. However Lumos will seek to build on the accelerated interactions with existing and new clients, and the demand for Lumos' products (for example the use of FebriDx® in emergency rooms in the United Kingdom) to generate future revenue opportunities for it. Refer to Section 3.2.4 for more information.

Figure 3.3: Lumos' Revenue Growth (A$m)



Lumos' main expenses in generating revenue include:

- Personnel costs, material costs (including payments for clinical trials), facility costs and capital equipment in its Products division;
- Consulting costs of sales (direct and contracted labour), material costs of sales, facility costs in its Commercial Services division; and
- Research and development, sales, marketing and general administration costs across both divisions.

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3.2.2. Products division overview

Lumos' Products division uses its capabilities (such as design, in-house expertise and facilities) to develop and manufacture proprietary and in-licensed POC diagnostic tests for commercial sale. Proprietary and in-licensed products are described in Sections 3.4 and 3.5. Lumos uses third-party distributors to sell its POC diagnostic tests to end customers.

Lumos' principal proprietary product is FebriDx®, a POC diagnostic test that can be used to establish whether a person has a microbial infection and, if they do, whether it is caused by a bacteria or virus. This test has regulatory clearance in some of Lumos' target markets, namely the United Kingdom, Germany and Canada. Lumos has filed a 510(k) submission with the FDA which is currently under review for the use of FebriDx® to differentiate between a viral and a bacterial infection.

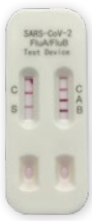
Further information regarding FebriDx® and its regulatory approval pathway is set out on Section 3.4. Lumos has already appointed distributors and commenced initial commercial sales of FebriDx® in the United Kingdom, Germany and Canada. FebriDx® accounted for the majority of Lumos' FY20 and 1H21 Product revenue.

Lumos has leveraged its existing technology and expertise in POC diagnostic testing to capture complementary market opportunities, including in-licensing components for an antigen test for COVID-19 called CoviDx™.[6] This test has received a CE Mark for sale in Europe and Lumos has applied for regulatory clearances in the United States and Canada as described in Section 2.7.

Lumos is also developing a number of proprietary tests for other infectious diseases including a combination test for respiratory viral infections (influenza and COVID-19) (ViraDx™), sepsis (SepsiDx™), and urinary tract infections (UriDx™). All pipeline tests will require regulatory clearances to allow commercial sale in Lumos' target markets (as outlined in Section 2.4) and will be subject to them meeting the regulatory requirements, in each market which usually needs to be supported with evidence from clinical studies.

Lumos' existing proprietary products and pipeline Products are outlined in Figure 3.4 below.

Figure 3.4: Lumos Products division's current products and pipeline

Current products being manufactured		Pipeline		
Rapid POC diagnostic test	**COVID-19 Antigen test**	**Test and formats in development**		
FebriDx **Multi-Use Disposable** 	**CoviDx™** 	**ViraDx™** 	**FebriDx** 	**UriDx™** • Urinary tract infection **SepsiDx™** • Blood stream infections
• Patented, easy-to-use, POC diagnostic test for microbial infection using a unique combination of two different host-specific markers • Commercial sales in United Kingdom, Germany and Canada • United States FDA submission under review	• CoviDx™ COVID-19 antigen test • CE Mark granted for commercial sales in Europe • Submitted for U.S. Emergency Use Authorisation (EUA)	• Viral respiratory infections covering influenza A and B and COVID-19	**Multi-Use Re-useable** • Connected platform for a menu of tests **Multi-Use Disposable** • Multiple readings providing digital results	

Note: development and successful commercialisation of pipeline products (including for multi-use disposable and re-useable desktop formats of FebriDx®), and sale of current products into new markets, is subject to requisite regulatory approvals and other uncertainties and is not guaranteed. Refer to Section 5. Human influenza A and B are highly contagious respiratory viruses known as "the flu" that cause epidemic seasonal infections (flu season).

6. Lumos sources the membrane used in the test, receives antibodies from a third party, Lumos cuts all the strips, uses its own cassette, and does all the assembly, packaging and kitting.

3.2.3. Commercial Services division overview

Lumos provides a comprehensive range of services to clients, which are typically multi-national or well-funded early-stage healthcare companies, through its Commercial Services division. As a fully integrated developer and manufacturer of rapid POC diagnostic tests, Lumos is able to provide its clients with services that span all stages of the development for a new POC diagnostic product, from the early stage of initial product concept, through development, clinical validation and verification, and finally to the manufacturing of the test at commercial scale.

Lumos' Commercial Services can be grouped into three areas:

- **Strategic innovation services:**
  - developing a POC diagnostic test product concept;
  - evaluating its commercial potential;
  - developing an assay for measuring and detecting a relevant diagnostic marker;
  - undertaking initial studies to measure diagnostic markers in human tissue samples; and
  - initial trials of the test on one or more diagnostic test readers.
- **Development and manufacturing:**
  - developing the POC diagnostic test into a commercial-ready form by optimising the test performance, either as a "visually read" test (similar to many home pregnancy tests), or in combination with one or more reader formats;
  - developing a commercially scalable manufacturing process; and
  - transferring that process to a commercial manufacturing line.
- **Validation and commercial manufacturing:**
  - completing and compiling the clinical and quality data requirements required to support applications for regulatory clearance across markets; and
  - manufacturing POC diagnostic tests for clients.

Lumos has the capability to develop, customise and supply digital readers for its clients. These are based on a range of digital reader formats developed by Lumos which differ in terms of size, portability, cost and complexity. The digital reader formats developed by Lumos include single-use disposable readers, multi-use disposable readers and desktop readers, as described further in Sections 3.3.2 and 3.3.3.

An example of a Commercial Services client is DiaSorin, a global leader in IVD. Lumos is providing its expertise and development services in relation to customised rapid POC diagnostic tests to DiaSorin. These tests will be used to support the DiaSorin LIAISON® IQ POC reader, which has been developed and supplied by Lumos. DiaSorin's LIAISON® IQ POC reader is capable of reading a number of different tests (referred to as a "menu") that use different health biomarkers, including a COVID-19 antibody test and a COVID-19 antigen test. The antigen test is white-labelled version of Lumos' CoviDx™ test which is manufactured by Lumos and compatible with their reader system. DiaSorin is planning to expand the test menu of LIAISON® IQ beyond the COVID-19 related tests and into other clinical areas including other infectious diseases such as Lyme disease or gastrointestinal tract infections.[7] Refer to Table 3.1 below for further details on the DiaSorin and Lumos strategic collaboration.

7. DiaSorin, DiaSorin announces its strategic collaboration with Lumos Diagnostics, published on April 2021.

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Table 3.1: DiaSorin Partnership Case Study

Item	Description	Key terms
Development and Commercialisation Agreement[1]	Development and Commercialisation Agreement between Lumos and DiaSorin	**Commencement**: Agreement entered into on 9 May 2021. Preliminary agreements and development activities commenced in September 2020. **Overview**: Provides for development of COVID-19 antibody test, COVID-19 antigen test, the LIAISON® IQ POC reader, tablet, cradle, and software solution. **Term**: seven years from date of first commercial sale of antibody test, with three year renewal terms until terminated with 24 months' advance notice required.
Readers, cradles, and tablets	Development and Commercialisation Agreement provides for manufacture of hardware by Lumos	**Initial order**: 2,000 readers, 2,000 cradles and 2,000 tablets. **Obligations**: DiaSorin is obligated to provide a running 12 month forecast wherein the first three months are a binding commitment by DiaSorin to purchase. If Lumos fails to meet its manufacturing obligations, Lumos and DiaSorin have agreed to find a third party manufacturer licensed by Lumos to meet the supply obligations.
COVID-19 antibody test	Development and Commercialisation Agreement provides for manufacture of tests by Lumos that optimise the performance of DiaSorin's biomarker onto Lumos' digital cassette	**Initial order**: 500,000 tests **Obligations**: DiaSorin is obligated to provide a running 12 month forecast wherein the first three months are a binding commitment by DiaSorin to purchase. If Lumos fails to meet its manufacturing obligations, Lumos and DiaSorin have agreed to find a third party manufacturer licensed by Lumos to meet the supply obligations.
COVID-19 antigen test	Designed and manufactured white labelled version of Lumos' CoviDx™. Development proposal provides for Lumos customisation of CoviDx™ product. Related Distribution Agreement provides rights to commercialise the white labelled version of Lumos' CoviDx™ product.	**Overview**: Approved program budget (fees and expenses) associated with the customization of the Lumos CoviDx™ test and integration with the LIASON IQ reader and software applications. Includes upfront deposit and monthly invoicing based on actual hours multiplied by fee rate and expense recharge with percentage markup. Indicative transfer pricing based on order volumes and end user pricing. **Distribution**: Distribution agreement to grant DiaSorin exclusive distribution rights to the COVID-19 antigen test provides rights to commercialise the white labelled version of Lumos' CoviDx™ product on the LIASON IQ reader on a worldwide basis, excluding the Lumos branded version of the test.
Payment		Initial orders for readers and tests are paid 50% on order, 50% on shipping of the readers and receipt of the tests. All other payments are net thirty days from the invoice date (which shall be issued on shipping).
Intellectual Property		Each of Lumos and Diasorin shall solely own its background technology (being all intellectual property rights existing before 19 October 2020) and its foreground technology (being improvements made to background technology after 19 October 2020) and the parties agree to jointly own co-inventor patent rights for inventions and discoveries made by employees of both Diasorin and Lumos.

Item	Description	Key terms
Wind-down and technology transfer		On notice of termination, Lumos to continue to supply Diasorin during a "wind-down" period defined as the period required to satisfy all outstanding orders and existing obligations under customer contracts. Diasorin has an option to request a technology transfer of tests developed under the agreement from Lumos and pay a royalty on net sales of these tests for an agreed period after the end of the wind-down period

Note: Other key terms associated with manufacturing of product for Diasorin are generally consistent with the terms of Lumos' template contract manufacturing agreement described in Section 3.6.5.2.

Lumos' Commercial Services division secures contracts through its business development and marketing efforts. This division has management personnel and dedicated business development professionals with industry knowledge and relationships to identify potential opportunities and establish commercial contracts with potential clients. Lumos also undertakes marketing activities in order to generate new initiatives, build brand awareness and expand its network of potential clients such as attendance at major industry conferences, delivering educational lectures/seminars, and providing news about Lumos via its website and through press releases that may be distributed through third party media outlets such as 360Dx. Lumos also receives development referrals that arise from its relationships with existing suppliers and clients.

3.2.4. Impact of COVID-19

The COVID-19 pandemic resulted in a number of changes to Lumos' operations but had minimal impact on Lumos' overall productivity. Lumos developed a COVID-19 plan to manage its staff and operations which includes daily temperature checks, on-site mask wearing, social distancing, flexible in-office hours, non-essential employees working from home, and strict post-exposure quarantine policies. This has enabled its R&D and manufacturing operations to remain active, despite contending with periodic positive COVID-19 infections in a small number of staff. Lumos addressed initial disruptions to its supply chain through the advanced purchase of critical components.

The COVID-19 pandemic has provided opportunities for companies developing or selling POC diagnostic tests, including Lumos, through an increased awareness of the need for rapid and accurate diagnostic tests for infectious diseases.[8] While governments are seeking to manage COVID-19 through widespread vaccination programs, Lumos expects that POC diagnostic tests will continue to be used for monitoring and managing COVID-19 infections for the foreseeable future.[8] This expectation is based on the existence and prevalence of mutations globally and, notwithstanding current vaccination programs, the potential for COVID-19 to become an endemic disease, much like influenza.[9]

8. Christopher Price and Andrew John, Will COVID-19 be the coming of age for point-of-care testing?, BMJ Innovations 2021 vol. 7, published on December 2020.
9. Nicky Phillips, The coronavirus is here to stay – here's what that means, published on February 2021.

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For Lumos specifically, the COVID-19 pandemic led to:

- FebriDx® sales growth in inpatient/hospital settings in the United Kingdom, Canada and Germany;
- the development of new infectious disease POC diagnostic tests (CoviDx™ and ViraDx™); and
- increased demand for Lumos' Commercial Services.

These opportunities supported additional investment in Lumos' infrastructure which included relocation to a new, larger facility in Sarasota, the purchase of additional automated equipment (such as packaging and labelling equipment) and an increase in Lumos' global headcount across manufacturing, operations, sales, marketing and administration.

3.2.4.1 FebriDx® sales ramp up

While COVID-19 temporarily reduced outpatient patient visits (as COVID-19 patients were generally diverted to hospitals), it enabled Lumos to target the hospital end-user setting (including emergency rooms), which was not a priority for Lumos' prior to the pandemic. This resulted from the need for healthcare professionals to rapidly assess the risk of suspected COVID-19 infected patients when they present at hospitals. FebriDx® could be used in the triaging process by providing a means to rapidly identify high risk patients (namely, those patients with an active, viral infection) for isolation while a COVID-19 specific confirmatory test, which can require several hours, was conducted. Multiple independent clinical studies have been published, described in Section 3.4.5, that demonstrate the effectiveness of FebriDx® as a triaging tool for suspected COVID-19 patients in hospital settings.[10] The publication of these clinical studies in respected journals has helped build global awareness of the product and its potential clinical impact, and is also being used to support FebriDx® marketing initiatives across the United Kingdom, Europe and Canada.

3.2.4.2 Development and distribution of new POC diagnostic tests

Lumos was able to leverage its technology platform to develop an antigen POC diagnostic test for COVID-19 testing (CoviDx™) for sale via Lumos' distribution channels (described in detail below). Lumos has also leveraged existing Commercial Services relationships for the distribution of these products, such as DiaSorin as described in Section 3.2.3. However, Lumos also intends to manufacture and distribute CoviDx™ itself through its own distribution partners subject to obtaining regulatory clearances, and may benefit from accelerated review timelines driven by temporary COVID-19 regulatory initiatives such as the FDA Emergency Use Authorization scheme (**EUA**).[11]

3.2.4.3 Investment in infrastructure and manufacturing capacity

COVID-19 has enabled Lumos' to accelerate its investment in facilities, equipment and resources to support contract manufacturing contracts (described in Section 3.6.5.2). These investments can also be used to support the manufacture of FebriDx® and future POC diagnostic tests.

3.2.4.4 Increased demand for Lumos' Commercial Services

The industry response to the COVID-19 pandemic has resulted in new agreements between Lumos and large healthcare businesses with significant resources and global distribution channels such as DiaSorin, described in Section 3.2.3.

10. Refer to footnotes in Section 3.4.5.
11. Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines and diagnostics, during public health emergencies, such as the current COVID-19 pandemic.

3.3. Lumos' technology platform

3.3.1. Overview

Lumos' Products and Commercial Services divisions are underpinned by its technology platform. A technology platform includes expertise and access to key technologies which form the basis of a range of related, but different, products, and the infrastructure, personnel and relationships that enable the development of those products. In the case of Lumos, this includes its patents, know-how, expertise, skills and capabilities for developing lateral flow POC diagnostic tests and the digital readers that are used with those tests. In addition to the core, underlying technology, a technology platform may also include[12]:

- **Components:** ready access to key components that are used in the different products;
- **Processes:** established design, development, production and delivery processes;
- **Knowledge:** experience, skills and methods for developing products; and
- **People:** team and organisational structure, supplier networks, established partnerships.

One of the key features of a technology platform is that it can be used to develop multiple products that have different applications for different commercial markets.[12] As a consequence, product development using a technology platform is generally faster, cheaper, and less risky compared to creating each new product from scratch.[12]

Lumos' technology platform enables it to develop multiple, different POC diagnostic test products, which are based on the same underlying technologies (Lateral flow assays (**LFAs**) and digital test readers), for different commercial applications and markets.

3.3.2. POC diagnostic tests

A POC diagnostic test is one that can be conducted without requiring access to a specialised laboratory or centralised testing facility and while the patient is present. Typically, all of the materials required to conduct a POC diagnostic test are either provided or readily available at the site where the patient is being provided with healthcare. POC diagnostic tests are usually able to deliver results in a rapid timeframe (for example 5-30 minutes) which can allow clinical decisions regarding potential treatments or interventions to be made while the patient is still present.

The typical components of a POC diagnostic test are:

- **Test strips:** test strips are the membranes or physical matrices on which a POC diagnostic test is conducted. In the case of LFAs, which are the main type of POC diagnostic test that Lumos develops, test strips typically have antibodies or other reagents on them. Diffusion of the test sample, which has been collected from the patient, from one end of the test strip to the other, sequentially exposes the test sample to different reagents on the test strip. This interaction provides the basis for the POC diagnostic test result.
- **Cassettes:** cassettes are physical containers in which test strips are housed for storage and use. The cassette helps protect the test strip, and the reagents on the test strip, from damage. In addition, the cassette may include functionality associated with conducting the test, such as the dispensing or application of reagents, or for interfacing with a digital test reader if one is used.
- **Digital Readers:** diagnostic tests may also use an electronic digital reader to capture, analyse, interpret and/or transmit the results from a POC diagnostic test. These readers can be formatted to have a range of different forms and functions depending on the test and the features that are included in the product design. Different features may be included to meet the needs of users in different settings.

POC diagnostic tests can be designed based on a range of digital reader formats and supported by different digital applications, described in Sections 3.3.3 and 3.3.4 below.

12. Platform-Based Product Design and Development- Knowledge Support Strategy and Implementation, Product platforms as a lever of competitive advantage on a company-wide level- a resource management perspective, published 2020.

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3.3.3. Digital reader formats

Lumos has developed a platform of proprietary digital reader formats that can be customised to meet the specific needs for a particular POC diagnostic test or product. This technology can be used in diagnostic test readers for Lumos' own POC diagnostic tests, or tailored to suit the specific requirements of its Commercial Services clients. These diagnostic test readers have built-in flexibility through the use of different sensing technologies and connectivity solutions. Lumos has developed a range of different digital reader formats for use in different user settings which vary in terms of their size, portability, cost and complexity, as outlined in Figure 3.5 below.

Figure 3.5: Reader systems that can use Lumos' digital reader formats

Single-use Disposable	Multi-use Disposable	Desktop

• Single use disposable tests
• Simple "yes/no" tests
• Out-of-clinic use
  • Over the counter
  • Consumers/at home testing
	• 10-50 single use test strips
	• Limited reuse disposable reader
	• Lower volume clinical settings
		• High performance desktop reader
		• Multiple tests using same reader
		• Higher volume/higher complexity settings e.g. Electronic Medical Record/Lab Information System connectivity

Types of reader formats: disposable and desktop

Lumos' disposable reader formats have been designed to easily "drop in" test strips and include custom "assay-specific" (ie test specific) analysis algorithms. Lumos offers the disposable reader in two formats: a multi-use disposable reader, where the device is supplied in kit form with 20-50 disposable test strips, and single-use disposable reader, where the test strip is fully integrated with the reader in a single-use, fully disposable system. These readers can be customised to meet the specific needs of Lumos or its clients. For example, test results can be measured using either colorimetric or fluorescent signals[13], displayed using on-device LED indicators, LCD numerical results or wirelessly transmitted to another device such as a tablet, and can be reported as qualitative (positive of negative), semi-quantitative (specific range) or quantitative (specific numerical measurement) readouts.[14]

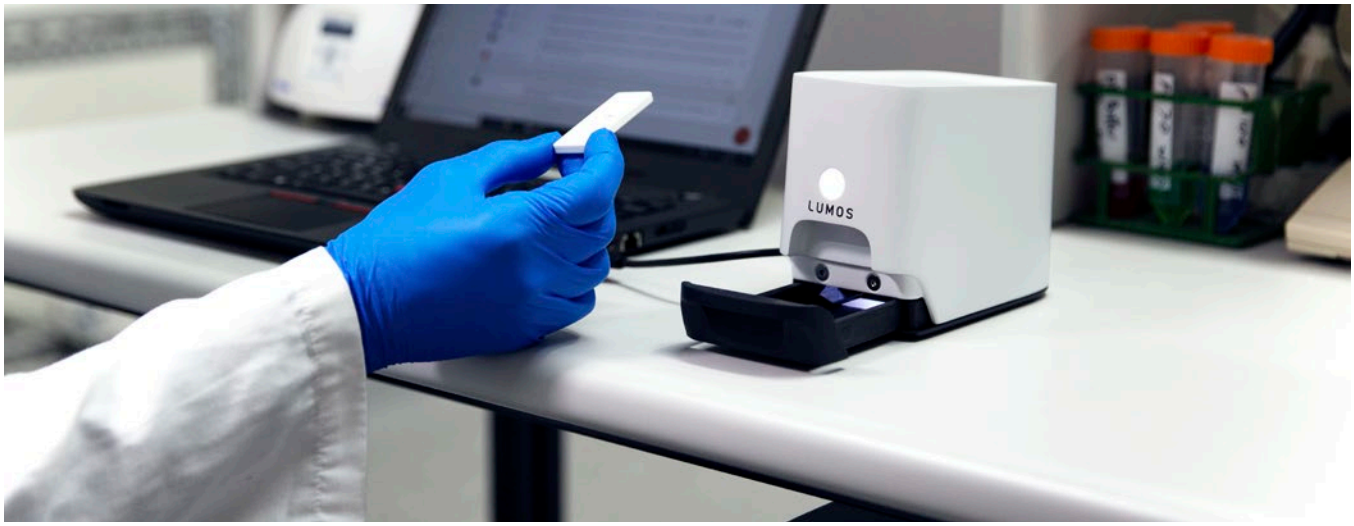
Lumos' desktop reader format may be used by clients who want to read a suite of different POC diagnostic tests using a single reader. Lumos' desktop reader uses high precision camera optics that are able to image (i.e. read or analyse) an entire test strip. There are no moving parts in the desktop reader which reduces the cost and complexity of the device. It is also suitable for qualitative, semi-quantitative, and quantitative applications and a variety of assay detector chemistries (such as colorimetric or fluorescent signals). Additional reader compatible tests can be added to desktop readers through software updates, including "over-the-air updates" (i.e. online).

13. Colorimetric signals illustrate the concentration of a chemical element or chemical compound in a solution with the aid of a colour reagent. Fluorescent signals are read by readers to detect the level of fluorescence in a test result.
14. Qualitative refers to a test that provides a result to determine the presence or absence of a diagnostic target in a sample, semi-quantitative refers to a test that provides a result which quantifies the specific range of a diagnostic target present in a sample (for example high, medium, low), and quantitative refers to a test that provides a numerical result which quantifies the amount of diagnostic target present in a sample e.g. 50 ng/ml.

Leelu Reader

Lumos has also developed the Leelu Reader which is sold to clients for research applications or for quality control purposes. The Leelu Reader is a lateral flow reader that allows the user to set and adjust a number of key parameters for the capture, analysis and reporting of results from a POC diagnostic test. The Leelu Reader allows clients to establish an optimised combination of settings for their specific POC diagnostic tests. The instrument can also be used to monitor test strip production quality. As the same camera optics are used in both Lumos' Leelu reader and its desktop readers, parameters determined using the Leelu Reader during assay development can be readily incorporated into a commercial digital reader. Similarly, the Leelu Reader can be used to define and optimise parameters to monitor and control the manufacture of POC diagnostic test strips.

Figure 3.6: Leelu Reader



3.3.4. Digital applications

Lumos is able to offer its clients access to customisable digital applications (hardware and software tools) to enhance the capability of its digital readers. This allows Lumos to develop products that can operate as part of an integrated system with the POC diagnostic tests and their digital reader able to communicate test results to external devices and systems. Applications can be developed which capture the location of a digital reader, test usage, test results and associated patient metrics either in on-premises applications or via the cloud. For example, test results can be viewed on smartphones or tablets via applications developed by Lumos. Test results can also be uploaded into Electronic Medical Record (**EMR**) systems directly or using a cloud-based interface (as described below). This is important in professional healthcare settings, such as primary care clinics and hospital settings, where EMR systems to play an important role in healthcare management.

Lumos defines the software requirements and manages its development but engages external firms, including Planet Innovation, under the Planet Innovation MSAs (refer to Section 6.7), to produce the software code. Lumos retains ownership of background intellectual property for the new software products, but typically the client takes ownership of intellectual property developed as part of the specific customisation of the software application.

3.4. Products division: FebriDx® Test

3.4.1. What Is FebriDx®?

FebriDx® is a 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. FebriDx® achieves this using a simple, rapid, lateral-flow assay based on a proprietary combination of two biomarkers that are produced by the human body in response to infection.

The results from the FebriDx® test may assist healthcare professionals and others to:

- determine if it is appropriate to prescribe an antibiotic to treat a patient;
- rapidly identify patients with an active microbial infection for isolation or management; and
- improve patient handling and workflow including the ability to provide telehealth consultations.

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3.4.2. How does FebriDx® work?

FebriDx® is a 'host-response test' in that it measures a patient's (the 'host's') immune response to an infection, rather than by directly detecting the infecting microbe itself. The FebriDx® test is based on evaluating the level of two human immune proteins that become elevated in a patient's bloodstream when they have a microbial infection:

- **C-reactive protein (CRP):** a general or non-specific marker for inflammation and infection; and
- **Myxovirus resistance protein A (MxA):** a marker specific for viral infections.

The advantage of using a host-response test is that a single test is able to detect clinically significant infections caused by a range of bacterial or viral pathogens.[15] By comparison, pathogen-specific tests, which detect the specific infecting microbe directly, may be limited to identifying one particular pathogen and thus will only be informative for infections caused by that specific pathogen.[15]

Another advantage is that a host-response test will only pick up active infections, which are the ones most likely to require medical intervention[15], and so may assist with more accurate treatment analysis and decision making. Tests that rely on detecting the pathogen itself often cannot distinguish between an active infection, that may require treatment, and a benign microbial colonization that usually does not require any intervention.[15]

The FebriDx® Test

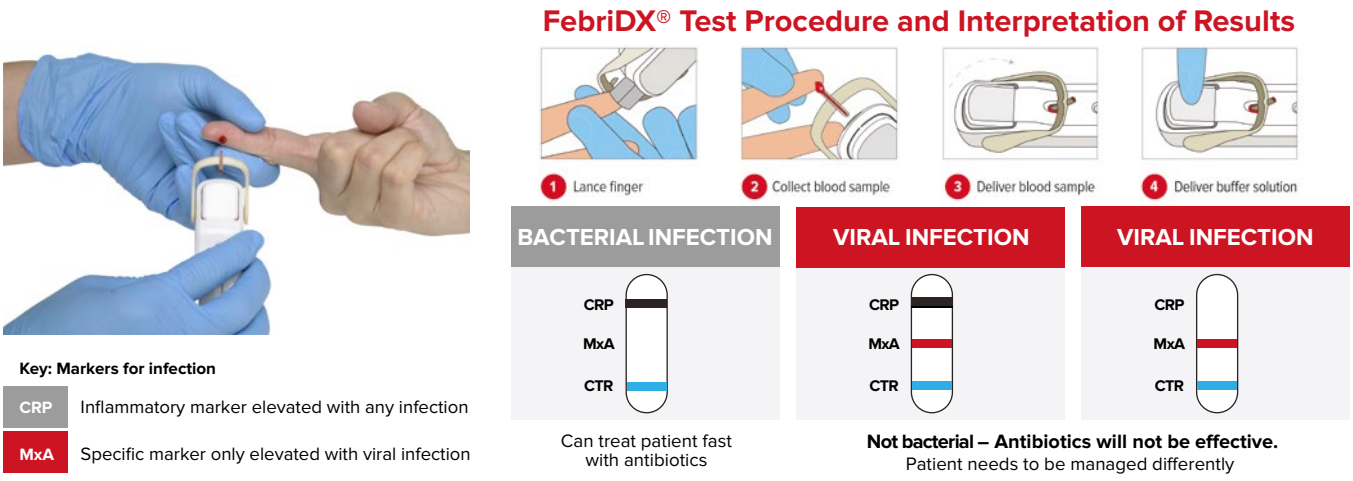
The FebriDx® test is based on simultaneously testing for both CRP and MxA to establish a patient's infection status. The combination of these biomarkers for determining a patient's infection status is the subject of granted patents held by Lumos.

FebriDx® results indicate the source of the infection:

- **CRP only positive:** means the patient has a bacterial infection; or
- **MxA positive (regardless of CRP status):** means the patient has a viral infection.

An illustration of how the results from the FebriDx® test can be used to determine if a patient has a bacterial or viral infection is provided below.

Figure 3.7: Use of FebriDx® test for microbial infection



Note: CTR stands for control.

15. Emily Lydon, The host response as a tool for infectious disease diagnosis and management, Expert Review of Molecular Diagnostics vol. 18, published on June 2018.

Like other POC diagnostic tests, FebriDx® brings testing to the patient quickly and conveniently. The analysis is performed rapidly, and results are provided to the patient without requiring access to a laboratory or specialist testing facility. This means that results can be provided to both the patient and physician faster, which allows for more immediate clinical treatment and management decisions to be made.[16]

As seen in Figure 3.7, the FebriDx® test utilises a cassette for blood collection and to house the test strip. Lumos has entered into a supply and development agreement (with a term to January 2033) with Atomo Diagnostics (**Atomo**) for the exclusive rights to use their all-in-one POC cassette for the manufacture, sale, supply, distribution or promotion of products that contain any combined POC diagnostic device that detects markers for viral infection and bacterial infection to assist in the differentiation of viral and bacterial infections (e.g. FebriDx®). FebriDx® has also been used in a different cassette format during clinical trials, including in trials submitted to the FDA as part of the 510(k) submission.

3.4.3. Where can FebriDx® be used?

FebriDx® can be used in a number of user settings, including both outpatient settings (such as doctors clinics), inpatient (hospitals and critical care centres), other community sites and possibly in home settings. Refer to Section 2.2.2 for further detail. FebriDx® is particularly relevant in a clinic setting, as results can be delivered within 10 minutes. This means that a doctor or nurse can conduct the test, read the results and act on them immediately (advising appropriate treatment), within the duration of a standard consultation appointment (approximately 15 minutes). In a hospital setting, the tests can be used by healthcare providers to quickly triage patients, to determine appropriate treatment or for further testing. Subject to obtaining any required regulatory clearances, results of FebriDx® could be used in a homecare setting to help decide whether someone is infectious and should remain home, or if they have a bacterial infection and should see a medical professional. Refer to Figure 3.8 for further details on use in end user settings.

FebriDx® product sales to date have resulted from purchases for use in both outpatient and inpatient settings in Lumos' key markets where it has regulatory clearance for commercial sale (namely the United Kingdom, Germany and Canada).

Figure 3.8: FebriDx® user settings

	Outpatient primary and urgent care	Inpatient hospitals/emergency	Homecare
Key Touch point	**GP**	**Emergency doctor**	**Patient**

Typical use case	• Confirm source of ARI infection:
	  • **Bacterial** – treat with antibiotics
	  • **Viral** – isolate or pathogen specific testing
		• Confirm source of ARI infection:
		  • **Bacterial** – treat with antibiotics
		  • **Viral** – isolate or pathogen specific testing
			• Patient to use directly or on family to determine source of infection:
			  • **Bacterial** – visit doctor
			  • **Viral** – isolate at home

Regulatory approvals[1]	• **Regulatory clearance in Canada (Health Canada), Australia (TGA), United Kingdom and Germany (CE mark)** • **United States: 510(k) application submitted to FDA (currently under review)**		• Future application to be submitted
Reimbursement[2]	• **Unites States: Potential to use existing CPT codes and FebriDx specific code post FDA clearance** • United States: Assumed reimbursement of approximately US$16 per FebriDx® test (generic CRP and infectious disease tests CPT codes)		
Format of FebriDx®	• **Current: A standalone, disposable, qualitative product** • Under development: Semi-quantitative versions of the FebriDx® test which use digital readers and software applications that can be integrated with the cloud and electronic patient medical record systems, as well as other healthcare applications		

Note:

1. Refer to Section 3.4.6 for information on the status of regulatory approvals.
2. Reimbursement is the process whereby private health insurers or government agencies pay for the costs (either partially or in full) of healthcare provided, which may include both the service and medical device. Refer to Section 3.4.7 for information on reimbursement.

16. NOW Diagnostics, Point of Care Testing: What it Means and Why You Should Know, published on October 2017.

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3.4.4. Clinical Applications for FebriDx®

The results from a FebriDx® test can be used to assist healthcare professionals to establish the most appropriate treatment or intervention for a patient, and allow more efficient management and processing of potentially infected patients.

In both inpatient and outpatient settings, being able to rapidly and accurately determine whether a patient has a bacterial and viral infection can assist with, and support, a healthcare provider's decision whether or not to prescribe antibiotics to a patient. Additionally, in an inpatient setting FebriDx® can be used to rapidly identify patients with either a bacterial or viral infection for isolation, further pathogen specific testing, or treatment.

3.4.4.1 FebriDx® can reduce clinical use of antibiotics

FebriDx® can assist in reducing the unnecessary use of antibiotics by providing doctors with a diagnostic test that is able to rapidly and objectively distinguish patients with a bacterial infection, who may benefit from a course of antibiotics, from those with a viral infection, who will get no benefit from using antibiotics. This can be used to support their treatment recommendation to their patient.

As discussed in Section 2.5.4:

- The symptoms that patients with an ARI present with can be very similar, regardless of whether they have either a bacterial or a viral infection[17];
- Leaving a bacterial infection untreated can result in several health complications, including potentially progressing to a bloodstream infection (sepsis)[18]; and
- Doctors frequently prescribe antibiotics as a precautionary measure if they are unsure whether a patient has a viral or bacterial infection.[19]

The unnecessary overprescribing of antibiotics can also have significant consequences for patients. As discussed in Section 2.5.4, these include:

- Immediate side effects: 1-in-10 patients experience side-effects and 1-in-15 experience allergic reactions to antibiotics, some of which can be serious and require additional interventions or even hospitalisation[20]; and
- AMR: the widespread use of antibiotics by patients who do not have a bacterial infection contributes to the emergence of antibiotic resistant strains that no longer respond to these drugs, and can have serious implications for a person who develops an antibiotic resistant infection.[21]

There are substantial financial costs to insurers and governments from AMR, stemming from the emergence of antibiotic resistant infections that require prolonged hospital stays and the allocation of expensive healthcare resources during the course of treatment (discussed in Section 2.5.4.3).[21]

A study of 21 patients at a single primary care practice in the United Kingdom in 2017 reported that use of FebriDx® to assess patients with a respiratory tract infection resulted in an 80% reduction in unnecessary antibiotic prescriptions, and altered the clinical management decisions for 48% of patients.[22] A second study of 20 children conducted at a pediatric outpatient clinic in Switzerland in 2019 showed that FebriDx® was able to reduce antibiotic prescription by 90%, whereas use of a CRP test alone only led to a 55% reduction.[23]

17. Martin Blaser et al, Accounting for variation in and overuse of antibiotics among humans, BioEssays, published on October 2020.
18. M.L. Martinez et al, An approach to antibiotic treatment in patients with sepsis, Journal of thoracic disease vol. 13(3), published on March 2020.
19. Chief Public Health Officer of Canada, Preserving Antibiotics, Spotlight Report, published on June 2019.
20. NHS, Antibiotics side effects, published on May 2019.
21. Porooshat Dadgostar, Antimicrobial Resistance: Implications and Costs, Infection and drug resistance vol. 12 3903-3910, published on December 2019.
22. Miles Davidson, FebriDx® Point-of-Care Testing to Guide Antibiotic Therapy, published on August 2017.
23. Xavier Onrubia, A pilot evaluation of the FebriDx test in an outpatient pediatric clinic, published on March 2020.

3.4.4.2 Management of patients

FebriDx® can potentially be used to improve how patients are managed and processed in healthcare facilities. This can include screening and prioritising patients when they arrive at a facility (triage), improvements to workflow efficiencies and patient handling, and providing the ability to conduct out-of-clinic consultations.

FebriDx® can be used to rapidly identify patients who may have a microbial infection. Patients, particularly those with a suspected COVID-19 infection, may need to be isolated until a pathogen-specific diagnosis is obtained, or may need to be prioritised for more rapid treatment depending on the result of their FebriDx® test and their symptoms. A negative result from FebriDx® (which excludes both a viral and bacterial infection) may allow healthcare professionals to more rapidly focus on higher-priority patients, or to look for other possible causes for a patient's health concern.

Two independent studies conducted at different hospital sites in the United Kingdom in 2020 demonstrated that FebriDx® can be used as a screening tool for the rapid identification of symptomatic patients infected with the COVID-19 virus.[24, 25] The results from these studies showed that FebriDx® was as reliable as pathogen-specific molecular tests at identifying viral positive patients infected with the COVID-19 virus and was able to deliver results in a significantly shorter timeframe (10 minutes) versus the POC molecular tests that is was compared against (over 1 hour) and laboratory molecular tests (over 17 hours).

FebriDx® also has the potential to assist with streamlining workflow by allowing practice staff to conduct initial testing prior to a consultation. A result from testing with FebriDx® may negate the need for further consultation with a doctor, or may provide an initial diagnosis that could make a consultation with the doctor more effective and efficient.

FebriDx® also has the potential to enable non-clinical sites (for example in aged care homes, prisons, immigration settings, cruise industry, at-home) to more easily test people in order to establish their infection status. This may allow these non-clinical sites to more rapidly identify people with infections who consequently may require isolation, follow-up medical assessment, or medical intervention.

24. Tristan W Clark et al, Diagnostic accuracy of the FebriDx host response point-of-care test in patients hospitalised with suspected COVID-19, The Journal of Infection vol. 81(4), published October 2020.
25. Nawazish Karim et al, Utility of the FebriDx® point-of-care test for rapid triage and identification of possible coronavirus disease 2019 (COVID-19), IJCP, published on September 2020.

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3.4.5. Clinical Studies of FebriDx®

Nine clinical studies using FebriDx® have been completed with eight published in peer-reviewed scientific journals and one recent study pending publication. Four of these studies, including two described in Section 3.4.4.2, were primarily focused on evaluating FebriDx® as a screening and triaging tool for use on patients arriving at healthcare centres with a suspected COVID-19 infection.[26] The remaining five studies were primarily focused on the use of FebriDx® to distinguish between bacterial and viral infections in patients with acute ARIs. Of these five studies, one was the initial pilot evaluation of FebriDx® in ARI patients[27], two were multi-centre prospective clinical trials[28], and two were single site retrospective outcome studies.[29]

Table 3.2: Summary of published clinical trials that have used FebriDx®

Study	Year	Primary Indication	Type of Trial	Patients Tested with FebriDx®	Journal
1	2015	Bacterial v Viral	Pilot evaluation	60	European Clinical Respiratory Journal
2	2017	Bacterial v Viral	Multi-centre, prospective	205	Journal of Clinical Medicine
3	2017	Bacterial v Viral	Single centre, outcome	21	Journal of Infectious Diseases & Preventative Medicine
4	2018	Bacterial v Viral	Multi-centre, prospective	220	Clinical Medical Investigations
5	2020	Bacterial v Viral	Single centre, outcome	20	Journal of Infection
6	2020	COVID-19	Single centre	251	International Journal of Clinical Practice
7	2020	COVID-19	Single centre	47	British Medical Journal
8	2021	COVID-19	Single centre	958	London North West University Healthcare NHS Trust (pending publication)
9	2021	COVID-19	Single centre	200	International Journal of Infectious Diseases

26. **First 2021 study:** Filippo Lagi et al, Use of the FebriDx point-of-care test for the exclusion of SARS-CoV-2 diagnosis in a population with acute respiratory infection during the second (COVID-19) wave in Italy, International Journal of Infectious Disease, published on April 2021; **second 2021 study:** Hamish Houston et al, Use of the FebriDx point-of-care assay as part of a triage algorithm for medical admissions with possible COVID-19, BMJ, published January 2021; **Third 2021 study**: Nawazish Karim et al, Utility of the FebriDx® point-of-care test for rapid triage and identification of possible coronavirus disease 2019 (COVID-19), IJCP, published on September 2020; **Fourth 2020 study:** Tristan W Clark et al, Diagnostic accuracy of the FebriDx host response point-of-care test in patients hospitalised with suspected COVID-19, The Journal of Infection vol. 81(4), published October 2020.
27. **2015 study:** Rob Sambursky and Nathan Shapiro, Evaluation of a combined MxA and CRP point of care immunoassay to identify viral and or bacterial immune response in patients with acute febrile respiratory infection, European Clinical Respiratory Journal vol. 2, published on December 2015.
28. **2017 study:** Wesley H Self et al, Diagnostic Accuracy of FebriDx: A Rapid Test to Detect Immune Responses to Viral and Bacterial, Journal of Clinical Medicine vol. 6(10), published on October 2017; **2018 study:** Nathan I Shapiro et al, A prospective, multi-centre United States clinical trial to determine accuracy of FebriDx point-of-care testing for acute upper respiratory infections with and without a confirmed fever, Annals of Medicine, vol 50(5), published on May 2018.
29. **2020 study:** Xavier Onrubia and Gonzelez, A pilot evaluation of the FebriDx test, Clin Med Invest vol. 5, published on March 2020; **2021 study:** FebriDx Point-of-Care Testing to Guide Antibiotic Therapy for Acute Respiratory Tract Infection in UK Primary Care: A Retrospective Outcome Analysis.

The multi-centre, prospective trial of 220 ARI patients that was published in 2018[30] included 121 patients who had a fever at the time of testing (febrile patients). The remaining 99 patients in this trial had experienced fever in the last 72 hours. Analysis was performed on the entire 220 patient group and separately on the 121 febrile ARI patients which Lumos considers best represents the patient group that will most often be tested using FebriDx®. The sensitivity and specificity of FebriDx® in this 121 patient group of febrile ARI patients is shown below.

Table 3.3: FebriDx® test performance in febrile patients

	Sensitivity	Specificity	PPV	NPV
Bacterial	95%	94%	76%	99%
Viral	90%	78%	89%	80%

Note: PPV stands for Positive Predictive Value and NPV stands for Negative Predictive Value.

In the full 220 patient population which included patients who had fever at the time of testing or in the preceding 72 hours, the sensitivity for detecting bacterial infections declined from 95% to 85%. However, the Negative Predictive Value (**NPV**) only declined from 99% to 97%. As described below, the NPV has clinical utility in reducing the unnecessary prescribing of antibiotics.

The sensitivity of a diagnostic test is its ability to correctly identify patients who are true positives (i.e. patients who have the condition and who record a positive result from the test), while the specificity of a diagnostic test is its ability to identify patients who are true negatives (i.e. patients who do not have the condition and who record a negative result from the test).[31]

These can be used to calculate the NPV of a test which is a measure of how reliable a negative result is from a test and is impacted by the prevalence of a disease.[31] Data from these studies have shown that FebriDx® has a 99% NPV for bacterial infections in patients who present with a fever. This means that doctors can be highly confident that a patient who has recorded a negative diagnosis for a bacterial infection using FebriDx® is unlikely to have a bacterial infection (i.e. it is a true negative) and therefore does not need to be treated with an antibiotic. Similarly, FebriDx®'s high sensitivity and specificity for bacterial infection can help to ensure that patients presumed to have an underlying bacterial infection are treated appropriately with antibiotics to reduce the progression to, or impact from, sepsis.

The data from the above studies has been used to support applications for regulatory clearances for FebriDx® in Europe, Canada and the other regions described in Section 3.4.6. Lumos has been conducting a prospective, multi-centre clinical trial in the United States using FebriDx® to distinguish bacterial and viral infections in ARI patients. Lumos intends to use the data from this trial along with data from published trials, including relevant patients from clinical trials that were primarily focused on COVID-19 applications, to support the 510(k) submission for FebriDx® that is currently under review by the FDA.

30. **2018 study:** Nathan I Shapiro et al, A prospective, multi-centre United States clinical trial to determine accuracy of FebriDx point-of-care testing for acute upper respiratory infections with and without a confirmed fever, Annals of Medicine, vol 50(5), published on May 2018.
31. Robert Trevethan, Sensitivity, Specificity, and Predictive Values: Foundations, Pliabilities, and Pitfalls in Research and Practice, Frontiers in public health vol. 5, published on November 2017.

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3.4.6. Regulatory filings and clearances for FebriDx®

Lumos has obtained regulatory clearances which allow the sale of FebriDx® in several markets including in Europe, Canada and Australia. Refer to Section 2.7 for further detail on regulation overseeing POC diagnostic testing. The regulatory status of FebriDx® in regions globally is summarised in Table 3.4 below.

Table 3.4: Regulatory status of FebriDx® globally

Region	Status of FebriDx
United States	A 510(k) submission for regulatory clearance which will allow commercial sale in the U.S., has been submitted with the FDA and is currently under review. The intended use that is provided in this submission is to differentiate viral from bacterial infections in patients with ARI and allow use with COVID-19.
Canada	Regulatory clearance granted (Health Canada).
Europe (excluding United Kingdom)	Regulatory clearance granted in Europe (CE Mark) under existing Directives (MDD framework). FebriDx® will be required to obtain CE Mark under the new legislative framework (IVDR) prior to 26 May 2024.[32]
United Kingdom	Regulatory clearance granted (CE Mark, effective until 30 June 2023).[33] Lumos has submitted for FebriDx® to be registered with MHRA in order to be sold in the United Kingdom and will be required to obtain a UKCA Mark.[34]
Australia	Regulatory clearance granted (Therapeutics Goods Association (TGA)).
Other non-target regions	• Regulatory cleared in Saudi Arabia (Saudi Food and Drug Authority (Saudi FDA) approval) • Regulatory cleared in Pakistan (Drug Regulatory Authority of Pakistan (DRAP) approved) • Regulatory cleared in Singapore (Health sciences Authority registered) • Regulatory cleared in Malaysia: (Malaysia Ministry of Health (MoH) approved).

32. For IVDs that are already certified by a Notified Body under the current Directive (such as FebriDx®), the IVDR will be fully applicable on 26 May 2024.
33. The CE Mark is expected to cease to be recognised as a regulatory clearance in the United Kingdom on 30 June 2023 for all medical devices, following Brexit. Clearances of medical devices in the United Kingdom will be governed by the MHRA with products conforming with its medical device directives to receive a “UKCA mark”.
34. Medicines and Healthcare products Regulatory Agency, In vitro diagnostic medical devices: guidance on legislation, published on January 2021.

3.4.7. Reimbursement for FebriDx®

The cost of diagnostic tests is either borne by the user or a payer (government or health insurer). Currently there is no established, specific reimbursement by public or private payers for FebriDx® globally. Treatments that are covered by reimbursement models, where the user has minimal or no out-of-pocket expenses, encourages more widespread use. There is no guarantee that a product will receive a reimbursement code or that a code, once obtained will not be removed or reduced in value.

The reimbursement status and potential strategies to achieve this status for FebriDx® in Lumos' target markets are summarised in Table 3.5 below.

Table 3.5: Reimbursement status of FebriDx® globally

Region	Status of FebriDx
United Kingdom	Currently, there is no established, specific reimbursement by public or private payers for the use of FebriDx®. In the United Kingdom, FebriDx® is currently being purchased by hospitals and emergency departments based on evidence of improved workflow and cost savings without government reimbursement. Accordingly, Lumos is currently targeting hospitals, while primary care patients remain diverted to these facilities in an effort to contain COVID-19. In the longer term, if reimbursement codes are established, Lumos plans to market FebriDx® to General Practitioners (**GPs**) that belong to Private Care Networks.
European markets (excluding United Kingdom)	While the CE Mark process provides a regulatory path that allows POC diagnostic tests to be marketed in most European countries, reimbursement of the tests varies throughout Europe, with the level of reimbursement determined on a country-by-country basis.[35] Lumos is generating relevant GP data through country-specific outcome studies to support coverage of FebriDx® from existing or new reimbursement codes in Europe. Provided these are secured in each market, Lumos intends to expand its marketing efforts from hospital and private health, to include public, primary care and other relevant settings.
United States	Final reimbursement can only be determined after regulatory clearance is granted. Once FebriDx® receives United States regulatory clearance, Lumos will be able to establish if any existing reimbursement codes, either separately or in combination, can be used to provide reimbursement coverage for FebriDx®, or if other strategies are required in order to secure reimbursement coverage.

35. WHO, Medicines Reimbursement Policies in Europe, published 2018.

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3.4.8. Distribution of FebriDx®

Lumos sells its products using one or more distributors in each region or country-defined market. Lumos provides marketing resources including local managers who support the in-country distributors. Lumos has already appointed distributors and commenced initial commercial sales of FebriDx® in the United Kingdom, Germany and Canada. The distributors focus on local marketing initiatives, local pricing, order fulfillment, inventory management and customer support. Lumos' staff focus on overseeing and managing the distributor relationships and on securing country-specific clinical data, regulatory clearances and reimbursement in each market. In addition to the existing appointed distributors, Lumos intends to appoint three to four national and regional distributors in the United States once FDA regulatory clearance for FebriDx® is obtained.

Distributors who specialise in selling POC diagnostics tests in outpatient settings in the United States include Henry Shein, McKesson and Cardinal Health. Lumos will provide additional support to United States distributors by assisting them with local marketing initiatives, product demonstration, training and support. Lumos may also seek to sell directly to alternative markets including cruise ships, border patrol, prisons, elder care, schools, and employee health.

Table 3.6: FebriDx® go to market strategy

Channel	Location	Approach
Primary/Urgent Care	United States	Distribution Partnership (e.g. McKesson, Henry Shein, Cardinal, Medline) Commissioned sales agents
	Ex-United States	In-country distribution and/or regional or international partnerships Commissioned sales agents
Alternative markets	Military, cruise ships, prisons	Direct
	Foreign Governments	Agents, in country distribution and partnerships

Lumos intends to use the same market strategy to distribute the other Products it develops once they receive the required regulatory clearances.

3.4.8.1 Distribution agreements

Agreements for distribution will generally follow a standard template, as summarised below. The template will, however, be modified and customised based on the restrictions and requirements applicable to the distribution of the product. Additionally, the distribution agreements include an appendix further detailing the specifics of the agreement, such as the territory, the field of use, pricing and the duration of the appointment. While generally the distributions agreements are between the distributor and RPS, in certain cases the distributor contracts with both Lumos and RPS.

Agreements currently in place include those for the distribution of FebriDx® in the United Kingdom, Canada, Germany and Austria, Greece, Italy, Singapore and Malaysia.

Table 3.7: Examples terms of distribution agreements

Term	Summary of Term
Service	The distributor agreements primarily concern the sale and distribution by the counterparty of specific Lumos products, such as FebriDx®, within a particular geographic area and field of use. The distributor is required to submit purchase orders to purchase the product that the distributor may then sell to customers. The distributor is authorised to distribute, sell or use the specified product within a field of use in a specified territory. Such a field of use includes, for example, the right to promote, distribute and sell FebriDx® in the territory for the sole use in testing acute respiratory tract infection applications and no other medical arenas and fields.
Fees	Pricing is based on the number of units purchased by the distributor, as set forth in the agreement and subsequent purchase orders. Price per unit decreases generally as the number of units purchased increases. Distributors also generally commit to an initial order minimum and to an annual minimum sales commitment based on a forecast that is provided by the distributor.
Term	The term of the distribution agreements generally range from one year to three years and thereafter automatically renew on an annual basis for one year terms so long as the minimum sales commitments for the following year are mutually agreed to prior to the expiration of the initial term. Certain agreements require additional conditions, for example, the distributor meeting minimum sales commitments and milestones for the previous year.
Termination for convenience	After the initial term, either party may terminate for convenience on written notice. The time for notice ranges from 60 days to 180 days before termination depending on the agreement. Lumos may terminate the agreement on written notice due to the distributor's failure to meet minimum sales commitments for the prior 12 months.
Intellectual property rights	Lumos owns all right, title, and interest in the products and all patents, trademarks, trade names, inventions, know-how, etc. related to the design, manufacture, operation or service of the products. Lumos owns any intellectual property rights developed, derived from, or otherwise generated by the counterparty in performing under the agreement. In connection with the agreement, parties execute a confidentiality and non-disclosure agreement.
Liability	Lumos must indemnify the distributor against any claims to the extent they arise from or occur as a result of: • a material breach of the representations and warranties of the agreement; or • gross negligence or wilful acts or omissions by the manufacturer.
Exclusivity	Generally, each distributor receives an exclusive right to promote, sell, and distribute the products in the territory for the distributor's specific field of use. The agreements also include limitations on such exclusivity, such as permitting Lumos to sell its products within the territory directly to certain customers. During the term of the agreement and for six months thereafter, the distributor: • may not use, promote, or sell any products that are similar in purpose or function to the products the distributor distributes for Lumos; and • agrees not to call upon, solicit, service, interfere with or divert any customers served by Lumos in the distributor's territory.
Restraints	Penalties exist if a party employs or otherwise engages any member of the other party's professional staff, during the course of the agreement and for 12 months after the termination date.

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3.4.9. Potential Competitors for FebriDx®

Direct competitors

As at the Prospectus Date, Lumos is aware of two companies which are directly competing for the same addressable market as Lumos for FebriDx®. These companies are developing POC diagnostics products to determine if patients have a bacterial or viral infection (as discussed in Section 2.6.2). Other direct competitors may exist or evolve in the future. Only one of these products (MeMedBV™) has received regulatory clearances that allow its sale and use for the evaluation of whether patients have a bacterial or viral infection.

The MeMed BV™ test is produced and marketed by MeMed, a private company based in Israel, and is approved for clinical u se in the Europe, Switzerland and Israel. MeMed BV™ is currently not available for sale in the United States.[36] Like FebriDx®, MeMedBV™ is a host-response test, but it uses the measurement of three proteins (rather than two) produced by the patient's body to evaluate if a patient may have a bacterial or viral infection.

Differences between Lumos' FebriDx® test and the MeMed BV™ test as at the Prospectus Date include:

1. **Markers**: FebriDx® is based on the measurement of two markers (CRP & MxA) whereas MeMed BV™ is based on three markers (CRP, TRAIL & IP-10);
2. **Speed and Throughput**: FebriDx® allows for high throughput testing and produces results within 10 minutes. Each MeMedBV™ test can take up to 15 minutes and use microfluidics requiring them to be conducted using the reader console; and
3. **Readers**: MeMed BV™ requires users to have a dedicated, electronic reader console at the testing site. FebriDx® can be conducted using a standalone POC test cassette.

The diagnostic performance of MeMedBV™ reported by MeMed of 91%, specificity of 94% and an NPV of 96% compares to the FebriDx® diagnostic performance outlined in Section 3.4.5.[36]

Further, a United States Company, Inflammatix reports it is developing the ViraBac™ acute infection test to distinguish between viral and bacterial infections.[37] This is also a host-response test but tests for changes in the expression of certain host genes (rather than protein levels) in response to an infection. The ViraBac™ test takes up to 30 minutes, requires a dedicated analyser and reader, and as at 1 June 2021 does not have any regulatory clearances.[38]

Lumos also notes that:

- a number of research groups at academic research facilities have announced programs to develop tests that distinguish between bacterial and viral infections in patients (including Stanford University, Duke University, University of Rochester and Ben-Gurion University[39]); and.
- a number of single-marker, generic tests are regulatory cleared and sometimes used to assess patients for a possible infection, including procalcitonin and CRP. These tests typically have lower sensitivity and specificity than FebriDx®.

Indirect competitors

A number of pathogen-specific tests are commercially available including tests for some of the pathogens responsible for acute respiratory infections such as influenza, respiratory syncytial virus, and, more recently, COVID-19. Each of these tests are specific for a single pathogen and so are better suited to establishing a final diagnosis as opposed to being targeted as a product for initial screening to determine a patient's infection status. These viral pathogen specific tests may complement the use of FebriDx® through use following a confirmed FebriDx® viral positive result.

36. MeMed, What is MeMed BV.
37. Inflammatix, Pipeline.
38. Inflammatix, Pipeline; Inflammatix, HostDx Test: Breakthroughs in the Diagnosis of Acute Infections and Sepsis, published December 2017.
39. American Associates, Ben-Gurion University, Quick test to diagnose bacterial or viral infection, ScienceDaily, published on July 2011; Duke Education, Genomic Test Accurately Sorts Viral vs. Bacterial Infections, published on September 2013; University of Rochester Medical Center, New tool to distinguish between viral, bacterial infections, ScienceDaily, published on July 2017; Brian Krans, A Blood Test That Can Tell If You Have a Virus or a Bacterial Infection, published on March 2019.

3.4.10. Growth strategy – commercial strategy for FebriDx®

Lumos is directing its initial commercial efforts for FebriDx® to settings where doctors and clinical staff require a diagnostic test to help determine if a patient has a bacterial or viral infection in order to determine if prescribing an antibiotic is appropriate.

In the first instance, this will primarily focus on patients with an ARI who are attending primary care practices, urgent care centres, or hospital emergency departments. In the United States, there is estimated to be approximately 150m patients presenting to inpatient and outpatient settings with ARI symptoms each year, as outlined in Section 2.4.2.[40] This provides a significant opportunity for FebriDx® if it obtains the necessary FDA clearance as it could assist doctors and clinical staff to establish an appropriate course of treatment for patients in these cases. Lumos' assessment of its FebriDx® opportunity and a summary of its commercial strategy is illustrated Figure 3.9 below.

Lumos is also currently developing new test formats for FebriDx® that will use multi-use disposable and desktop readers. The multi-use disposable version of FebriDx® refers to the FebriDx® test supplied in kit form with 20-50 disposable cassettes and a limited reuse disposable reader. The desktop reader version of FebriDx® refers to the FebriDx® test being provided in a cassette format that can be used in a multi-test desktop reader that has extensive functionality including being able to quantify POC test results and integrate them with a healthcare facility's EMR systems and Laboratory Information Systems.

Figure 3.9: Overview of Lumos' commercial strategy for FebriDx®

	Status		Strategy
 United Kingdom	**Initial Launch**	• Non-exclusive distributor sale model – Henry Schein and Una Health	• Expand FebriDx® into GP practices and NHS system once National Institute for Health and Care Excellence (NICE) guidelines updated
 Germany	**Initial Launch**	• Initial focus on use of FebriDx® on hospital testing in emergency departments • FebriDx® reimbursement in private sector using IGeL where available	• Expand FebriDx® reimbursement through EBM/GOA in 2021
 Canada	**Initial Launch**	• Northern Diagnostics appointed as non-exclusive distributor in Canada for FebriDx • FebriDx® covered under health savings account	• Expand use of FebriDx® into corporate employee health testing
 United States	**Under FDA review**	• 510k application lodged October 2020 to differentiate viral from bacterial infections in patients with ARI and to allow use with COVID-19	• Potential to use existing CRP and general infectious disease immunoassay codes to secure initial reimbursement coverage • Distribution through national and regional distributors

Note: EBM/GOA is the German fee schedule for statutory/private health insurance, respectively. If EBM/OGA is not available reimbursement may be available through IGeL.

Refer to Section 2.7 for further information on regulatory approvals.

40. Tamar Barlam et al, Unnecessary Antibiotics for Acute Respiratory Tract Infections: Association With Care Setting and Patient Demographics, Open forum infectious diseases vol. 3(1), published on February 2016; Patricia Sweeney, Improving Appropriate Antibiotic Use For Common Clinical Conditions in Urgent Care, The Journal of Urgent Care Medicine, published on June 2017.

3.5. Products division: other products

In addition to FebriDx® and CoviDx™, Lumos has a pipeline of tests it is developing for other infectious disease applications as described below. All products in the pipeline will need to obtain the regulatory clearances required to allow sales in each market.

3.5.1. COVID-19 antigen test

Lumos manufactures a Lumos branded test for a rapid, lateral-flow test which detects antigens present on the COVID-19 virus called CoviDx™. Lumos uses its intellectual property and single source third party proprietary reagents, to enable it to produce CoviDx™. CoviDx™ may be used to test subjects for an active COVID-19 infection. CoviDx™ has been granted a CE Mark clearance in Europe and Lumos has submitted applications for Emergency Use Authorization in the United States, and a Health Canada interim order approval for Canada.

CoviDx™ has features that Lumos believes will be attractive to certain customer segments including performance against reputable lab-based gold standards, data showing efficacy against COVID-19 variants, and individual buffer vials for user convenience. CoviDx™ directly competes against a number of other approved and marketed tests designed for the same or similar purposes. DiaSorin is a distributor of a white labelled version of CoviDx™ as described in Section 3.2.3.

3.5.2. Pipeline tests in development

Lumos has an active research and development program aimed at growing its portfolio of POC diagnostic test products for commercial sale. Lumos is currently developing new POC diagnostic tests for three different infectious diseases:

- **ViraDx**™: a rapid, lateral-flow test for simultaneously detecting infection by either influenza A or B (being two strains of the influenza virus) and COVID-19. ViraDx™ is in the process of clinical validation. If validation is successful, Lumos intends to apply for regulatory clearances to sell the test in Europe, the United Kingdom and the United States;
- **UriDx**™: a rapid, lateral-flow test for patients who potentially have a urinary tract infection; and
- **SepsiDx**™: a rapid, lateral-flow test for patients who potentially have a bloodstream infection (sepsis).

Lumos' targeted launch timeframe for sales of ViraDx™ is CY21. UriDx™ and SepsiDx™ are still in development.

The development and successful commercialisation of each of Lumos' pipeline tests is subject to uncertainties, including successful clinical validation that supports regulatory clearances in Lumos' target markets and obtaining those regulatory approvals, and is not guaranteed. Lumos will also need to successfully extend its existing agreements with distributors to include new products, and invest in sales and marketing activities to build awareness and drive product sales. Lumos intends to use the distributor marketing channels it establishes for FebriDx® to commercialise pipeline products as they complete their development and obtain necessary regulatory clearances required to allow their sale in different markets.

3.6. Commercial Services Operations

3.6.1. Overview

The provision of commercial services to clients has been the core foundation of Lumos' business since its inception. Lumos develops and manufactures POC diagnostic tests for its clients by providing a comprehensive range of services across the following three key areas:

- **Strategic innovation services**: developing a POC diagnostic test product concept, including evaluating its commercial potential, developing an assay, undertaking initial studies and clinical trials;
- **Development and manufacturing**: developing the POC diagnostic test (including the integration of a digital reader) into a commercial-ready form and developing the manufacturing process; and
- **Validation and commercial manufacturing transfer**: supporting applications for regulatory clearance (the compiling of clinical and quality data) and undertaking commercial manufacturing.

As discussed in Section 3.3.3, Lumos has the capability to develop and manufacture customised digital readers for its clients using its range of digital reader formats: single-use disposable readers, multi-use disposable readers and desktop readers.

Lumos has generated revenue from the provision of commercial services since 2017. Since this date, Lumos has continued to build and expand its core competencies and capabilities to provide more extensive services to its commercial clients. This includes the development and manufacture of digital POC diagnostic tests which encompass assays, digital readers and associated software applications. Current development projects being conducted by Lumos for its clients include tests in traditional healthcare areas such as cancer screening, maternal fetal health, anemia, and food safety and COVID-19 (antibody/antigen) tests.

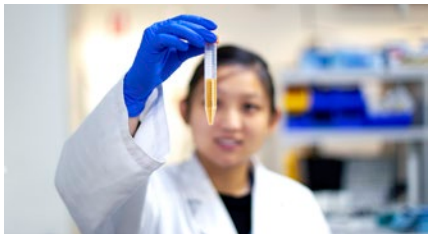
3.6.2. What Lumos' Commercial Services division provides for its clients

Lumos is a fully integrated developer and manufacturer of rapid, POC diagnostic tests with extensive capabilities that include technological and in-house expertise. As Lumos' client base and project pipeline has grown, Lumos has identified commercial opportunities which have allowed it to broaden its capabilities through a combination of acquisitions and internal investment. Since its inception Lumos has expanded the capabilities it is able to offer clients to include:

- **assay development**: research and development activities with the primary objective of producing a POC diagnostic test that is ready for commercial manufacture and regulatory clearance in the client's target markets;
- **digital reader development**: research and development activities with the primary objective of developing digital test reader formats that can be customised to meet the clients' requirements in the development stage and, later, supplied by Lumos;
- **digital software application development**: research and development activities with the primary objective of producing software applications which enhance the performance and usability of digital readers when used in combination with a POC diagnostic test; and
- **contract manufacturing**: activities which cover the establishment of product manufacturing including POC diagnostic tests and digital readers in compliance with quality and regulatory requirements and the ongoing manufacture of the products for commercial sale by the Commercial Services clients.

Lumos' Commercial Services division has commercial contracts with each of its clients that specifies the scope of POC diagnostic test and reader development or manufacturing services they require and the commercial terms under which Lumos will provide those services. The scope of projects can vary from a relatively short, specific development activity to more comprehensive product development projects with potential ongoing contract manufacturing if the product is successful.

Figure 3.10: Lumos' fully integrated Commercial Services process

Strategic Innovation	Development and Manufacturing Transfer	Validation and Commercial Manufacturing
		
• Product profiling • Commercial evaluation • Assay development • Clinical assessment • Reader platform trialling	• Assay/reader combinations • Full reader platform integration • Test optimisation • Production process development • Transfer to manufacturing	• Clinical verification • Product validation • Regulatory and clinical affairs • Manufacturing • Post-launch support

3.6.2.1 Strategic innovation services

Strategic innovation services covers the development of a POC diagnostic test product concept, evaluating its commercial potential, developing an assay for measuring and detecting a relevant diagnostic marker, undertaking initial feasibility studies to measure that diagnostic marker in human tissue samples and initial trials of the test on one or more diagnostic test readers.

3.6.2.2 Development and manufacturing transfer

Development and manufacturing transfer encompasses activities focused on developing the POC diagnostic product into a commercial-ready form by optimising a visually read test, or in combination with one or more reader formats, developing a commercially scalable manufacturing process, and transferring that process to a commercial manufacturing line.

3.6.2.3 Validation and commercial manufacturing

Validation and commercial manufacturing covers completing and compiling the clinical and quality data requirements required to support applications for regulatory clearance in markets such as North America, Europe, and the United Kingdom. In addition, this includes the provision of contracted commercial manufacturing of POC diagnostic tests for clients.

3.6.3. Lumos' Commercial Services clients

Lumos' clients represent a combination of established multi-national companies and well-funded early stage healthcare companies seeking to develop one or more POC diagnostic tests which, if successful, may lead to on-going manufacturing contracts. In many, but not all cases, these test are developed in conjunction with a digital reader that uses one of Lumos' digital reader formats.

Lumos has a diverse client base and has undertaken various degrees of contracted development work for over 20 different clients since its inception. Clients that Lumos has worked with are spread across various complementary industries to Lumos, including:

- Human diagnostics and wellbeing;
- Food safety and quality;
- Animal health; and
- Pharmaceuticals and clinical trials.

Approximately 41% of 1H21 revenue derived from Commercial Services projects was primarily related to diagnosis and management of COVID-19, with the remainder relating to other infectious diseases and POC diagnostic tests and technology platform customisation.

Lumos' clients include a number of multinational diagnostics and health care companies such as DiaSorin, Merck KG&A and Hitatchi Chemical. Some of these companies have engaged Lumos for multiple development projects or have significantly expanded the scope of work as projects have progressed.

Until the recent addition of its POC diagnostic test manufacturing capability, all the projects that Lumos conducted for its Commercial Services clients were for the development of new POC diagnostic tests and digital readers. Lumos recently added a manufacturing capability to provide a more comprehensive Commercial Services offering for its clients and to provide the option to continue the commercial relationship with its clients beyond the development of the POC diagnostic tests and digital readers. Manufacturing contracts (described in section 3.6.5.2) are typically multiyear and can have a "high switching cost" where the site of manufacture is included as a component of the regulatory clearance for the POC diagnostic test. Lumos has already commenced production under its first Commercial Services manufacturing contract, and is in the process of transferring three other POC diagnostic tests that it has developed for clients into commercial manufacturing.

3.6.4. Examples of Lumos' projects

Typically, Lumos will have between four to ten active client projects at any one time. This provides a diverse client revenue base and reduces its commercial dependence on any single project or client. Depending on individual client's needs, these projects can range from relatively small, defined projects of short duration (weeks-to-months), to comprehensive POC diagnostic test development and manufacturing projects that can last several years. Lumos has a strong pipeline of upcoming projects with clients. Below are examples of three active projects:

Table 3.8: Examples of Lumos' Commercial Services projects

Client Type	Services provided
DiaSorin – Global leader in IVD	DiaSorin, is an example of a strategic collaboration. As described in Section 3.2.3, Lumos is contributing expertise in the development, customisation and manufacture of a digital reader and two POC diagnostic tests along with the potential for additional test development and manufacture in the future dependent on DiaSorin's menu expansion plans.
Global leader in maternal/fetal testing	Lumos has partnered with a global leader in maternal/fetal testing to develop a digital POC platform to replace an existing product of theirs that is currently in the market. As part of this collaboration, Lumos will develop two lateral flow immunoassays compatible with the Lumos camera reader and provide an annual contract manufacturing service.
European leader in *in vitro* fertilisation	Lumos has partnered with Planet Innovation and a European leader in *in vitro* fertilisation to develop a digital at home platform to assist patients through the assisted reproduction process. As part of this collaboration, Lumos has developed test strips, a reader and a digital cloud-based ecosystem, and will provide ongoing test manufacturing and reader supply.

3.6.5. Lumos' Commercial Services client agreements

3.6.5.1 Development agreements

Agreements for development are generally based on the Lumos terms of business (refer to Table 3.9 below) with necessary amendments for the client, but may also be based on client specific agreements. Where the Lumos terms of business are used, the specifics of the agreement, such as the program of work and phase budget are included in a separate project specific document (which is governed by the terms of business).

Table 3.9: Examples terms of development agreements

Term	Summary of Term
Services	Lumos' development agreements primarily concern the provision of development services by Lumos for a client, in exchange for consideration paid by the client. Development services primarily relate to either development of POC diagnostic tests or customisation of the Lumos readers. Development services are generally provided and invoiced based on phases of work, including for example feasibility, development and clinical trial phases.
Fees	Fees are based on predicted phases of work and are set out in each phase document. Fees are estimated (but not fixed) based on predicted time and materials costs. An up-front authorisation fee may be charged, whilst actual costs are invoiced monthly. The client pays Lumos cost plus mark-up for materials, services of third parties, use of third parties' equipment and other third party expenses incurred by Lumos.
Term	The term is set out in the project document and is generally based on phases of consulting/development, which usually range from 1 month to 7 months.

Term	Summary of Term
Intellectual property rights	Lumos' intellectual property rights under its patents or in its know-how are not transferred to the client and the client is not permitted to modify or reverse engineer Lumos' materials without Lumos' consent. Each party retains ownership of any intellectual and industrial property rights in background IP (being any IP created or developed prior to or after the term of the agreement and any IP created or developed during the term of the agreement other than as a result of the agreement). The client grants Lumos a non-exclusive free license to use the client's background IP for the purposes of Lumos undertaking the project. Subject to the above, with effect from the termination date and provided that the client has paid to Lumos all outstanding fees and charges due to Lumos, Lumos will assign to the client all intellectual and industrial property rights subsisting in the project IP (being all IP created or developed by Lumos as a result of, and in the course of, carrying out the specific project for the client and excludes all background IP).
Liability	Lumos' liability is typically limited to: • in the case of services, either suppling the services again or the cost of the services being supplied again; and • in the case of goods or materials, replacing the goods, suppling equivalent goods or paying the cost of having the goods repaired or replaced. To the extent permitted by law, Lumos' total aggregate liability under or related to the agreement is typically limited to the aggregate fees paid by the client to Lumos under the agreement.
Exclusivity	Subject to the terms of any confidentiality and non-disclosure agreement between the parties, Lumos is not restricted from publishing any document relating to the materials or to distributing the same to other parties. Lumos is usually restricted from using the identity of the client, images of the products or references to the project or to Lumos' role in its publicity materials without the client's prior written consent.
Restraints	Penalties exist if a party employs or otherwise engages any member of the other party's professional staff, during the course of the project and for 12 months after the project termination date.
Termination for convenience	Either party may terminate the agreement by giving typically two months written notice to the other party.

3.6.5.2 Contract manufacturing agreements

Agreements for manufacturing are intended to follow a standard template, key terms of which are summarised in Table 3.10 below. The template will, however, be modified and customised for the needs of the specific client and requirements of the product being manufactured. Lumos currently only has one manufacturing agreement in place, which is with Diabetomics and is materially consistent with the terms set out in Table 3.10, including in respect of fee structure, term, liability and exclusivity.

Table 3.10: Key terms of Lumos' standard template contract manufacturing agreement

Term	Summary of Term
Services	Primarily involves the verification, validation, manufacturing, and packaging by Lumos of products (in this case developed by the client). Lumos is responsible for manufacturing the products in accordance with certain specifications and a quality agreement agreed by the parties.
Fees	An initial fee is (for set up costs associated with manufacturing, assembling, packaging, and labelling of the products) and a deposit (toward an initial set of product units) is paid by the client, with the deposit credited toward future purchase price payments. The client pays for products purchased in a given month. Minimum monthly order quantities are specified in a product plan submitted by the client to Lumos each year. During the three months following submission of a product plan, these quantities are binding. For the remaining nine months, the quantities become binding once the client submits a product order specifying the product quantities and delivery dates, however, Lumos is not required to accept a product order that varies above or below an agreed percentage from the quantity of any product as specified in the applicable product plan.

Term	Summary of Term
Term	Term is for an initial term of three years, which automatically renews for successive one year terms thereafter.
Termination for convenience	Either party may terminate the agreement by giving six months written notice to the other party.
Intellectual property rights	All trademarks, trade dress, and other designations of the product labels and packages are client's property. All intellectual property relating to the product, its formulation, the specifications, and the manufacture, labelling and use of the products remains the client's property. The client grants Lumos a non-exclusive, non-sublicensable and non-transferrable license during the term to use such property solely to manufacture the product. All inventions, improvements and discoveries made or ideas conceived by either party, whether patentable or not, will be the property of such respective party.
Other key terms	Lumos is responsible for compliance with all laws and obtaining all permits, licenses, and approvals applicable to the manufacturing facility and the production and manufacturing of the products. The client is responsible for obtaining any and all product registrations, import licenses, and permits and any other governmental or certifying body authorisations necessary for the entry or sale of the product into any country. Lumos is required to pack, mark, and make the products in accordance with the written specifications provided in the agreement. However, the client may make changes in the specifications in certain circumstances (typically at the client's cost).
Liability	Lumos agrees to indemnify client against all liabilities, damages, costs or expenses, resulting from any third party claims made or legal proceedings brought against the client that arise from or in connection with any misuse of the product prior to delivery to the client, Lumos' compliance or non-compliance with applicable laws, Lumos' infringement of third party intellectual property, Lumos' failure to perform under the agreement or breach of the agreement (including failure of a product to meet specifications) or any injury, death or damage to property caused by breach of the agreement by Lumos. To the extent permitted by law, Lumos' indemnification obligation will not exceed the total amounts paid by the client to Lumos' reduced by the cost of raw materials it supplied. Client will indemnify Lumos against all liabilities, damages, costs or expenses, resulting from any third party claims made or legal proceedings brought against Lumos that arise from or in connection with any misuse of the product by the client after delivery, the content of product labelling or packaging, Lumos' infringement of any third party intellectual property as a result of client's specifications, any failure of client to perform its obligations under the agreement, or any injury, death or damage to property caused by breach of the agreement by the client.
Exclusivity	With regard to any product specifically manufactured by Lumos for the client, Lumos must not: • manufacture or sell the product to anyone other than the client or an authorised purchaser • enter into any agreement relating to the manufacture or sale of the product to be manufactured under this agreement with anyone other than client; or • use the client's intellectual property to manufacture or sell the product to be manufactured under the agreement to any other buyer.
Restraints	Penalties exist if a party employs or otherwise engages any member of the other party's professional staff, during the course of the project and for 12 months after the project termination date.

As noted in Section 3.2.3 Lumos also has a Development and Commercialisation Agreement in place with DiaSorin. The manufacturing terms of that agreement generally follow the form of the above template except as noted in Section 3.2.3.

3.6.6. Growth Strategy – Commercial services

Lumos aims to grow its Commercial Services business by seeking long-term strategic collaborations with clients and engaging in comprehensive projects and activities with longer-term revenue potential. This includes converting development projects into multi-year contract manufacturing agreements.

Lumos' strategy with its Commercial Services division is to:

- Streamline the core service business to focus on assay development, digital reader customisation, and manufacturing for high value, long-term partnerships with non-competitive pharmaceutical and medical device companies who target non-infectious medical conditions;
- Partner with companies with novel reagents that seek assay development as well as with existing assay providers to develop or translate commercially viable tests on to a digital platform;
- Strive to translate development services into long-term supply relationships (e.g. test strips, digital readers); and
- Limit COVID-19 projects to be a minority of the base business.

As part of its overall business strategy, Lumos intends to enter contracts that will utilise available capacity and drive economies of scale to lower the overall cost of goods across both contract manufacturing services and Lumos' branded products. Following the establishment of the Sarasota commercial manufacturing facility in April 2021, Lumos' has the capacity to produce approximately 10m POC diagnostic tests per month in total. Lumos will market its existing site certifications, such as MDSAP and ISO13485, to seek further manufacturing contracts from new and existing clients (as the site of manufacturing and its compliance with quality and regulatory standards forms part of the regulatory clearance for POC diagnostic tests).

3.7. Further Information on Lumos

3.7.1. Facilities

As described in Section 3.1.3, Lumos has established two manufacturing facilities located in Sarasota, Florida and Carlsbad, California which include manufacturing facilities, research and development laboratories and offices for sales, marketing, product support and general administration support in the United States. Lumos' manufacturing facilities currently combine manual and semi-automated manufacturing equipment and processes and will shortly employ automated packaging and labeling processes.

Lumos moved to and commenced operations at its new Sarasota facility in April 2021, which is 32,000 square feet. Lumos also has an option to expand the Sarasota facility to 40,000 square feet.[41] Currently, Lumos has a 10,000 square foot facility in Carlsbad, CA. Lumos is currently actively prospecting for a new local facility in Carlsbad with approximately 30,000-35,000 square feet to serve as a Commercial Services business showroom and support pilot strip manufacturing and future reader assembly. As at 1 May 2021, the two United States facilities cover 42,000 square feet (3,900 square metres) and have a combined manufacturing capacity of approximately 10m tests per month. Lumos' United States facilities are MDSAP certified and ISO13485 compliant.[42]

3.7.2. Employees

As at 1 May 2021, Sarasota has approximately 63 FTEs and Carlsbad has 42 FTEs. Two FTEs are located in the United Kingdom, and three FTEs are located in Melbourne. Sarasota is the operational headquarters and contains the majority of the administrative, finance, regulatory, and clinical functions while both sites have human resources and quality assurance functions. While both sites have strong R&D and operations, Sarasota is dedicated to higher volume production. In general, more branded portfolio product development occurs in Sarasota while the majority of service development occurs in Carlsbad. The choice of manufacturing location is dictated largely by the required volume.

41. This option is exercisable before 31 December 2023.
42. Medical Device Single Audit Program (MDSAP) certified is a program established by a regulatory working group covering the United States, Canada, Brazil, Japan and Australia that allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory jurisdictions. ISO13485 is an International Organization for Standardization (ISO) standard which establishes essential requirements for a comprehensive quality management system for the design and manufacture of medical devices.

3.7.3. Intellectual property rights and patents

As at 1 May 2021, Lumos had 42 existing patents granted or validated and 34 patents pending. Further information in relation to Lumos intellectual property, including its patents and patents pending is contained in Section 9. It also has licensed rights to use intellectual property and 4 patents from third parties including Atomo as referred to in Section 3.4.2.

Lumos' proprietary Products and Commercial Services products utilise Lumos' intellectual property in their production which may include:

- Patents that cover the test strip components, specific biomarkers and combination thereof, and the use of an electronic reader'
- Trademarks;
- Specialised and novel external controls;
- Use of Lumos-owned plastic housings which allow for high throughput manufacturing;
- Mechanical design drawings, schematics and test procedures;
- Electronics design drawings, schematics and test procedures;
- Software code, applications and test procedures;
- Manufacturing bill-of-materials, work instructions and quality control procedures; and
- Quality and regulatory documentation including clinical trial protocols, verification and validation procedures, product labelling and packaging.

Figure 3.11: Lumos' Intellectual property portfolio

	Patents Owned		Patents Owned		Patent in-licensed	
	Issued Foreign	Issued US	Pending Foreign	Pending US	Issued Foreign	Issued US
FebriDx + General	16	19	16	5	2	2
Readers	2	5	11	2	0	0

Note: Patents validated in multiple European countries are counted as one patent in the table above.

3.7.4. Approach to risk management and insurance

Lumos has a risk management framework in place, comprised of the totality of systems, structures, policies, processes and people within Lumos that identify, measure, monitor, report and control or mitigate internal and external sources of material risk. As part of the framework, Lumos has set a risk appetite reflecting the degree of risk Lumos is prepared to accept in the pursuit of its strategic objectives and business plan which is detailed in the Board approved Risk Appetite Statement. Lumos monitors the effectiveness of the risk management framework and its operation, including regular management presentations to the Board on risks and risk mitigation initiatives, and a sophisticated quality management system which involves the assessment and mitigation of product and process related risks in accordance with international medical device standards.

3.7.4.1 General risk management

Lumos plans and conducts regular risk management activities across the business. These activities are guided by the Risk Appetite Statement described above, which defines risk tolerance levels across strategic, financial, fundraising, innovation, reputational, legal and regulatory, people, information technology, product and service delivery, operational and health and safety risks. Lumos maintains a risk register which includes an assessment of the likelihood and severity of identified risks, associated mitigation activities and an assessment of the residual risk once risk mitigation activities have been completed.

3.7.4.2 Financial risk management

Lumos employs financial risk management practices to control finance processes and to monitor financial performance and risks. Lumos has defined delegations of authority and financial controls to oversee approval and integrity of expenditure including payments and investments. Lumos manages customer credit risk for material transactions by performing customer diligence, requiring pre-payments on product purchase orders and services contracts, and regular or milestone based invoicing on commercial services projects. Lumos manages foreign exchange risk through the use of USD and AUD denominated bank accounts, planned regular funding of United States and Australian operating subsidiaries in their local currency and employment of natural hedging practices, such as establishing commercial customer and supplier contracts in the same currency as the main costs to deliver the contract, which is typically in USD.

3.7.4.3 Product risk management

Lumos has an established quality management system which includes procedures to assess designs to mitigate product risk during research and development, establish controls to monitor manufactured product conformity to approved specifications and perform post mark surveillance to monitor product safety once it is commercially available and in-use in the field. Lumos employs quality, regulatory and clinical affairs personnel with responsibility to ensure adherence with Lumos processes and ongoing product and process compliance with applicable quality and regulatory standards.

3.7.4.4 Insurance

Lumos obtains insurance that it considers to be necessary and prudent for a business of its nature, as well as those required in order to comply with contractual obligations. Policies taken out by Lumos include those at a group level, as well as a number that cover the United States only. Policies in place currently include product liability and life science liability which cover premises, operations, product, services, clinical trials, advertising injury, personal injury and errors or omissions liability. As the needs of Lumos business change so may Lumos' approach to insurance. Not all risks are insurable and there is no guarantee that the insurance policies Lumos holds will protect the Group against all risks and liabilities.

3.7.5. Data protection and privacy

Lumos has established policies which define processes and controls on the collection, processing, storage and transfer of personally identifiable information. Lumos does not expect to receive any confidential patient information in order for it to carry out its business activities, however, to manage the potential inadvertent receipt of sensitive patient data, clinical group employees are trained in specific policies related to patient confidentiality as defined by the United States Health Insurance Portability and Accountability Act (**HIPAA**) and other jurisdiction specific privacy and security regulations (for example **GDPR**).

3.7.6. Supply contracts

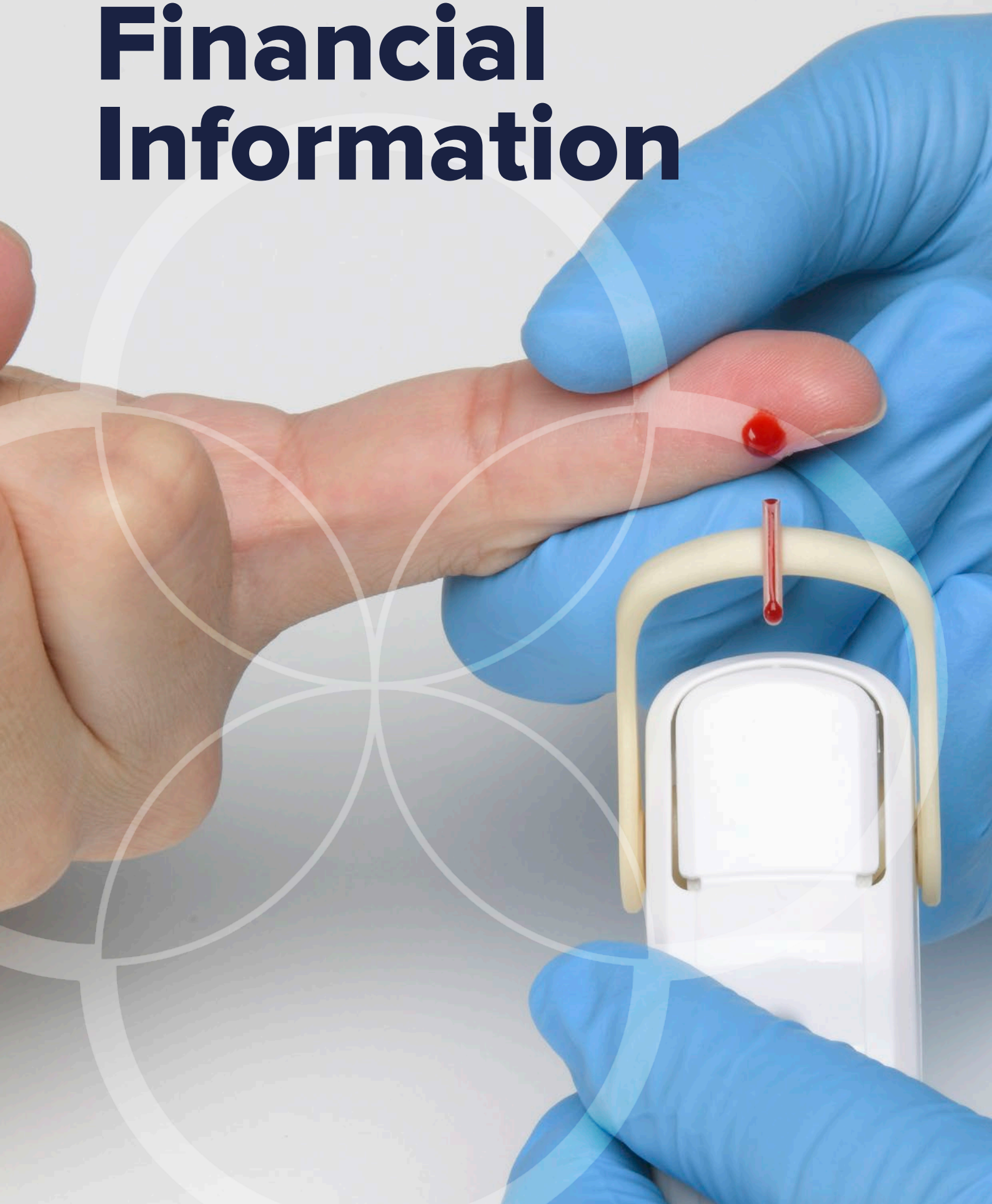
Lumos' supply contracts, generally, consist of:

- agreements with suppliers of test components using supplier contracts; and
- invoices, proposals, or agreements for standard off-the-shelf IT-related products and related services.

Under these agreements, the supplier generally provides certain components or assembly services to Lumos which are utilized in components or assembled devices to develop and sell diagnostic products. Lumos' IT agreements are "off the shelf" agreements for products such as NetSuite, Arena, Adobe, and Office 365.

Section 4

Financial Information



Section 4
Financial Information

4.1. Introduction

The financial information is set out below for the historical financial years ended 30 June 2019 (**FY19**), 30 June 2020 (**FY20**) and six-month periods ended 31 December 2019 (**1H20**) and 31 December 2020 (1H21) together with the forecast financial information for the year ending 30 June 2021 (**FY21F**), comprising the actual six-month period ended 31 December 2020 and the forecast six-month period ending 30 June 2021 (**2H21F**). The financial information contained in this section includes:

Historical Financial Information

- **Statutory Historical Financial Information** of the Company, comprising the:
  - statutory historical consolidated statements of profit or loss for FY19, FY20, 1H20 and 1H21 (**Statutory Historical Results**);
  - statutory historical consolidated statements of cash flows for FY19, FY20, 1H20 and 1H21 (**Statutory Historical Cash Flows**); and
  - statutory historical consolidated statement of financial position as at 31 December 2020 (**Statutory Historical Statement of Financial Position**);
- **Pro Forma Historical Financial Information** of the Company, comprising the:
  - pro forma historical consolidated statements of profit or loss for FY19, FY20, 1H20 and 1H21 (**Pro Forma Historical Results**);
  - pro forma historical consolidated statements of cash flows for FY19, FY20, 1H20 and 1H21 (**Pro Forma Historical Cash Flows**);
  - pro forma historical consolidated statement of financial position as at 31 December 2020 (**Pro Forma Historical Statement of Financial Position**);

(together the Statutory Historical Financial Information and the Pro Forma Historical Financial Information are referred to as the **Historical Financial Information**).

Forecast Financial Information

- **Statutory Forecast Financial Information** of the Company, comprising the:
  - statutory forecast consolidated statement of profit or loss for FY21F (**Statutory Forecast Results**);
  - statutory forecast consolidated statement of cash flows for FY21F (**Statutory Forecast Cash Flows**); and
- **Pro Forma Forecast Financial Information** of the Company, comprising the:
  - pro forma forecast consolidated statement of profit or loss for FY21F (**Pro Forma Forecast Results**);
  - pro forma forecast consolidated statement of cash flows for FY21F (**Pro Forma Forecast Cash Flows**);

(together the Statutory Forecast Financial Information and the Pro Forma Forecast Financial Information are referred to as the **Forecast Financial Information**).

Historical Financial Information and Forecast Financial Information together form the **Financial Information**.

The Statutory Historical Financial Information and Statutory Forecast Financial Information together form the **Statutory Financial Information**.

The Pro Forma Historical Financial Information and the Pro Forma Forecast Financial Information together form the **Pro Forma Financial Information**.

Also summarised in this Section are:

- the basis of preparation and presentation of the Financial Information (refer Section 4.2);
- information regarding certain non AAS or IFRS financial measures (refer Section 4.2.4);
- summary of key pro forma operating metrics (refer Section 4.8.3);
- the pro forma adjustments to the Statutory Historical Financial Information and the Statutory Forecast Financial Information, and reconciliations to the Pro Forma Historical Financial Information and the Pro Forma Forecast Financial Information respectively (refer Sections 4.3.2, 4.4.2 and 4.5.1);
- details of Lumos' indebtedness and capitalisation (refer Section 4.5.2);
- information regarding Lumos' liquidity and capital resources (refer Section 4.5.3);
- information regarding contractual liabilities (refer Section 4.5.5)
- management's discussion and analysis of the Pro Forma Historical Financial Information and the Pro Forma Forecast Financial Information (refer Section 4.8);

- the specific and general assumptions underlying the Forecast Financial Information (refer Sections 4.6.1 and 4.6.2);
- an analysis of the key sensitivities of the Pro Forma Forecast Financial Information (refer Section 4.7); and
- details of the proposed dividend policy (refer Section 4.9).

The Financial Information provided in this Section 4 should be read together with the information provided in this Prospectus, including:

- the sensitivity analysis outlined in Section 4.7;
- our significant accounting policies set out in Appendix A;
- the risk factors outlined in Section 5;
- the description of the use of the proceeds of the Offer described in Section 7.1.3;
- the Independent Limited Assurance Report, set out in Section 8; and
- the indicative capital structure described in Section 6.3.

4.2. Basis of preparation and presentation of the financial information

4.2.1. Overview

The Financial Information included in this Prospectus is intended to present potential investors with information to assist them in understanding the underlying historical financial performance, cash flows and financial position of Lumos, together with its forecast financial performance and cash flows. Lumos is responsible for the preparation and presentation of the Financial Information.

The Financial Information presented in this Prospectus has been reviewed by BDO Corporate Finance (East Coast) Pty Ltd (**BDO**) in accordance with the *Australian Standard on Assurance Engagements (ASAE) 3450 Assurance Engagements involving Corporate Fundraisings and/or Prospective Financial Information* as stated in its Independent Limited Assurance Report. Investors should note the scope and limitations of the Independent Limited Assurance Report (refer to Section 8).

Lumos operates on a financial year ended 30 June. All amounts disclosed in this Section 4 are presented in Australian Dollars and, unless otherwise noted, are rounded to the nearest $1,000. Rounding in the Financial Information may result in some discrepancies between the sum of components and the totals outlined within the tables and percentage calculations. As with the rest of this Prospectus, this Section assumes all forward looking forecast financial tables are stated at AUD0.78/USD1.00.

Measurement and Recognition Principles

The Statutory Financial Information has been prepared and presented in accordance with the measurement and recognition principles prescribed in Australian Accounting Standards (**AAS**) (including the Australian Accounting Interpretations issued by the Australian Accounting Standards Board (**AASB**)), which are consistent with International Financial Reporting Standards (**IFRS**) and interpretations issued by the International Accounting Standards Board (**IASB**)

The Statutory Financial Information is presented in an abbreviated form insofar as it does not include all the disclosures, statements or comparative information as required by the AAS and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the Corporations Act.

Following Completion, Lumos will continue to prepare its financial statements in accordance with AAS and its financial statements will be audited and reviewed by Lumos' auditor in accordance with Australian Auditing Standards.

Treatment of acquisitions in the Historical and Forecast Financial Information

On 22 May 2019 Lumos completed the acquisition of 100% of Rapid Pathogen Screening Inc (**RPS**) via a share purchase agreement (**RPS Acquisition**). RPS was purchased for a total consideration of $12.4m, net of cash acquired. The consideration was made up of the issue of ordinary shares in Lumos Diagnostics Holdings Pty Ltd to the vendors of RPS shares and forgiveness of loans made to the RPS parent company which were advanced during the financial year, including accrued interest. The Statutory Financial Information includes the results of RPS for the period since acquisition.

IFRS 3 requires that the identifiable assets and liabilities acquired (including intangible assets) are measured at their respective fair values at acquisition date. Lumos has performed an assessment of the fair value of the identifiable assets and liabilities acquired.

The increase in intangible asset values has been allocated between identifiable intangible assets $16.6m, consisting of the technology and patents held by RPS and the remainder to goodwill. This allocation is based on advice from a qualified external valuer and adopted by the Directors.

The financial results of RPS are included in the Pro Forma Financial Information as if the business had been acquired as at 1 July 2018 and in the Statutory Forecast Financial Information from the date that control was established. The financial information for RPS used in preparing the Pro Forma Historical Financial Information has been derived from the financial statements of RPS for the calendar year ending 31 December 2018 which were audited by Frazier & Deeter in accordance with US GAAP accounting standards and converted to Australian dollars. Frazier & Deeter has issued an unqualified audit opinion in respect of RPS's financial statements as of 31 December 2018 and for the year then ended.

Significant Accounting Policies

The significant accounting policies adopted in the preparation of the Financial Information are set out in Appendix A and have been consistently applied throughout the financial periods presented in this Prospectus, including, in relation to the Pro Forma Historical Financial Information, the retrospective application of Australian Accounting Standard AASB 16 *Leases* (referred to below).

Lumos adopted AASB 16 from 1 July 2019. The standard replaces AASB 117 'Leases' and for lessees eliminates the classifications of operating leases and finance leases. Except for short-term leases and leases of low value assets, right-of-use assets and corresponding lease liabilities are recognised in the statement of financial position. Straight-line operating lease expense recognition is replaced with a depreciation charge for the right-of-use assets (included in operating costs) and an interest expense on the recognised lease liabilities (included in finance costs). In the earlier periods of the lease, the expenses associated with the lease under AASB 16 will be higher when compared to lease expenses under AASB 117. However, EBITDA (refer to Section 4.2.4) results improve as the operating expense is now replaced by interest expense and depreciation in profit or loss. For classification within the statement of cash flows, the interest portion is disclosed in operating activities and the principal portion of the lease payments is separately disclosed in financing activities. For lessor accounting, the standard does not substantially change how a lessor accounts for leases. AASB 16 was adopted using the modified retrospective approach and, as such, the comparatives have not been restated.

AASB 16 has been applied to the preparation of the Pro Forma Historical Financial Information on a consistent basis as if this standard applied from 1 July 2018.

Lumos adopted AASB 15 Revenue from contracts with clients and AASB 9 Financial Instruments from 1 July 2018. The adoption of AASB 15 and AASB 9 did not materially impact the Financial Information.

Lumos has one reporting segment under AASB 8 Operating Segments being the provision of services and sale of products to clients operating in the POC diagnostics testing market.

4.2.2. Preparation of the Historical Financial Information

Statutory Historical Financial Information

The Statutory Historical Financial Information has been extracted from the audited consolidated financial statements of Lumos for FY19 and FY20, together with the reviewed consolidated interim financial statements for 1H20 and 1H21.

Lumos' consolidated financial statements for FY19 and FY20 have been audited by William Buck Audit (Vic) Pty Ltd (**William Buck**) in accordance with Australian Auditing Standards.

The consolidated financial statements of Lumos for 1H20 and 1H21 have been reviewed by William Buck in accordance with Australian Auditing Standards on Review Engagements ASRE 2410, Review of a Financial Report Performed by the Independent Auditor of the entity.

An unqualified audit and review opinion in respect of these periods was issued. No modified audit reports were issued for Lumos in those periods.

Lumos' statutory consolidated financial statements for FY19 and FY20 and the statutory consolidated financial statements for 1H20 and 1H21 are available at lumosdiagnostics.com/investors.

Pro Forma Historical Financial Information

The Pro Forma Historical Financial Information has been prepared solely for the purpose of inclusion in this Prospectus.

The Pro Forma Historical Results and Pro Forma Historical Cash Flows have been derived from the Statutory Historical Financial Information, with pro forma adjustments being made to reflect the impact of historical acquisitions, to eliminate certain non-recurring items, as well as adjustments to reflect Lumos' operating and capital structure following Completion (refer to Section 6.3).

The Pro Forma Historical Statement of Financial Position as at 31 December 2020 is based on the reviewed financial statements of Lumos at that date adjusted to reflect the impact of the Offer and other material transactions post 31 December 2020 (refer to Section 4.5.1).

The Pro Forma Historical Financial Information has been presented on a comparable basis to the Pro Forma Forecast Financial Information and has been adjusted to reflect the impact of all material events occurring before 31 December 2020 including:

- incremental costs of being a publicly listed entity;
- eliminating certain items inconsistent with the future operating structure of the Company;
- impact of the Offer including capital raised and Offer costs, and the capital structure in place after the IPO; and
- the acquisition of RPS as acquired at 22 May 2019.

Refer to Section 4.3.2 for a reconciliation between Statutory Historical and Forecast Results and Pro Forma Historical and Forecast Results, to Section 4.4.2 for a reconciliation between the Statutory Historical and Forecast Cash Flows and the Pro Forma Historical and Forecast Cash Flows and to Section 4.5.1 for a reconciliation between the Statutory Historical Statement of Financial Position and the Pro Forma Historical Statement of Financial Position.

The Pro Forma Historical Financial Information included in the prospectus has been reviewed, but not audited, by BDO. Investors should note the scope and limitations of the Independent Limited Assurance Report (**ILAR**).

Investors should note that past results are not a guarantee of future performance.

4.2.3. Preparation of the Forecast Financial Information

The Forecast Financial Information is unaudited and has been prepared solely for inclusion in this Prospectus. The basis of preparation and presentation of the Forecast Financial Information, to the extent applicable, is consistent with the basis of preparation and presentation of the Historical Financial Information. The FY21F forecast financial information comprises the actual six-month period ended 31 December 2020 and the forecast six-month period ending 30 June 2021.

The Forecast Financial Information has been reviewed by BDO in accordance with the *Australian Standard on Assurance Engagements ASAE 3450 Assurance Engagements involving Corporate Fundraisings and/or Prospective Financial Information*, as stated in its Independent Limited Assurance Report. Investors should note the scope and limitations of the Independent Limited Assurance Report on the Forecast Financial Information (refer to Section 8).

Statutory Forecast Financial Information

The Statutory Forecast Financial Information has been prepared by Lumos based on an assessment of present economic and operating conditions and on a number of assumptions, including the general and specific assumptions set out in Sections 4.6.1 and 4.6.2.

Lumos considers the general and specific assumptions, when taken as a whole, to be reasonable at the time of preparing this Prospectus. However, this information is not fact and investors are cautioned to not place undue reliance on the Statutory Forecast Financial Information. In addition, the assumptions upon which the Forecast Financial Information is based are by their very nature subject to significant uncertainties and contingencies, many of which will be outside the control of Lumos, the Directors and management. Events and outcomes might differ in amount and timing from the assumptions, with a material consequential impact on the Forecast Financial Information. Accordingly, none of Lumos and its Directors and management or any other person can give investors any assurance that the outcomes disclosed in the Statutory Forecast Financial Information will arise.

This information is intended to assist investors in assessing the reasonableness and likelihood of the assumptions occurring and is not intended to be a representation that the assumptions will occur. Investors should be aware that the timing of actual events and the magnitude of their impact might differ from that assumed in preparing the Statutory Forecast Financial Information, and that this may have a material positive or negative effect on Lumos' actual financial performance, cash flows or financial position. Investors are advised to review the assumptions set out in Sections 4.6.1 and 4.6.2 in conjunction with the sensitivity analysis set out in Section 4.7, the risk factors set out in Section 5, the significant accounting policies set out in Appendix A, and other information set out in this Prospectus.

Pro Forma Forecast Financial Information

The Pro Forma Forecast Financial Information has been derived from the Statutory Forecast Financial Information. In preparing the Pro Forma Forecast Financial Information, pro forma adjustments have been made to the Statutory Forecast Financial Information to:

- reflect Lumos' operating and capital structure following Completion;
- to eliminate certain non-recurring items, including costs of the Offer; and
- to reflect public company expenses.

Refer to Sections 4.3.2 and 4.4.2 for reconciliations between the Statutory Forecast Financial Information and Pro Forma Forecast Financial Information.

The Directors have no intention to update or revise the Forecast Financial Information or other forward-looking statements or to publish prospective financial information in the future, regardless of whether new information, future events or any other factors affect the information contained in this Prospectus, except where required by law or regulation.

4.2.4. Non-AAS or IFRS financial measures

Lumos uses certain measures to report on its business that are not recognised under AAS or IFRS. These measures are collectively referred in Section 4, and under Regulatory Guide 230 'Disclosing non-IFRS financial information' published by ASIC, as "non-IFRS financial measures".

The principal non-IFRS financial measures that are referred to in this Prospectus are as follows:

- **Gross Profit** represents total revenue, including Products revenue and Commercial Services revenue, less cost of sales.
- **Cost of sales** includes direct labour costs associated with the provision of Commercial Services and the assembly of Products, direct materials costs associated with the provision of Commercial Services and as used in the assembly of Products as well as indirect costs including freight costs, indirect labour costs including supervisors, and other overhead costs. The provision of services also includes Commercial Services provided by Planet Innovation under the Planet Innovation MSAs (refer to Section 6.7).
- **EBITDA** is earnings before interest, tax, depreciation and amortisation. Lumos uses EBITDA to evaluate the operating performance of the business without the non-cash impact of depreciation and amortisation and before interest and tax charges, which are affected by the capital structure and historical tax position of Lumos.

  Lumos also calculates **EBITDA margin** which is EBITDA divided by revenue, expressed as a percentage. EBITDA margin is a measure that management uses to evaluate the profitability of the overall business.

  Because it does not include the non-cash charges for depreciation and amortisation, EBITDA can be useful to help understand the cash generation potential of the business. However, Lumos believes that it should not be considered as an alternative to net free cash flow from operations and investors should not consider EBITDA in isolation from, or as a substitute for, an analysis of the results of Lumos' operations.
- **EBITDA before non-operating items** is EBITDA before non-operating income/expenses.
- **EBIT** is earnings before interest and tax.
- **Net finance costs** includes interest expenses and transaction costs associated with the Pre-IPO Convertible Notes, and right of use leased assets interest expense.
- **Capital expenditure** includes investment into property, plant and equipment as well as costs in FY21F associated with the establishment of the new facility at Sarasota, including manufacturing automation.
- **Capitalised development costs** include costs incurred and payments to Planet Innovation for product development, for example costs associated with development of the reader formats under the Planet Innovation MSAs (refer to Section 6.7).

- **Operating cash flow** is EBITDA before non-operating items adjusted to add back non-cash charges such as share-based payments, bad debts, inventory write-offs and unrealised foreign currency gains/(losses), and after adjusting for non-operating revenue/expenses and changes in working capital.
- **Non-operating income/expense** comprises items that are considered non-operating by Lumos, including export market development government grants as well as other one-off project and advisory costs.
- **Free cash flow** is operating cash flow less capital expenditure, payments for investment and capitalised product development costs.
- **Working capital** is trade and other receivables, prepayments, inventory and accrued income less trade and other payables, unearned income and employee benefits.

Although Lumos believes that these measures provide useful information about the financial performance of Lumos, they should be considered as supplements to the financial statement measures that have been presented in accordance with the AAS and IFRS and not as a replacement for them. Because these non-IFRS financial measures are not based on AAS or IFRS, they do not have standard definitions, and the way Lumos calculated these measures may differ from similarly titled measures used by other companies. Investors should therefore not place undue reliance on these non-IFRS financial measures.

Table 4.1 below provides detail in relation to the Commercial Services and Products divisions within Lumos and the nature of the revenue generated within each.

Table 4.1: Summary of Lumos' business divisions and key revenue types

Division	Product/Service type	Description
Commercial Services (See Section 3.6)	Fee for service	Revenue is generated by consulting services offered to clients in the healthcare industry. Consulting services include developing POC solutions which involves feasibility studies, assay development and readers integration prior to intellectual property commercialisation. Projects vary based on the client, size, consulting phase and phase success.
	Materials	Materials used in consulting projects are charged to clients at cost plus an agreed mark-up.
	Contract Manufacturing	Lumos manufactures client POC products (which may include readers) and assists in a verification and validation capacity for regulatory submissions
Products (See Sections 3.4 and 3.5)	FebriDx®	FebriDx® is a POC diagnostic test which distinguishes between bacterial and viral infections for patients with acute respiratory infections. Refer to Section 3.4.
	Other products	Includes the Leelu reader which is a customisable platform sold for research use only applications, and products other than FebriDx®, including CoviDx™ which is an antigen test for COVID-19. Refer to Sections 3.3 and 3.5.

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4.3. Consolidated Pro Forma Historical Results, Pro Forma Forecast Results and Statutory Forecast Results

4.3.1. Overview

Table 4.2 below sets out the Pro Forma Historical Results for FY19, FY20, and the Pro Forma Forecast Results for FY21F, and the Statutory Forecast Results for FY21F.

Table 4.2: Summary of Pro Forma Historical Results, Pro Forma Forecast Results and Statutory Forecast Results

A$('000)		Pro Forma Historical		Pro Forma Forecast	Statutory Forecast
June year-end	Notes	FY19	FY20	FY21F	FY21F
Products revenue	1	244	499	2,907	2,907
Commercial Services revenue		6,231	7,898	20,859	20,859
Revenue		**6,474**	**8,396**	**23,765**	**23,765**
Cost of sales	2	(4,217)	(5,211)	(12,528)	(12,056)
Gross profit		**2,257**	**3,186**	**11,238**	**11,709**
Sales and marketing expenses	3	(2,791)	(2,629)	(3,218)	(3,218)
General and administrative expenses	4	(10,142)	(15,713)	(20,549)	(20,124)
Research and development expenses	5	(316)	(2,541)	(2,041)	(2,041)
Total operating expenses		**(13,248)**	**(20,883)**	**(25,808)**	**(25,382)**
EBITDA before non-operating items		**(10,991)**	**(17,697)**	**(14,570)**	**(13,673)**
Non-operating income/expenses		105	14	(141)	(1,686)
EBITDA		(10,885)	(17,683)	(14,711)	(15,358)
Depreciation		(290)	(362)	(508)	(508)
Amortisation		(502)	(323)	(597)	(597)
EBIT		**(11,677)**	**(18,368)**	**(15,816)**	**(16,463)**
Net finance costs		(14)	(13)	(156)	(4,003)
Profit (loss) before taxation		**(11,691)**	**(18,381)**	**(15,972)**	**(20,466)**
Income tax (expense)/benefit		–	86	–	–
Net profit/(loss) after tax		**(11,691)**	**(18,295)**	**(15,972)**	**(20,466)**
Other comprehensive income, net of tax		98	(74)	–	–
Total comprehensive income		**(11,593)**	**(18,369)**	**(15,972)**	**(20,466)**

A reconciliation of net profit/(loss) from Statutory Financial Results to Pro Forma Financial Results is set out below in Table 4.4.

Notes:

1. **Products revenue**: FY19 Products revenue includes a pro forma adjustment to reflect RPS' revenue contribution for the eleven months to May 2019 prior to Lumos' acquisition of RPS.
2. **Cost of sales**: The pro forma historical and forecast cost of sales includes a pro forma adjustment to the direct labour costs associated with the provision of Commercial Services to reflect the additional costs that would have been incurred by Lumos had the Amended Planet Innovation MSA (which will become effective on 1 July 2021) been in place since 1 July 2018.
3. **Sales and marketing expenses**: Includes business development, marketing and sales which includes both labour and associated overheads. Refer to 4.6.2.3 for further explanation.
4. **General and administrative expenses:** Includes administrative, manufacturing and clinical/quality overhead which includes both labour and associated overheads. Refer to 4.6.2.3 for further explanation.
5. **Research and development expenses**: Predominately includes personnel costs, refer to 4.6.2.3 for further detail.

Table 4.3 below sets out the Pro Forma Historical Results for 1H20 and 1H21.

Table 4.3: Summary of Pro Forma Historical Results

A$('000)		Pro Forma Historical	
June year-end	Notes	1H20	1H21
Products revenue	1	102	1,721
Commercial Services revenue		3,307	9,836
Revenue		**3,409**	**11,557**
Cost of sales	2	(2,078)	(5,576)
Gross profit		**1,331**	**5,981**
Sales and marketing expenses	3	(1,210)	(1,352)
General and administrative expenses	4	(5,589)	(8,475)
Research and development expenses	5	(1,062)	(849)
Total operating expenses		**(7,861)**	**(10,676)**
EBITDA before non–operating items		**(6,530)**	**(4,696)**
Non–operating income/expenses		15	151
EBITDA		**(6,515)**	**(4,545)**
Depreciation		(234)	(164)
Amortisation		(208)	(100)
EBIT		**(6,956)**	**(4,809)**
Net finance costs		39	(170)
Profit (loss) before taxation		**(6,918)**	**(4,980)**
Income tax (expense)/benefit		–	–
Net profit/(loss) after tax		**(6,918)**	**(4,980)**
Other comprehensive income, net of tax		(52)	(997)
Total comprehensive income		**(6,970)**	**(5,977)**

Refer to Table 4.2 for the notes relating to Table 4.3.

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4.3.2. Pro forma adjustments to the Statutory Historical Results and Statutory Forecast Results

Table 4.4 below sets out the pro forma adjustments that have been made to Lumos' Statutory Historical Results and Statutory Forecast Results to reflect the full year impact of the operating and capital structure that will be in place following Completion as if it were in place as at 1 July 2018. These adjustments are summarised below.

Table 4.4: Pro forma adjustments to the Statutory Historical Results for FY19, FY20 and Statutory Forecast for FY21F

A$('000)		Pro Forma Historical		Pro Forma Forecast
June year-end	Notes	FY19	FY20	FY21F
Statutory net profit/(loss) after tax		(6,546)	(13,447)	(20,442)
Net impact of RPS Acquisition	1	(5,028)	–	–
Acquisition transaction costs	2	648	–	–
Offer costs	3	–	–	1,903
Incremental public company costs	4	(2,329)	(2,329)	(2,329)
2019 Convertible Notes	5	565	731	–
Pre-IPO Convertible Notes	6	–	–	3,847
Forgiveness of accrued interest	7	(415)	–	–
Impact of IFRS 16	8	7	(31)	–
Impairment	9	2,530	–	–
Amended Planet Innovation MSA	10	(712)	(497)	(472)
Removal of PPP grant	11	–	(2,722)	1,545
Removal of R&D tax refund	12	(871)	–	–
RPS convertible notes	13	459	–	–
Pro forma net profit/(loss) after tax		**(11,691)**	**(18,295)**	**(15,948)**

Notes:

1. **Net impact of RPS Acquisition**: Reflects the financial performance contribution for the eleven months to May 2019 prior to Lumos' acquisition of RPS.
2. **Acquisition transaction costs**: Reflect the one-off transaction costs incurred on the RPS Acquisition such as financial and legal due diligence costs and other advisory costs.
3. **Offer costs**: Total expenses of the Offer are estimated to be $4.7m of which $1.9m relates to the IPO and is therefore expensed in the FY21F Statutory Forecast Results and reversed as a non-recurring item. The remaining $2.8m is directly attributable to the issue of Offer Shares and will be offset against equity raised in the Offer.
4. **Incremental public company costs**: Lumos estimates that it will incur $2.3m in annual incremental public company cost. These costs reflect the additional costs associated with being a listed company. These costs include Non-executive Director remuneration, additional legal fees, audit fees, annual listing fees, annual general meeting and annual report costs, additional directors' and officers' insurance premiums, company secretarial fees, registry fees, public relations costs, investor relations services fees and registry costs. The pro forma historical and forecast statements of profit and loss are adjusted to include the incremental costs of being listed from 1 July 2018 through to Completion.
5. **2019 Convertible Notes**: Reflects the removal of interest costs associated with the 2019 Convertible Notes which converted into Preference Shares in November 2019.
6. **Pre-IPO Convertible Notes**: Reflects the removal of interest and amortised transaction costs associated with the Pre-IPO Convertible Notes (as they do not form part of the normal course of trading and are non-operational costs) and which convert into ordinary shares at Completion.

7. **Forgiveness of accrued interest**: Reflects the removal of interest receivable in relation to accrued interest on loans forgiven as part of the RPS Acquisition consideration.
8. **Impact of IFRS 16**: Lumos adopted IFRS 16 from 1 July 2019. The adjustment retrospectively applies IFRS 16 as if it had been adopted on 1 July 2018.
9. **Impairment**: Related to an impairment of previously capitalised development costs in FY19.
10. **Amended Planet Innovation MSA**: Reflects the additional costs that would have been incurred by Lumos had the Amended Planet Innovation MSA (which will become effective on 1 July 2021) been in place since 1 July 2018. The additional costs are reflected in both cost of sales in Tables 4.2 and 4.3 and capitalised development costs in Tables 4.6 and 4.7.
11. **Removal of PPP grant**: Reflects the removal of the PPP grant received in FY20 which was classified as income in non-operating income/ expenses. The adjustment in FY21F reflects the Lumos' decision to repay part of the PPP grant monies received in FY20 due to an administrative error resulting in an over claim. Refer to Section 5.1.11 for further information.
12. **Removal of R&D tax refund**: Reflects the removal of the tax refund in connection with research and development activities in FY19.
13. **RPS convertible notes**: Reflects the removal of interest costs payable by RPS to Lumos associated with funding provided by Lumos prior to the RPS Acquisition.

Table 4.5: Pro forma adjustments to the Statutory Historical Results 1H20 and 1H21

A$('000)		Historical	
June year-end	Notes	1H20	1H21
Statutory net profit/(loss) after tax		(6,232)	(4,637)
Offer costs	3	–	119
Incremental public company costs	4	(1,164)	(1,164)
2019 Convertible Notes	5	731	–
Pre-IPO Convertible Notes	6	–	1,004
Impact of IFRS 16	8	(21)	–
Amended Planet Innovation MSA	10	(232)	(302)
Pro forma net profit/(loss) after tax		**(6,918)**	**(4,980)**

Refer to Table 4.4 for the notes relating to Table 4.5.

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4.4. Consolidated Pro Forma Historical Cash Flows, Pro Forma Forecast Cash Flows and Statutory Forecast Statements of Cash Flows

4.4.1. Overview

Table 4.6 below sets out the Pro Forma Historical Cash Flows for FY19, FY20, the Pro Forma Forecast Cash Flows for FY21F, and the Statutory Forecast Cash Flows for FY21F.

Table 4.6: Pro Forma Historical Cash Flows for FY19 and FY20, Pro Forma Forecast Cash Flows for FY21F and Statutory Forecast Cash Flows for FY21F.

A$('000)		Pro Forma Historical		Pro Forma Forecast	Statutory Forecast
June year-end	Notes	FY19	FY20	FY21	FY21F
EBITDA before non-operating items		(11,127)	(17,697)	(14,570)	(13,673)
Adjustments to EBITDA	1	1,041	1,380	1,209	1,209
Non-operating income/expenses		105	14	151	(1,394)
Changes in working capital	2	1,839	762	1,238	1,238
Operating cash flow		**(8,143)**	**(15,541)**	**(11,972)**	**(12,620)**
Capital expenditure		(920)	(438)	(10,756)	(10,756)
Payments for purchase of business, net of cash acquired	3	–	–	–	–
Payments for investment		(271)	–	–	–
Capitalised development costs	4	(4,270)	(5,606)	(3,442)	(2,712)
Free cash flow		**(13,603)**	**(21,584)**	**(26,170)**	**(26,088)**
Net interest income/(expense)	5	2	(5)	(324)	(324)
Proceeds from issue of shares	6	–	12,000	2,000	2,000
Proceeds from borrowings		5,712	–	–	–
Proceeds from issue of convertible notes	7	16,037	–	25,261	24,108
Repayment of lease liabilities		(121)	(236)	(896)	(896)
Net cash flow before the impact of the offer		**8,027**	**(9,824)**	**(130)**	**(1,200)**
Offer proceeds, net of costs	8	–	–	38,000	35,198
Net cash flow		**8,027**	**(9,824)**	**37,870**	**33,998**

Notes:

1. **Adjustments to EBITDA**: Includes non-cash items including share-based payments, bad debts, inventory write-offs and unrealised foreign currency gains/(losses).
2. **Changes in working capital**: Are impacted by changes in trade receivables, trade payables, inventory levels, prepayments, accrued income, unearned income and employee provisions.
3. **Payment for purchase of business, net of cash acquired**: Relates to the RPS Acquisition in FY19, of which the costs associated have been removed as a pro forma adjustment to reflect the one-off nature of the costs. Items are the subject of pro forma adjustments (refer to Section 4.4.2) therefore no amounts are identified in this row.
4. **Capitalised development costs**: Includes a pro forma adjustment to the direct labour costs associated with the provision of Commercial Services to reflect the additional costs that would have been incurred by Lumos had the Amended Planet Innovation MSA (which will become effective on 1 July 2021) been in place since 1 July 2018.
5. **Net interest income/(expense)**: Includes interest on right of use lease liabilities.
6. **Proceeds from issue of shares**: Reflects the proceeds from the issuance of Preference Shares to Planet Innovation in November 2019, April 2020 and July 2020.
7. **Proceeds from issue of convertiblen notes**: Reflects the proceeds from the issuance of the 2019 Convertible Notes in March 2019 (which converted into Preference Shares in November 2019), and the issuance of the Pre-IPO Convertible Notes in September 2020, net of transaction costs.
8. **Offer proceeds, net of costs**: Reflects the proceeds from the Offer, net of transaction costs capitalised to equity.

Table 4.7 below sets out the Pro Forma Historical Cash Flows for 1H20 and 1H21

Table 4.7: Pro Forma Historical Cash Flows for 1H20 and 1H21

A$('000)		Pro Forma Historical	
June year-end	Notes	1H20	1H21
EBITDA before non-operating items		(6,530)	(4,696)
Adjustments to EBITDA	1	–	879
Non-operating income/expenses		10	151
Changes in working capital	2	(32)	(2,423)
Operating cash flow		**(6,551)**	**(6,089)**
Capital expenditure		(248)	(5,336)
Payments for investment		(33)	–
Capitalised development costs	4	(2,461)	(1,733)
Free cash flow		**(9,293)**	**(13,159)**
Net interest income/(expense)	5	14	(170)
Proceeds from issue of shares	6	4,801	2,000
Proceeds from borrowings		–	–
Proceeds from issue of convertible notes	7	–	25,261
Repayment of lease liabilities		(72)	(83)
Net cash flow		**(4,551)**	**13,849**

Refer to Table 4.6 for the notes relating to Table 4.7.

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4.4.2. Pro forma adjustments to the Statutory Historical Cash Flows and the Statutory Forecast Cash Flows

Table 4.8 below sets out the pro forma adjustments that have been made to Lumos' Statutory Historical Statements of Cash Flows and Statutory Forecast Statements of Cash Flows to reflect the full year impact of the operating and financing structure that will be in place on Completion as if it were in place as at 1 July 2018. These adjustments are summarised below.

Table 4.8: Pro forma adjustments to the Statutory Historical Cash Flows for FY19, FY20 and the Statutory Forecast Cash Flows for FY21F

A$('000)		Historical		Forecast
June year-end	Notes	FY19	FY20	FY21F
Statutory free cash flow		(16,050)	(14,886)	(26,088)
Net impact of RPS Acquisition	1	(1,287)	–	–
RPS Acquisition costs	2	8,087	–	–
Offer costs within EBITDA	3	–	–	1,903
Incremental public company costs	4	(2,329)	(2,329)	(2,329)
Impact of IFRS 16	5	121	–	–
Amended Planet Innovation MSA	6	(2,145)	(1,647)	(1,202)
Removal of PPP grant	7	–	(2,722)	1,545
Pro forma free cash flow		**(13,603)**	**(21,584)**	**(26,170)**

Notes:

1. **Net impact of RPS Acquisition**: Reflects the cash flow contribution for the eleven months to May 2019 prior to the RPS Acquisition by Lumos.
2. **RPS Acquisition costs**: Reflects the cash costs of acquiring RPS, net of cash acquired as well as transaction costs related to the acquisition.
3. **Offer costs within EBITDA**: Total expenses of the Offer are estimated to be $4.7m of which $1.9m relates to the listing and is therefore expensed in the FY21F Statutory Forecast Results. The remaining $2.8m is directly attributable to the issue of all shares under the Offer by Lumos and will be offset against equity raised in the Offer. These costs are reversed as non-recurring items.
4. **Incremental public company costs**: Lumos estimates that it will incur $2.3m in annual incremental public company cost. These costs reflect the additional costs associated with being a listed company. These costs include non-executive Director remuneration, additional legal fees, audit fees, annual listing fees, annual general meeting and annual report costs, additional directors' and officers' insurance premiums, company secretarial fees, registry fees, public relations costs, investor relations services fees and registry costs. The Pro Forma Historical Statements of Cash Flows and Pro Forma Forecast Statements of Cash Flows are adjusted to include the incremental costs of being listed from 1 July 2018 through to Completion.
5. **Impact of IFRS 16**: Lumos adopted IFRS 16 from 1 July 2019. The adjustment retrospectively applies IFRS 16 as if it had been adopted on 1 July 2018. Although there is no impact to total net cash flow, this adjustment reclassified lease payments from 'cash flow from operations' to 'cash flows from financing' in accordance with IFRS 16. The reclassification from 'cash flows from operations' is reflected within free cash flow.
6. **Amended Planet Innovation MSA**: Reflects the additional costs that would have been incurred by Lumos had the Amended Planet Innovation MSA (which will become effective on 1 July 2021) been in place since 1 July 2018. The additional costs are reflected in both cost of sales in Tables 4.2 and 4.3 and capitalised development costs within Tables 4.6 and 4.7.
7. **Removal of PPP grant**: Reflects the removal of the PPP grant received in FY20 which was classified as income in non-operating income/expenses. The adjustment in FY21F reflects Lumos' decision to repay part of the PPP grant monies received in FY20 due to an administrative error resulting in an over claim. Refer to Section 5.1.11 for further information.

Table 4.9 below sets out the pro forma adjustments that have been made to Lumos' Statutory Historical Statements of Cash Flows and Statutory Forecast Statements of Cash Flows to reflect the full year impact of the operating and financing structure that will be in place following Completion as if it was in place as at 1 July 2018. These adjustments are summarised below.

Table 4.9: Pro forma adjustments to the Statutory Historical cash flows for 1H20 and 1H21

A$('000)		Historical	
June year-end	Notes	1H20	1H21
Statutory free cash flow		(7,239)	(11,446)
Offer costs within EBITDA	3	–	119
Incremental public company costs	4	(1,164)	(1,164)
Amended Planet Innovation MSA	6	(890)	(667)
Pro forma free cash flow		**(9,293)**	**(13,159)**

Refer to Table 4.8 for the notes relating to Table 4.9.

4.5. Statutory Historical Statement of Financial Position and Pro Forma Historical Statement of Financial Position

4.5.1. Overview

Table 4.10 below sets out the pro forma adjustments that have been made to the Statutory Historical Statement of Financial Position for Lumos at 31 December 2020 in order to prepare the Pro Forma Statement of Financial Position for Lumos to take into account the effect of, amongst other things, the Offer proceeds, transaction expenses and other material transactions. These adjustments reflect the impact of the changes in capital structure that will take place as part of the Offer, as if they had occurred or were in place as at 31 December 2020.

The Pro Forma Statement of Financial Position is provided for illustrative purposes only and is not necessarily indicative of Lumos' view of its financial position upon Completion or at a future date. Further information on the sources and uses of funds of the Offer is set out in Section 7.1.3.

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Table 4.10: Statutory Historical Statement of Financial Position and Pro Forma Statement of Financial Position as at 31 December 2020

A$('000)	Statutory 31 Dec 2020	Preference Share conversion	Repayment of PPP grant	Interest on Pre-IPO Convertible Notes	Pre-IPO Convertible Notes conversion	Impact of the Offer	Pro Forma 31 Dec 2020
Notes		1	2	3	4	5	
ASSETS							
Current assets							
Cash and cash equivalents	15,329	–	(1,545)	–	–	33,414	47,198
Trade and other receivables	4,195	–	–	–	–	–	4,195
Inventories	1,075	–	–	–	–	–	1,075
Prepayments and other assets	8,071	–	–	–	–	–	8,071
Total current assets	**28,670**	**–**	**(1,545)**	**–**	**–**	**33,414**	**60,539**
Non-current assets							
Financial assets held at cost	271	–	–	–	–	–	271
Deferred tax assets	78	–	–	–	–	–	78
Right-of-use assets	5,256	–	–	–	–	–	5,256
Property, plant and equipment	909	–	–	–	–	–	909
Intangibles	32,629	–	–	–	–	–	32,629
Total non-current assets	**39,143**	**–**	**–**	**–**	**–**	**–**	**39,143**
Total assets	**67,813**	**–**	**(1,545)**	**–**	**–**	**33,414**	**99,681**
LIABILITIES							
Current liabilities							
Trade and other payables	3,166	–	–	–	–	–	3,166
Lease liabilities	1,048	–	–	–	–	–	1,048
Employee benefits	1,087	–	–	–	–	–	1,087
Deferred revenue	4,197	–	–	–	–	–	4,197
Total current liabilities	**9,499**	**–**	**–**	**–**	**–**	**–**	**9,499**
Non-current liabilities							
Pre-IPO Convertible Notes	25,112	–	–	2,842	(27,955)	–	–
Lease liabilities	4,188	–	–	–	–	–	4,188
Total non-current liabilities	**29,301**	**–**	**–**	**2,842**	**(27,955)**	**–**	**4,188**
Total liabilities	**38,800**	**–**	**–**	**2,842**	**(27,955)**	**–**	**13,687**
Net Assets	**29,013**	**–**	**(1,545)**	**(2,842)**	**27,955**	**33,414**	**85,994**
EQUITY							
Ordinary shares	23,130	29,549	–	–	27,955	35,198	115,831
Preference Shares	29,549	(29,549)	–	–	–	–	–
Reserves	1,009	–	–	–	–	–	1,009
Accumulated losses	(24,674)	–	(1,545)	(2,842)	–	(1,784)	(30,845)
Total Equity	**29,013**	**–**	**(1,545)**	**(2,842)**	**27,955**	**33,414**	**85,994**

Notes:

1. **Preference Share conversion**: Reflects the conversion of the Preference Shares on Completion to Shares on a one-for-one basis.
2. **Repayment of PPP grant**: Reflects Lumos' decision to repay part of the PPP grant monies received in FY20 due to an administrative error resulting in an over claim. Refer to Section 5.1.11 for further information.
3. **Interest on Pre-IPO Convertible Notes**: Reflects the accrual of interest and amortisation of transaction costs which will take place between 31 December 2020 and Completion.
4. **Pre-IPO Convertible Notes conversion**: Reflects the conversion of the Pre-IPO Convertible Notes and accrued interest into Shares.
5. **Impact of the Offer**: Represents total proceeds of the Offer less IPO transaction costs. As a result of the Offer, Lumos will issue approximately 30.4m Shares at the Offer Price and receive gross proceeds of approximately $38.0m. Lumos will incur IPO transaction costs of $4.7m, of which $0.1m was expensed in 1H21. Of the remaining IPO transaction costs, $2.8m is offset against the Offer proceeds and $1.8m expensed.

4.5.2. Net cash/(indebtedness) and capitalisation

Table 4.11: Summary of net cash/(indebtedness) and capitalisation as at 31 December 2020

A$('000)	Notes	Statutory	Pro Forma
Cash and cash equivalents	1	15,329	47,198
Current lease liabilities		(1,048)	(1,048)
Non-current lease liabilities		(4,188)	(4,188)
Net cash/(indebtedness)		**10,092**	**41,961**
Ordinary Shares	2	23,130	115,831
Preference Shares	3	29,549	–
Reserves		1,009	1,009
Accumulated losses	4	(24,674)	(30,845)
Total equity		**29,013**	**85,994**
Net cash/(indebtedness) and capitalisation		**39,105**	**127,955**

Notes:

1. **Cash and cash equivalents**: Are expected to increase by $31.9m as a result of the proceeds of the Offer ($38.0m), assuming the issuance of 30.4m Shares at the Offer Price per Share, offset by the cash impact of Offer costs ($4.6m). Cash and cash equivalents are also reducing by $1.5m as a result of the repayment of part of the PPP grant monies.
2. **Ordinary Shares**: Have been adjusted for the Impact of the Offer ($38.0m) less capitalised transaction costs ($2.8m).
3. **Preference Shares**: Reflects the conversion of the Preference Shares on Completion to Shares on a one-for-one basis.
4. **Accumulated losses**: Includes adjustments relating to the repayment of part of the PPP grant monies ($1.5m), interest and amortised transaction costs on the Pre-IPO Convertible Notes ($2.8m) and expensed transaction costs ($1.8m) relating to the impact of the Offer.
5. Refer to Tables 4.10 and 4.11 for further details on the notes to Table 4.11.

4.5.3. Liquidity and capital resources

Following Completion, Lumos' principal sources of funds are expected to be cash flow generated from operations and cash on hand (including the proceeds of the Offer).

Lumos' main use of cash is to fund working capital, sales and marketing expenses and capital expenditure. Lumos expects that it will have sufficient cash flow from operations to meet its operational requirements and business needs during the Forecast Period. Lumos' ability to generate sufficient cash depends on its future performance which, to a certain extent, is subject to a number of factors beyond its control including general economic, financial and competitive conditions. Over time, Lumos may seek additional funding from a range of sources to diversify its funding base.

4.5.4. Quantitative and qualitative disclosures about market risk

Lumos is exposed to market risk in the ordinary course of its business. Market risk represents the risk of loss that may impact Lumos' financial position due to adverse changes in financial market prices and rates. Lumos' market risk exposure is primarily a result of fluctuations in foreign currency exchange rates and interest rates. Exposure to market risk for changes in interest rates relates primarily to Lumos' cash, cash equivalents and leased assets debt.

Lumos transacts in various currencies other than its reporting currency, the Australian dollar, including the United States dollar, Euro, and Pounds Sterling, with the United States dollar comprising the majority. Lumos has not historically hedged its foreign currency exposure and as a result its earnings are exposed to the net impact of movements in foreign exchange rates on sales, employee expenses and purchases in the foreign currencies in which the transactions occur. The potential impact on revenue and gross profit of movements in foreign currency exchange rates over the forecast period is considered in Table 4.12, Lumos has foreign currency bank accounts, receivable and payables that are denominated in a currency other than its reporting currency and it holds investments in overseas subsidiaries which are not hedged. Any foreign exchange rate movements in respect to the transactional currency in which the net investment in foreign subsidiaries is held, are recognised in the foreign currency translation reserve.

4.5.5. Off balance sheet items

Lumos will not have any statutory contractual obligations and commitments on Completion.

4.6. Forecast Financial Information

The Forecast Financial Information is based on various specific and general assumptions concerning future events including those set out below. The assumptions set out below should be read in conjunction with the sensitivity analysis set out in Section 4.7, the risk factors set out in Section 5, the key significant policies in Appendix A and the Independent Limited Assurance Report set out in Section 8. A reconciliation of the Pro Forma Forecast Results to the Statutory Forecast Results is set out in Section 4.3.2.

In preparing the Forecast Financial Information, Lumos has undertaken an analysis of historical performance and applied assumptions, where appropriate, in order to forecast future performance for FY21F. The basis of preparation of the Forecast Financial Information is further described in Section 4.2.3.

4.6.1. General assumptions

In preparing the Pro Forma Forecast Financial Information, the following general assumptions have been adopted:

- no material change in the competitive environment in which Lumos operates;
- no significant deviation from current market expectations of economic conditions relevant to the POC diagnostic test sector, e.g. business confidence and consumer sentiment;
- no significant interruptions, disruptions or disturbances in relation to Lumos' business (including its technology platform) or that of its clients, suppliers and distributors, including as a result of any additional adverse impacts of COVID-19 in Lumos' target markets;
- no material changes in key personnel, including key management personnel, and Lumos maintains its ability to recruit and retain the personnel required to support future growth;
- no material change in applicable AAS, IFRS or other mandatory professional reporting requirements of the Corporations Act which have a material effect on Lumos' financial performance or cash flows, financial position, accounting policies, financial reporting or disclosure of Lumos during the Forecast Period;
- no loss (or obtaining) or material change in product, premises or other clearances, approvals or licences relied on by Lumos or its clients or distributors issued by any governmental, semi-governmental or other third party;
- no material changes in Government laws, regulation and policy including in relation to money laundering, interest rates, foreign investment or taxation which may impact Lumos' business, clients or levels of investment or business activity in areas in relation to which Lumos products are commonly used;
- receipt of the Offer proceeds in accordance with the timetable set out in the Important Information section of this Prospectus;
- no material industry disturbances or disruptions to the continuity of operations of Lumos, no material industrial actions, and no other material changes in its business;
- no material amendment, variation, breach or termination to any material contract, agreement, project or arrangement to which Lumos is a party;
- no material changes in currency;
- no material adverse impact in relation to litigation or claims;
- no material change in Lumos' corporate and funding structure (other than as a result of the Offer);

- no material impairment of intangible assets;
- no material acquisitions, divestments, restructuring or investments other than as set out in, or contemplated by, this Prospectus; and
- none of the key risks listed in Section 5 occurs, or if they do, none of them has a material adverse impact on the operations of Lumos.

4.6.2. Specific assumptions

The basis of the specific assumptions that have been used in the preparation of the Pro Forma Forecast Financial Information is set out below.

4.6.2.1 Revenue assumptions

The forecast increase in revenue is based on the following key assumptions:

Commercial Services revenue:

- Fee for service and materials revenue forecasts are based on active projects under existing client contracts, including statements of work, with the split of materials and fee for service based on those contracts and consistent with the Historical Period.
- Contract manufacturing revenue forecasts are based on volumes (to commence in 2H21F) and selling prices contracted under existing supply agreements.

Products revenue:

- FebriDX® revenue is based on an assessment of Lumos' pipeline of potential POC diagnostic test sales by distributors to hospitals in the UK, Europe and Canada and consistent with sales (including revenue from shipping) achieved in 1H21 after removing a single large stocking order fulfilled in November 2020.
- Other products revenue is based on expected sales of the Leelu reader, and monthly minimum contracted volumes of CoviDx™.

All:

- Commercial Services and Products revenue assumes commencement and completion of project phases occur in accordance with current project schedules.

4.6.2.2 Cost of sales

- Fee for service cost of sales have been calculated based on expected headcount by department using recent average direct wages costs and Planet Innovation contracted labour costs and applied against expected requirements of existing contracts referred to in Section 4.6.2.1. Lumos expects lower staff utilisation on revenue generating projects in 2H21F than 1H21 due to a roll-off of COVID-19 related services projects over that period and, similarly, a reduction of contracted labour requirements from Planet Innovation.
- Materials costs of sales are assumed to be consistent with historical average costs and applied to expected requirements of existing contracts referred to in Section 4.6.2.1.
- Contract manufacturing cost of sales are based on direct materials costs as well as an allocation for direct labour and overheads based on a per test volume basis with the balance of manufacturing costs not absorbed by contract manufacturing volumes recognised as manufacturing establishment costs within operating expenses. Cost of sales under the Diasorin contract are forecast based on gross margins consistent with FebriDx® and initial contract manufacturing batches.
- FebriDx® cost of sales are based on direct materials costs per test as well as an allocation for direct labour and overheads based on a per test volume basis with the balance of manufacturing costs not absorbed by FebriDx® volumes recognised as manufacturing establishment costs within operating expenses.
- Other products cost of sales are based on direct materials costs per test as well as an allocation for direct labour and overheads based on a per test volume basis with the balance of manufacturing costs not absorbed by other products volumes recognised as manufacturing establishment costs within operating expenses. CoviDx™ costs of sales are forecast based on gross margins consistent with FebriDx® and initial manufacturing batches.

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4.6.2.3 Operating expenses

Sales and marketing

- Sales and marketing expenses include personnel costs of the various sales, business development and marketing teams as well as other marketing spend such as advertising at trade shows and are calculated consistently with the Historical Period (for salaries and wages, payroll taxes, employee benefits and other employee-related expenses) allowing for the expected increase in headcount over 2H21F of 4 FTEs to drive growth in Lumos' target markets.

General and administrative

- General and administrative expenses primarily consist of personnel costs of the various functions included within general and administrative expenses (for example finance, administration, quality, regulatory, clinical and manufacturing establishment) and are calculated consistently with 1H21 (for example salaries and wages, payroll taxes, employee benefits and other employee-related expenses) allowing for the expected increase in headcount over FY21F of 37 FTEs.
- Assumes bonus and commissions for Lumos staff will be accrued based on achievement of 100% on-target performance in FY21F.
- Other material costs, include payments for clinical trials and associated materials expenses are calculated consistently in line with comparable expenses in 1H21 based on expected patient recruitment timetables.

Research and development

- Research and development costs include predominately personnel costs which are forecast based on headcount (assumed to increase by 7 FTEs) and salaries and wages, payroll taxes, employee benefits and other employee-related expenses which are assumed to be consistent with 1H21.
- Other material costs include laboratory supplies which are assumed to be incurred at rates consistent with those in with 1H21.

4.6.2.4 Depreciation and amortisation

Depreciation and amortisation charges are forecast based on the anticipated depreciation and amortisation schedules for existing capital assets, and new capital assets relating to the Sarasota facility, such as property plant and equipment and capitalised development costs. Amortisation expense also includes the anticipated right of use asset amortisation expense from Lumos' leased premises.

4.6.2.5 Capitalised development costs

Capitalised development costs are forecast based on the personnel costs (both internal Lumos resources and contracted Planet Innovation resources) required for the development of both hardware and software applications related to the digital reader platform and are calculated to be consistent with 1H21.

4.6.3. Statutory Forecast Financial Information

The Statutory Forecast Financial Information is based on the same specific and general assumptions as those underlying the Pro Forma Forecast Financial Information as set out in Section 4.6.1 and 4.6.2 above, with the exception of the specific assumptions set out below.

4.6.3.1 Public company expenses

Public company expenses are assumed to be incurred post-Completion (refer to Section 4.3.2) and reflect Lumos' estimate of the incremental annual expenses that Lumos will incur as a public entity.

4.6.3.2 One-off IPO and other transaction expenses

IPO and transaction expenses are assumed to be incurred in FY21F (approximately $4.7m) and reflect Lumos' estimate of expenses directly in connection with its initial public offering.

4.7. Sensitivity analysis of Forecast Financial Information

The Forecast Financial Information is based on a number of specific and general assumptions, as described in Sections 4.6.1 and 4.6.2. These specific and general assumptions are subject to business, economic and competitive uncertainties and contingencies, many of which are beyond the control of Lumos, the Directors and management, and upon assumptions with respect to future business decisions, which are subject to change.

Set out in Table 4.12 below is a summary of the sensitivity of the Pro Forma Forecast Financial Information to changes in key assumptions. The changes in the key assumptions set out in the sensitivity analysis are intended to provide a guide only and are not intended to be indicative of the complete range of variations that may be experienced. Variations in actual performance could exceed the ranges shown, and these variances may be substantial.

Care should be taken in interpreting these sensitivities. In order to illustrate the likely key impact on the Pro Forma Forecast Financial Information, the estimated impact of changes in each of the assumptions has been calculated in isolation from changes in other assumptions. In practice, changes in assumptions may offset each other or be additive, and it is likely that Lumos management would respond to an adverse change in one item to seek to minimise the net effect on Lumos' earnings and cash flow.

For the purpose of the sensitivity analysis in Table 4.12, each sensitivity is presented in terms of the impact on 2H21F pro forma forecast revenue and gross profit.

Table 4.12: Sensitivity analysis on pro forma forecast revenue and gross profit for FY21F

		Increase/ Decrease	Revenue		Gross Profit	
A$('000)	**Notes**		**+**	**–**	**+**	**–**
Change in AUD/USD FX rate	1	+/- 5%	$643	$581	$286	$259
		+/- 10%	$1,357	$1,110	$603	$494
Change in contract manufacturing volumes	2	+/- 5%	$178	$178	$82	$82
		+/- 10%	$357	$357	$163	$163

Sensitivities have been applied to 2H21F only.

Notes:

1. FX sensitivities applied to the AUD0.78/USD1.00 used in the Forecast Financial Information.
2. Contract manufacturing volumes commenced in 2H21F.

4.8. Management discussion and analysis of Pro Forma Financial Information

4.8.1. General factors affecting the operating and financial performance, including key measures and their drivers

This Section 4.8. sets out the main factors affecting Lumos' operating and financial performance in FY19, FY20, 1H20 and 1H21, and a general discussion underpinning the FY21F forecast. Comments relating to the forecast financial performance in FY21F should be read in conjunction with the key forecast assumptions set out in Sections 4.6.1 and 4.6.2. The discussion of these factors is intended to provide a summary only and does not detail all the factors that affected Lumos' historical operating and financial performance, nor everything which may affect Lumos' operating and financial performance in the future.

Unless otherwise stated, all metrics and financial information presented in this Section and the related commentary is on a pro forma adjusted basis only.

The information in this Section 4.8 should also be read in conjunction with the general and specific assumptions in Sections 4.6.1 and 4.6.2, the sensitivities in Section 4.7, key risk factors set out in Section 5 and the other information contained in this Prospectus.

This discussion of general factors is followed by a year-on-year discussion in Section 4.8.10 (FY20 compared to FY19), 4.8.11 (FY21F compared to FY20) that outline factors discrete to the relative periods presented. Section 4.8.10 also contains a discussion of 1H21 compared to 1H20 that outline factors discrete to that comparison.

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4.8.2. Key financial metrics

Table 4.13 below sets out a summary of Lumos' key historical operating metrics for FY19 and FY20 derived from the Pro Forma Historical Results, and the key pro forma forecast operating metrics for FY21 derived from the Pro Forma Forecast Results.

Table 4.13: Key financial metrics

		Pro Forma Historical		Pro Forma Forecast
Financial metrics	**Notes**	**FY19**	**FY20**	**FY21F**
Pro forma revenue growth (%)	1	*n.a.*	*29.7%*	*183.0%*
Products revenue as a % of total revenue	2	*3.8%*	*5.9%*	*12.2%*
Commercial Services revenue as a % of total revenue	2	*96.2%*	*94.1%*	*87.8%*
Pro forma gross margin (%)	3	*34.9%*	*37.9%*	*47.3%*
Sales and marketing expenses % of revenue	4	*43.1%*	*31.3%*	*13.5%*
General and administrative expenses % of revenue	4	*156.6%*	*187.1%*	*86.5%*
Research and development expenses % of revenue	4	*4.9%*	*30.3%*	*8.6%*

Notes:

1. **Pro forma revenue growth (%)**: Calculated as the year on year (YoY) movement in revenue divided by the prior year revenue, expressed as a percentage.
2. **Products revenue/Commercial Services revenue as a % of total revenue**: Calculated by using Products revenue/Commercial Services revenue divided by the pro forma total revenue, expressed as a percentage.
3. **Pro forma gross margin (%)**: Calculated by deducting cost of sales from pro forma total revenue, and dividing the result by the pro forma total revenue, expressed as a percentage.
4. **Sales and marketing/general and administrative/research and development expenses % of revenue**: Relates to sales and marketing expense, general and administrative expense and research and development expense divided by the pro forma revenue, expressed as a percentage.

Table 4.14 below sets out a summary of Lumos' key historical operating metrics for 1H20 and 1H21 derived from the Pro Forma Historical Results.

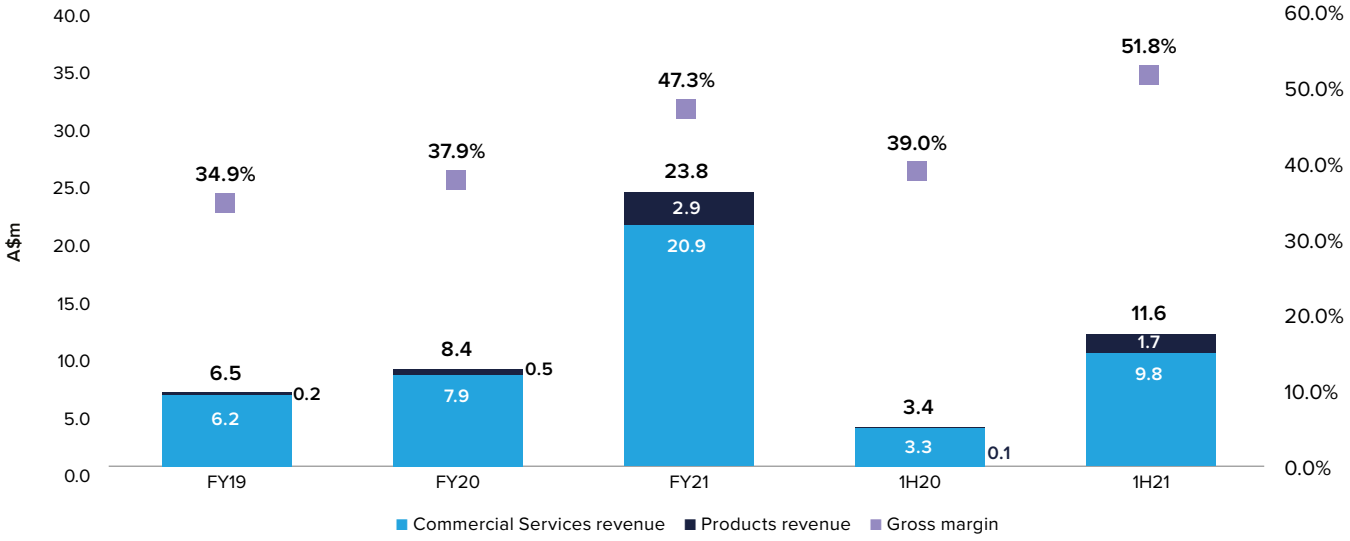
Table 4.14: Key financial metrics

		Pro Forma Historical	
Financial metrics	**Notes**	**1H20**	**1H21**
Pro forma revenue growth (%)	1	n.a.	239.0%
Products revenue as a % of total revenue	2	3.0%	14.9%
Commercial Services revenue as a % of total revenue	2	97.0%	85.1%
Pro forma gross margin (%)	3	39.0%	51.8%
Sales and marketing expenses % of revenue	4	15.4%	12.7%
General and administrative expenses % of revenue	4	71.1%	79.4%
Research and development expenses % of revenue	4	13.5%	8.0%

Refer to Table 4.13 for the notes relating to Table 4.14.

4.8.3. Revenue

Figure 4.1: FY19 to FY21F and 1H20, 1H21 pro forma revenue by division and gross margin



Lumos derives its revenue from Products revenue and Commercial Services revenue as further described below:

Commercial Services revenue

- **Fee for service**: Revenue is generated by consulting services offered to clients in the healthcare industry. Revenue is recognised based on actual time spent by an employee on a project for that month, at an agreed rate. Deposits are paid prior to project commencement and recognised as unearned income, typically released as revenue at the first project invoice. If the deposit is not consumed by the first invoice, unearned income will be released in the following invoice.
- **Material**s: Revenue associated with materials used by Lumos in fee for service activities which are charged to clients at cost plus an agreed mark-up in the month used.
- **Contract manufacturing**: Revenue generated from contract manufacturing arrangements that have a set price per contract, with revenue recognised at the point of product delivery, generally ex-works, representing the transfer of title.

Products revenue

- **FebriDx®**: FebriDx® revenue is recognised when shipped to various global distributors. Distributors initiate FebriDx® orders through a purchase order for prospective delivery. FebriDx® orders require an upfront deposit that is recognised as unearned income. On product shipment, generally ex-works, the deposit is recognised as revenue.
- **Other product**s: Revenue is generated from sales of other products, for example sales of the Leelu reader to research organisations, and from sales of CoviDx™, typically based on monthly minimum contracted volumes at agreed prices.

Lumos' revenue increased 29.7% in FY20 from FY19 predominantly as a result of an increase in Commercial Services revenue which increased from $6.2m in FY19 to $7.9m in FY20 (refer Section 4.8.10.1 for further detail). FY21F revenue is forecast to increase by 183.0% from FY20 as a result of an increase in Commercial Services revenue from $7.9m to $20.9m including revenue from the commencement of contract manufacturing, and Products revenue is forecast to grow from $0.5m to $2.9m (refer Section 4.8.11.1 for further detail). Revenue increased 239.0% in 1H21 from 1H20 primarily as a result of increased Commercial Services revenue from $3.3m to $9.8m and an increase in Products revenue from $0.1m to $1.7m (refer Section 4.8.10.1 for further detail).

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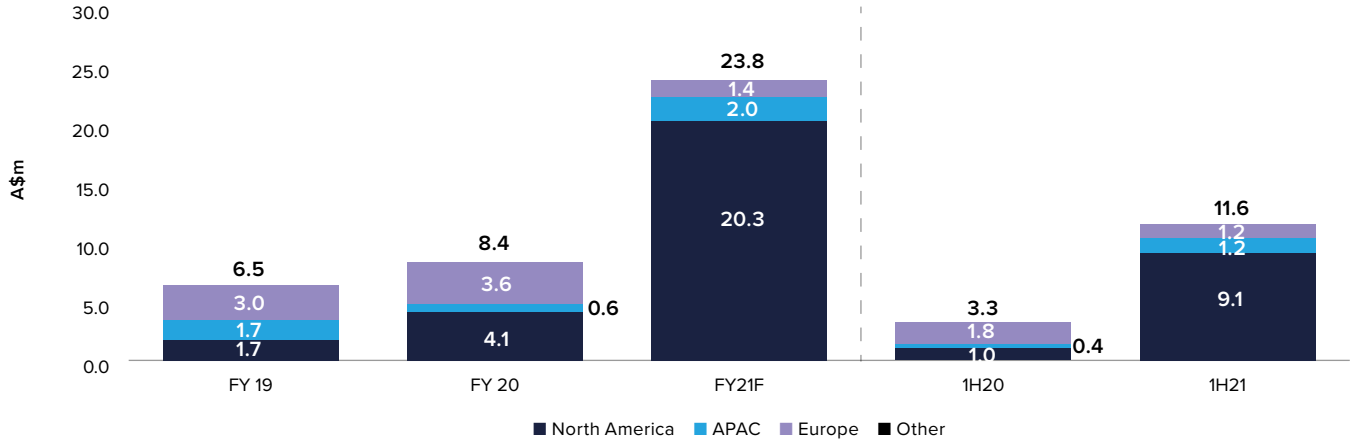
Figure 4.2: FY19 to FY21 and 1H20, 1H21 pro forma revenue by region

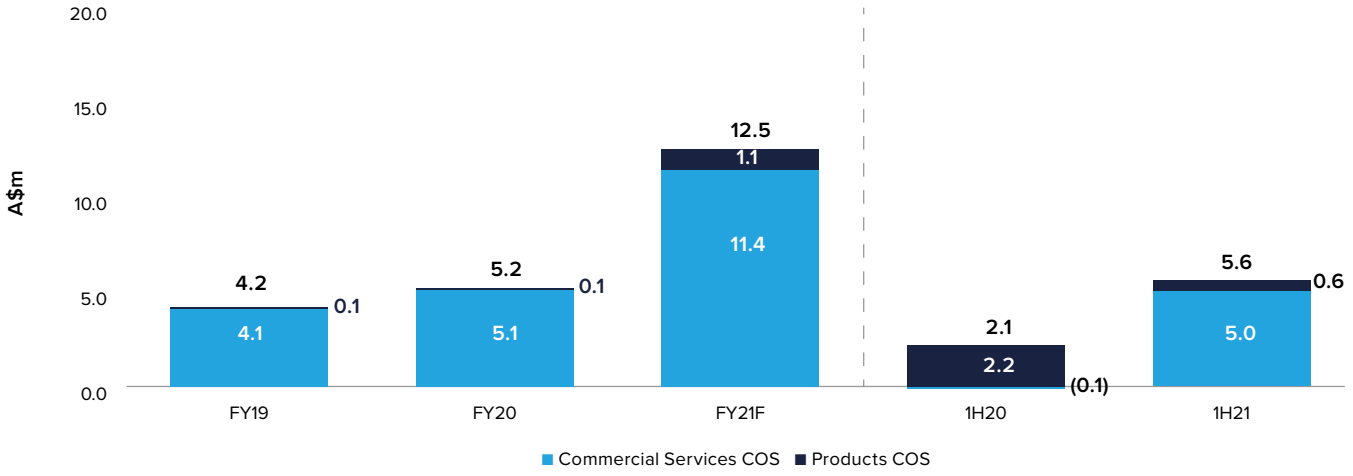


Note: Other revenue numbers not illustrated in Figure 2, being less than $0.2m in each period.

Lumos' revenue is predominately generated from North American clients and is forecast to represent approximately 85.3% of total pro forma revenue in FY21F, up from approximately 48.4% in FY20 and approximately 26.0% in FY19. The increase in FY21F is principally as a result of increased Commercial Services revenue from North American clients including from the commencement of contract manufacturing (refer Section 4.8.11.1 for further details). North America contributed approximately 78.5% of total pro forma revenue in 1H21, up from approximately 31.2% in 1H20 predominately as a result of increased Commercial Services revenue. Revenue from European and APAC clients is principally derived from the Commercial Services division.

4.8.4. Cost of sales

Figure 4.3: FY19 to FY21F and 1H20, 1H21 pro forma cost of sales



Note: The 1H20 gross margin was impacted by the volatility of early FebriDx® production volumes and an adjustment in inventory value that resulted in a lower cost of sales.

The main factors driving Lumos' cost of Sales include:

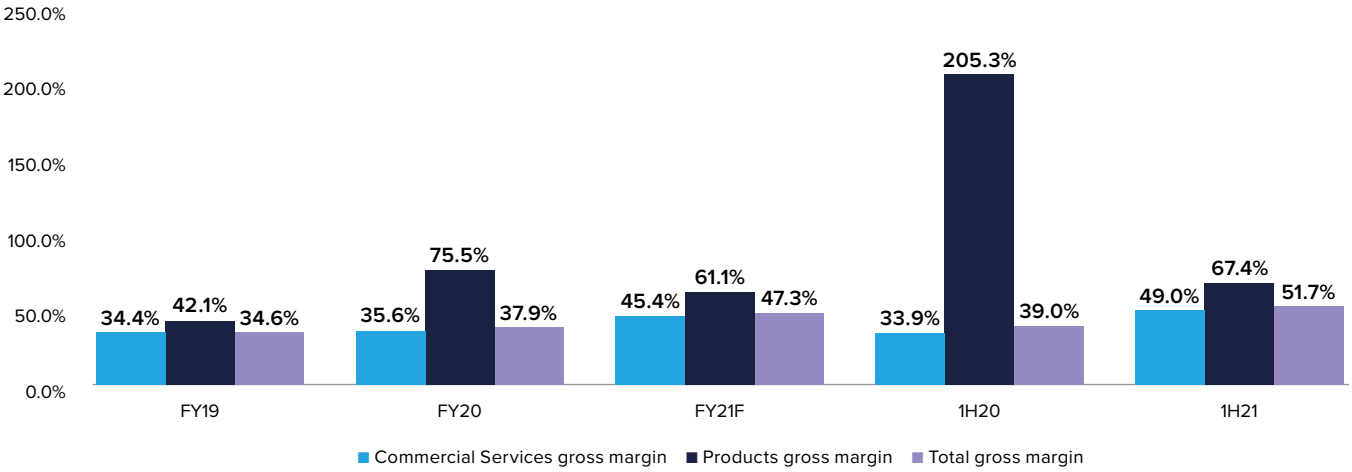
- **Fee for service**: Fee for service costs of sales relate to the labour costs associated with the provision of these services. Lumos utilises both its own internal labour resources as well as labour resources provided by Planet Innovation under the Planet Innovation MSAs.
- **Materials**: Materials cost of sales include direct materials that are utilised in fulfilling the provision of Commercial Services.
- **Contract manufacturing**: Contract manufacturing cost of sales includes direct materials and packaging costs as well as direct labour costs associated with the assembly of client products. Cost of sales also includes an allocation of indirect labour and other overheads.
- **FebriDx®**: FebriDx® cost of sales includes direct materials costs as well as direct labour costs associated with the assembly of the product. Cost of sales also includes an allocation of indirect labour and other overheads.
- **Other products**: Other products cost of sales includes direct materials costs as well as direct labour costs associated with the assembly or other products. Cost of sales also includes an allocation of indirect labour and other overheads.

Pro forma cost of sales increased from $4.2m in FY19 to $5.2m in FY20 and are forecast to increase further to $12.5m in FY21F. The increase in FY21F is principally related to additional costs incurred to support the increased Commercial Services (including the commencement of contract manufacturing) and Products revenue growth (refer to Section 4.8.11.2 for further details). Cost of sales increased from $2.1m in 1H20 to $5.6m in 1H21 which reflected the additional costs incurred to support the growth in Commercial Services and Products revenue (refer to Section 4.8.10.2 for further details).

4.8.5. Gross margin

Gross margin represents revenue less cost of sales expressed as a percentage.

Figure 4.4: FY19 to FY21F and 1H20, 1H21 pro forma gross margin by division



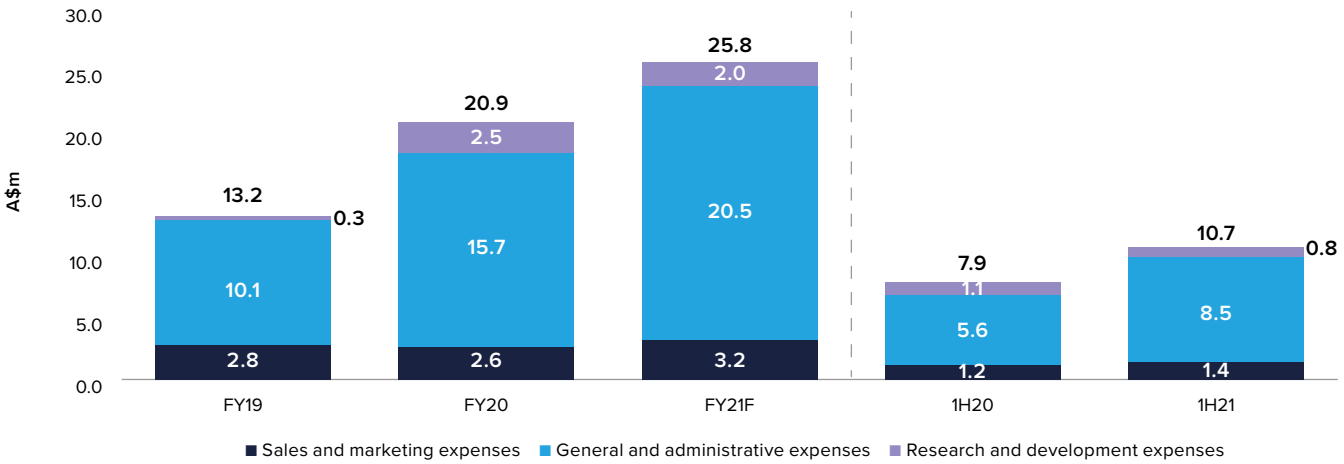
Note: The 1H20 gross margin was impacted by the volatility of early FebriDx® production volumes and an abnormal adjustment in inventory value that resulted in a lower cost of sales.

The main factors affecting gross margins are discussed above in 4.8.3 and 4.8.4. A discussion on the trends in the gross margin over time is discussed in 4.8.10.2 and 4.8.11.2.

4.8.6. Operating expenses

4.8.6.1 Overview

Figure 4.5: FY19 to FY21F and 1H20, 1H21 pro forma operating expenses by function



Operating expenses have grown progressively from FY19 to FY20 and are forecast to grow further in FY21F, principally as a result of an increase in staff cost within general & administrative expenses (refer Section 4.8.11.3) as the business is scaled for growth.

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4.8.6.2 General and administrative expenses

Table 4.15: FY19 to FY21F and 1H20, 1H21 breakdown of general and administrative expenses

A$(m)	Pro Forma Historical		Pro Forma Forecast	Pro Forma Historical	
June year-end	FY19	FY20	FY21F	1H20	1H21
Administrative overhead	10,061	10,006	13,358	4,034	6,436
Manufacturing overhead	–	692	3,692	229	609
Clinical and quality overhead	83	5,013	3,499	1,327	1,431
General and administrative expenses	**10,144**	**15,711**	**20,549**	**5,589**	**8,476**

Below are some observations on movements in general and administrative expenses in key categories:

Administrative overhead:

Administrative overhead includes the administration and finance cost centres in Sarasota, Carlsbad and Melbourne as well as listed company costs. The administrative and finance costs are principally personnel costs including share-based payments as well as consultants and external advisor costs for regulatory matters, government and public relations and management fees paid to Planet Innovation. The administrative overhead in FY20 of $10.0m stayed consistent from FY19 but is forecast to increase to $13.4m in FY21F as a result of a broad-based performance bonus of approximately $1.4m accrued in FY21F and an increase of internal finance and administration headcount from 6 to 17. Lumos has forecast to build out its internal resources consistent with the increase in operational activities and begins to undertake additional activities in-house including finance and human resources rather than contracting Planet Innovation to perform them. The build-up of internal finance and administration resources also contributed to an increase in administrative overhead from $4.0m in 1H20 to $6.4m in 1H21.

Manufacturing overhead:

Manufacturing overhead expenses of $0.7m were incurred in FY20 as production of FebriDx® commenced and Lumos incurred pre-launch costs associated with the establishment of contract manufacturing client products. The forecast increase to $3.7m in FY21F principally relates to the build-up of manufacturing capacity at the new facility in Sarasota (refer to Section 3.7). This investment to increase manufacturing capacity is being made to prepare for an expected increase in demand for FebriDx®, other products and contract manufacturing for third parties. It is expected that the facilities in Sarasota and Carlsbad will have manufacturing capacity of approximately 10m units per month by June 2021. The increase in manufacturing overhead from $0.2m in 1H20 to $0.6m in 1H21 related to the initial stages of manufacturing capacity build-up at the new Sarasota facility.

Clinical and quality overhead:

Clinical and quality overhead principally includes personnel and third-party costs as well as materials and consumables associated with product validation and clinical trials. The increase from $0.1m in FY19 to $5.0m in FY20 was predominately due to approximately $3.0m in clinical trial expenses associated with FebriDx® trials. The forecast decrease in clinical and quality overhead in FY21F primarily relates to a reduction in clinical trial expenses of approximately $1.0m as a result of lower patient recruitment for the FebriDx® trials. Clinical and quality overhead remained relatively flat at $1.4m in 1H21 compared to 1H20.

4.8.6.3 Sales and marketing expenses

Table 4.16: FY19 to FY21F and 1H20, 1H21 sales and marketing expenses

A$(m)	Pro Forma Historical		Pro forma Forecast	Pro Forma Historical	
June year-end	FY19	FY20	FY21F	1H20	1H21
Sales and marketing expenses	2,791	2,629	3,218	1,210	1,352

Sales and marketing expenses remained relatively flat in FY20 relative to FY19 and are forecast to grow to $3.2m in FY21F as Lumos focuses on market development activities in Europe, investing in increased personnel and marketing communication materials. Sales and marketing expenses increased to $1.4m in 1H21 as Lumos began to focus on market development activities in Europe.

4.8.6.4 Research and development expenses

Table 4.17: FY19 to FY21F and 1H20, 1H21 research & development expenses

A$(m)	Pro Forma Historical		Pro Forma Forecast	Pro Forma Historical	
June year-end	FY19	FY20	FY21	1H20	1H21
Research and development expenses	316	2,541	2,041	1,062	849

Research and development expenses principally relate to personnel costs. These costs increased from $0.3m in FY19 to $2.5m in FY20 due to increased expenditure on assay development associated with the FebriDx® digital reader. Research and development expenses are forecast to decrease in FY21F to $2.0m due to a lower expenditure profile on the FebriDx® digital reader and the development of a broader set of diagnostic tests. These factors also contributed to the decrease in research and development expenses in 1H21 compared to 1H20. Research and development expenses in operating expenses exclude reader development costs which are capitalised in accordance with Lumos' research and development policy (refer to Appendix A).

4.8.7. EBITDA before non-operating items and EBITDA

Table 4.18: FY19 to FY21F and 1H20, 1H21 EBITDA before non-operating items and EBITDA

A$(m)	Pro Forma Historical		Pro forma Forecast	Pro Forma Historical	
June year-end	FY19	FY20	FY21F	1H20	1H21
EBITDA before non-operating items	(10,991)	(17,697)	(14,523)	(6,530)	(4,696)
Non-operating income/expenses	105	14	(141)	15	151
EBITDA	**(10,885)**	**(17,683)**	**(14,663)**	**(6,515)**	**(4,545)**

EBITDA before non-operating items is a key non-IFRS measure used by Lumos to assess operating profitability. Non-operating income/expenses include items that Lumos considers to be outside its core operating activities. It comprises items that are considered non-operating by Lumos, including export market development government grants as well as other one-off project and advisory costs.

The main factors affecting EBITDA before non-operating items and EBITDA are discussed in Sections 4.8.3, 4.8.4 and 4.8.6.

4.8.8. Operating cash flows

Table 4.19: FY19 to FY21F and 1H20, 1H21 Operating cash flows

A$(m)	Pro Forma Historical		Pro forma Forecast	Pro Forma Historical	
June year-end	FY19	FY20	FY21F	1H20	1H21
EBITDA before non-operating items	(11,127)	(17,697)	(14,570)	(6,530)	(4,696)
Adjustments to EBITDA	1,041	1,380	1,209	–	879
Non-operating income/expenses	105	14	151	10	151
Changes in working capital	1,839	762	1,238	(32)	(2,423)
Operating cash flow	**(8,143)**	**(15,541)**	**(11,972)**	**(6,551)**	**(6,089)**

Operating cash flows are affected by the level of EBITDA in the period (including non-operating revenue/expenses) as well as adjustments to EBITDA relating to non-cash items (share-based payments, bad debts, inventory write downs/write backs and foreign currency translation gains/(losses)) and changes in working capital (trade receivables, trade payables, inventory levels, prepayments, accrued income, unearned income and employee provisions).

Further discussion of specific factors affecting operating cash flows is provided in Sections 4.8.12 and 4.8.13.

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4.8.9. Capital expenditure and capitalised development costs

Table 4.20: FY19 to FY21F and 1H20, 1H21 capital expenditure and capitalised development costs

Capital expenditure relates to payment for property, plant and equipment as well as costs associated with the new Sarasota facility including manufacturing automation. Capitalised development costs comprise personnel costs associated with the development of reader formats. These personnel costs are incurred by Planet Innovation and included in this table on the basis that the Amended Planet Innovation MSA (to commence on 1 July 2021) had been in place over the Historical Period.

A$(m)	Pro Forma Historical		Pro forma Forecast	Pro Forma Historical	
June year-end	FY19	FY20	FY21F	1H20	1H21
Capital expenditure	920	438	10,756	248	5,336
Capitalised development costs	4,270	5,606	3,442	2,461	1,733
Capital expenditure and capitalised development costs	**5,190**	**6,043**	**14,198**	**2,709**	**7,069**

4.8.10. Pro Forma Historical Results for FY20 compared to FY19, and 1H21 compared to 1H20

Table 4.21: Pro Forma Historical Results Comparison of FY19 to FY20 and 1H20 to 1H21 for FY20 compared to FY19, and 1H21 compared to 1H20

A$(m)		Pro Forma Historical			Pro Forma Historical		
June year-end	Notes	FY19	FY20	% change	1H20	1H21	% change
Products revenue	1	244	499	104.8%	102	1,721	1,581.6%
Commercial Services revenue		6,231	7,898	26.8%	3,307	9,836	197.4%
Revenue		**6,474**	**8,396**	**29.7%**	**3,409**	**11,557**	**239.0%**
Cost of sales	2	(4,217)	(5,211)	23.6%	(2,078)	(5,576)	168.3%
Gross profit		2,257	3,186	41.1%	1,331	5,981	349.4%
Sales and marketing expenses	3	(2,791)	(2,629)	(5.8%)	(1,210)	(1,352)	11.7%
General and administrative expenses	4	(10,142)	(15,713)	54.9%	(5,589)	(8,475)	51.7%
Research and development expenses	5	(316)	(2,541)	705.3%	(1,062)	(849)	(20.1%)
Total operating expenses		**(13,248)**	**(20,883)**	**57.6%**	**(7,861)**	**(10,676)**	**35.8%**
EBITDA before non-operating items		**(10,991)**	**(17,697)**	**61.0%**	**(6,530)**	**(4,696)**	**(28.1%)**
Non-operating income/expenses		105	14	(86.9%)	15	151	891.1%
EBITDA		**(10,885)**	**(17,683)**	**62.5%**	**(6,515)**	**(4,545)**	**(30.2%)**
Depreciation		(290)	(362)	24.7%	(234)	(164)	(29.9%)
Amortisation		(502)	(323)	(35.6%)	(208)	(100)	(51.6%)
EBIT		**(11,677)**	**(18,368)**	**57.3%**	**(6,956)**	**(4,809)**	**(30.9%)**
Net finance costs		(14)	(13)	(8.7%)	39	(170)	(540.5%)
Profit (loss) before taxation		**(11,691)**	**(18,381)**	**57.2%**	**(6,918)**	**(4,980)**	**(28.0%)**
Income tax (expense)/benefit		–	86	n.a.	–	–	–
Net profit/(loss) after tax		**(11,691)**	**(18,295)**	**56.5%**	**(6,918)**	**(4,980)**	**(28.0%)**
Other comprehensive income, net of tax		98	(74)	(175.8%)	(52)	(997)	1,813.2%
Total comprehensive income		**(11,593)**	**(18,369)**	**58.4%**	**(6,970)**	**(5,977)**	**(14.2%)**

Refer to Table 4.2 for the notes relating to Table 4.21.

4.8.10.1 Revenue

FY19 v FY20

Revenue increased from $6.5m in FY19 to $8.4m in FY20, an increase of 29.7%. Products revenue increased 104.8% from $0.2m in FY19 to $0.5m in FY20 to represent 5.9% of total pro forma revenue. Commercial Services revenue increased 26.8% from $6.2m in FY19 to $7.9m in FY20. The increase in revenue was driven by the following factors:

- **Fee for service**: Fee for service revenue increase from $5.8 to $6.3m, driven principally by the maturity of existing development contracts, and the early stages of new programs with North American clients.
- **Materials**: Materials revenue increase from $0.4m to $1.6m, in-line with higher activity in mature development projects preparing for transfer to manufacture.
- **FebriDx®**: FebriDx® revenue increased from $0.1m to $0.4m reflecting early sales activity in the UK.

1H20 v 1H21

Revenue increased from $3.4m in 1H20 to $11.6m in 1H21, an increase of 239.0%. Products revenue increased 1,581.6% from $0.1m in 1H20 to $1.7m in 1H21 to represent 14.9% of total pro forma revenue. Commercial Services revenue increased 197.4% from $3.3m in 1H20 to $9.8m in 1H21. The increase in revenue was driven by the following factors:

- **Fee for service**: Fee for service revenue increased from $2.8m to $8.2m, driven principally by the maturity of existing development contracts, new larger projects and increased activity with North American clients including those focussing on novel COVID-19 tests.
- **Materials**: Materials revenue increase from $0.5m to $1.6m, in-line with higher activity in mature development projects preparing for transfer to manufacture and an increase in the number of development projects.
- **FebriDx®**: FebriDx® revenue increased from $0.0m to $1.6m primarily as a result of initial sales into the Canadian market.

4.8.10.2 Cost of sales, gross profit and gross margin

FY19 v FY20

Gross profit increased from $2.3m in FY19 to $3.2m in FY20, and gross margin increased from 34.9% to 37.9%. The increase in gross profit was driven by the following factors:

- **Commercial Services**: Commercial Services gross profit increased from $2.1m in FY19 to $2.8m in FY20, and gross margin increased from 34.4% to 35.6% with the increase in cost of sales consistent with the increase in revenue in the period.
- **Products**: Products gross profit increased from $0.1m in FY19 to $0.4m in FY20, and gross margin increased from 42.1% to 75.5% reflecting the volatility of early FebriDx® production volumes and an abnormal adjustment in inventory value that resulted in a lower cost of sales.

1H20 v 1H21

Gross profit increased from $1.3m in 1H20 to $6.0m in 1H21, and gross margin increased from 39.0% to 51.8%. The increase in gross profit was driven by the following factors:

- **Commercial Services**: Commercial Services gross profit increased from $1.1m in 1H20 to $4.8m in 1H21, and gross margin increased from 33.9% to 49.0% driven by higher staff utilisation from increased fee for service work and an increase in fee rates from higher client demand with larger projects.
- **Products**: Products gross profit increased from $0.2m in 1H20 to $1.2m in 1H21. As described above, the 1H20 gross margin was impacted by the volatility of early FebriDx® production volumes and an abnormal adjustment in inventory value that resulted in a lower cost of sales.

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4.8.10.3 Operating expenses

FY19 v FY20

Operating expenses increased from $13.2m in FY19 to $20.9m in FY20, an increase of 57.6%. The main factors driving this increase include:

- **Sales and marketing**: Sales and marketing expenses remained relatively stable at $2.6m in FY20 reflecting stable headcount and limited sales and marketing investments in North America in FY20.
- **General and administrative**: General and administrative expenses increased 54.9% to $15.7m in FY20 as a result of:
  - **Administrative overhead**: Administrative overhead remained flat in FY20 at $10.0m reflecting a stable headcount.
  - **Manufacturing overhead**: Manufacturing overhead of $0.7m was first incurred in FY20 as Lumos expensed manufacturing establishment costs supporting the early sales of FebriDx®.
  - **Clinical and quality overhead**: Clinical and quality overhead increased from $0.1m in FY19 to $5.0m in FY20 as a result of significant clinical trial activity in the U.S. for FebriDx®.
- **Research and development**: Research and development expenses increased from $0.3m in FY19 to $2.5m in FY20 due to an increase in investment in assay development associated with the FebriDx® digital reader.

1H20 v 1H21

Operating expenses increased from $7.9m in 1H20 to $10.7m in 1H21, an increase of 35.8%. The main factors driving this increase include:

- **Sales and marketing**: Sales and marketing expenses increased 11.7% from $1.2m in 1H20 to $1.4m in 1H21 as a result of increased headcount and marketing activity in North America.
- **General and administrative**: General and administrative expenses increased from $5.6m in 1H20 to $8.5m in 1H21, principally as **a result of higher administrative overhead costs.**
  - **Administrative overhead**: Administrative overhead expenses increased from $4.0m to $6.4m due to an increase of internal finance and administration headcount (from 4 to 9) as well as expenses associated with outsourcing of certain finance and company secretary functions. This occurred as Lumos began to build out its internal resources consistent with the increase in operational activities and began to undertake additional activities in-house including within finance and human resources rather than contracting Planet Innovation to perform them.
  - **Manufacturing overhead**: Manufacturing overhead increased from $0.2m in 1H20 to $0.6m in 1H21 reflecting increased activity associated with FebriDx® sales and the establishment of Contract Manufacturing for Commercial Services division clients.
  - **Clinical and quality overhead**: Clinical and quality overhead remained relatively stable in 1H21 at $1.4m.
- **Research and development**: Research and development expenses decreased from $1.1m in 1H20 to $0.8m in 1H21 as a result of lower expenditure on the FebriDx® digital reader.

4.8.11. Pro Forma Forecast Results for FY21F compared to FY20

Table 4.22: Pro Forma Forecast Results for FY21F compared to FY20

A$('000)		Pro forma Historical	Pro forma Forecast	
June year-end	Notes	FY20	FY21F	% change
Products revenue	1	499	2,907	482.5%
Commercial Services revenue		7,898	20,859	164.1%
Revenue		**8,396**	**23,765**	**183.0%**
Cost of sales	2	(5,211)	(12,528)	140.4%
Gross profit		**3,186**	**11,238**	**252.7%**
Sales and marketing expenses	3	(2,629)	(3,218)	22.4%
General and administrative expenses	4	(15,713)	(20,549)	30.8%
Research and development expenses	5	(2,541)	(2,041)	(19.7%)
Total operating expenses		**(20,883)**	**(25,808)**	**23.6%**
EBITDA before non-operating items		**(17,697)**	**(14,570)**	**(17.7%)**
Non-operating income/expenses		14	(141)	(1,118.6%)
EBITDA		**(17,683)**	**(14,711)**	**(16.8%)**
Depreciation		(362)	(508)	40.3%
Amortisation		(323)	(597)	84.9%
EBIT		**(18,368)**	**(15,816)**	**(13.9%)**
Net finance costs		(13)	(156)	1,141.6%
Profit (loss) before taxation		**(18,381)**	**(15,972)**	**(13.1%)**
Income tax (expense)/benefit		86	–	(100.0%)
Net profit/(loss) after tax		**(18,295)**	**(15,972)**	**(12.7%)**
Other comprehensive income, net of tax		(74)	–	(100.0%)
Total comprehensive income		**(18,369)**	**(15,972)**	**(13.0%)**

Refer to Table 4.2 for the notes relating to Table 4.22.

4.8.11.1 Revenue

Revenue is forecast to increase from $8.4m in FY20 to $23.8m in FY21F, an increase of 183.0%. Products revenue is forecast to increase 482.5% from $0.5m in FY20 to $2.9m in FY21F to represent 12.2% of total pro forma revenue. Commercial Services revenue is forecast to increase 164.1% from $7.9m in FY20 to $20.9m in FY21F. The forecast increase in revenue is driven by the following factors:

- **Fee for service**: Fee for service revenue is forecast to increase 124.6% from $6.3m in FY20 to $14.2m in FY21F (with 57.7% of this revenue earned in 1H21) as a result of an increased fee for service pipeline related to assay development projects, digital reader development projects and transfer to manufacturing projects.
- **Materials**: Materials revenue is forecast to increase from $1.6m in FY20 to $3.1m in FY21F (with 53.0% of this revenue earned in 1H21) in-line with the increased fee for service activity.
- **Contract manufacturing**: Contract manufacturing commenced in FY21F and is forecast to generate $3.6m in FY21F Contract manufacturing sales are based on purchase orders with agreed selling prices supported by contracted monthly minimum volumes. Volumes relate to the manufacture and supply of readers and diagnostic tests for Commercial Services clients.
- FebriDx®: FebriDx® revenue is forecast to increase from $0.4m in FY20 to $1.8m in FY21F (with 90.2% of this revenue earned in 1H21) as a result of increased sales into the UK market and initial sales into Canada.
- **Other products**: Other products revenue is forecast to increase from $0.1m in FY20 to $1.1m in FY21F (with 9.7% of this revenue earned in 1H21) principally due to initial sales of the CoviDx™ product with volumes based on purchase orders in hand with agreed selling prices.

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4.8.11.2 Cost of sales, gross profit and gross margin

Pro forma gross profit is forecast to increase from $3.2m in FY20 to $11.2m in FY21F, and gross margin is forecast to increase from 37.9% to 47.3%. The increase in gross profit is forecast to increase based on the following factors:

- **Commercial Services**: Commercial Services gross profit is forecast to increase from $2.8m in FY20 to $9.5 in FY21F, representing an increase in gross margin from 35.6% to 45.4%. This increase in gross margin reflects increased staff utilisation, larger projects and higher demand for Lumos' POC diagnostic test development capabilities, and the resulting ability to charge higher rates for its services.
- **Products**: Products gross profit is forecast to increase from $0.4m in FY20 to $1.8m in FY21F, whilst there is a forecast decrease in gross margin from 75.5% to 61.1%. The decrease in gross margin in FY21F is as a result of the absence of any abnormal inventory adjustments as well as an increase in allocation of manufacturing overhead in FY21F coinciding with the forecast increase in Products revenue.

4.8.11.3 Operating expenses

Operating expenses are forecast to increase 23.6% from $20.9m in FY20 to $25.8m in FY21F as a result of:

- **Sales and marketing**: Sales and marketing expenses are forecast to increase 22.4% in FY21F to $3.2m primarily as a result of growth in the sales team (from 4 to 10).
- **General and administrative**: General and administrative expenses are forecast to increase 30.8% in FY21F to $20.6m:
  - **Administrative overhead**: Administrative overhead costs are forecast to increase from $10.0m in FY20 to $13.4m in FY21F as a result of an increase of internal finance and administration headcount (from 6 to 17) due to Lumos bringing finance and human resources in-house having previously been provided by Planet Innovation. FY21F administrative overhead costs also include a provision for short-term incentive payment of $1.4m which represents 100% of on-target performance.
  - **Manufacturing overhead**: Manufacturing overhead is forecast to increase from $0.7m in FY20 to $3.7m in FY21F, consistent with the increase in manufacturing establishment activity across both the Products and Commercial Services divisions.
  - **Clinical and quality overhead**: Clinical and quality overhead is forecast to decrease from $5.0m in FY20 to $3.5m in FY21F primarily due to a reduction in clinical trial expenses of approximately $1.0m as a result of lower patient recruitment for the FebriDx® trials.
- **Research and development**: Research and development expenses are forecast to decrease from $2.5m in FY20 to $2.0m in FY21F as a result of lower expenditure on assay development associated with the FebriDx® digital reader.

4.8.12. Pro Forma Historical Cash Flows for FY20 compared to FY19, and 1H21 compared to 1H20

Table 4.23: Summary of Pro Forma Historical Cash Flows for FY20 compared to FY19, and 1H21 compared to 1H20

A$('000)		Pro Forma Historical			Pro Forma Historical		
June year-end	Notes	FY19	FY20	% change	1H20	1H21	% change
EBITDA before non-operating items		(11,127)	(17,697)	59.0%	(6,530)	(4,696)	(28.1%)
Adjustments to EBITDA	1	1,041	1,380	32.6%	–	879	–
Non-operating income/expenses		105	14	(86.9%)	10	151	1,344.1%
Changes in working capital	2	1,839	762	(58.5%)	(32)	(2,423)	7,458.0%
Operating cash flow		**(8,143)**	**(15,541)**	**90.9%**	**(6,551)**	**(6,089)**	**(7.1%)**
Capital expenditure		(920)	(438)	(52.4%)	(248)	(5,336)	2,053.5%
Payments for purchase of business, net of cash acquired	3	–	–	–	–	–	–
Payments for investment		(271)	–	(100.0%)	(33)	–	(100.0%)
Capitalised development costs	4	(4,270)	(5,606)	31.3%	(2,461)	(1,733)	(29.6%)
Free cash flow		**(13,603)**	**(21,584)**	**58.7%**	**(9,293)**	**(13,159)**	**41.6%**

Refer to Table 4.7 for the notes relating to Table 4.23.

FY19 v FY20

Pro forma operating cash flow decreased from ($8.1m) in FY19 to ($15.5m) in FY20. The main factors contributing to the decrease include:

- **EBITDA before non-operating items**: EBITDA before non-operating items increase from ($11.1m) in FY19 to ($17.7m) in FY20 as a result of the factors affecting revenue, gross profit and operating expenses described above.
- **Adjustments to EBITDA**: Adjustments to EBITDA increased from $1.0m in FY19 to $1.4m in FY20 primarily as a result of increased share-based payments.
- **Changes in working capital**: Changes in working capital decreased from $1.8m in FY19 to $0.8m in FY20 consistent with the increase in activities across both Products and Commercial Services.

Pro forma free cash flow in FY20 of ($21.6m) was lower than ($13.6m) in FY19 principally due to the higher operating cash outflow described above as well an increased capitalised development costs of $1.3m, primarily related to further investment in the Lumos reader formats.

1H20 v 1H21

Pro forma operating cash flow of ($6.1m) in 1H21 were in-line with the ($6.6m) recorded in 1H20 which was a result of:

- **EBITDA before non-operating items**: EBITDA before non-operating items increased from ($6.5m) in 1H20 to ($4.7m) in 1H21 as a result of the factors affecting revenue, gross profit and operating expenses described above.
- **Changes in working capital**: Changes in working capital decreased from ($0.0m) in 1H20 to ($2.4m) in 1H21 primarily as a result of higher accounts receivable balances related to the increase in Commercial Services revenue.

Pro forma free cash flow in 1H21 of ($13.2m) was lower than the ($9.3m) recorded in 1H20 due mainly to capital expenditure investment in the new Sarasota facility and equipment automation of ($5.3m) to increase capacity at the facility.

4.8.13. Pro Forma Forecast Statement of Cashflows for FY21F compared to FY20

Table 4.24: Summary of Pro Forma Cash Flows for FY21F compared to FY20

A$('000)	Pro forma Historical	Pro forma Forecast	
June year-end	FY20	FY21F	% change
EBITDA before non-operating items	(17,697)	(14,570)	(17.7%)
Adjustments to EBITDA	1,380	1,209	(12.4%)
Other income	14	151	992.9%
Changes in working capital	762	1,238	62.4%
Operating cash flow	**(15,541)**	**(11,972)**	**(23.0%)**
Capital expenditure	(438)	(10,756)	2,357.9%
Capitalised development costs	(5,606)	(3,442)	(38.6%)
Free cash flow	**(21,584)**	**(26,170)**	**21.2%**

Pro forma operating cash flow is forecast to increase from ($15.5m) in FY20 to ($12.0m) in FY21F with the main factors affecting this relating to:

- **EBITDA before non-operating items**: EBITDA loss before non-operating items decreases from ($17.7m) in FY20 to ($14.6m) in FY21F as a result of the factors affecting revenue, gross profit and operating expenses described above.

Pro forma free cash flow is forecast to decrease from ($21.6m) in FY20 to ($26.2m) in FY21F due primarily to the increase in capital expenditure from ($0.4m) in FY20 to ($10.8m) in FY21F as a result of establishing the new Sarasota facility including manufacturing automation.

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4.9. Dividend policy

The payment of a dividend by Lumos, if any, is at the discretion of the Directors and will be a function of a number of factors (many of which are outside the control of the Directors), including the general business environment, the operating results, cash flows and the financial condition of Lumos, future funding requirements, capital management initiatives, taxation considerations, any contractual, legal or regulatory restrictions on the payment of dividends by the Company, and any other factors the Directors may consider relevant.

The Directors do not provide any assurance of the future level of dividends paid by the Company. The Company intends to retain future earnings to fund the development and growth of the business. The Company does not anticipate paying dividends to shareholders for the foreseeable future. Moreover, to the extent that the Company pays any dividends, its ability to pay franked dividends will be contingent on making Australian taxable profits. The Company's' Australian taxable profits may be difficult to predict, making the payment of franked dividends unpredictable.

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Introduction

There are a number of risk factors associated with Lumos and a number of general risk factors associated with an investment in the Shares. These risks may individually or in combination materially and adversely affect the future operating and financial performance of Lumos and, accordingly, the value of Shares. Many of these risks are outside the control and influence of Lumos'. There can be no guarantee that Lumos will achieve its stated objectives or that any of the forward-looking statements or projections will eventuate.

This Section 5 describes potential risks associated with Lumos' business and an investment in its Shares. It does not list every risk that may be associated with Lumos and the occurrence or consequences of some of the risks described in this Section 5 are partially or completely outside the control of Lumos. The risks have been separated into risk factors specific to an investment in Lumos, and general risk factors associated with an investment in Lumos.

All investors need to be aware that this is not an exhaustive list of risks associated with an investment in Lumos and this information needs to be considered in conjunction with all the other information disclosed in this Prospectus. The selection of risks has been based on an assessment of a combination of the probability of the risk occurring and the impact of the risk if it did occur. The assessment is based on the knowledge of the Directors and Management as at the Prospectus Date. The risks may change or other risks may emerge after that date.

Before applying for Shares, you should review this Prospectus carefully and in its entirety, and satisfy yourself that you have a sufficient understanding of the risks involved in making an investment in Lumos and whether it is a suitable investment, having regard to your investment objectives, financial circumstances and taxation position. It is recommended that you seek professional guidance from your financial adviser, stockbroker, lawyer, accountant or other independent professional adviser before deciding whether to invest.

5.1. Risks specific to an investment in Lumos

5.1.1. 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.

For example, as described in Section 2.7, Lumos has obtained regulatory approvals such as CE-Mark and regulatory clearances from Health Canada and the TGA, which enable it to sell FebriDx® in initial priority markets including in Canada, Europe and the United Kingdom however FebriDx® and Lumos' other Products currently under development have not received the requisite clearances under the FDCA and as such are not currently permitted to be marketed in the United States.

Lumos' manufacturing facilities are 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. Products may also need to comply with registration and product listings, and regulations governing product labelling and manufacturing quality systems, as is required, for example, by the FDA.

A loss of these approvals, accreditations, registrations or listings (or a failure to obtain additional required clearances of this nature) would likely materially impact Lumos' ability to fulfil its contracts and produce or distribute its own Products, which would have a negative impact on Lumos' financial performance, position and prospects. Approvals or clearances could be revoked (and products recalled) for example if a product or its associated marketing failed to comply or function in accordance with that certification or applicable laws and regulations or where those approvals or clearances were temporary in nature (for example in the case of special or emergency access schemes).

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 and the success of earlier clearance or approvals may not necessarily be predictive of the success of subsequent product clearance or approval applications. All of these outcomes could materially affect Lumos' revenue growth objectives.

Regulatory authorities may change their clearance and approval policies (refer for example to Section 2.7), adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of Lumos' future products under development. New laws and regulations or changes to existing laws and regulations may also impose additional obligations on Lumos in order to maintain existing clearances or approvals, require Lumos to comply with "trail off periods" in respect of existing clearances or approvals or obtain new clearances or approvals, or prohibit or restrict Lumos from producing or distributing a particular product. These regulatory changes may adversely affect Lumos' ability to sell its products and consequently negatively impact its financial performance, position or prospects. For example, the European Union announced (as stated in Section 2.7) in 2017 that medical device regulations were changing and In-Vitro Diagnostic (IVD) manufacturers are required to update their technical documentation and processes to meet new requirements over a five-year transition period which may increase costs of compliance for Lumos.

Lumos' failure to comply with ongoing regulatory responsibilities or requirements could jeopardise Lumos' ability to produce or sell its products and result in enforcement action by the FDA, the European Union or the applicable regulatory authorities in other markets in which Lumos sells/markets its products. Such enforcement actions may include recalls or seizures of products, fines, total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current approvals, resulting in prohibitions on sales of Lumos' products; and in the most serious cases, criminal penalties. Any of the above actions could negatively impact Lumos' reputation and have an adverse effect on Lumos' operating and financial performance.

5.1.2. Reliance on Distributors

The success of Lumos' Products division relies on its ability to attract, retain, support and motivate distributors. For example, Lumos derives revenue from the sale of its FebriDx® product through distribution partnerships with Una Health and Henry Schein in the UK, with Northern Diagnostics in Canada, and with Bestbion in Germany. 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 such as Henry Schein, McKesson, Cardinal and/or Thermo to distribute FebriDx® in North America which will increase Lumos' reliance on distribution partners for its revenue.

The ability to retain Lumos' existing distributors and end clients, and the capacity to attract new distributors and clients, will be dependent on many factors including the capability, cost-effectiveness, pricing, customer support, and the value of Lumos' product offerings compared to competing products. Lumos' distributors do not exclusively sell Lumos' Products and may prefer a competing product to Lumos (for example where they are offered a better incentive to sell a competing product). If product distributors or end clients 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.

Lumos is also reliant on the success of its distributors' sales and marketing teams to adequately promote Lumos' Products, and for the distributors to promote the Products in accordance with the relevant regulatory requirements governing advertising including labelling and promotional materials. If distributors do not expend sufficient resources to promote the marketing and sales of Lumos' Products, or do not promote the Products in accordance with the relevant regulatory requirements, Lumos' operating and financial performance may be adversely affected.

5.1.3. Reliance on Commercial Services' clients

A significant portion of Lumos' revenues come from the provision of contract services for the development and manufacture of POC diagnostic tests, as described in Section 3.2.1. 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.

Lumos' Commercial Services clients and partners rely on having regulatory approved products and the sale of these products relies on obtaining or maintaining regulatory approvals or other clearances. The Commercial Services clients are responsible for obtaining and maintaining the regulatory approvals for finished products and Lumos is therefore dependent on these parties to do so. 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 Services customer's purchase volumes and consequently negatively impact Lumos' financial performance.

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Commercial Services clients are also reliant on the performance of their distributors to sell their products to end clients. If those Distributors do not expend sufficient resources to promote the marketing and sales of the Services clients' products, then this could negatively impact the revenues of Lumos' Services business.

5.1.4. Reliance on suppliers

Lumos is reliant on third party suppliers for the development and manufacture of outsourced Commercial Services 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.

If Lumos is not able to manage these risks, it may not be able to meet existing order demand, which could lead to dissatisfaction amongst distributors and end users. This may in turn have a negative impact on Lumos' ability to attract new distributors or end users if Lumos suffers any reputational damage due to supply issues. The combination of these factors could adversely impact Lumos' operating and financial performance.

5.1.5. Timing of orders and services

Lumos is expected to supply products to distributors and Commercial 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 if a client requires a change to product labelling). 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 Commercial Services clients and may adversely impact Lumos' operating and financial performance within a specific period or in general.

5.1.6. 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 Commercial Services divisions. 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.

5.1.7. Loss making

Lumos has operated at a loss since its incorporation. Lumos had a statutory net loss after tax of $13.5m and $18.3m on a pro forma basis in FY20 . Please refer to Sections 4.3.1 and 4.3.2.

Lumos anticipates that its operating expenses will continue to rise as it expands its operations and continues to invest in developing its product pipeline. These expenses may prove more costly than Lumos' budgets and Lumos' revenue may not increase sufficiently to turn an operating profit and become cash flow positive. Should these extra expenses occur, Lumos will continue to incur losses, or it may have to reduce its product development expenditure, either of which may have a negative impact on Lumos' financial performance.

5.1.8. 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 (see Section 9 for an overview of Lumos' intellectual property portfolio). 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. The granting of a patent does not guarantee that competitors will not develop competing intellectual property that misappropriates, circumvents or works around the patent. Lumos' competitors may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with Lumos' ability to make, use and sell its products. Additionally, the process of obtaining patent protection is expensive and time consuming and Lumos may not be able to file and obtain all necessary or desirable patents applicable, or do so at a reasonable cost or in a timely manner. Changes in either the patent laws or their interpretation in the United States

and other countries may diminish Lumos' ability to protect its inventions, obtain, maintain and enforce its intellectual property rights and, more generally, could affect the value of its intellectual property or narrow the scope of its patents. Lumos cannot predict whether any patent applications that it is currently pursuing will be issued as patents in any particular jurisdiction, 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 U.S. Patent and Trademark Office, the European Patent Office or other intellectual property regulators to re-examine or oppose Lumos' patents. 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. Further, third parties may claim involvement in, or ownership of, Lumos' intellectual property and any disputes as to intellectual property ownership could adversely affect the financial performance and reputation of Lumos. In addition, under a number of commercial contracts, Lumos indemnifies the other party to the contract, against any claims for an infringement of third-party intellectual property. Consequently, a successful infringement claim could have substantial financial and reputational implications for Lumos.

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. Lumos also cannot be certain that others will not independently develop similar technologies on their own, gain access to Lumos' trade secrets or have such technologies disclosed to them by employees, consultants or third parties. This could allow competitors to commercialise products in competition with Lumos' Products and erode Lumos' competitive advantage.

There is also a risk that effective intellectual property protection, including patents, trademark, copyright and trade secrets, may not be available in every country in which Lumos' Products are available. As Lumos expands the sale of its Products into new geographic locations, Lumos' exposure to unauthorised copying and use of Lumos' Products may increase. Further, Lumos cannot assure that protective measures such as non-disclosure agreements or confidentiality provisions in agreements will prevent unauthorised disclosure or reverse engineering of Lumos' intellectual property.

Any of the above, in combination or isolation, may have an adverse impact on Lumos' operating and financial performance and position.

5.1.9. Reimbursement and coverage

Third-party payers, whether U.S. or non-U.S., or governmental or commercial, are developing increasingly sophisticated methods of controlling rising healthcare costs. These include, evaluating the cost-effectiveness and economic impact of using different procedures, products and services when making coverage and payment decisions. Payers continually review new and existing technologies and can, without notice, deny or reverse coverage or alter pre-authorisation requirements for new or existing procedures, products or services.

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.

In the United States for example, there has been, and continues to be, a number of legislative initiatives aimed at containing healthcare costs. These initiatives may impact on the reimbursement for certain healthcare products and services. Any state and federal healthcare policies and reform measures adopted in the future, could also limit reimbursement for healthcare products and services. Furthermore, private health insurance companies often follow United States federal coverage policy and payment limitations in setting their owner reimbursement rates.

There is therefore 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. This could have a material impact on the viability of new Products or demand for existing Products and have an adverse impact on Lumos' financial performance.

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5.1.10. Ability to attract and retain key personnel

Lumos relies heavily on existing 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, in particular in light of increased investment in the healthcare and health-technology sectors. Where talent markets are tight, this may result in longer recruitment processes and increased cost of hiring.

Lumos' internal policies governing recruitment and succession planning and structured incentive programs to assist recruitment and staff retention may not be sufficient to retain key personnel or to attract new personnel in a timely manner. 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, and the movement of any key personnel to a competitor may negatively impact Lumos' competitive advantage.

Any of the above circumstances, in isolation or combination, could have an adverse impact on Lumos' financial and operating performance.

5.1.11. Repayment of monies advanced under the PPP

In 2020, Lumos' two U.S. subsidiaries applied for and obtained an aggregate of US$1.88m in loans under the U.S. Small Business Administration's Paycheck Protection Program (**PPP**), which were made available to U.S. companies to help retain employees through the COVID-19 pandemic. Under the PPP, loans made to eligible borrowers qualify for full loan forgiveness subject to satisfying certain conditions, which forgiveness can be applied for once all proceeds for which the borrower is requesting forgiveness have been used for authorised purposes and within the time required by the program. When applying for the PPP loans, Lumos' subsidiaries expected to apply for and receive forgiveness on all monies provided under the PPP. Accordingly, Lumos classified the PPP monies as a "PPP grant", as the loan forgiveness criteria was expected to be satisfied. This classification is consistent with the recognition criteria of a grant per AASB 120 – Accounting for Government Grants and Disclosure of Government Assistance and was recorded in non-operating income/expenses within Lumos' FY20 financial statements (in the amount of $2,722,000).

Based on a recent review of monies provided under the PPP, Lumos has determined that, although its subsidiaries' applications under the PPP were made in good faith, Lumos' subsidiaries mistakenly received loan proceeds in excess of the amounts permitted under PPP program requirements as a result of an error in the initial calculation of the amount it was entitled to receive (the "excess amount"). Lumos has determined that the proper amounts the subsidiaries were entitled to borrow and receive forgiveness for was approximately US$671,000 in the aggregate, and has informed the applicable PPP bank lenders of this determination. Lumos' subsidiaries will repaid the excess amount to the PPP lenders together with any accrued interest on 27 March 2021. (Pro forma adjustments to Lumos' Statutory Financial Information in relation to the receipt of monies initially provided under the PPP in FY20, and the repayment of the excess amount in FY21F, are described in Sections 4.3.2, 4.4.2 and 4.5.1).

Lumos' subsidiaries anticipate that they will seek that the amounts they were entitled to receive under the PPP (being US$671,000) be forgiven. While Lumos' subsidiaries believe that they have complied with necessary requirements to receive forgiveness of this amount, the impact of Lumos' application for, and receipt of, the excess amount is uncertain. For example, there is a risk that Lumos may not be able to receive forgiveness for the amount it was entitled to receive, or that its PPP bank lenders will seek to accelerate and demand the immediate repayment of that amount (in addition to the excess amount).

If it is determined that Lumos' subsidiaries did not comply with the PPP laws, rules, regulations, or statements of procedure in relation to the matters described above, they may be subject to material criminal, civil and/or administrative penalties.

Further, while there is no change in the immediate shareholdings of the subsidiaries, there is a risk that the PPP bank lenders may determine that the Offer constitutes a change in control of the subsidiaries, and seek to accelerate and demand the immediate repayment of amounts received.

5.1.12. 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, including hospitals and critical care centres.

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;
- the preference by healthcare professionals for competing products due to familiarity with those products or for other reasons;
- Lumos' Products performing to expected standards and quality; and
- Lumos' ability to successfully market its Products by providing clinical and economic data that demonstrate the clinical efficacy, accuracy, cost-effectiveness and patient benefits from the Products.

Furthermore, changes in the healthcare delivery system, particularly in the United States, 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, which could adversely affect its results or operations.

The adoption of Lumos' own Products may take longer or have lower market penetration due to difficulty in securing market acceptance by healthcare professionals. Further, there is no guarantee that the adoption of Lumos' Products will be sufficient enough to meet Lumos' sales objectives. Insufficient market acceptance would likely impact Lumos' operating and financial performance.

5.1.13. Reduction in demand for Lumos' products currently being used in relation to COVID-19

Demand for Lumos' services in the last 12 months 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. For example, as described in Section 3.5.1, Lumos has obtained the rights to manufacture and is currently producing for itself and a client a COVID-19 related antigen test (marketed by Lumos as CoviDx™) and FebriDx® could be used in hospitals as a triaging tool by providing a means to rapidly identify high risk patients (namely, those patients with an active, viral infection) for isolation while a COVID-19 specific confirmatory test, which can require several hours, was conducted.

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) as discussed in Section 3.5.1, there is a risk that the demand for these products could decline as the impact of the COVID-19 pandemic is reduced, for example through widespread global vaccination programs. 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.

5.1.14. 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 as noted above in Section 5.1.13. 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. Competitors may also seek to copy, commoditise or devalue Lumos' capabilities and customer value proposition through negative marketing or other sales tactics.

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, requirements and preferences. 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. Lumos may also fail to anticipate or adequately respond to changing opportunities, technology, or standards, or more broadly to customer requirements, as quickly as Lumos' competitors.

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Lumos' ability to respond quickly to medical and other changes through the development and introduction of new products is important for Lumos to stay competitive. This can be capital intensive and time consuming. Product development involves a high degree of risk, and there are no guarantees that new product development efforts will result in any clinically or commercially successful products.

Difficulties or delays in research, development or production of new products, or the failure to gain market acceptance of new products and technologies is likely to reduce future revenues and adversely affect Lumos' competitive position.

5.1.15. Product pipeline and development of new product

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;
- adequately respond to unanticipated structural changes to the markets in which it operates, including changes to clinical practices, consumer preferences and government policy;
- manufacture and supply new products that meet quality requirements, are cost effective, and can be produced in a timely manner;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals;
- secure adequate reimbursement coverage for Lumos' new products from the relevant public or private payers; and
- establish an effective sales and marketing effort to generate commercial revenue from the products that it develops.

The success of Lumos' product pipeline will depend on, among other things, the factors outlined above. Some products may be delayed as a result of regulatory approvals. Additional research and development may determine that other products are unlikely to be clinically or commercially viable. Lumos cannot guarantee that any products under development will result in the launch of a commercially viable product. If any of these events were to occur, Lumos' ability to enhance its competitive position and achieve its revenue growth objectives through expanding its product offering is likely to be impaired and its performance and prospects adversely affected.

5.1.16. 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 by the FDA or other regulatory authorities and manufactured in facilities licensed and regulated by the FDA (such as Lumos' facility) or other 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. For example, Lumos may be subject to product liability claims if its products cause, or merely appear to have caused, patient injury or death. 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.

5.1.17. Manufacturing/Production risks

Lumos' manufacturing facilities in Sarasota, Florida and Carlsbad, California (as described in Section 3.7) 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. If there were to be a significant or protracted manufacturing failure and its stock levels were exhausted before production is able to be resumed it is likely that Lumos' operating and financial performance would be adversely affected.

Lumos is currently investing in expansion of both the Sarasota and Carlsbad facilities however new, replacement or expanded manufacturing facilities will need to comply with applicable quality and regulatory requirements and therefore any delays in necessary certifications may lead to delays in delivering product to distributors and Commercial Services clients.

5.1.18. Early termination of customer contracts

A number of Lumos' direct contracts with Commercial Services clients allow for termination based on a specified notice period. While Lumos has established relationships with many of these clients, should a customer decide to terminate its contract with Lumos for convenience (i.e. by providing the requisite prior notice), Lumos will suffer a loss of the customer 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.

5.1.19. Management of growth

Lumos is currently in a significant growth phase, with the business experiencing a recent substantial increase in the number of both employees and clients. Lumos expects that this growth will continue into the near-term future which may place strain on Lumos' management, operational and financial resources. Further, in the case of significant increases in customer demand for Lumos' products, there is no assurance that Lumos' systems and processes are robust and efficient enough to handle this increased demand.

5.1.20. Currency movements may be unfavourable

Lumos currently conducts the majority of its business in the United States with a majority of costs denominated in foreign currency (most notably USD). As such, unhedged, unfavourable movements in the exchange rate between the Australian dollar and the U.S. dollar, or other foreign currencies in which Lumos conducts business, may cause Lumos to incur foreign currency losses. Such losses may impact and reduce Lumos' revenue, profitability, ability to pay dividends and service any potential debt obligations.

5.1.21. 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. If any of these matters eventuate they could adversely affect the reputation and future financial performance of Lumos.

5.1.22. Execution of strategic vision

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 of 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 strategic vision 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 which could impact on its ability to generate revenue from the sale of its Commercial Services and Products.

5.1.23. Future acquisitions

Lumos may seek to acquire other businesses or companies in order to achieve its objectives. There is a risk, notwithstanding that Lumos will seek to undertake appropriate due diligence investigations in relation to any potential acquisition and ensure certain standard warranty and indemnity protections are contained in the relevant sale and purchase agreements, those due diligence investigations will not identify issues which are material to the acquisition and which could result in additional liabilities affecting Lumos in the future.

5.1.24. Work 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.

During COVID-19, as Lumos' workers are considered "essential" and are permitted to continue to work from Lumos' physical facilities, there is a risk of employees being infected with COVID-19 while working or travelling to and from work, notwithstanding measures put in place by Lumos to protect employees and reduce the likelihood of infection spreading at work. If this occurred, in addition to the impact on infected employees, there is a risk that Lumos' production could be adversely impacted.

Additionally, as a result of COVID-19, the administrative employees in the Lumos business worked remotely, which may have different risks to employee wellbeing, including health concerns relating to mental health and overall wellbeing, as well as the impact of remote working on daily life obligations and potentially sub-optimal working conditions. Remote working also means that it is more difficult for Lumos to monitor work environments and employee wellbeing and engagement. These risks may increase employee dissatisfaction or attrition, and lead to lower levels of productivity.

5.1.25. Country/Region specific risks

As described in Section 3.7.1, 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.

As Lumos expands the sales of its products geographically into new international jurisdictions, it is subject to the risks associated with conducting its business in those new international jurisdictions. These include adapting to, and complying with, the differing laws and regulations, differing business and clinical practices, and differing patient preferences in foreign countries. Other risks include developing and managing foreign relationships and operations and being subject to the political and economic climate of the various 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. Further, Lumos may not become aware of contraventions of laws for some time, which may exacerbate the nature of the contraventions or their consequences.

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. There is also a risk that Lumos could face other legal, tax or regulatory sanctions as a result of any failure to comply with applicable laws, regulations and standard of good practice.

If any of the above events were to occur, these have the potential to interrupt or adversely affect parts of Lumos' business and so may have an adverse effect on Lumos' operating and financial performance.

5.2. General risks of an investment in Lumos

5.2.1. Macro-economic risks, including the impact of COVID-19

Lumos' business is exposed to changes in general global economic conditions. For example, adverse macroeconomic conditions such as economic recessions, downturns or extended periods of uncertainty or volatility may influence Lumos' clients to defer or cancel expenditure or lead to downward pricing pressure. This in turn may affect Lumos' future financial performance and operating performance, the price of the Shares and Lumos' ability to pay dividends (should it choose to do so).

COVID-19 is a significant community and economic concern, which is impacting business operations and business and consumer confidence globally. The long-term effect of COVID-19 on economies and the Lumos business is not known, nor is the time-period in which COVID-19 will continue to have a global impact. There is also a risk that government or industry measures taken in response to COVID-19, such as lockdowns and other restrictions on movements, may restrict Lumos' undertaking of ordinary business operations. There is also a risk that persons whom Lumos is reliant on to conduct its business may be unable to work for a period of time if they contract COVID-19 or are required to isolate or quarantine. These business interruptions may have an adverse impact on Lumos' operations.

Any general economic slowdown, whether specifically related to COVID-19 or not, could potentially impact both suppliers and clients and is likely to have an impact on Lumos' financial performance which, depending on the depth and length of the slowdown, could be material.

5.2.2. Market conditions

Stock market conditions may affect the value of Lumos' quoted securities regardless of Lumos' operating performance. These conditions may cause the Shares to trade at prices below the price at which the Shares are being offered under this Prospectus. There is no assurance that the price of the Shares will increase following their quotation on the ASX, even if Lumos' earnings increase. Stock market conditions are affected by many factors such as:

- general economic conditions, including interest rates, inflation rates, exchange rates, commodity and oil prices or changes to government fiscal, monetary or regulatory policies, legislation or regulation;
- introduction of tax reform or other new legislation;
- change in investor sentiment toward particular market sectors and fluctuations in the domestic and international market for listed shares;
- the demand for, and supply of, capital;
- the nature of the markets in which Lumos operates; and
- terrorism or other hostilities and outbreaks of disease, severe viruses or a pandemic (e.g. COVID-19).

The market price of securities can fall as well as rise and may be subject to varied and unpredictable influences on the market for equities in general and industrial stocks in particular. Neither Lumos nor its Directors warrant the future performance of Lumos or any return on an investment in Lumos.

In light of the COVID-19 pandemic, extra care should be taken when assessing the risks associated with investment. The rapidly changing COVID-19 situation has the potential to bring unprecedented challenges and volatility to global financial markets, and economies as a whole.

5.2.3. Security holders may suffer dilution

In the future, Lumos may elect to issue Shares (including pursuant to incentive arrangements) or engage in fundraising activities, including to fund potential acquisitions or growth initiatives. While Lumos will be subject to the constraints of the ASX Listing Rules regarding the percentage of its capital that it is able to issue within a 12 month period without shareholder approval (other than where exceptions apply), shareholders holdings may be diluted as a result of such issues and fundraisings.

5.2.4. Trading and liquidity in Shares

There is no guarantee that there will be an active market in the Shares listed on the ASX. There may be few potential buyers and sellers of Shares at any point in time which will impact upon Share liquidity. This may increase the volatility of the market price of the Shares. This may also impact upon the ability of the shareholders to be able to sell their Shares at a price that is more or less than that paid by the shareholder.

Upon Completion, the Existing Securityholders of Lumos will hold 66.4% of the total issued Share capital of Lumos. Of these, approximately 75.6% will be subject to voluntary escrow arrangements (representing approximately 50.2% of Shares on Completion). The escrow arrangements will end between the release of Lumos' FY21 results through to the release of Lumos' FY23 results (subject to early release in certain cases). Further details are set out in Section 6.5.. Following the end of the relevant escrow period, a significant sale of shares by the Escrowed Shareholders, or the perception that such sales could occur, could adversely affect the market price of Lumos' Shares.

5.2.5. Adverse taxation changes may occur

Any change to the current rates of taxes imposed on Lumos (including in foreign jurisdictions in which Lumos operates) may affect returns to Shareholders.

An interpretation of taxation laws by the relevant tax authority that is contrary to Lumos' view of those laws may increase the amount of tax to be paid or cause changes in the carrying value of tax assets in Lumos' financial statements. In addition, any change in tax rules and tax arrangements could have an adverse effect on the level of dividend franking and Shareholder returns.

Investors should seek their own taxation advice before applying for Shares.

5.2.6. Litigation risk

In the ordinary course of its business, Lumos may be subject to the risk of litigation and other disputes with its clients, employees, consultants, lessors, regulators and other third parties. Proceedings may result in high legal costs, adverse monetary judgements and/or damage to Lumos' reputation, which ultimately is likely to have an adverse effect on Lumos' financial performance.

5.2.7. Possible changes in accounting standards

Australian Accounting Standards (AAS) are set by the Australian Accounting Standards Board (AASB) and are outside the control of either Lumos or its Directors. The AASB may, from time to time, introduce new or refined AAS. This may affect the way that Lumos measures and recognises accounting items, which could have an adverse impact on the reported financial position of Lumos and may affect the comparability of results from year to year.

There is also a risk that the interpretation of existing AAS may differ. Any changes to the AAS or to the interpretations of those standards may adversely affect Lumos' reported financial performance and position.

5.2.8. Insurance

Lumos obtains insurance where it is considered appropriate for its needs and at levels and for the costs that it considers appropriate. However, Lumos would not expect to be insured against all risks, either if appropriate cover is not available or because the Directors consider the required premiums to be excessive having regards to the benefits that would accrue.

Accordingly, Lumos may not be fully insured against all losses and liabilities that could arise from its operations. If Lumos incurs losses or liabilities for which it is uninsured, this may adversely affect its financial position or performance.

5.2.9. Inability to pay dividends or make other distributions

The ability for future dividends or other distributions to be made by Lumos will be contingent on its ability to generate profits and certain other factors, including the capital and operational expenditure requirements of the business. Where Lumos is in a position to pay dividends, the amount, timing, and payment of future dividends is dependent on a range of factors including future capital, and research and development requirements, as well as the overall financial position of Lumos. There will be factors outside the control of Lumos that may affect the ability of Lumos to pay dividends.

Lumos does not expect to pay dividends in the short or medium term and Lumos is unable to give any assurance regarding the payment of dividends in the future, if at all.

Finally, if and when dividends are declared, no assurance can be given in relation to whether franking credits attaching to dividends can be given by Lumos. Shareholders should otherwise be aware that the ability to use franking credits, either as a tax offset or to claim a refund after the end of the income year, will depend on the individual tax position of each shareholder.

5.2.10. Force majeure events may occur

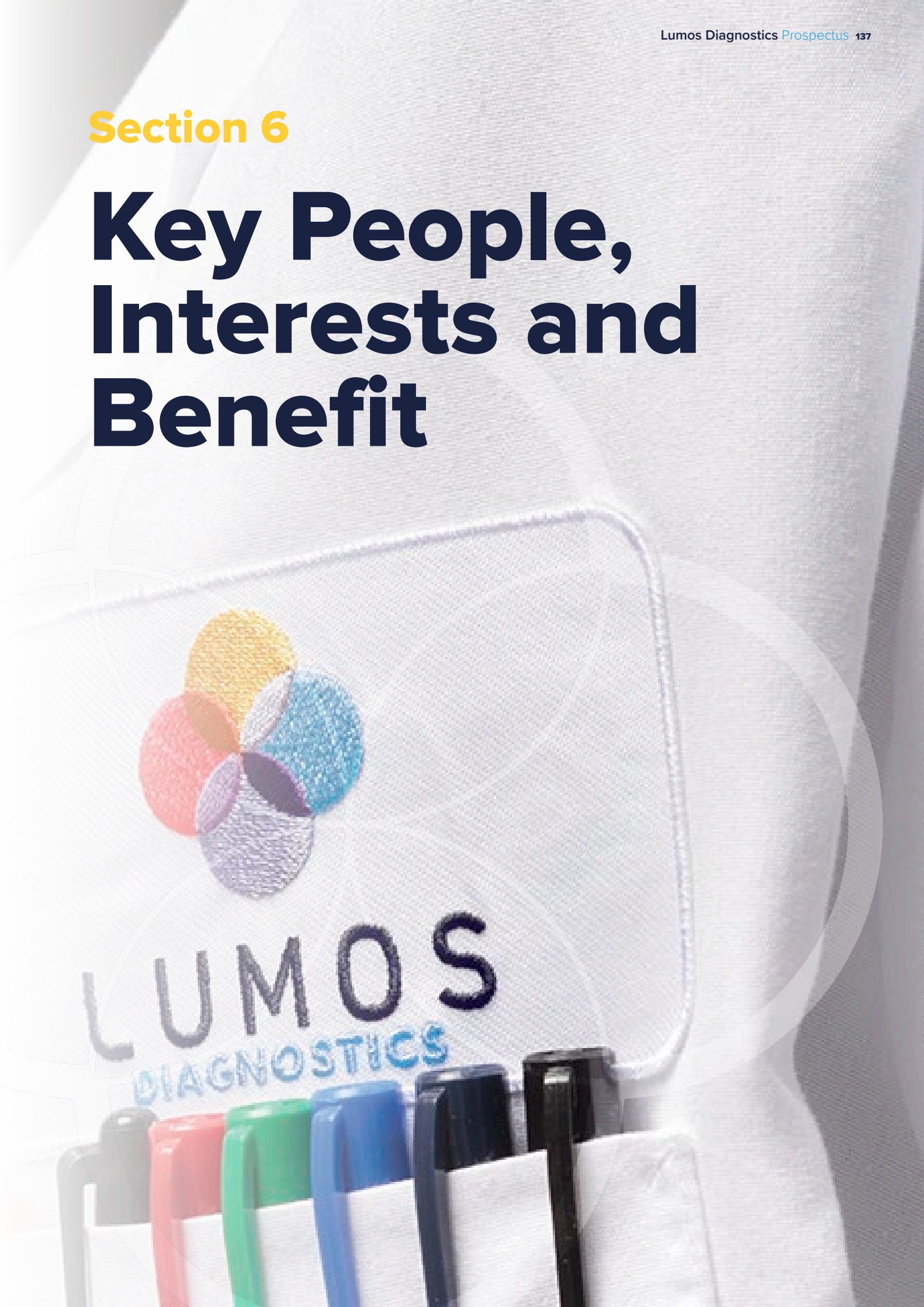
Events may occur within or outside the U.S., Australia or other jurisdictions in which Lumos operates that could impact upon a jurisdiction's economy, Lumos' operations, investor sentiment and the price of the Shares. The events include but are not limited to acts of terrorism, an outbreak of international hostilities, fires, floods, earthquakes, labour strikes, civil wars, natural disasters, outbreaks of disease or severe viruses (e.g. COVID-19) or other natural or man-made events or occurrences that can have an adverse effect on the demand for Lumos' products and its ability to conduct business. Lumos has only a limited ability to insure against some of these risks.

5.2.11. Combination of risks

Lumos may be subject to a combination of risks, including any of the risks outlined in this Section 5, which in aggregate could affect the financial performance, position, prospects and valuation of Lumos.

Section 6

Key People, Interests and Benefit



Section 6
Key People, Interests and Benefit

6.1. Board of Directors

The Directors bring to the Board relevant experience and skills, including industry and business knowledge, financial management and corporate governance experience.

Table 6.1: Lumos' Board of Directors

Director	Experience
 **Samuel Lanyon** *Executive Chair*	Sam has served as Chair of the Board since 2019 and has over 25 years' experience in business strategy, R&D and operational roles in the healthcare and technology markets. Sam co-founded and serves as co-CEO of Planet Innovation, a technology and commercialisation company focussed on global health-tech markets. Planet Innovation has assisted in the development/ creation of four standalone businesses (Lumos Diagnostics, Visus Therapeutics, Zen Ecosystems and Atmo Biosciences) since 2015. Sam previously served as an executive at ASX listed Vision Systems, where he was responsible for establishing and growing international commercial operations for its Vision Systems division until its acquisition by Danaher Corporation in 2007. Sam currently serves on the boards of Visus Therapeutics, Planet Innovation and Paragon Funds, and previously served on the boards of Zen Ecosystems and Waterwerx. Sam holds an Honours degree in Mechanical Engineering from the University of Melbourne and Post Graduate Diploma in Management from Melbourne Business School and has undertaken governance training from the Australian Institute of Company Directors (**AICD**).
 **Lawrence Mehren** *Non-executive Director and Deputy Chair*	Lawrence joined the Lumos Board in November 2020 and has over 20 years' experience working in the diagnostics industry, in both operational and financial roles. Between 2007 and 2012 Lawrence served as CFO and then COO of Ventana Medical Systems, a global supplier of cancer diagnostics systems which was acquired by Roche in 2008. In 2012 Lawrence assisted in the re-launch of Accelerate Diagnostics, a company dedicated to modernising disease diagnostics, which went public on NASDAQ in 2012. Lawrence served as President, CEO and Director of the company from 2012 to January 2020. Lawrence has a Bachelor of Arts from the University of Arizona and a Masters of Business Administration from North-western University Kellogg School of Management.
 **Robert Sambursky** *Chief Executive Officer*	As CEO of Lumos and the co-founder of Rapid Pathogen Screening, Inc. (**RPS**), Rob has over 25 years' commercial and medical industry experience in both ophthalmology and infectious disease market segments. Rob co-founded RPS, in 2004, a biotechnology company strategically focused on designing, developing, manufacturing, and marketing novel point-of-care tests for infectious diseases (which merged with Lumos in 2019). With Rob as President and CEO of RPS, the company developed multiple POC diagnostic tests which obtained international regulatory clearances, including U.S. FDA 510(k) clearances with clinical laboratory improvement amendment (CLIA) waiver designations. Rob has served as a consultant and/or acted on the advisory Board of a number of medical companies, including Allergen Inc., NovaBay Pharmaceuticals and Actin BioMed. Rob currently acts as an advisor for Quidel Corporation, a U.S. based manufacturer of diagnostic healthcare products. Rob holds a bachelor of Arts in Biology from Brown University and a Master of Arts in Medical Sciences and a Doctor of Medicine from Boston University School of Medicine.

Director	Experience
 **Bronwyn Le Grice** *Non-executive Director*	Bronwyn joined the Lumos Board in 2020 and has 20 years' experience in the technology and health technology sectors focussed on commercialisation, company growth, corporate development, investment and advocacy. Bronwyn previously served as a non-executive director for ASX listed Imagion BioSystems. Bronwyn is the founder and managing director of ANDHealth, a leading Australian dedicated digital health commercialisation organisation. Prior to founding ANDHealth, Bronwyn served as an Investment Director and Special Advisor for Bioscience Managers Pty Ltd, a leading healthcare fund manager and as Head of Commercial Development and Corporate Affairs for Adherium Ltd, including as project leader for their IPO in 2015. Bronwyn holds a Bachelor of Commerce from the University of Western Australia and a Master of Commercial Law from Melbourne Law School and completed both the AICD's company director's course and the New Zealand Institute of Director's company directors course.
 **Catherine Robson** *Non-executive Director*	Catherine joined the Lumos Board in December 2020 and has more than 20 years' experience in management, finance and investment. Having commenced her career at Macquarie Bank, Catherine held senior roles at NAB before founding financial services business Affinity Private. Catherine is a non-executive director of ASX-listed EQT Holdings Limited, where she is the Chair of the risk committee and a member of the audit, remuneration and strategy committees. She is also a non-executive Director of Greater Bank and SCALE Investors and chairs education technology innovator TalkiPlay. Catherine is a member of WEHI's Advocacy & Support Committee and Cancer Council Victoria's Investment Committee. Catherine has an Honours Degree in Law and Arts Degree majoring in Asian Studies from the Australian National University, a Graduate Diploma in Applied Finance from FINSIA, a Master's Degree in Law majoring in Tax from the University of Melbourne and is a graduate of the Australian Institute of Company Directors course.

The composition of the Board committees and a summary of Lumos' corporate governance policies are set out in Section 6.6.

Each Director has confirmed to Lumos that they anticipate being available to perform their duties as a Director without constraint from other commitments. The Directors will continually evaluate their other commitments, including the number of boards on which they serve, to ensure that proper time and attention is given to their appointment, and role, as a Director.

Directors may have business interests other than those of Lumos, and are expected to declare any conflict (or potential conflict) of interest or material personal interests at appointment, or as soon as apparent. The conflict (or potential conflict) of interest or material personal interest may require them to not be present at a Board or Board Committee meeting or vote on a matter which concerns the conflict or material personal interest.

No Director has been the subject of any disciplinary action, criminal conviction, personal bankruptcy or disqualification in Australia or elsewhere in the last 10 years which is relevant or material to the performance of their duties as a Director, or which is relevant to an investor's decision as to whether to subscribe for Shares.

Section 6
Key People, Interests and Benefit

6.2. Senior Leadership Team

Lumos' Senior Leadership Team is led by CEO Robert Sambursky, who is supported by a number of experienced and skilled personnel, who together have extensive knowledge of the Lumos business and the industry in which the Group operates.

Table 6.2: Lumos' Senior Leadership Team

Executive	Experience
Robert Sambursky *CEO*	See Section 6.1.
 **Melanie Leydin** *CFO and Company Secretary*	Melanie is the co-founder and principal of Leydin Freyer and has over 25 years' experience in accounting and nearly 15 years' experience in company secretarial and corporate accounting roles for ASX listed companies. Melanie's experience includes ASX and ASIC compliance, control and implementation of corporate governance, statutory financial reporting and shareholder relations. Melanie is a chartered accountant and a registered company auditor, holds a Bachelor of Business, majoring in accounting and corporate law and is a Fellow of the Governance Institute of Australia.
 **Tracy Weimar** *Company Secretary*	Tracy has over 20 years of commercial experience in the pharmaceutical/biotech industry in both the large and small cap sectors as well as over 10 years of Board level experience as a company secretary and a non-executive director, including as Vice President Operations and Finance and company secretary at ImmuPharma plc, a UK AIM-listed pharmaceutical drug development company. Prior to this Tracy had several roles at GlaxoSmithKline plc including worldwide business development/ licensing, sales and marketing. Prior to joining GlaxoSmithKline, Tracy was a consultant in the tax practice of Arthur Andersen in San Francisco and London. Tracy has a BA in Economics from the University of California, Berkeley and an MBA from London Business School. She is also a Graduate of the Australian Institute of Company Directors (GAICD) and a Fellow of the Governance Institute of Australia (FGIA). Melanie and Tracey have been engaged by Lumos through the accounting and governance firm Leydin Freyer Corp Pty Ltd.
 **Jill Thompson** *Senior VP of Corporate Strategy and Development*	Jill Thompson joined Lumos in 2020 and currently serves as the Senior Vice President of Corporate Strategy and Development. Jill has more than 25 years' experience in the life science and diagnostics industry, including most recently having served as President and Practice Leader for the JoLT Group where she provided management and consulting services to individuals and companies in all stages of business development. Jill also served as Senior Vice President of Business Development at Orasure Technologies where she negotiated agreements that led to the rapid point-of-care Ebola test that was launched in Africa, and as Vice President of Business Development for Alere where she was pivotal in developing and launching three new diagnostic testing devices to expand the company's product portfolio. Jill holds a Bachelor of Science majoring in Psychology from Texas A&M University in Texas.

Executive	Experience
 **Sacha Dopheide** *Chief Technology Officer*	Sacha currently serves as Lumos' CTO and has held an executive leadership role within Lumos since its acquisition of Kestrel Bioscience in 2017. Sacha has taken a leading role in identification and due diligence of M&A targets and integration activities for Lumos and also leads Lumos' Commercial Services divisions' business development activities, including directly conducting global market research, establishing partnerships and generating strategic product roadmaps for new tests. Sacha has more than 15 years' experience in the in IVD device industry, ranging from POC devices to laboratory analysers. Her experience includes managing the full range of product development for both immunoassays and their accompanying electronic readers from proof of concept through development, verification and external validation trials. Sacha holds a Bachelor of Science in Biochemistry and Molecular Biology and a PHD in Medicine from Monash University.
 **Jeffrey Bishop** *Senior VP of Research and Development*	Jeffrey joined Lumos in 2019 and serves as Senior Vice President of Research and Development. Jeffrey is a technical leader responsible for the successful development of more than 30 commercialised diagnostic assay products, including both instruments and assays for point-of-care, laboratory, life science and IVD applications. Jeffrey has previously developed POC assays in the areas of cardiovascular disease, infectious disease, women's health and toxicology. Jeffrey has more than 20 years of diagnostic industry experience, including having served as Chief Scientific Officer and Senior Vice President of Diagnostic Operations and a member of the executive team at Singulex. Additionally, he held a variety of leadership positions within the research and development organization at Alere, Inc. (formerly Biosite, Inc.), including as Vice President, Research and Development for specific platforms and disease areas. Jeffrey holds a Bachelor's degree in Chemical Engineering from Brigham Young University and Masters and Ph.D. degrees in Bioengineering from U.C. San Diego.
 **Aaron Erlandson** *Senior VP of Finance*	Aaron joined Lumos in 2020 and serves as Senior Vice President of Finance, with responsibility for Lumos' financial and accounting activities, including long-term business planning, forecasting, compliance, and audit functions. Aaron has over 20 years of experience in financial leadership positions. including in the diagnostics industry experience, with key roles in manufacturing, sales, corporate planning and analysis. Aaron holds undergraduate degrees in Corporate Finance and Psychology (Industrial/Organizational) from The University of Minnesota, as well as an MBA, with an emphasis in Corporate Entrepreneurship, from Babson College.
 **Kurt Phinney** *Vice President of Operations*	Kurt joined RPS in 2014 and serves as Senior Director of Operations, responsible for overseeing all product and service contract manufacturing, automation, global supply chain management and facilities expansion. Kurt has 15 years of experience leading biomedical project management and manufacturing, including development of biochemical assays (lateral flow, ELISA, western blot, and cell-based) with the State Laboratory Institute of Massachusetts, Immunetics and Floria Biosystems. Kurt has also provided consultation to biotechnology, information technology and pharmaceutical firms in the U.S. and overseas and served as a Health Service Corpsman with the United States Coast Guard. Kurt holds a Bachelors degree in Biology from the State University of New York at Albany.

Section 6
Key People, Interests and Benefit

Executive	Experience
 **Annie Bell** *Senior Director of Medical Affairs*	Annie joined Lumos in 2018 and currently serves as the Director of Medical Affairs responsible for managing all Lumos and third party initiated clinical and outcome trials, overseeing Lumos' evidence based publication strategy, supporting regulatory activities, and serving as a medical science liaison to the commercial organisation. Annie has more than 15 years of professional experience in the medical device and IVD industry including direct patient management, medical education and clinical study management. Annie also has expertise in the initiation and oversight of clinical trials including FDA registration trials. Annie holds a Bachelors in Nursing from Pennsylvania State University, a Masters in Nursing from Rush University Chicago, IL, and is a graduate of the Global Clinical Trials Clinical Research Program, Harvard Medical School, Boston MA.
 **Sue Hibbeln** *Senior Director of Regulatory Affairs*	Sue joined Lumos in 2020 and currently serves as Lumos' Senior Director of Regulatory Affairs, specializing in global strategy, registration, regulatory/cultural intelligence and quality systems. Sue has over 15 years' experience in regulatory affairs and quality assurance at start-up, mid- and large-sized companies for a variety of medical devices, including in vitro diagnostic devices, software, hardware, implants and sutures. Sue is a CMMI Associate and a certified appraisal team member for the Medical Device Discovery Appraisal Program – a joint initiative of the FDA, MDIC, and CMMI.
 **Paul Kase** *Vice President of North American Sales*	Paul re-joined Lumos in 2020 after a previous tenure as the Senior Director of U.S. Sales for RPS in 2017. Paul has over 27 years' experience of medical sales and sales leadership in the point of care diagnostic testing market. As Vice President of North America Sales, he is responsible for leading the North American commercial sales efforts, while implementing marketing strategies focused on revenue growth, building strong customer partnerships, generating end user demand and adoption of Lumos branded products. During his previous tenure at RPS, Paul developed the commercial sales infrastructure and client base that was transitioned to Quidel Corporation as part of the eyecare asset sale. Paul then served as Senior Director, U.S. Sales for Quidel's Eye Health Division. Paul's experience includes building and leading sales teams, managing customer and technical support divisions, commercial product launches, key opinion leader development, and building distributor and customer networks. Paul holds a Bachelor in Economics and English from Bucknell University.
 **Jeff Bauer** *Vice President of Product and Business Development*	Jeff joined Lumos in 2017 as part of the Kestrel Biosciences acquisition and currently serves as Lumos' Vice President of Product and Business Development. Jeff has over 35 years' experience working in the diagnostics industry, including having co-founded Diagnostic Consulting Network, where he was the Executive Vice President and Chief Scientific Officer. Jeff has experience in product development and manufacturing in both human and animal health sectors, as well as in developing immunoassays, such as enzyme immunoassays, lateral flow, and point-of-care assays. Jeff has taken several products through FDA 510(k) clearance and international product registrations. Jeff is a graduate of the U.S. Army Medical School in Texas and is a Certified Medical Technologst with a specialty in Medical Microbiology.

Executive	Experience
 **Sarah Glubka** *Senior Director of Human Resources*	Sarah joined Lumos in 2017 and currently serves as Senior Director of Human Resources. Sarah has over 17 years' experience in human resources, with her most recent role being as US Director of Human Resources for Planet Innovation where she developed people based business initiatives, including recruitment, employee engagement and talent deployment. Prior to joining Planet Innovation, Sarah was the supervisor of administrative services for Kaiser Permanente. Sarah also has expertise establishing human resource infrastructures for U.S. entities, including policies, standardised processes and procedures, and documentation to ensure compliance with all state and federal regulations. Sarah holds a Bachelor's degree in Business Management from the University of Phoenix.
 **Huan Tran** *Director of Quality*	Huan joined Lumos in 2018 and currently serves as Director of Quality. Huan has 18 years of experience in both quality and regulatory affairs within the medical device and in vitro diagnostics industry, and in healthcare and medical device technology, data privacy, quality engineering and regulatory affairs, both in the design and manufacture of immunoassay based products. Huan has specific expertise in FDA QSR, ISO 13485 certification, Canadian certification audits and HIPAA certification audits and in achieving both U.S. and international regulatory clearances. Huan's current responsibilities at Lumos include overseeing all policies, procedures and product specifications to ensure continued compliance with quality, regulatory and privacy requirements. Huan holds a Bachelor's degree in Biochemistry from the University of California, San Diego and is a certified Lead Quality Management System Auditor, Certified Quality Engineer and Certified HIPAA Professional.

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6.3. Interests in Shares of existing and new investors

Details of interests in Shares and Options at the Prospectus Date and as expected on Completion are set out in Figure 6.1 below.

Figure 6.1: Securityholdings as at Prospectus Date and on Completion

	Prospectus Date				Sold under the Offer	On Completion			
	Shares[1]		Options[2]	Fully diluted[3]	Shares	Shares[1]		Options[2]	Fully diluted[3]
Shareholder	**Number**	**%**	**Number**	**%**	**Number**	**Number**	**%**	**Number**	**%**
Planet Innovation[4]	59,822,600[5]	50.0%	–	45.3%	19,697,685	40,124,915	26.7%	–	24.7%
RPS Diagnostics[6]	15,647,189	13.1%	–	11.9%	–	15,647,189	10.4%	–	9.6%
Other securityholders[7]	44,282,624	37.0%	–	33.6%	302,315[8]	43,980,309	29.3%	–	27.1%
Optionholders[8]	–	–	12,203,663	9.2%	–	–	0.0%	12,203,663	7.5%
Investors in the Offer	–	–	–	0.0%	–	50,400,000[9]	33.6%	–	31.0%
Total	**119,752,413**	**100.0%**	**12,203,663**	**100.0%**	**20,000,000**	**150,152,413**	**100.0%**	**12,203,663**	**100.0%**

Notes:

1. **Shares on the Prospectus Date** comprises Shares (ie ordinary shares), Preference Shares (each of which will convert into 1 Share on Completion) and the number of Shares which will be issued in respect of the conversion of Pre-IPO Convertible Notes on Completion. Shares on the Prospectus Date includes the Shares to be issued to Robert Sambursky prior to Completion (see note 8 below). **Shares on Completion** comprises only Shares. The exact number of Shares to be on issue (or held by particular Existing Securityholders) at Completion will depend on the date Completion occurs (refer to Section 6.3 for a further information). The Prospectus assumes that Completion occurs on 29 June 2021. No Preference Shares or Pre-IPO Convertible Notes will remain on issue on Completion.
2. **Options** comprises the Options (each over 1 Share) on issue at the Prospectus Date and on Completion (as referred to in Section 6.4.6) Includes 5,498,515 Options held by Robert Sambursky as referred to in Section 6.4.6. Refer also to Notes 6 and 7 below.
3. **Fully diluted:** refers to the number of Shares on the Prospectus Date (or Shares on Completion) as described in Note 1 above, plus the number of Shares which would be issued on exercise of Options (each in respect of one Share).
4. Sam Lanyon does not hold any securities in Lumos at the Prospectus Date, however he holds 10.98% of Planet Innovation directly (in the form of options and restricted shares), and a trust held in his wife's name holds 256,417 Preference Shares in Lumos, resulting in an indirect economic interest in Lumos of approximately 5.7% on the Prospectus Date and 3.1% on Completion (each on an undiluted basis).
5. Represents Planet Innovation's 10,359,587 Shares and 49,463,013 Preference Shares in Lumos as at the Prospectus Date.
6.. Robert Sambursky holds shares and warrants over shares in RPS Diagnostics, a Shareholder of Lumos (and 5,498,515Options in Lumos excluding the Options referred to in Note 7) at the Prospectus Date, resulting in a potential indirect economic interest in Lumos of approximately 5.1% on the Prospectus Date and, after taking into account Rob's sell-down referred to in Note 8 below, 3.9% on Completion. These percentages are calculated on an undiluted basis.
7. **Other securityholders** comprises (i) holders of 11,459,323 Preference Shares as at the Prospectus Date (excluding Planet Innovation) which will convert into 11,459,323 Shares on Completion;(ii) holders of Pre-IPO Convertible Notes which will convert into 32,561,467 Shares on Completion; and (iii) 261,834 Shares to be issued to Robert Sambursky prior to Completion pursuant to his exercise of 261,834 Options prior to the Prospectus Date. Catherine Robson's interest in Preference Shares and Pre-IPO Convertible Notes is described in Section 6.4.2.7.
8. Robert Sambursky will sell 261,834 Shares (referred to in Note 7) s at the Offer Price per Share through SaleCo under the Offer to receive $327,292.50 in aggregate. These Shares will be issued with disclosure under this Prospectus. Also includes the sale by an unrelated other Securityholder of 40,481 Shares at the Offer Price per Share through SaleCo.
9.. Includes 208,800 Shares expected to be applied for by Directors (directly and indirectly) under the Offer at the Offer Price as referred to in Section 6.4.2.7.

6.4. Interests and benefits

This Section 6.4 sets out the nature and extent of the interests and fees of certain persons involved in the Offer. Other than as set out below or elsewhere in this Prospectus, no:

- Director or proposed Director of Lumos or SaleCo;
- person named in this Prospectus and who has performed a function in a professional, advisory or other capacity in connection with the preparation or distribution of this Prospectus;
- promoter of Lumos; or
- underwriter to the Offer or financial services licensee named in the Prospectus as a financial services licensee involved in the Offer,

holds as at the time of lodgement of this Prospectus with ASIC, or has held in the two years before lodgement of this Prospectus with ASIC, an interest in:

- the formation or promotion of Lumos;
- property acquired or proposed to be acquired by Lumos in connection with its formation or promotion or the Offer; or
- the Offer,

and no amount (whether in cash, Shares or otherwise) has been paid or agreed to be paid, nor has any benefit been given or agreed to be given, to any such person for services in connection with the formation or promotion of Lumos or the Offer or to any Director or proposed Director to induce them to become, or qualify as, a Director of Lumos or SaleCo.

6.4.1. Interests of advisers

Lumos has engaged the following professional advisers in relation to the Offer:

- Bell Potter Securities Limited and Wilsons Corporate Finance Limited have acted as Joint Lead Managers to the Offer and the fees payable to the Joint Lead Managers pursuant to the Underwriting Agreement are described in Section 10.6;
- Clayton Utz has acted as Australian legal adviser to Lumos in relation to the Offer. Lumos has paid, or agreed to pay, approximately $450,000 (excluding disbursements and GST) for the services up to the Prospectus Date. Further amounts may be paid to Clayton Utz in accordance with its normal time-based charges;
- Foley Lardner has acted as U.S. legal adviser to Lumos in relation to the Offer. Lumos has paid, or agreed to pay, approximately US$375,000 (excluding disbursements and relevant taxes) for the services up to the Prospectus Date. Further amounts may be paid to Foley Lardner in accordance with its normal time-based charges;
- Blackpeak Capital has acted as the financial adviser to Lumos in relation to the Offer. Lumos has paid, or agreed to pay, approximately $705,000 (excluding disbursements and GST) for the services up to the Prospectus Date. Further amounts may be paid to Blackpeak under time-based charges.
- BDO has acted as the Investigating Accountant on, and has performed work in relation to due diligence enquiries, the Financial Information in relation to the Offer and has performed work in relation to its Investigating Accountant's Report in Section 8. Lumos has paid, or agreed to pay, approximately $350,000 (excluding disbursements and GST) for these services up to the date of this Prospectus. Further amounts may be paid to BDO under time-based charges; and
- BDO has acted as the Tax Adviser to Lumos in relation to the Offer. Lumos has paid, or agreed to pay, approximately $70,000 (excluding disbursements and GST) for the services up to the Prospectus Date. Further amounts may be paid to BDO under time-based charges.

These amounts, and other expenses of the Offer, will be paid by Lumos out of funds raised under the Offer or available cash. Further information on the use of proceeds and payment of expenses of the Offer is set out in Section 7.1.3.

6.4.2. Directors' interests and benefits

6.4.2.1 Non-executive Directors' appointment letters

Each Non-executive Director has entered into an appointment letter with Lumos, confirming the terms of their appointment, roles and responsibilities and Lumos' expectations of them as Directors.

The letters also set out a restraint clause that prohibits the Non-executive Directors from being connected with or interested in any business in competition with Lumos, except with the Board's prior written consent.

Non-executive Directors may resign at any time. They will also cease to be a Director if they are not re-elected at the relevant annual general meeting, or if any of the disqualifying events prescribed in the Constitution or as prescribed by law occur.

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6.4.2.2 Non-executive Director compensation

Directors are to be paid or provided remuneration for services provided to Lumos on terms decided by the Board. Under the ASX Listing Rules, the total amount or value of remuneration paid to Non-executive Directors in any year may not exceed the amount approved by Shareholders at Lumos' general meeting. This amount is currently fixed at $600,000 per annum. It is expected that the annual directors fees payable to the current Non-executive Directors in FY21F will be approximately $235,000 (exclusive of superannuation) in aggregate.

Position	Expected Annual Directors fees
Non-executive Directors	$55,000
Committee chair (per committee)	$15,000
Committee member (per committee)	$10,000

Note: Rob Sambursky and Sam Lanyon will not receive any fees for their services as a Director while executive directors of Lumos.

Lumos will contribute statutory superannuation to a complying superannuation fund where required. Remuneration is reviewed annually and any increase to it will be at the discretion of the Board but will not exceed $600,000 per annum or such other aggregate amount approved by Shareholders.Non-executive Directors are entitled to participate in the New Lumos LTIP, but are not eligible to receive any performance based awards (see Section 6.4.5).

Non-executive Directors will receive a one-off payment (to the value of $50,000 each) in consideration for services provided prior to the Offer. These Directors will apply after tax proceeds from this payment to apply for Shares under the Offer (refer to Section 6.4.2.7).

6.4.2.3 Executive Chair compensationn

Sam Lanyon is employed as Executive Chair and the terms of his employment are contractually governed by an employment agreement with Lumos.

Sam's total fixed remuneration is currently $148, 493 (exclusive of super) for services provided on a part time basis (equivalent to 2.5 days per week). Sam's agreement does not provide for the award of an STI or LTI.

Sam's employment agreement includes a restraint of trade period of one year post termination of employment within Australia (subject to enforceability). The agreement can be terminated by either party by providing six months' written notice.

6.4.2.4 CEO compensation

Robert Sambursky is employed as Chief Executive Officer and the terms of his employment are contractually governed by an employment agreement and executive severance agreement with Lumos. Rob's remuneration is comprised of:

- total fixed remuneration of US$295,000 per annum from Completion. Rob's base compensation will permanently increase based on the achievement of certain corporate milestones being: product revenue greater than US$10m on a rolling 12 month period (increased to US$335,000); market capitalisation greater than $120m for more than one month after Listing (increased to US$350,000) or market capitalisation greater than $150m for more than one month after Listing (increased to US$375,000);
- a discretionary annual short-term incentive (**STI**) as determined by the Board from time to time. Rob's FY21 STI will entitle him to receive 35% of his total fixed remuneration subject to Lumos' FY performance against targets; and
- a discretionary annual long-term incentive (**LTI**) as determined by the Board from time to time. The terms of Rob's Options are described in Section 6.4.5.

The grant of any equity-based LTIs to Rob as a Director after Completion will be made under the New Lumos LTIP and will be subject to obtaining approvals from Shareholders as required by the ASX Listing Rules (refer to Section 6.4.6).

Rob's employment agreement provides for an at will employment relationship which can be terminated at any time without notice by either party. His employment agreement also includes confidentiality provisions covering Lumos information, as well as restrictions during his employment and one year post-employment on solicitation of employees and on use of trade secrets to solicit clients or prospects of Lumos.

Under the terms of Rob's executive severance agreement, if Rob is terminated other than for cause by Lumos or resigns with good reason, he is entitled to 90 days' base salary severance pay, plus an additional two weeks' base salary severance pay for each year of his employment (provided Lumos has $2m in cash reserves within 7 days of termination). However if termination is within one year of a change in control (being where 50% of the voting stock or assets of Lumos are sold to a third party, and excluding an IPO), Lumos must have at least $1m in cash reserves at the time of termination for Rob to receive 90 days' severance pay, and more than $2m in cash reserves (within 7 days of termination) for Rob to receive the additional two weeks' severance per year of service. Rob's entitlement to severance pay is contingent upon a release of claims against Lumos.

Rob will also receive a one-off payment of $50,000 for services provided to Lumos in preparation for the IPO.

6.4.2.5 Deeds of access, insurance and indemnity

Lumos has entered into deeds of indemnity, insurance and access with each Director and with the CFO and each Company Secretary. Each deed contains the right of access to certain books and records of Lumos or a related body corporate of Lumos for the period from the date of the deed until seven years after the person ceases to hold office of Lumos or a related body corporate of Lumos. This seven year period can be extended where certain actions or proceedings commence before the period expires. Pursuant to the Constitution and to the extent permitted by law, Lumos may enter into such deeds with any past or present officer of Lumos or a related body corporate of Lumos.

Pursuant to the Constitution, Lumos must indemnify all Directors, executive officers and other officers, past and present, against all liabilities incurred as an officer of Lumos, to the maximum extent permitted by law. Under the deed, Lumos indemnifies each Director and relevant officers against any liability that may arise from their position as an officer of Lumos or of a related body corporate, to the extent permitted by law. The deed provides that Lumos must meet the full amount of any such liabilities, including legal costs that are reasonably incurred, charges and expenses.

Pursuant to the Constitution, Lumos may arrange directors and officer's insurance for each of its Directors and any relevant officers, to the extent permitted by law. Under the deed, Lumos must maintain such insurance for the period from the date of the deed until seven years after the Director, CFO or Company Secretary ceases to hold their position as an officer of Lumos except in certain cases. This seven year period can be extended where certain actions or proceedings commence before the period expires.

6.4.2.6 Other information about Directors' interests and benefits

Directors are also entitled to be reimbursed for all reasonable travel, accommodation and other expenses incurred while attending meetings of Lumos, the Board or a Board Committee, or when otherwise engaged on business of Lumos in carrying out their duties as a Director.

Directors who serve on any Board Committee, who devote special attention to the business of Lumos, who otherwise perform services which, in the opinion of the Board, are outside of the scope of the ordinary duties of a Director or who, at the request of the Board, travel on the business of Lumos, may be paid extra remuneration as the Board decides.

Additionally, subject to the Corporations Act, any person (including an officer of Lumos) may be paid a benefit in connection with the retirement from office (including loss of office, resignation from office or death of a person who held office at the time immediately preceding his or her death) of any officer of Lumos. The Board may make arrangements with any officer with respect to providing for or making payment of benefits in accordance with this.

6.4.2.7 Directors' Shares and Options

Directors are not required by the Constitution to hold any Shares.

It is expected that the following Directors will personally (or through entities with which they are associated) hold the following Shares and/or Options on Completion:

Table 6.3: Directors' interests on Completion

Director	Shares on Completion	Options on Completion
Sam Lanyon[1]	–	–
Robert Sambursky[2]	–	5,498,515
Catherine Robson[3]	278,839	–
Bronwyn Le Grice[4]	28,400	–
Lawrence Mehren[4]	80,000	–

Notes:

1. Sam Lanyon does not hold any securities in Lumos at the Prospectus Date, however he holds 10.98% of Planet Innovation directly (in the form of options and restricted shares) and a trust held in his wife's name holds 256,417 Preference Shares in Lumos, resulting in an indirect economic interest in Lumos of approximately 5.7% on the Prospectus Date and 3.1% on Completion (each on an undiluted basis).
2. Robert Sambursky holds shares and warrants over shares in RPS Diagnostics a Shareholder in Lumos (and 5,760,349 Options in Lumos) at the Prospectus Date, resulting in a potential indirect economic interest in Lumos of approximately 5.1% on the Prospectus Date (on an undiluted basis). Robert Sambursky exercised 261,834 Options prior the Prospectus Date and will receive 261,834 Shares prior to Completion and will sell those Shares at the Offer Price per Share through SaleCo under the Offer to receive $327,292.50 in aggregate). This will give him approximately 3.9% indirect economic interest in Lumos on Completion (on an undiluted basis). These Shares will be issued with disclosure under this Prospectus.
3. Catherine's holding comprises 128,209 Shares to be issued upon conversion of Preference Shares, 90,230 Shares to be issued on conversion of Pre-IPO Convertible Notes, and 60,400 to be applied for under the Offer at the Offer Price per Share. These holdings may be held by Catherine or through an entity associated with her.
4. To be applied for under the Offer at the Offer Price per Share. These holdings may be held by the Director or through an entity associated with them.

Shares acquired by the Directors under the Offer will not be subject to escrow arrangements.

6.4.3. Interests and compensation of the Senior Leadership Team (Other than the CEO)

6.4.3.1 Overview of Senior Leadership Team compensation (other than the CEO, CFO and Company Secretaries)

Members of the Senior Leadership Team based in Australia have employment agreements with Lumos. Members of the Senior Leadership Team based in the United States have at will employment letters with Lumos. Remuneration packages include a total fixed remuneration component (including base salary and any statutorily required superannuation or benefits) and potential to earn an STI and/or an LTI in the form of awards under the New Lumos LTIP based on time and/or performance targets set from time to time by the Board.

The employment agreements generally include a restraint of trade period of one year post termination of employment within the employee's jurisdiction of employment (subject to enforceability), whilst the at will offer letters generally include a non-solicitation requirement of one year post termination of employment. The employment agreements can be terminated by either party by providing four weeks written notice, whereas the at will offer letters may be terminated at any time by either party without providing notice to the other party.

6.4.3.2 Leydin Freyer Engagement

Lumos entered into an engagement agreement with Leydin Freyer (of which Melanie Leydin is a director) on or about 23 September 2020 pursuant to which Leydin Freyer has agreed to provide company secretarial and accounting services to Lumos. Pursuant to this agreement, Leydin Freyer provides the services of Melanie Leydin (CFO and Company Secretary) and Tracy Weimar (Company Secretary). This agreement is a contract for services and is not an employment agreement.

Fees payable to Leydin Freyer are based on hourly rates as set out in the engagement letter. These vary according to the level of skill of the professional undertaking the task and complexity of the activity.

Either party may terminate the agreement by providing one months' notice, or a lesser period as mutually agreed by both parties (unless there is wilful misconduct, in which case the agreement will terminate immediately).

6.4.4. Short-term incentives

Lumos' employment agreements and at will offer letters recognise the potential for the award of cash STIs for its employees in future years, which may become payable upon satisfaction of specified performance criteria. Participation in any STI program will be determined by the Board in its absolute discretion and is assessed following the conclusion of the relevant financial year and publication of Lumos' audited financial statements.

Current STI percentage targets for the CEO are described in Section 6.4.2.4. Whether an STI is granted will depend on satisfaction of various criteria, including individual performance against KPIs and Lumos' financial performance outcomes, as determined by the Board. STIs are not payable to Sam Lanyon, or to Melanie Leydin and Tracy Weimar (who are engaged through Leydin Freyer).

6.4.5. New Lumos Long Term Incentive Plan

On the Prospectus Date, Lumos adopted the Lumos Long Term Incentive Plan (**New Lumos LTIP**) which provides the framework under which future individual grants of equity incentives (awards) may be made to employees of Lumos (including the Senior Leadership Team). The New Lumos LTIP has been designed to attract and retain employees, and to provide additional incentive to employees of Lumos to promote Lumos' success. No grants under the New Lumos LTIP will have been made on or prior to Completion. The key terms of the New Lumos LTIP are set out in Table 6.4.

Table 6.4: Terms of the New Lumos LTIP

Term	Description
Administration	The New Lumos LTIP will be administered by the Board.
Eligibility	Full-time and part-time employees and Non-executive Directors of Lumos and any other person that the Directors determine is eligible to receive awards under the New Lumos LTIP.
Awards	The New Lumos LTIP provides Lumos with flexibility to grant the following types of awards: • options to subscribe for Shares, including, for participants who are subject to the U.S. Internal Revenue Code (**Code**), options that qualify as incentive stock options (within the meaning of Section 422 of the Code) or options that do not so qualify (each an **Option**); • rights to be paid a cash amount determined by the price of Shares at a specified time or the movement in price over a period of time (**Incentive Rights**); • ability to subscribe for Shares that are subject to restrictions, including on transfer, until specified conditions are satisfied (**Restricted Shares**); or • rights to receive Shares or cash, based on specified performance factors (**Performance Rights**), (together **Awards**).
Shares	Shares issuable under the New Lumos LTIP may be newly issued Shares or already issued Shares acquired and held (except in the case of participants who are citizens or residents of the United States of America or otherwise subject to the Code (**U.S. Participants**)) by an employee benefit trust established by Lumos. Up to 15% of the Shares on issue at the date of adoption of the New Lumos LTIP may be issued pursuant to awards granted to U.S. Participants under the New Lumos LTIP, all of which may be issued pursuant to incentive stock options (within the meaning of Section 422 of the Code).
Conditions	The Board will determine the terms and conditions of each award, including: • the type of Award; • the number or value of Shares or other consideration subject to the Award; • if the Award is an Option, the exercise price of the Option, or if it is any other type of Award, the purchase price (if any) payable for the Shares under the Award (except that, in the case of an Option granted to a U.S. Participant, the exercise price may never be lower than the fair market value on the date of grant); and • any vesting conditions, including service and/or performance conditions. The terms and conditions of each award will be set out in an award agreement. Options that are intended to qualify as incentive stock options (within the meaning of Section 422 of the Code) will have terms and conditions that satisfy the requirements of Section 422 of the Code.
Exercise price or Purchase price	The exercise price or purchase price will be determined by the Board (except that, in the case of an Option granted to a U.S. Participant, the exercise price may never be lower than the fair market value of a Share on the date of grant). In the case of an Option intended to qualify as an incentive stock option (within the meaning of Section 422 of the Code) granted to a U.S. Participant who owns Shares representing more than 10% of the total combined voting power of all classes of shares of Lumos or any parent or subsidiary (**Ten Percent Shareholder**), the exercise price must be at least 110% of the fair market value of a Share on the date of grant.
Vesting and exercise	Options will become exercisable when the applicable vesting conditions have been satisfied. Incentive Rights and Performance Rights will vest and be settled by the delivery of Shares (or, where applicable, cash) when the applicable vesting or performance conditions have been satisfied. Restricted Shares will cease to be restricted when the applicable vesting conditions have been satisfied in accordance with the award agreement.

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Term	Description
Lapsing and forfeiture	An Option will lapse on the date specified in the grant (or three years after vesting if not specified), or any earlier date specified in the award agreement (for example, upon failure to satisfy a vesting condition). However, an Option granted to a U.S. Participant who is also a California resident may not have an expiration date earlier than the 10th anniversary of the date of grant. An Option intended to qualify as an incentive stock option (within the meaning of Section 422 of the Code) may not have an expiration date later than the 10th anniversary of the date of grant, and such an Option granted to a Ten Percent Shareholder may not have an expiration date later than the 5th anniversary of the date of grant. Restricted Shares will become subject to forfeiture or compulsory transfer, and Incentive Rights and Performance Rights will lapse, on the occurrence of a date or circumstance specified in the award agreement (for example, upon failure to satisfy a vesting or performance condition).
Dealing restrictions	A participant may not dispose of an award in any manner, other than on his or her death or if permitted by Lumos or under an award transfer program approved by Lumos that permits transfers in specified circumstances.
Cessation or change of employment	The Board may specify in the terms of an invitation or make a determination as to how an employee's Awards will be treated on the occurrence of cessation of employment of the employee. Applicable treatment may include: • vesting on the cessation date; • options only be exercisable within a specified period; or • lapse or forfeit of the Awards.
Change of control	Where there is a change of control event (for example, a takeover bid, scheme of arrangement, merger or any other transaction or event that in the Board's opinion is a change of control event), the Board may determine, subject to the ASX Listing Rules, with respect to each award, that: • Awards, to the extent not fully vested, will become vested and exercisable in full or in part; • Options may be exercised within a specific period only, otherwise they will lapse; • disposal restrictions or any other terms which apply to the Awards cease to apply; or • Lumos, on behalf of the employee, will direct the trustee to transfer trust shares into the employee's name.
Award adjustments	In order to minimise material advantage or disadvantage to a participant resulting from a variation in Lumos' issued share capital, before the delivery of Shares or payment to a participant, Lumos may, subject to the ASX Listing Rules, appropriately and proportionately adjust the exercise price and/or number and/or class of Shares subject to each outstanding Option or Award, provided that the exercise price or purchase price of any Share may not be less than the nominal value of a Share, and a fraction of a Share will not be issued. For Options granted to U.S. Participants who are residents of the State of California, a proportionate adjustment shall be made to the number of shares purchasable and the Exercise Price thereof under any Option granted pursuant to the Plan in the event of a stock split, reverse stock split, stock dividend, recapitalisation, combination, reclassification or other distribution of or on the Shares without the receipt of consideration by Lumos.
Amendments	The Board may amend or supplement the New Lumos LTIP, however it may not do so without employee consent or approval of more than 50% of the employees holding Awards where the amendment adversely affects the existing rights of employees in respect of any granted Awards.
ASX Listing Rules	The New Lumos LTIP and awards made under it are always subject to the ASX Listing Rules and applicable law.

6.4.6. Options remaining on Completion

As at the Prospectus Date, Lumos has on issue 12,465,497 Options (including 5,760,349 Options held by the CEO) which were granted under the Existing Lumos Incentive Plan. On Completion, Lumos will have on issue 12,203,663 Options (following the exercise of 261,834 Options prior to Completion by the CEO as referred to in Section 6.3). Key terms of these Options are set out in Table 6.5 below. Lumos does not intend to grant further Options after the Prospectus Date under the Existing Lumos Incentive Plan.

Table 6.5: Key Terms of Options under the Existing Lumos Incentive Plan

Term	Description
Exercise Price	The exercise price is $0.567 per Option.
Rights	Each Option entitles the holder to one Share on exercise of the Option.
Vesting	Some Options will be unvested on Completion and will vest subject to various vesting schedules or performance criteria, as set out in Table 6.6 below. Only vested Options are exercisable.

Expiry	An Option will lapse on the earliest of:
	• the expiry date of the Option, which is outlined in the vesting schedule in Table 6.6;
	• for:
	  • vested Options, 90 days following lawful termination of a participant's engagement (unless the Board determines otherwise) or, in the case of a termination of the employment of a participant who is a resident of the State of California as a result of total and permanent disability or death, 6 months following such termination;
	  • unvested Options, immediately upon lawful termination of a participant's engagement (unless the Board determines otherwise); or
	• 180 days following unlawful termination by Lumos of a participant's engagement.

Other provisions	If at any time prior to the exercise of an Option there is a reorganization of the share capital of Lumos, then the terms of the Options shall be proportionately reorganised in accordance with governing plan terms. If, prior to the exercise of an Option, Lumos makes a pro rata bonus issue to the holders of its Shares, and the Option is not exercised prior to the closing date in respect of that bonus issue, the Option will, when exercised, entitle the holder to one Share plus the number of bonus Shares that would have been issued to the holder of the Options if the Option had been exercised prior to the books closing date. Options are not transferrable (other than to certain permitted transferees) and will not be quoted. The exercise of rights and obligations under the Options will be subject to the ASX Listing Rules.

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Key People, Interests and Benefit

Table 6.6: Options

Option vesting details	Grant date	Expiry Date[1]	Number of Options held by the CEO on Completion	Expected number vested on Completion	Number of Options held by others[2] on Completion	Expected number vested on Completion
Time based – vested on grant[3]	12 August 2019	12 August 2026	1,567,892	1,567,892	1,665,050	1,665,050
Time based – four year vesting[4]	12 August 2019	12 August 2026	1,829,726	965,689	2,605,066	1,482,901
Performance based[5]	12 August 2019	12 August 2026	1,372,295	457,432	1,395,170	249,301
Time based – four year vesting[4]	4 November 2019	4 November 2026	–	–	320,202	142,312
Performance based[6]	4 November 2019	4 November 2026	–	–	137,229	–
Time based – four year vesting[4]	2 March 2020	2 March 2027	–	–	320,202	106,734
Performance based – vesting on IPO	4 March 2020	4 March 2027	–	–	137,229	137,229
Performance based[7]	1 October 2020	1 October 2027	728,602	–	–	–
Time based – vesting on IPO	30 November 2020	1 October 2027	–	–	125,000	125,000
Total[8]			**5,498,515**	**2,991,012**	**6,705,148**	**3,908,527**

Notes:

1. Options may expire prior to this date in accordance with their terms (refer to Table 6.5).
2. Other holders of Options are 19 current Lumos employees as at the Prospectus Date and one former director.
3. Robert Sambursky holds 5,760,349 Options at the Prospectus Date. He exercised 261,834 Options prior to the Prospectus Date and will receive 261,834 Shares prior to Completion and sell those Shares at the Offer Price per Share through SaleCo under the Offer to receive $327,292.50 in aggregate. These Shares will be issued with disclosure under this Prospectus. This table reflects the Options on Completion and so excludes the 261,834 exercised Options.
4. 25% vest on the first anniversary of the grant date, with the remaining vesting monthly (in equal amounts) for the next 36 months after the first anniversary of the grant date. These Options are not subject to performance conditions.
5. In respect of the CEO: 1/3 vest on a "Series A Closing"(which has occurred); 1/3 vest on Lumos obtaining FDA clearance for FebriDx®; and 1/3 vest on Lumos' revenue being equal to or greater than $20m or Lumos' revenue for the sale of FebriDx® exceeding $10m (in either case measured over a rolling 12 month period).

   In respect of holders other than the CEO, vesting varies based on performance criteria related to the roles of the relevant holder, including for example: Lumos' revenue being equal to or greater than $20m or Lumos' revenue for the sale of FebriDx® exceeding $10m (in either case measured over a rolling 12 month period); Lumos' Commercial Services' revenue exceeding $15m (measured over a rolling 12 month period); successful buildout of Carlsbad manufacturing facility; successful integration of Netsuite ERP; Lumos obtaining MDSAP approval and eQMS integration; and Lumos obtaining FDA clearance for FebriDx®. If the relevant performance criteria occur in respect of a particular holder – 100% of that holder's Options vest.
6. 100% vest if a format of FebriDx® that uses a digital reader enters into clinical trials.
7. 50% vest if Lumos' market capitalisation is maintained at greater or equal to $150m (measured on a monthly rolling average using volume weighted average pricing) for one month. 100% vest if Lumos' FebriDx® revenue is equal to or greater than $20m (over a rolling 12 month period).
8. For all Options described as "performance based", those Options will lapse if vesting does not occur by the fourth anniversary of the grant date.

6.5. Escrow

The parties listed in Table 6.7 have agreed to enter into voluntary escrow arrangements in relation to the Shares indicated in that table and held on Completion under which they will be restricted from dealing with those Shares from Completion for various time periods, as set out in Table 6.7.

The restriction on "dealing" is broadly defined and includes, among other things, selling, assigning, transferring or otherwise disposing of any interest in the Shares, encumbering or granting a security interest over the Shares (except to the extent outlined in this Section 6.5), doing, or omitting to do, any act if the act or omission would have the effect of transferring effective ownership or control of any of the Shares or agreeing to do any of those things. There are limited circumstances in which the escrow may be released, or escrowed securities otherwise dealt with, early including:

- to allow the Escrowed Shareholder to accept an offer under a takeover or similar transaction in relation to its escrowed Shares if holders of at least half of the securities the subject of the transaction that are not subject to similar escrow arrangements have accepted the transaction or relevant offer and the takeover is unconditional or all its conditions have been satisfied or waived (subject to a requirement to return the escrowed Shares to escrow if the Offer does not proceed);
- to allow the Escrowed Shareholder to tender escrowed Shares into a bid acceptance facility established in connection with a takeover, provided that holders of not less than half of the securities to which the takeover relates that are not subject to similar escrow arrangements have either accepted the takeover or tendered their securities into the bid acceptance facility (subject to a requirement to return the escrowed Shares to escrow if the Offer does not proceed);
- to allow the escrowed Shares held by the Escrowed Shareholders to be transferred or cancelled as part of a merger;
- to allow Escrowed Shareholders to participate in an equal share buyback, capital return or capital reduction in accordance with applicable law;
- the grant of securities over any or all of their escrowed Shares to a bona fide third party financial institution as security for a loan, hedge or other financial accommodation, provided that the encumbrance does not in any way constitute a direct or indirect disposal of the economic interests, or decrease an economic interest, that the relevant Escrowed Shareholder has in any of its escrowed Shares and no escrowed Shares may be transferred to the financial institution in connection with the encumbrance (with the documentation for such an encumbrance making clear that the escrowed Shares remain in escrow and subject to the voluntary escrow arrangements for the term of those arrangements);
- a transfer (in one or more transactions) of any or all escrowed Shares to a member of a commonly controlled group which includes the Escrowed Shareholder provided such member transferee agrees to be bound by the voluntary escrow arrangements for the term of those arrangements, or in the case of certain limited reorganisations involving the Escrowed Shareholder;
- to the extent required by applicable law (including an order of a court of competent jurisdiction); or
- on the death, serious disability or permanent incapacity through ill health of the Escrowed Shareholder who is an individual.

Table 6.7: Escrowed Shares on Completion

Escrowed Party	Escrow Period[1] (from Completion until)	Number of Escrowed Shares[2] at Completion	Percentage of total issued Shares[2] at Completion
Planet Innovation	FY23 Results Release Time	40,124,915	25.7%
RPS Diagnostics	1HFY22 Results Release Time	7,823,595	5.2%
	FY22 Results Release Time	7,823,594	5.2%
Other Existing Securityholders[3]	FY21 Results Release Time, subject to an early release mechanism described below*	9,836,197	6.6%
	4:15pm on Friday, 26 November 2021, subject to an early release mechanism described below*	9,836,197	6.6%
	* If the 30%+ Share Price Condition is satisfied, all other Existing Securityholders' escrowed shares will be released on the Early Release Time		
Total[4]		**75,444,498**	**50.2%**

Section 6
Key People, Interests and Benefit

Notes:

1. **FY23 Results Release Time** means 4.15pm on the date on which Lumos releases its preliminary results to ASX for the financial year ending 30 June 2023.
   1HFY22 Results Release Time means 4.15pm on the date on which Lumos releases its preliminary results to ASX for the financial half year ending 31 December 2021.
   FY22 Results Release Time means 4.15pm on the date on which Lumos releases its preliminary results to ASX for the financial year ending 30 June 2022.
   FY21 Results Release Time means 4.15pm on the date on which Lumos releases its preliminary results to ASX for the financial year ending 30 June 2021.
   The **30%+ Share Price Condition** will be satisfied on the first date on which the volume-weighted average price of Shares traded on the ASX for 5 consecutive trading days (excluding any trading day which the Company is subject to a trading halt or suspension for the entirety of that day) exceeds the Offer Price by more than 30%. The **Early Release Time** in this case will be 4.15pm on the fifth business day after the Company advises ASX that this condition has been satisfied.
2. Number of Shares is calculated on an undiluted basis. Percentage of Shares at Completion refers to the number of Escrowed Shares divided by the total number of issued Shares at Completion.
3. **Other Existing Securityholders** comprises select institutional Pre-IPO Convertible Noteholders and certain other Existing Securityholders.
4. Certain Existing Securityholders who are allocated Shares under the Priority Offer may agree with the Company to enter into voluntary escrow deeds on equivalent terms to those entered into by Other Existing Securityholders referred to in the table above. Details of any such escrow arrangements will be advised to ASX by Listing.

All of the Shares held by Planet Innovation and RPS Diagnostics on Completion will be escrowed as described in Table 6.7 above.

6.6. Corporate Governance

6.6.1. Overview

This Section 6.6 explains how the Board will oversee the management of Lumos' business. The Board is responsible for the overall corporate governance of Lumos and monitors the operational and financial position and performance of Lumos and oversees its business strategy, including approving its strategic goals. The Board is committed to maximising performance, generating appropriate levels of shareholder value and financial returns, and sustaining the growth and success of Lumos.

With these objectives in mind, the Board is concerned to ensure that Lumos is properly managed to protect and enhance shareholder interests and that Lumos, its Directors, officers and employees, operate in an appropriate environment of corporate governance. Accordingly, the Board has created a framework for managing Lumos including adopting relevant internal controls, risk management processes and corporate governance policies and practices which it believes are appropriate for Lumos' business and which are designed to promote the responsible management and conduct of Lumos.

The ASX Corporate Governance Council has developed and released its fourth edition of the corporate governance recommendations for Australian listed entities (**ASX Recommendations**) in order to promote investor confidence and to assist companies to meet stakeholder expectations. The recommendations are not prescriptions, but guidelines. However, under the ASX Listing Rules, Lumos will be required to provide a statement in its annual report disclosing the extent to which it has followed the ASX Recommendations in the relevant reporting period. Where Lumos does not follow a recommendation, it must identify the recommendation that has not been followed and give reasons for not following it and must also disclose what (if any) alternative governance practices it has adopted in lieu of the recommendation during that period.

The key aspects of the Board's charters and policies are summarised below. These charters and policies are available from Completion on Lumos' website at lumosdiagnostics.com/investors. Except as set out in Section 6.6.2 below, the Board does not anticipate that it will depart from the recommendations of the ASX Recommendations, however, it may do so in the future if it considers that such a departure would be reasonable or appropriate.

6.6.2. Board of Directors

The Board considers an independent Director to be a Non-executive Director who is free of any interest, position, association or relationship that might influence, or reasonably be perceived to influence, his or her capacity to bring an independent judgement to bear on issues before the Board and to act in the best interests of Lumos and its securityholders generally. The Board will consider the materiality of any given relationship on a case-by-case basis and has adopted guidelines to assist in this regard. The Board reviews the independence of each Director in light of interests disclosed to the Board from time to time.

The Board Charter sets out guidelines of materiality for the purpose of determining independence of Directors in accordance with the ASX Recommendations and has adopted a definition of independence that is based on that set out in the ASX Recommendations.

The Board will consider whether there are any factors or considerations which may mean that a Director's interest, position, association or relationship might influence, or reasonably be perceived to influence, the capacity of the Director to bring an independent judgement to bear on issues before the Board and to act in the best interests of Lumos and its securityholders generally.

The Board considers that each of Bronwyn Le Grice, Catherine Robson and Lawrence Mehren is free from any interest, position, association or relationship that might influence, or reasonably be perceived to influence, the independent exercise of the Director's judgement and that each of them is able to fulfil the role of independent Director for the purpose of the ASX Recommendations.

Rob Sambursky and Samuel Lanyon are currently considered by the Board not to be independent on the basis that they are the CEO of Lumos and a Director of Lumos' majority pre-IPO shareholder respectively.

Accordingly, as at Listing, the Board will consist of a majority of independent Directors consistent with Recommendation 2.4 of the ASX Recommendations.

As Sam Lanyon is not considered to be independent, Recommendation 2.5 of the ASX Recommendation will not be followed at Listing. However, the Directors, other than Sam, consider that he is the most appropriate person to act as Chair of the Board given his industry experience and expertise and understanding of the Lumos business. Lawrence Mehren has been appointed as deputy chair of the Board.

As the Lumos business grows, the Directors will continue to review Lumos' corporate governance arrangements and the composition of the Board, including for example, whether it is appropriate for the Company to engage an independent Chair.

6.6.3. Board Charter

The Board Charter adopted by the Board sets out the responsibilities of the Board in greater detail. It provides that the Board should comprise Directors with the appropriate mix of skills, experience, expertise and diversity which are relevant to Lumos' businesses and the Board's responsibilities. The Board Charter allows the Board to delegate powers and responsibilities to committees established by the Board. The Board retains ultimate accountability to Shareholders in discharging its duties.

The composition of the Board, its performance and the appointment of new Directors will be reviewed periodically by the Board, taking advice from external advisers where considered appropriate.

The Board has developed protocols setting out the structures and procedures to be followed with the aim of ensuring that the consideration of matters by the Board and any Board committees is undertaken free from any actual influence or appearance of influence from persons with conflicts of interest, and that the disclosure of Lumos' confidential information is subject to appropriate corporate governance controls.

6.6.4. Board Committees

The Board may from time to time establish appropriate committees to assist in the discharge of its responsibilities. The Board has established an Audit and Risk Committee and a Nomination and Remuneration Committee.

Other committees may be established by the Board as and when required. Membership of Board committees will be based on the needs of Lumos, relevant legislative and other requirements, and the skills and experience of individual Directors.

6.6.4.1 Audit and Risk Committee

The role and responsibilities, composition and membership requirements of the Audit and Risk Committee are documented in an Audit and Risk Committee Charter. The purpose of the Audit and Risk Management Committee is to assist the Board in fulfilling its responsibilities for corporate governance and overseeing Lumos' financial reporting, internal control structure, risk management systems and internal and external audit functions. This includes confirming the quality and reliability of the financial information prepared by Lumos, working with the external auditor on behalf of the Board and reviewing non-audit services provided by the external auditor to confirm they are consistent with maintaining external audit independence.

The Audit and Risk Management provides advice to the Board and reports on the status and management of the risks to Lumos. The purpose of the Committee's risk management process is to assist the Board in relation to risk management policies, procedures and systems and ensure that risks are identified, assessed and appropriately managed.

In accordance with the ASX Recommendations, the Audit and Risk Committee comprises of at least three members, each of whom is an independent Non-executive Director, being Catherine Robson (Chair), Bronwyn Le Grice and Lawrence Mehren.

6.6.4.2 Remuneration and Nomination Committee

The role and responsibilities, composition, structure and membership requirements of the Committee are documented in a Remuneration and Nomination Committee Charter.

The purpose of the Nomination and Remuneration Committee is to assist the Board in fulfilling its responsibilities for corporate governance and overseeing Lumos' nomination and remuneration policies and practices.

This includes reviewing and making recommendations to the Board on remuneration packages and policies related to the Directors and senior executives. The Nomination and Remuneration Committee is also responsible for administering short term and long term incentive plans (including any equity plans). In addition, the Committee is responsible for reviewing and making recommendations in relation to the composition and performance of the Board and its committees and ensuring that adequate succession plans are in place (including for the recruitment and appointment of Directors and senior management). Independent advice will be sought where appropriate.

In accordance with the ASX Recommendations, the Remuneration and Nomination Committee Charter will have three members, each of whom is an independent Non-executive Director, being Bronwyn Le Grice (Chair), Catherine Robson and Lawrence Mehren.

6.6.5. Corporate Governance Policies

6.6.5.1 Purpose, strategy and values

Lumos' vision is to drive impactful health improvements as a global leader in innovative and cost-effective rapid, POC diagnostic test solutions. Lumos' mission is to develop, manufacture and provide access to rapid, accurate and actionable diagnostic solutions for a diverse range of unmet needs in order to improve outcomes, reduce unnecessary treatments, minimize disease spread or contribute to more effective clinical management and therapeutic decisions.

Lumos' core values are to:

- **Act with integrity and accountability**: Uphold the highest ethical standards in all actions, both in and out of the workplace. Deliver on commitments and measure ourselves against the highest standards of honesty, fairness and fiscal responsibility.
- **Value teamwork and collaboration**: Work together without blame to support your colleagues and position Lumos for success by leveraging our collective skills to build, achieve, problem solve and simultaneously meet both internal goals and the needs of our partners and customers.
- **Embrace and respect diversity**: Understand that growth, creativity and synergy evolve out of our differences. It takes a team with our unique set of personalities, lifestyles, thought processes, work experiences, ethnicities, races, colours, religions, genders, gender identities, sexual orientations, marital statuses, ages, national origins, disabilities, veteran statuses, ideas, strengths and experiences to make our company succeed. Listen and welcome healthy, considerate debate and differences of opinion.
- **Lead by example**: Provide and accept feedback. Lead through your actions and commit to growing, innovating and improving while still enjoying the ride.
- **Commit to quality and accuracy**: Provide outstanding products and unsurpassed service that, together, deliver premium value to our customers, clients, partners and the communities we serve. Think differently to overcome obstacles, find solutions and provide exceptional results.

6.6.5.2 Code of Conduct

Lumos is committed to instilling and continually reinforcing a culture across the organisation of acting lawfully, ethically and responsibly in all business practices. Accordingly, the Board has adopted a formal Code of Conduct that outlines how it expects its representatives to behave and conduct business in the workplace and includes legal compliance and guidelines on appropriate ethical standards.

The Code of Conduct is designed to provide a benchmark for professional behaviour throughout Lumos' business, support its business reputation and corporate image within the community and make Lumos' Directors and employees aware of the consequences if they breach this policy.

All suspected breaches of the Code of Conduct will be investigated by Lumos and appropriate and proportionate disciplinary and remedial action will be taken.

6.6.5.3 Anti-bribery and Corruption Policy

Lumos takes a zero-tolerance approach to bribery and corruption and is committed to acting professionally, fairly and with integrity in all its business dealings and relationships wherever Lumos operates, and implementing and enforcing effective systems to counter bribery and corruption. The anti-bribery and corruption policy set out the responsibilities of Lumos' personnel, including in their dealings with, and through, third parties. It addresses protection of Lumos' personnel in seeking to comply with this policy, dealing with false reports, investigations, consequences for breach, examples of improper conduct, contact with government officials, donations, in-kind gifts and corporate hospitality, political and charitable contributions and sponsorships, facilitation payments and secret commissions.

6.6.5.4 Communications Policy

Lumos is committed to effective communication with its customers, Shareholders, market participants, employees, suppliers, other stakeholders and the wider community. Lumos will ensure that all stakeholders, market participants and the wider community are informed of its activities and performance.

To achieve this, Lumos will communicate information regularly to Shareholders and other stakeholders through a range of forums and publications, including Lumos' website, at Lumos' Annual General Meeting and through the Company's Annual Report and ASX announcements.

6.6.5.5 Continuous Disclosure Policy

Once listed, the Company will be required to comply with the continuous disclosure requirements of the ASX Listing Rules and the Corporations Act. Subject to the exceptions contained in the ASX Listing Rules, the Company will be required to immediately advise ASX of any information concerning the Company that a reasonable person would expect to have a material effect on the price or value of the Shares.

Lumos has adopted a Continuous Disclosure Policy to take effect from Listing, which reinforces Lumos' commitment to its continuous disclosure obligations, and describes the processes in place that enable Lumos to provide Shareholders with timely disclosure in accordance with those obligations. Information will be communicated to Shareholders through the lodgement of all relevant financial and other information with ASX, and copies of Lumos' announcements to ASX will be available on Lumos' website.

6.6.5.6 Diversity Policy

Lumos values and is proud of its strong and diverse workforce and is committed to supporting and further developing this diversity through attracting, recruiting, engaging and retaining diverse talent and aligning Lumos' culture and management systems with this commitment. The Board has approved a Diversity Policy, which sets out the Company's commitment to an inclusive and diverse workforce. Lumos will include in its corporate governance statement each year details of the measurable objectives set under the Diversity Policy of the year to which the corporate governance statement relates, and a summary of the Company's progress towards achieving those measurable objectives.

6.6.5.7 Securities Trading Policy

Lumos has adopted a Securities Trading Policy that is intended to explain the types of conduct in relation to dealing in securities that are prohibited by law and establish procedures for the buying and selling of securities to ensure that public confidence is maintained in the reputation of the Company and the Company's Directors and employees, and in the trading of the Company's securities.

The Securities Trading Policy provides that Directors, employees and contractors must not deal in the Company's securities when they are aware of 'inside' information. Directors and certain restricted employees must not deal in the Company's securities during any of the following blackout periods:

- from Lumos' year end until the business day after the release of the full year results;
- from Lumos' half year end until the business day after the release of the half year results; and
- any additional period imposed by the Board from time to time.

Directors and restricted employees must receive prior approval for any proposed dealing in Lumos' securities outside of the above blackout periods (including any proposed dealing by one of their connected persons).

6.6.5.8 Remuneration Policy

Lumos is committed to attracting and retaining the best people to work in the organisation, including Directors and senior management. A key element in achieving that objective is to ensure that Lumos is able to appropriately remunerate its key people. Lumos has adopted a remuneration policy, the purpose of which is to establish a framework for remuneration that is designed to:

- ensure that coherent remuneration policies and practices are observed which enable the attraction and retention of Directors and management who will create value for Shareholders;
- fairly and responsibly reward Directors and senior management having regard to Lumos' performance, the performance of the senior management and the general pay environment; and
- comply with all relevant legal and regulatory provisions.

Remuneration for Executive Directors and senior executives may incorporate fixed and variable pay performance elements with both a short-term and long-term focus. The incentives for Non-executive Directors will be designed so as not to conflict with their obligation to bring an independent judgement to matters before the Board.

6.6.5.9 Risk Management Policy

Risk recognition and management are viewed by Lumos as integral to its objectives of creating and maintaining Shareholder value, and to the successful execution of Lumos' strategies.

The purpose of the Risk Management policy adopted by the Board is to ensure that:

- appropriate systems are in place to identify (to the extent reasonably practicable) all material risks that may impact on the Company's business;
- the financial and non-financial impact of identified risks is understood, and appropriate internal control systems are in place to limit the Company's exposure to such risks;
- appropriate responsibilities are delegated to control the identified risks effectively; and
- any material changes to the Company's risk profile are disclosed in accordance with the Company's Continuous Disclosure policy.

6.6.5.10 Whistleblower Policy

Lumos is committed to the highest standards of conduct and ethical behaviour in all of its business activities and to promoting and supporting a culture of honest and ethical behaviour, corporate compliance and good corporate governance. The whistleblower policy has been adopted to provide a safe and confidential environment where concerns can be raised by whistleblowers without fear of reprisal or detrimental treatment. The whistleblower policy outlines how Lumos will protect such persons for raising concerns and how reported concerns are received and, where appropriate, investigated by Lumos.

6.6.5.11 Health, Safety and Environment Policy

Lumos is committed to the provision of safe and healthy working conditions for all of its employees and contractors and to the safe custody of visitors to its operations and premises. Lumos recognises the duty to provide and maintain, so far as is practicable, a working environment that is safe, without risk to health and with a focus on fairness and respect. Lumos has adopted a Health, Safety and Environment Policy which outlines the steps Lumos encourages employees to take in maintaining their health and safety at work, and that Lumos will provide ongoing education and training regarding risks and hazards at work.

6.7. Planet Innovation MSAs

Since 1 April 2019, Lumos has been party to a master services agreement with Planet Innovation Pty Ltd (**PIPL**), a subsidiary of Planet Innovation (**Existing Planet Innovation MSA**), under which PIPL agreed to provide services to Lumos, including development services related to the Lumos readers, connected software services and Lumos Products. PIPL also provided Lumos with ad hoc support and management services. Under the Existing Planet Innovation MSA, the parties typically contracted at commercially favourable terms to Lumos of between 1.3x and 1.6x of PIPL's direct labour cost (**DLC**) by employee classification. The Existing Planet Innovation MSA also provided that if Lumos ceased to be controlled by Planet Innovation, contracted rates charged to Lumos would increase to between 2.1x - 2.4x DLC.

Project costs paid by PIPL to Lumos under the Existing Planet Innovation MSA in FY20 and 1H21 were $3.2m and $0.8m respectively. Project costs paid by the Lumos to PIPL under the Existing Planet Innovation MSA in FY20 and 1H21 were $4.4m and $2.7m respectively.

In anticipation of Planet Innovations' shareholding in Lumos falling below 50% on Completion, Lumos negotiated amendments to the Existing Planet Innovation MSA with PIPL to apply from 1 July 2021 (**Amended Planet Innovation MSA**). The Amended Planet Innovation MSA will be bi-directional, providing for the provision of development services from Lumos to PIPL, as well as the provision of development services from PIPL to Lumos. With Lumos' expanding its support and management capability in the lead up to Completion, Lumos does not anticipate requiring ad hoc services of that nature from PIPL going forward (with services of that nature therefore not included in the Amended Planet Innovation MSA).

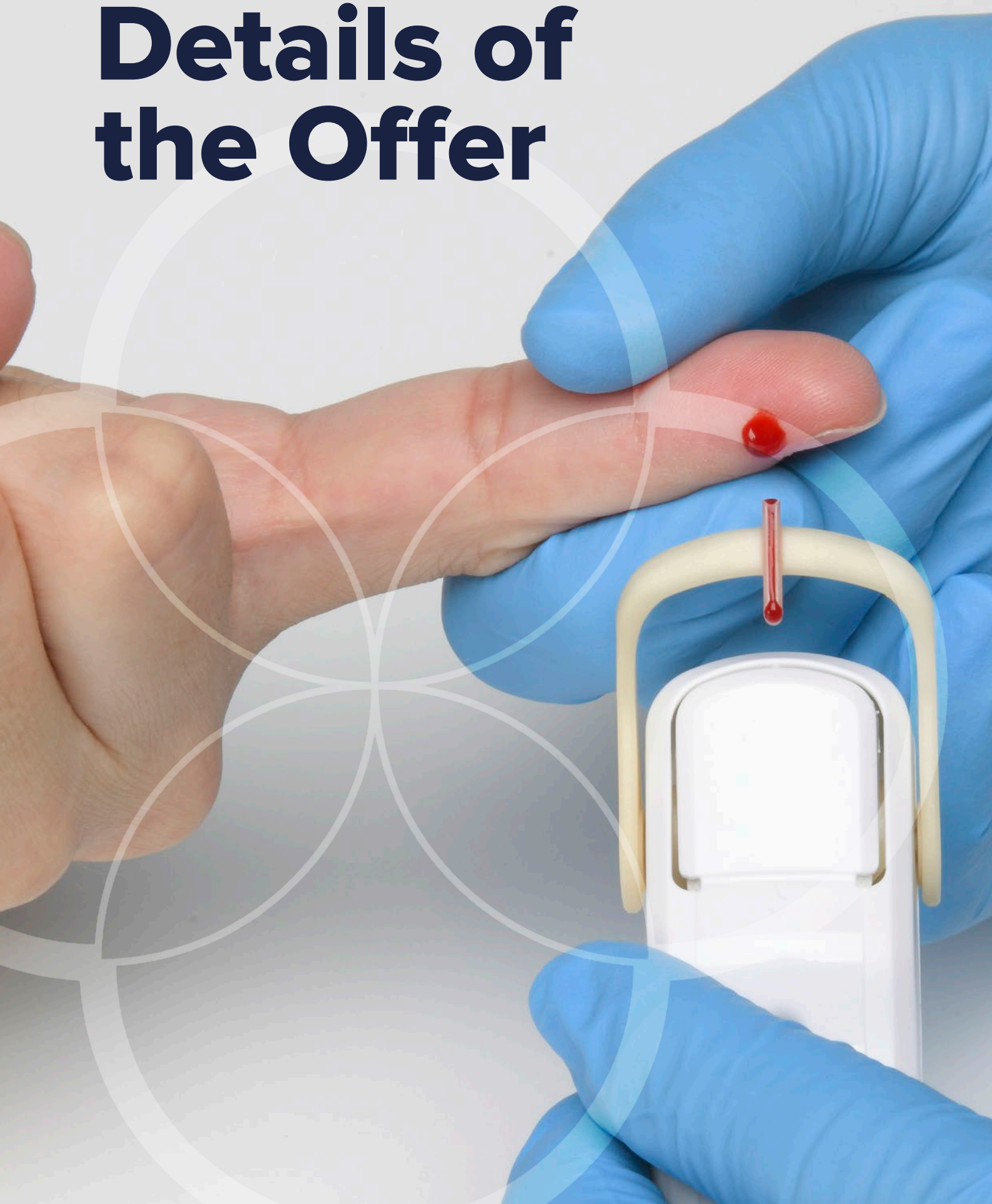
Fee rates have also been updated in the Amended Planet Innovation MSA to reflect agreed arm's length terms between the parties, with the rates for development services agreed to be provided by PIPL to Lumos set at 2.1x DLC, and the rates for development services agreed to be provided by Lumos to PIPL set at 2.2x DLC. Neither party is obliged to acquire development services from the other under (nor are there any minimum volume commitments in) the Amended Planet Innovation MSA.

6.8. Related Party Agreements

Lumos does not anticipate that it will be party to any material related party arrangements with its Directors, officers or Shareholders (or affiliates from them) from Completion other than as set out in this Prospectus.

Section 7

Details of the Offer



Section 7
Details of the Offer

7.1. The Offer

This Prospectus relates to an initial public offering of 30,400,000 Shares at the Offer Price of $1.25 per Share and the sale of 20,000,000 Shares by SaleCo. The 50,400,000 Shares offered under this Prospectus will represent approximately 33.6% of the Shares on issue at Completion

The Offer is expected to raise $63,000,000. The total number of Shares on issue at Completion will be approximately 150,152,413 assuming Completion occurs on 29 June 2021 (refer to Note 3 of the Key Offer Statistics on page 4) and all Shares will, once issued, rank equally with each other. A summary of the rights attaching to the Shares is set out in Section 7.11.

The Offer is made on the terms, and is subject to the conditions, set out in this Prospectus.

7.1.1. Structure of the Offer

The Offer comprises:

- the Broker Firm Offer, which is open to Australian retail clients of Brokers who have received a firm allocation from their Broker; and
- the Priority Offer, which is open to investors who receive an invitation to participate in the Offer from the Company and who have a registered address in Australia; and
- the Institutional Offer, which consisted of an invitation to bid for Shares made to Institutional Investors in Australia and certain other eligible jurisdictions.

No general public offer of Shares will be made under the Offer. Shares offered under the Offer are offered and issued with disclosure under this Prospectus.

Details of the Broker Firm Offer and the allocation policy under it are described in Section 7.3. Details of the Priority Offer and the allocation policy under it are described in Section 7.4.

Details of the Institutional Offer and the allocation policy under it are described in Section 7.5. The allocation of Shares between the Broker Firm Offer, the Priority Offer and the Institutional Offer was determined by the Joint Lead Managers and the Company and SaleCo, having regard to the allocation policies outlined in Sections 7.3, 7.4 and 7.5.

The Offer has been fully underwritten by the Joint Lead Managers. A summary of the Underwriting Agreement, including the events which would entitle the Joint Lead Managers to terminate the Underwriting Agreement, is set out in Section 10.6.

7.1.2. Purpose of the Offer and use of proceeds

The purpose of the Offer is to:

- provide funding and financial flexibility to support Lumos' growth strategy and future growth opportunities;
- broaden Lumos' shareholder base and provide a liquid market for Shares;
- provide Lumos with the benefits of an increased brand profile that may arise from being a publicly listed entity; and
- provide existing securityholders with an opportunity to realise a portion of their investment in Lumos.

The proceeds of the Offer will be applied as described in Section 7.1.3.

7.1.3. Sources and uses of funds

The Offer proceeds received by the Company and SaleCo will be applied as described in Figure 7.1.

Figure 7.1: Sources and uses of funds

Sources of funds	A$ million	Uses of funds[1]	A$ million
The Company			
Cash proceeds received by the Company under the Offer from the issue of Shares	38.0	Infrastructure and capacity expansion[2]	5.8
		Sales and Marketing[3]	8.4
		Regulatory, Clinical and Quality[4]	3.7
		Development of test pipeline[5]	3.1
		Technology platform development[6]	5.4
		Working capital[7]	7.0
		Offer costs	4.6
SaleCo			
Cash proceeds received by SaleCo from the sale of Shares by SaleCo	25.0	Payments to Selling Shareholders for Shares in the Company	25.0
Total sources	**63.0**	**Total uses**	**63.0**

Notes:

1. This represents a statement of the Company's current intentions as at the Prospectus Date. 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. In addition, as the proceeds of the Offer will be received in Australian dollars and, as the expenditure will predominantly be in US dollars, the actual amount of the proceeds used for each of the items above will depend on the AUD:USD exchange rate at the time that the funds are converted to US dollars.
2. Infrastructure and capacity expansion related to Carlsbad facility including fit-out and manufacturing equipment for capacity increase.
3. Sales and marketing relates to increase in sales headcount and expenses for product division & commercial services divisions and establishment of commercial manufacturing e.g. pre-launch/product demonstration costs.
4. Regulatory, Clinical and Quality relates to headcount, compliance and clinical trials costs associated with Lumos branded products.
5. Development of test pipeline related to investment in new POC diagnostic tests.
6. Technology platform development related to investment in technology platform related assets e.g. digital readers and associated software applications.
7. Working capital includes general and administrative (corporate, finance, travel and general expenses) and changes in working capital in line with revenue growth.

Lumos' stated business objectives, which it will use cash reserves, cash flow from existing operations and the net proceeds of the Offer to fund, are described further in Section 3.4.10 in relation to FebriDx®, in Sections 3.2.2 and 3.5.3 in relation to its Products division pipeline development, in Section 3.6.6 in relation to Commercial Services division and in Section 3.7.1 in relation to its Carlsbad infrastructure and capacity expansion. Lumos will also continue to assess opportunities to seek regulatory clearances and provide further support to existing sales efforts in new projects and client acquisitions across its target markets of North America and Europe.

The Board retains the right to vary these uses of funds, acting in the best interests of Shareholders and as circumstances require.

7.1.4. Shareholding structure of the Company

The details of the Company's shareholding structure as at the Prospectus Date and on Completion are set out in Section 6.3.

Section 7
Details of the Offer

7.1.5. Control implications of the Offer

On Completion, no Shareholder will have a controlling interest (as defined by section 50AA of the Corporations Act) in the Company.

7.1.6. Potential effect of the Offer on the future of the Company

The Company believes that from Completion it will have sufficient funds available from the proceeds of the Offer and from its operations to fulfil the purposes of the Offer and meet Lumos' stated business objectives during the Forecast Period.

7.2. Terms and conditions of the Offer

Topic	Summary
What is the type of security being offered?	Shares (being fully paid ordinary shares in the capital of the Company).
What are the rights and liabilities attached to the Shares being offered?	A description of the Shares, including the rights and liabilities attaching to them, is set out in Section 7.11.
What is the consideration payable for each Share being offered?	Successful applicants under the Offer will pay the Offer Price, being $1.25 per Share. Except as required by law, applicants cannot withdraw or vary their application.
What is the Broker Firm Offer and Priority Offer period?	The key dates, including details of the Offer Period, are set out in the important information section of this Prospectus on page 5. The Broker Firm Offer and Priority Offer open at 9.00am (AEST) on Tuesday, 15 June 2021 and will close at 5.00pm (AEST) on Wednesday, 23 June 2021. No securities will be issued on the basis of this Prospectus later than the Expiry Date. The timetable is indicative only and may change. Unless otherwise indicated, all times are stated in AEST. The Company and SaleCo, in consultation with the Joint Lead Managers, reserve the right to vary both of the above times and dates without notice (including, subject to the ASX Listing Rules and the Corporations Act, to close the Offer early, to extend the Closing Date, to accept late Applications or bids, either generally or in particular cases, or to cancel or withdraw the Offer before settlement, in each case without prior notice). If the Offer is cancelled or withdrawn before the allocation of Shares, then all application monies will be refunded in full (without interest) as soon as possible in accordance with the requirements of the Corporations Act.
What are the cash proceeds to be raised?	Approximately $63.0 million will be raised if the Offer proceeds, comprising $38.0m from the issue of Shares by the Company and $25.0m from the sale of Shares by SaleCo.
Is the Offer underwritten?	Yes. The Joint Lead Managers have fully underwritten the Offer pursuant to the Underwriting Agreement. Details are provided in Section 10.6.
What is the minimum and maximum Application size under the Broker Firm Offer and Priority Offer?	The minimum Application under the Broker Firm Offer is 1,600 Shares ($2,000). There is no maximum value of Shares that may be applied for under the Broker Firm Offer. The minimum application under the Priority Offer is 1,600 Shares ($2,000).

Topic	Summary
What is the allocation policy?	The allocation of Shares between the Broker Firm Offer, the Priority Offer and the Institutional Offer was determined the Joint Lead Managers, the Company and SaleCo, having regard to the results of the Bookbuild and the allocation policies outlined in Sections 7.37.4 and 7.5 (as applicable). For Broker Firm Offer participants, the relevant Broker will decide as to how they allocate Shares among their retail clients. The Joint Lead Managers and the Company have absolute discretion regarding the allocation of Shares to applicants under the Offer and may reject an Application, or allocate a lesser number of Shares than applied for. The Joint Lead Managers and the Company also reserve the right to aggregate any Applications that they believe may be multiple Applications from the same person.
When will I receive confirmation that my Application has been successful?	It is expected that initial holding statements will be dispatched by standard post on Wednesday, 30 June 2021. Refunds (without interest) to applicants who make an application and receive an allocation of Shares, the value of which is smaller than the amount of the application monies they have paid, will be made as soon as practicable after Completion.
Will the Shares be quoted?	Lumos will apply to the ASX within seven days after the Prospectus Date for admission to the Official List and quotation of Shares on the ASX (which is expected to be under the code LDX). Completion is conditional on ASX approving this application. If approval is not given within three months after such application is made (or any longer period permitted by law), the Offer will be withdrawn and all application monies received will be refunded (without interest) as soon as practicable in accordance with the requirements of the Corporations Act. The ASX takes no responsibility for this Prospectus or the investment to which it relates. The fact that the ASX may admit the Company to the Official List is not to be taken as an indication of the merits of an investment in the Company.
When are the Shares expected to commence trading?	It is expected that trading of the Shares on ASX will commence on or around Monday, 5 July 2021 on a normal settlement basis. It is expected that holding statements will be dispatched by standard post on or about Wednesday, 30 June 2021. It is the responsibility of each Applicant to confirm their holding before trading in Shares. Applicants will be able to confirm their allocations by telephoning the Company's Offer Information Line on 1300 040 690 between 8:30 am and 5:00 pm (Sydney time) Monday to Friday (excluding public holidays). If you sell Shares before receiving a holding statement, you do so at your own risk. The Company, SaleCo, the Share Registry and the Joint Lead Managers disclaim all liability, whether in negligence or otherwise, if you sell Shares before receiving your holding statement, even if you received confirmation of your allocation from the Offer Information Line, by a Broker or otherwise.
Are there any escrow arrangements?	Yes. Details are provided in Section 6.5.
Has any ASIC relief or ASX waiver been sought or obtained?	Yes. Details are provided in Section 10.9.
Are there any taxation considerations?	The tax consequences of any investment in the Shares will depend upon an investor's particular circumstances. Applicants should obtain their own tax advice prior to deciding whether to invest. Refer to Section 10.11 for general Australian taxation considerations.
Are there any brokerage, commission or stamp duty considerations?	No brokerage, commission or stamp duty is payable by applicants on the acquisition of Shares under the Offer. Refer to Section 6.4.1 for details of the fees payable by the Company to the Joint Lead Managers.

Section 7
Details of the Offer

Topic	Summary
What should you do with any enquiries?	All enquiries in relation to this Prospectus should be directed to the Lumos Offer Information Line on 1300 040 690 between 8:30 am and 5:00 pm (Sydney Time), Monday to Friday (Business Days only) during the Offer Period. All enquiries in relation to the Broker Firm Offer should be directed to your Broker. If you are unclear in relation to any matter or are uncertain as to whether Shares are a suitable investment for you, you should seek professional guidance from your solicitor, stockbroker, accountant, financial adviser or other independent professional adviser before deciding whether to invest.

7.3. Broker Firm Offer

7.3.1. Who may apply

The Broker Firm Offer is open to persons who have received a firm allocation of Shares from their Broker and who have a registered address in Australia. If you have received a firm allocation of Shares from your Broker, you will be treated as a Broker Firm Offer Applicant in respect of that allocation. You should contact your Broker to determine whether you can receive an allocation of Shares from them under the Broker Firm Offer. The Broker Firm Offer is not open to persons in the United States.

7.3.2. How to apply

If you have received an allocation of Shares from your Broker and wish to apply for those Shares under the Broker Firm Offer, you should contact your Broker for information about how to submit your Broker Firm Offer Application Form and for payment instructions. Applicants under the Broker Firm Offer must not send their Application Forms or payment to the Share Registry.

Applicants under the Broker Firm Offer should contact their Broker or the Lumos Offer Information Line 1300 040 690 to request a copy of this Prospectus and Application Form, or download a copy at lumosdiagnostics.com/investors. Your Broker will act as your agent and it is your Broker's responsibility to ensure that your Application Form and Application Monies are received before 5.00pm (AEST) on the Closing Date or any earlier closing date as determined by your Broker.

If you are an investor applying under the Broker Firm Offer, you should complete and lodge your Broker Firm Offer Application Form with the Broker from whom you received your firm allocation. Broker Firm Offer Application Forms must be completed in accordance with the instructions given to you by your Broker and the instructions set out on the reverse of the Application Form.

The minimum application size for investors in the Broker Firm Offer is 1600 Shares ($2,000 worth of Shares), rounded up to the value of the nearest share). There is no maximum value of Shares that may be applied for under the Broker Firm Offer.

The Company, SaleCo and the Joint Lead Managers reserve the right to aggregate any applications that they believe may be multiple applications from the same person or reject or scale back any applications in the Broker Firm Offer. The Company and SaleCo may determine a person to be eligible to participate in the Broker Firm Offer, and may amend or waive the Broker Firm Offer application procedures or requirements, in their discretion in compliance with applicable laws.

By making an Application, you declare that you were given access to this Prospectus, together with an Application Form. The Corporations Act prohibits any person from passing an Application Form to another person unless it is attached to, or accompanied by, a hard copy of this Prospectus or the complete and unaltered electronic version of this Prospectus.

The Company, SaleCo, the Joint Lead Managers and the Share Registry take no responsibility for any acts or omissions committed by your Broker in connection with your Application.

The Company and the Joint Lead Managers may elect to close the Offer or any part of it early, extend the Offer or any part of it, or accept late Applications either generally or in particular cases. The Offer or any part of it may be closed at any earlier time and date, without further notice. Your Broker may also impose an earlier closing date. Applicants are therefore encouraged to submit their Applications as early as possible. Please contact your Broker for instructions.

7.3.3. Payment methods

Applicants under the Broker Firm Offer must pay their application monies to their Broker in accordance with instructions provided by that Broker.

7.3.4. Allocation policy under the Broker Firm Offer

The allocation of Shares to the Broker Firm Offer, and the identity and level of participation of Brokers participating in the Broker Firm Offer, has been determined by agreement between the Joint Lead Managers, the Company and SaleCo.

Shares that are allocated to Brokers for allocation to their clients will be issued or transferred to the applicants nominated by those Brokers (subject to Lumos' right, the right of SaleCo and the right of the Joint Lead Managers to reject, aggregate or scale back applications). It will be a matter for each Broker as to how they allocate Shares among their retail clients, and they (and not the Company, SaleCo or the Joint Lead Managers) will be responsible for ensuring that retail clients who have received an allocation from them receive the relevant Shares.

Applicants will be able to confirm their allocations by telephoning the Lumos Offer Information Line on 1300 040 690 between 8:30am to 5:00pm (Sydney time) Monday to Friday (excluding public holidays). Applicants under the Broker Firm Offer will also be able to confirm their allocation through the Broker from whom they received their allocation.

If you sell Shares before receiving a holding statement, you do so at your own risk. The Company, SaleCo, the Joint Lead Managers, the Share Registry and the Existing Securityholders, disclaim all liability, whether in negligence or otherwise, if you sell Shares before receiving your holding statement, even if you received confirmation of allocation from the Lumos Offer Information Line, by a Broker or otherwise.

7.3.5. Acceptance of Applications

An Application in the Broker Firm Offer is an offer by you to the Company and SaleCo to apply for the number of Shares specified in the Application Form at the Offer Price on the terms and conditions set out in this Prospectus (including any supplementary or replacement document) and the Application Form. To the extent permitted by law, an Application by an Applicant under the Offer may not be varied and is irrevocable.

By making an Application, you declare that you were given access to this Prospectus, together with an Application Form. The Corporations Act prohibits any person from passing an Application Form to another person unless it is attached to, or accompanied by, a paper copy of this Prospectus or the complete and unaltered electronic version of this Prospectus.

An Application may be accepted in respect of the full number of Shares specified in the Application Form or any lower number, without further notice to the Applicant. Acceptance of an Application will give rise to a binding contract on allocation of Shares to successful applicants.

The Company and the Joint Lead Managers reserve the right to reject any Application which is not correctly completed or which is submitted by a person who they believe is ineligible to participate in the Broker Firm Offer, or to waive or correct any errors made by an Applicant in completing their Application.

Successful applicants in the Broker Firm Offer will be issued Shares at the Offer Price. Acceptance of an Application will give rise to a binding contract, conditional on Settlement and quotation of Shares on the ASX.

7.3.6. Application monies

Application monies received under the Broker Firm Offer will be held in a special purpose account until Shares are issued or transferred to successful applicants. Applicants under the Broker Firm Offer whose Applications are not accepted, or who are allocated a lesser number of Shares than the amount applied for, will be mailed a refund (without interest) of all or part of their application monies, as applicable. No refunds pursuant solely to rounding will be provided. Interest will not be paid on any monies refunded and any interest earned on application monies pending the allocation or refund will be retained by Lumos.

7.4. Priority Offer

7.4.1. Who can apply?

The Priority Offer is open to investors who have received an invitation to participate in the Offer from the Company and who have a registered address in Australia unless otherwise agreed by the Company, SaleCo and the Joint Lead Managers in their complete discretion. If you have been invited by the Company to participate in the Priority Offer, you will be treated as an Applicant under the Priority Offer in respect of those Shares that are allocated to you.

7.4.2. How to apply

If you have received a personalised invitation to apply for Shares under the Priority Offer and you wish to apply for Shares, you should follow the instructions on your personalised invitation to complete and lodge your Application.

By making an Application under the Priority Offer, you declare that you were invited to participate in the Priority Offer and were given access to this Prospectus (and any supplementary or replacement prospectus), together with a Priority Offer Application Form.

The minimum application under the Priority Offer is 1,600 Shares ($2,000).

The Company reserves the right to scale back or reject Applications in whole or part, without giving any reason, subject to the terms of the guaranteed minimum allocation described above. Applicants under the Priority Offer whose Applications are not accepted, or who are allocated a lesser number of Shares than the amount applied for (subject to the guaranteed minimum allocation) will receive a refund of all or part of their application monies, as applicable. Interest will not be paid on any monies refunded. The Company may amend or waive the Priority Offer Application procedures or requirements, in its discretion in compliance with applicable laws.

The Company and the Joint Lead Managers may elect to extend the Offer or any part of it, or accept late Applications either generally or in particular cases. The Offer, or any part of it, may be closed at any earlier date and time, without further notice (subject to the ASX Listing Rules and the Corporations Act). Applicants are therefore encouraged to submit their Applications as early as possible.

Certain Existing Shareholders who are allocated Shares under the Priority Offer may agree with the Company to enter into voluntary escrow deeds on equivalent terms to those entered into by Other Existing Securityholders as described in Section 6.5. Details of any such escrow arrangements will be advised to ASX by Listing.

7.4.3. Payment methods

Applicants under the Priority Offer must pay by following the instructions outlined in their personalised invitation and Priority Offer Application Form.

For more details, you should contact the Lumos Offer Information Line 1300 040 690 between 8:30 am and 5:00 pm (Sydney Time), Monday to Friday (excluding public holidays).

7.4.4. Allocation policy

Allocations under the Priority Offer will be at the absolute discretion of the Company.

7.4.5. Acceptance of Applications

An Application in the Priority Offer is an offer by you to Lumos to apply for the number of Shares specified in the Priority Offer Application Form at the Offer Price on the terms and conditions set out in this Prospectus (including any supplementary or replacement document) and the Application Form. To the extent permitted by law, an Application by an Applicant under the Offer is irrevocable.

An Application may be accepted in respect of the full number of Shares specified in the Application Form or any lower number, without further notice to the Applicant. Acceptance of an Application will give rise to a binding contract on allocation of Shares to successful applicants.

Lumos and the Joint Lead Managers reserve the right to reject any Application which is not correctly completed or which is submitted by a person who they believe is ineligible to participate in the Priority Offer, or to waive or correct any errors made by an Applicant in completing their Application.

7.4.6. Application monies

Application monies received under the Priority Offer will be held in a special purpose account until Shares are issued or transferred to successful applicants. Applicants under the Priority Offer whose Applications are not accepted, or who are allocated a lesser number of Shares than the amount applied for, will be mailed a refund (without interest) of all or part of their application monies, as applicable. No refunds pursuant solely to rounding will be provided. Interest will not be paid on any monies refunded and any interest earned on application monies pending the allocation or refund will be retained by Lumos.

7.5. Institutional Offer

7.5.1. Invitations to bid

The Company invites certain Institutional Investors in Australia and a number of other eligible jurisdictions outside the United States to bid for an allocation of Shares at the Offer Price. The Joint Lead Managers separately advised Institutional Investors of the application procedures for the Institutional Offer.

7.5.2. Allocation policy under the Institutional Offer

The allocation of Shares among bidders in the Institutional Offer has been determined by agreement between the Joint Lead Managers, the Company and SaleCo. The Company, SaleCo and the Joint Lead Managers have absolute discretion regarding the basis of allocation of Shares among Institutional Investors.

The allocation policy was influenced, but not constrained, by the following factors:

- number of Shares bid for by particular applicants;
- the timeliness of the bid by particular applicants;
- Lumos' desire for an informed and active trading market following Listing;
- Lumos' desire to establish a wide spread of institutional Shareholders;
- overall level of demand under the Broker Firm Offer, Priority Offer and Institutional Offer;
- the size and type of funds under management of particular applicants;
- the likelihood that particular applicants will be long-term Shareholders; and
- any other factors that the Company, SaleCo and the Joint Lead Managers considered appropriate.

Participants in the Institutional Offer have been advised of their allocation of Shares, if any, by the Joint Lead Managers.

7.6. Voluntary escrow arrangements

Escrowed Shares held at Completion by the Escrowed Shareholders will be subject to voluntary escrow arrangements. Further details of these arrangements are provided in Section 6.5.

7.7. Restrictions on distribution

No action has been taken to register or qualify this Prospectus, the Shares or the Offer or otherwise to permit a public offering of the Shares in any jurisdiction outside Australia.

This Prospectus does not constitute an offer or invitation to apply for Shares in any jurisdiction in which, or to any person to whom, it would not be lawful to make such an offer or invitation or issue under this Prospectus.

This Prospectus may not be released or distributed in the United States or elsewhere outside Australia, unless it has attached to it the selling restrictions applicable in the jurisdictions outside Australia, and may only be distributed to persons to whom the Institutional Offer may lawfully be made in accordance with the laws of any applicable jurisdiction.

The Shares have not been, and will not be, registered under the U.S. Securities Act or the securities laws of any state or other jurisdiction of the United States and may not be offered or sold, directly or indirectly, in the United States.

The distribution of this Prospectus in jurisdictions outside Australia may be restricted by law and persons who come into possession of this Prospectus should observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws. This Prospectus may not be released or distributed in the United States.

7.8. Acknowledgements

Each Applicant in the Broker Firm Offer and Priority Offer and each person in Australia to whom the Institutional Offer is made under this Prospectus, will be taken to have represented, warranted, agreed and acknowledged as follows:

- it agrees to become a member of the Company and to be bound by the terms of the Constitution and the terms and conditions of the Offer;
- it acknowledges having personally received a printed or electronic copy of this Prospectus (and any supplementary or replacement prospectus) accompanying the Application Form and having read them all in full;
- declared that all details and statements in their Application Form are complete and accurate;
- declared that the Applicant(s), if a natural person, is/are over 18 years of age;
- acknowledged that, once the Company, the Share Registry or a Broker receives an Application Form (including electronically), it may not be withdrawn;
- applied for the number of Shares at the Australian dollar amount shown on the front of the Application Form;
- agreed to being allocated and issued the number of Shares applied for (or a lower number allocated in a way described in this Prospectus), or no Shares at all;
- authorised the Company, SaleCo and the Joint Lead Managers and their respective officers or agents, to do anything on behalf of the Applicant(s) necessary for Shares to be allocated to the Applicant(s), including to act on instructions received by the Share Registry upon using the contact details in the Application Form;
- acknowledged that, in some circumstances, the Company may not pay dividends, or that any dividends paid may not be franked;
- acknowledged that the information contained in this Prospectus (or any supplementary or replacement prospectus) is not financial product advice or a recommendation that Shares are suitable for the Applicant(s), given the investment objectives, financial situation or particular needs (including financial and tax issues) of the Applicant(s);
- declared that the Applicant(s) is/are a resident of Australia (except as applicable to the Institutional Offer);
- acknowledged and agreed that the Offer may be withdrawn by the Company or may otherwise not proceed in the circumstances described in this Prospectus; and
- acknowledged and agreed that if Listing does not occur for any reason, the Offer will not proceed.

Each Applicant under the Institutional Offer will be required to make certain representations, warranties, acknowledgements and covenants set out in the confirmation of allocation letter distributed to it. Refer to Appendix B for further details on the selling restrictions relating to foreign jurisdictions.

7.9. Discretion regarding the Offer

The Company and SaleCo may withdraw the Offer at any time before the issue of Shares to successful applicants under the Offer. If the Offer, or any part of it, does not proceed, all relevant application monies will be refunded (without interest) as soon as possible.

The Joint Lead Managers, the Company and SaleCo also reserve the right to, subject to the Corporations Act, extend the Offer or any part of it, accept late Applications or bids either generally or in particular cases, reject any Application or bid, or allocate to any Applicant or bidder fewer Shares than the amount applied or bid for.

7.10. ASX listing, registers and holding statements

7.10.1. Application for ASX listing and quotation of Shares

The Company will apply to ASX within seven days of the Prospectus Date, for admission to the Official List and quotation of the Shares on ASX under the code 'LDX'.

The ASX takes no responsibility for this Prospectus or the investment to which it relates. The fact that ASX may admit the Company to the Official List is not to be taken as an indication of the merits of the Company or the Shares offered for subscription.

If approval is not given within three months after such application is made (or any longer period permitted by law), the Offer will be withdrawn and all application monies received will be refunded without interest, as soon as practicable in accordance with the requirements of the Corporations Act.

Upon Listing, the Company will be required to comply with the ASX Listing Rules, subject to any waivers obtained by the Company from time to time.

7.10.2. CHESS and issuer sponsored holdings

The Company has applied to participate in ASX's Clearing House Electronic Subregister System (**CHESS**) and must comply with the ASX Listing Rules and ASX Settlement Operating Rules. CHESS is an electronic transfer and settlement system for transactions in securities quoted on ASX under which transfers are effected in an electronic form.

When the Shares become approved financial products (as defined in ASX Settlement Operating Rules), holdings will be registered in one of two sub-registers, being an electronic CHESS sub-register or an issuer sponsored sub-register. For all successful applicants, the Shares of a Shareholder who is a participant in CHESS or a Shareholder sponsored by a participant in CHESS will be registered on the CHESS sub-register. All other Shares will be registered on the issuer sponsored sub-register.

Following Completion, Shareholders will be sent a holding statement that sets out the number of Shares that have been allocated to them. This statement will also provide details of a Shareholder's Holder Identification Number (**HIN**) for CHESS holders or, where applicable, the Securityholder Reference Number (**SRN**) of issuer sponsored holders. Shareholders will subsequently receive statements showing any changes to their Shareholding. Certificates will not be issued.

Shareholders will receive subsequent statements during the first week of the following month if there has been a change to their holding on the register and as otherwise required under the ASX Listing Rules and the Corporations Act. Additional statements may be requested at any other time either directly through the Shareholder's sponsoring broker in the case of a holding on the CHESS sub-register or through the Share Registry in the case of a holding on the issuer sponsored sub-register. The Company and the Share Registry may charge a fee for these additional issuer sponsored statements.

7.11. Summary of rights and liabilities attaching to Shares and other material provisions of the Constitution

7.11.1. Introduction

A summary of the significant rights, liabilities and obligations attaching to the Shares and a description of other material provisions of the Constitution are set out below. This summary is not intended to be exhaustive and is qualified by the fuller terms of the Constitution. This summary does not constitute a definitive statement of the rights and liabilities of Shareholders.

The summary assumes that the Company is admitted to the Official List of the ASX.

7.11.2. Meetings of members

Each Shareholder is entitled to receive notice of and, except in certain circumstances, to attend and vote at general meetings of the Company and receive all financial statements, notices and other documents required to be sent to shareholders under the Constitution, the Corporations Act and the ASX Listing Rules. At least 28 days' notice of a meeting must be given to shareholders.

7.11.3. Voting at a general meeting

At a general meeting of the Company, every Shareholder present in person or by proxy, attorney or representative has (a) on a show of hands, one vote and (b) on a poll, one vote for each Share held.

On a poll, every member (or his or her proxy, attorney or representative) is entitled to vote for each fully paid share held and in respect of each partly paid Share, is entitled to a fraction of a vote equivalent to the proportion which the amount paid up (not credited) on that partly paid Share bears to the total amounts paid and payable (excluding amounts credited) on that Share. Amounts paid in advance of a call are ignored when calculating the proportion.

7.11.4. Dividends

Subject to the Corporations Act, the Constitution and any special terms and conditions of issue, the Directors may, from time to time, pay, resolve to pay, or declare any interim, special or final dividend as, in their judgement, the financial position of the Company justifies.

The Board may also pay any dividend required to be paid under the terms of issue of a Share, and fix a record date for a dividend and method of payment.

7.11.5. Transfer of Shares

Subject to the Constitution and to the rights or restrictions attached to any shares or class of shares, a member may transfer all or any of the member's shares by:

- a Proper ASTC transfer (as that term is defined in the Corporations Regulations); or
- an instrument in writing in any usual form or in any other form that the Board approves, as permitted by the Corporations Act and ASX Listing Rules.

The Board may, in circumstances permitted under the ASX Listing Rules or ASX Settlement Rules, decline to register a transfer of Shares or apply a holding lock to prevent a transfer of Shares.

7.11.6. Issue of further Shares

Subject to the Constitution, the ASX Listing Rules, the ASX Settlement Operating Rules and the Corporations Act, the Board may issue shares or grant options over unissued shares to any person and they may do so at such times and on the conditions they think fit.

7.11.7. Preference shares

The Company may issue preference shares including preference shares which are liable to be redeemed or convertible to ordinary shares. The rights attaching to preference shares are those set out in the Constitution unless other rights have been approved by special resolution of the Company.

7.11.8. Winding up

If the Company is wound up, then subject to the Constitution and to the rights or restrictions attached to a class of shares, any surplus assets must be divided among the Company's members in proportion to the shares held by them (irrespective of the amounts paid or credited as paid on the shares), less any amounts which remain unpaid on these shares at the time of distribution.

If the Company is wound up, the liquidator may, with the sanction of a special resolution, divide among the Shareholders the whole or part of Lumos' property and decide how the division is to be carried out as between Shareholders or different classes of Shareholders.

7.11.9. Sale of non-marketable parcels

In accordance with the Corporations Act, the ASX Listing Rules and the ASX Settlement Operating Rules, the Board may sell the Shares of a Shareholder who holds less than a marketable parcel of those Shares by following the procedures set out in the Constitution. A marketable parcel of shares is defined in the ASX Listing Rules and is, generally, a holding of shares with a market value of less than $500.

7.11.10. Proportional takeover provisions

The Constitution contains provisions requiring Shareholder approval in relation to any proportional takeover bid. These provisions will cease to apply unless renewed by Shareholders passing a special resolution by the third anniversary of either the date those provisions were adopted or the date those rules were last renewed.

7.11.11. Variation of class rights

Subject to the Corporations Act and the terms of issue of a class of shares, wherever the capital of the Company is divided into different classes of shares, the rights attached to any class of shares may be varied:

- with the written consent of the holders of at least 75% of the issued shares in the particular class; or
- by a special resolution passed at a separate meeting of the holders of shares in that class.

7.11.12. Directors – appointment and removal

Under the Constitution, the minimum number of Directors is three and the maximum is 10 or such lower number as the Directors determine, provided the proposed lower number has been authorised by general meeting of the Company's members if required under the Corporations Act.

Directors are elected or re-elected by resolution at a general meeting of Shareholders. Except as permitted by the ASX Listing Rules, no Director (other than the managing director) may hold office without re-election after three years or beyond the third annual general meeting following the meeting at which the Director was last elected or re-elected (whichever is later). The Board may also appoint a Director to fill a casual vacancy on the Board or in addition to the existing Directors, who (other than the managing director) will then hold office until the next annual general meeting of the Company following their appointment.

A person is eligible for election to the office of a Director at a general meeting if they are nominated by the Board or by another Shareholder in accordance with procedures in the Constitution (subject to timing requirements).

7.11.13. Directors – voting

Questions arising at a meeting of Directors will be decided by a majority of votes of the Directors present at the meeting and entitled to vote on the matter. In the case of an equality of votes on a resolution, the chair of the meeting has a casting vote, unless there are only two Directors present or qualified to vote, in which case the proposed resolution is taken as having been lost.

A written resolution of the Board may be passed without holding a meeting of the Board, if all of the Directors sign or assent to the resolution (other than Directors not permitted to vote on the resolution in accordance with the terms of the Constitution).

7.11.14. Directors – remuneration

Under the Constitution, the Board may decide the remuneration from the Company to which each Director is entitled for his or her services as a Director. The total aggregate amount provided to all Non-executive Directors for their services as Directors must not exceed in any financial year the amount fixed by the Company in general meeting for that purpose. The remuneration of a Director must not include a commission on, or a percentage of operating revenue. The current maximum aggregate sum of Non-executive Director remuneration is set out in Section 6.4.2.2. Any change to that maximum aggregate amount needs to be approved by Shareholders.

Directors may be reimbursed for travel and other expenses properly incurred in attending to the Company's affairs, including attending and returning from general meetings of the Company, Board meetings or meetings of committees of the Board. If a Director renders or is called on to perform extra services, or make any special exertions in connection with the affairs of the Company, the Directors may arrange for special remuneration to be paid to that Director either in addition to or in substitution for that Director's remuneration. Directors' remuneration is discussed in Section 6.4.2.

7.11.15. Powers and duties of Directors

The Directors are responsible for managing the business of the Company and may exercise to the exclusion of the Company in a general meeting all the powers of the Company which are not required by law or by the Constitution to be exercised by the Company in a general meeting.

7.11.16. Variation of the Constitution

The Constitution can only be amended by a special resolution passed by at least 75% of members present (in person or by proxy, attorney or representative) and entitled to vote on the resolution at a general meeting of the Company.

7.11.17. Directors' and officers' indemnity

The Company, to the extent permitted by law, may indemnify each person who is a current or former Director, executive officer, officer or auditor of the Company, and such other officers or former officers of the Company or its related bodies corporate as the Directors in each case determine, against any losses or liability incurred by that person as an officer or auditor of the Company or of a related body corporate of the Company including, but not limited to, a liability for negligence or for reasonable legal costs on a full indemnity basis.

The Company, to the extent permitted by law, may enter into and pay premiums on a contract insuring any person who is a current or former Director, executive officer, officer or auditor of the Company, and such other officers or former officers of the Company or its related bodies corporate as the Directors in each case determine, against any liability incurred by the person as an officer or auditor of the Company or of a related body corporate of the Company including, but not limited to, a liability for negligence or for legal costs.

Section 8

Investigating Accountant's Report

Section 8
Investigating Accountant's Report

Tel: +61 2 9251 4100
Fax: +61 2 9240 9821
www.bdo.com.au

Level 11, 1 Margaret St
Sydney NSW 2000
Australia

The Directors
Lumos Diagnostics Holdings Limited
436 Elgar Road
BOX HILL VIC 3128

The Directors
Lumos Diagnostics SaleCo Limited
436 Elgar Road
BOX HILL VIC 3128

5 June 2021

Dear Directors

INDEPENDENT LIMITED ASSURANCE REPORT

INTRODUCTION

BDO Corporate Finance (East Coast) Pty Ltd (**BDO**) has been engaged by Lumos Diagnostics Holdings Limited (**Lumos** or the **Company**) and Lumos SaleCo Limited (**SaleCo**) to prepare this Independent Limited Assurance Report (**Report**) for inclusion in a prospectus proposed to be issued, in relation to the initial public offering of new ordinary shares in Lumos as well as the potential sale of existing shares in Lumos by SaleCo, on or about June 2021 (**Prospectus**) and listing on the Australian Securities Exchange (**ASX**) (the **Offer**).

Unless stated otherwise in this Report, expressions defined in the Prospectus have the same meaning in this Report.

This Report has been prepared for inclusion in the Prospectus. We disclaim any assumption of responsibility for any reliance on this Report or on the financial information to which it relates for any purpose other than that for which it was prepared.

SCOPE

You have requested BDO to perform a limited assurance engagement in relation to the financial information described below and disclosed in the Prospectus.

The financial information is presented in the Prospectus in an abbreviated form, insofar as it does not include all of the presentation and disclosures required by Australian Accounting Standards (**AAS**) and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the Corporations Act 2001 (the **Act**).

STATUTORY HISTORICAL FINANCIAL INFORMATION

You have requested BDO to review the following statutory historical financial information included in the Prospectus:

- The statutory historical consolidated statement of profit or loss for the financial years ended 30 June 2019 (**FY19)** and 30 June 2020 **(FY20)** and financial half years ended 31 December 2019 (**1H20**) and 31 December 2020 (**1H21**);
- The statutory historical consolidated statement of cash flows for FY19, FY20, 1H20 and 1H21; and
- The statutory historical consolidated statement of financial position as at 31 December 2020,

together the **Statutory Historical Financial Information**.

The Statutory Historical Financial Information has been prepared in accordance with the stated basis of preparation, being the recognition and measurement principles contained in AAS and the company's adopted accounting policies.

The Statutory Historical Financial Information has been extracted from the financial statements of Lumos for the financial periods ended FY19 and FY20 (audited by William Buck Audit (Vic) Pty Ltd (**William Buck**)) and half years ended 1H20 and 1H21 (reviewed by William Buck). The audit and review were performed in accordance with Australian Auditing Standards.

William Buck issued an unqualified opinion with respect to the abovementioned financial reports.

PRO FORMA HISTORICAL FINANCIAL INFORMATION

You have requested BDO review the following pro forma historical financial information included in the Prospectus:

- The pro forma historical consolidated statements of profit or loss for FY19, FY20, 1H20 and 1H21;
- The pro forma historical consolidated statements of cash flow for FY19, FY20, 1H20 and 1H21;
- The pro forma historical consolidated statement of financial position as at 31 December 2020; and
- Associated details of the pro forma adjustments,

together the **Pro Forma Historical Financial Information**.

The Pro Forma Historical Financial Information has been derived from the Statutory Historical Financial Information of Lumos, after adjusting for the effects of pro forma adjustments described in Section 4 of the Prospectus. The stated basis of preparation is the recognition and measurement principles contained in AAS applied to the Statutory Historical Financial Information and the event(s) or transaction(s) to which the pro forma adjustments relate, as described in Section 4 of the Prospectus, as if those event(s) or transaction(s) had occurred as at 31 December 2020. Due to its nature, the Pro Forma Historical Financial Information does not represent the company's actual or prospective financial position, financial performance, and/or cash flows.

STATUTORY FORECAST FINANCIAL INFORMATION

You have requested BDO review the following statutory forecast financial information of Lumos included in Section 4 of the Prospectus:

- The statutory forecast consolidated statement of profit or loss, for the financial year ending 30 June 2021 (which comprises the actual 1H21 period and the forecast six month period ending 30 June 2021 (**2H21F**)) (**FY21F**); and
- The statutory forecast consolidated statement of cash flows for FY21F,

together the **Statutory Forecast Financial Information**.

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Investigating Accountant's Report

The Statutory Forecast Financial Information has been prepared in accordance with the stated basis of preparation, being the recognition and measurement principles contained in AAS and the company's adopted accounting policies set out in Section 4 of the Prospectus.

The directors' best-estimate assumptions underlying the statutory forecast financial information are described in Section 4 of the Prospectus.

PRO FORMA FORECAST FINANCIAL INFORMATION

You have requested BDO review the following pro forma forecast financial information of Lumos included in Section 4 of the Prospectus:

- The pro forma forecast consolidated statement of profit or loss for FY21F; and
- The pro forma forecast consolidated statement of cash flows for FY21F,

together the **Pro Forma Forecast Financial Information**.

The Pro Forma Forecast Financial Information has been derived from the Statutory Forecast Financial Information of Lumos, after adjusting for the effects of pro forma adjustments described in Section 4 of the Prospectus. The stated basis of preparation is the recognition and measurement principles contained in AAS applied to the Statutory Forecast Financial Information and the event(s) or transaction(s) to which the pro forma adjustments relate, as described in Section 4 of the Prospectus, as if those event(s) or transaction(s) had occurred as at 1 July 2018.

The Pro Forma Forecast Financial Information is pro forma information only and does not represent Lumos' actual or prospective financial performance for the year ending 30 June 2021. Care should be taken when considering and interpreting the Pro Forma Forecast Financial Information as this information does not forecast financial results which are actually expected to occur in the form presented.

DIRECTORS' RESPONSIBILITY

The directors of Lumos are responsible for:

- the preparation of the Statutory Historical Financial Information and Pro Forma Historical Financial Information, including the selection and determination of pro forma adjustments made to the Statutory Historical Financial Information and included in the Pro Forma Historical Financial Information;
- the preparation of the Statutory Forecast Financial Information including the best-estimate assumptions underlying the Statutory Forecast Financial Information.
- the preparation of the Pro Forma Forecast Financial Information, including the selection and determination of the pro forma adjustments made to the Statutory Forecast Financial Information and included in the Pro Forma Forecast Financial Information; and
- such internal controls as the directors determine are necessary to enable the preparation of Historical Financial Information and Forecast Financial Information (as defined in Section 4 of the Prospectus) that are free from material misstatement, whether due to fraud or error.

OUR RESPONSIBILITY

Our responsibility is to express a limited assurance conclusion on whether anything has come to our attention that the Historical Financial Information and Forecast Financial Information (as defined in Section 4 of the Prospectus), including the best-estimate assumptions underlying the Statutory Forecast Financial Information and Pro Forma

Forecast Financial Information (and the reasonableness of the Statutory Forecast Financial Information and Pro Forma Forecast Financial Information themselves), based on the procedures performed, and the evidence we have obtained, has not been properly compiled in all material respects by Lumos, in accordance with the stated basis of preparation.

We have conducted our engagement in accordance with the Standard on Assurance Engagement ASAE 3450 *Assurance Engagements involving Corporate Fundraisings and/or Prospective Financial Information*.

The limited assurance procedures we performed were based on our professional judgement and included consideration of work papers, accounting records and other documents, including those dealing with the derivation of the Historical Financial Information of Lumos from its audited financial statements for the years ended FY19 and FY20 and half years ended 1H20 and 1H21 respectively, as well as those dealing with the derivation of the Forecast Financial Information of Lumos from management forecasts prepared for the year ending FY21F.

Our limited assurance procedures consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A limited assurance engagement is substantially less in scope than an audit conducted in accordance with AAS and consequently does not enable us to obtain reasonable assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Our engagement did not involve updating or re-issuing any previously issued audit or review report on any financial information used as a source of the Historical Financial Information.

CONCLUSION

STATUTORY HISTORICAL FINANCIAL INFORMATION

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the Statutory Historical Financial Information, as described in Section 4 of the Prospectus, and comprising:

- The statutory historical consolidated statement of profit or loss FY19, FY20, 1H20 and 1H21;
- The statutory historical consolidated statement of cash flows for FY19, FY20, 1H20 and 1H21; and
- The statutory historical consolidated statement of financial position as at 31 December 2020

is not presented fairly, in all material respects, in accordance with the stated basis of preparation, as described in Section 4 of the Prospectus.

PRO FORMA HISTORICAL FINANCIAL INFORMATION

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the Pro Forma Historical Financial Information, as described in Section 4 of the Prospectus, and comprising:

- The pro forma historical consolidated statements of profit or loss for FY19, FY20, 1H20 and 1H21;
- The pro forma historical consolidated statements of cash flow for FY19, FY20, 1H20 and 1H21;and
- The pro forma historical consolidated statement of financial position as at 31 December 2020,

is not presented fairly in all material respects, in accordance with the stated basis of preparation as described in Section 4 of the Prospectus.

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STATUTORY FORECAST FINANCIAL INFORMATION

Based on our review, which is not an audit, nothing has come to our attention which causes us to believe that:

- the Company's best-estimate assumptions, used in the preparation of the Statutory Forecast Financial Information, do not provide reasonable grounds for the Statutory Forecast Financial Information; and
- in all material respects, the Statutory Forecast Financial Information:
  - is not prepared on the basis of the director's best-estimate assumptions as described in Section 4 of the Prospectus;
  - is not presented fairly in accordance with the stated basis of preparation, as described in Section 4 of the Prospectus; and
- the Statutory Forecast Financial Information itself is unreasonable.

PRO FORMA FORECAST FINANCIAL INFORMATION

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that:

- the Company's best-estimate assumptions, used in the preparation of the Pro Forma Forecast Financial Information, do not provide reasonable grounds for the Pro Forma Forecast Financial Information; and
- in all material respects, the Pro Forma Forecast Financial Information:
  - is not prepared on the basis of the directors' best-estimate assumptions, as described in Section 4 of the Prospectus;
  - is not presented fairly in accordance with the stated basis of preparation, as described in Section 4 of the Prospectus; and
- the Pro Forma Forecast Financial Information itself is unreasonable.

FORECAST FINANCIAL INFORMATION

The Statutory Forecast Financial Information and Pro Forma Forecast Financial Information (together the **Forecast Financial Information**) have been prepared by management and adopted by the directors of Lumos in order to provide prospective investors with a guide to the potential financial performance of Lumos for the financial year ending 30 June 2021. There is a considerable degree of subjective judgement involved in preparing forecasts since they relate to event(s) and transaction(s) that have not yet occurred and may not occur. Actual results are likely to be different from the statutory forecast and pro forma forecast since anticipated event(s) or transaction(s) frequently do not occur as expected and the variation may be material.

The directors' best-estimate assumptions on which the Forecast Financial Information relate to future event(s) and/or transaction(s) that management expect to occur and actions that management expect to take and are also subject to uncertainties and contingencies, which are often outside the control of Lumos. Evidence may be available to support the directors' best-estimate assumptions on which the Forecast Financial Information are based however such evidence is generally future-oriented and therefore speculative in nature. We are therefore not in a position to express a reasonable assurance conclusion on those best-estimate assumptions, and accordingly, provide a lesser level of assurance on the reasonableness of the directors' best-estimate assumptions. The limited assurance conclusion expressed in this report has been formed on the above basis.

Prospective investors should be aware of the material risks and uncertainties in relation to an investment in Lumos, which are detailed in the Prospectus, and the inherent uncertainty relating to the Forecast Financial Information. Accordingly, prospective investors should have regard to the investment risks and sensitivities as

described in Section 4 of the Prospectus. The sensitivity analysis described in Section 4 of the Prospectus demonstrates the impact on the Pro Forma forecast Financial Information of changes in key best-estimate assumptions. We express no opinion as to whether the Forecast Financial Information will be achieved.

We disclaim any assumption of responsibility for any reliance on this report, or on the Forecast Financial Information to which it relates, for any purpose other than that for which it was prepared. We have assumed, and relied on representations from certain members of management of Lumos, that all material information concerning the prospects and proposed operations of Lumos has been disclosed to us and that the information provided to us for the purpose of our work is true, complete and accurate in all respects. We have no reason to believe that those representations are false.

SUBSEQUENT EVENTS

Apart from the matters dealt with in this Report, and having regard to the scope of this Report and the information provided by the Directors, to the best of our knowledge and belief no material transaction(s) or event(s) outside of the ordinary business of Lumos not described in the Prospectus, has come to our attention that would require comment on, or adjustment to, the information referred to in our Report or that would cause such information to be misleading or deceptive.

INDEPENDENCE

BDO is a member of BDO International Ltd. BDO does not have any interest in the outcome of the Prospectus other than in connection with the preparation of this Report and participation in due diligence procedures, for which professional fees will be received. From time to time, BDO provides Lumos with certain other professional services for which normal professional fees are received.

GENERAL ADVICE WARNING

This Report has been prepared, and included in the Prospectus, to provide investors with general information only and does not take into account the objectives, financial situation or needs of any specific investor. It is not intended to be a substitute for professional advice and potential investors should not make specific investment decisions in reliance on the information contained in this Report. Before acting or relying on any information, potential investors should consider whether it is appropriate for their objectives, financial situation or needs.

Without modifying our conclusions, we draw attention to Section 4 of the Prospectus, which describes the purpose of the financial information, being for inclusion in the Prospectus. As a result, the financial information may not be suitable for use for another purpose.

BDO has consented to the inclusion of this Report in the Prospectus in the form and context in which it is included. At the date of this Report this consent has not been withdrawn. However, BDO has not authorised the issue of the Prospectus. Accordingly, BDO makes no representation regarding, and takes no responsibility for, any other statements or material in or omissions from the Prospectus.

Section 8
Investigating Accountant's Report

Tel: +61 2 9251 4100
Fax: +61 2 9240 9821
www.bdo.com.au

Level 11, 1 Margaret St
Sydney NSW 2000
Australia

FINANCIAL SERVICES GUIDE

Our Financial Services Guide follows this Report. This guide is designed to assist retail clients in their use of any general financial product advice in our Report.

As set out in the Financial Services Guide, this Report provides general information only. It does not take into account the objectives, financial situation or needs of any specific investor. It is not intended to be a substitute for professional advice and potential investors should not make specific investment decisions in reliance on the information contained in this Report. Before acting or relying on any information, potential investors should consider whether it is appropriate for their objectives, financial situation or needs.

If you require any additional information and/or clarification on any matter please contact us.

Yours faithfully
BDO Corporate Finance (East Coast) Pty Ltd

Sebastian Stevens
Director

Tel: +61 2 9251 4100
Fax: +61 2 9240 9821
www.bdo.com.au

Level 11, 1 Margaret St
Sydney NSW 2000
Australia

FINANCIAL SERVICES GUIDE

Dated: 5 June 2021

This Financial Services Guide (**FSG**) helps you decide whether to use any of the financial services offered by BDO Corporate Finance (East Coast) Pty Ltd (**BDO Corporate Finance, we, us, our**).

The FSG includes information about:

- Who we are and how we can be contacted;
- The services we are authorised to provide under our Australian Financial Services Licence, Licence No: 247420
- Remuneration that we and/or our staff and any associates receive in connection with the financial services
- Any relevant associations or relationships we have
- Our complaints handling procedures and how you may access them.

FINANCIAL SERVICES WE ARE LICENSED TO PROVIDE

We hold an Australian Financial Services Licence which authorises us to provide financial product advice to retail and wholesale clients about securities and certain derivatives (limited to old law securities, options contracts and warrants). We can also arrange for customers to deal in securities, in some circumstances. Whilst we are authorised to provide personal and general advice to retail and wholesale clients, we only provide *general* advice to retail clients.

Any general advice we provide is provided on our own behalf, as a financial services licensee.

GENERAL FINANCIAL PRODUCT ADVICE

Our general advice is typically included in written reports. In those reports, we provide general financial product advice that is prepared without taking into account your personal objectives, financial situation or needs. You should consider the appropriateness of the general advice having regard to your own objectives, financial situation and needs before you act on the advice. Where the advice relates to the acquisition or possible acquisition of a financial product, you should also obtain a product disclosure statement relating to the product and consider that statement before making any decision about whether to acquire the product.

FEES, COMMISSIONS AND OTHER BENEFITS THAT WE MAY RECEIVE

We charge fees for providing reports. These fees are negotiated and agreed to with the person who engages us to provide the report. Fees will be agreed on an hourly basis or as a fixed amount depending on the terms of the agreement. In this instance, the Company has agreed to pay us $350,000 for preparing the Report.

Except for the fees referred to above, neither BDO Corporate Finance, nor any of its directors, employees or related entities, receive any pecuniary benefit or other benefit, directly or indirectly, for or in connection with the provision of general advice.

All our employees receive a salary. Our employees are eligible for bonuses based on overall company performance but not directly in connection with any engagement for the provision of a report.

REFERRALS

We do not pay commissions or provide any other benefits to any person for referring customers to us in connection with the reports that we are licensed to provide.

ASSOCIATIONS AND RELATIONSHIPS

BDO Corporate Finance is a member firm of the BDO network in Australia, a national association of separate entities (each of which has appointed BDO (Australia) Limited ACN 050 110 275 to represent it in BDO International). The general financial product advice in our report is provided by BDO Corporate Finance and not by BDO or its related entities. BDO and its related entities provide services primarily in the areas of audit, tax, consulting and financial advisory services.

We do not have any formal associations or relationships with any entities that are issuers of financial products. However, you should note that we and BDO (and its related entities) might from time to time provide professional services to financial product issuers in the ordinary course of business.

COMPLAINTS RESOLUTION

Internal Complaints Resolution Process

As the holder of an Australian Financial Services Licence, we are required to have a system for handling complaints from persons to whom we provide financial product advice. Complaints can be in writing, addressed to the Complaints Officer, BDO Corporate Finance, Level 11, 1 Margaret St, Sydney NSW 2001 or by telephone or email, using the contact details at the top of this FSG.

When we receive a complaint we will record the complaint, acknowledge receipt of the complaint within 15 days and investigate the issues raised. As soon as practical, and not more than **45 days** after receiving the written complaint, we will advise the complainant in writing of our determination.

Referral to External Dispute Resolution Scheme

If a complaint relating to general advice to a retail client is not satisfied with the outcome of the above process, or our determination, has the right to refer the matter to the Australian Financial Complaints Authority (**AFCA**). AFCA is an independent company that has been established to impartially resolve disputes between consumers and participating financial services providers.

BDO Corporate Finance is a member of AFCA (Member Number 11843).

Further details about AFCA are available at the AFCA website www.afca.org.au or by contacting them directly via the details set out below.

Australian Financial Complaints Authority
GPO Box 3
MELBOURNE VIC 3001
Toll free: 1800 931 678
Email: info@afca.org.au

COMPENSATION ARRANGEMENTS

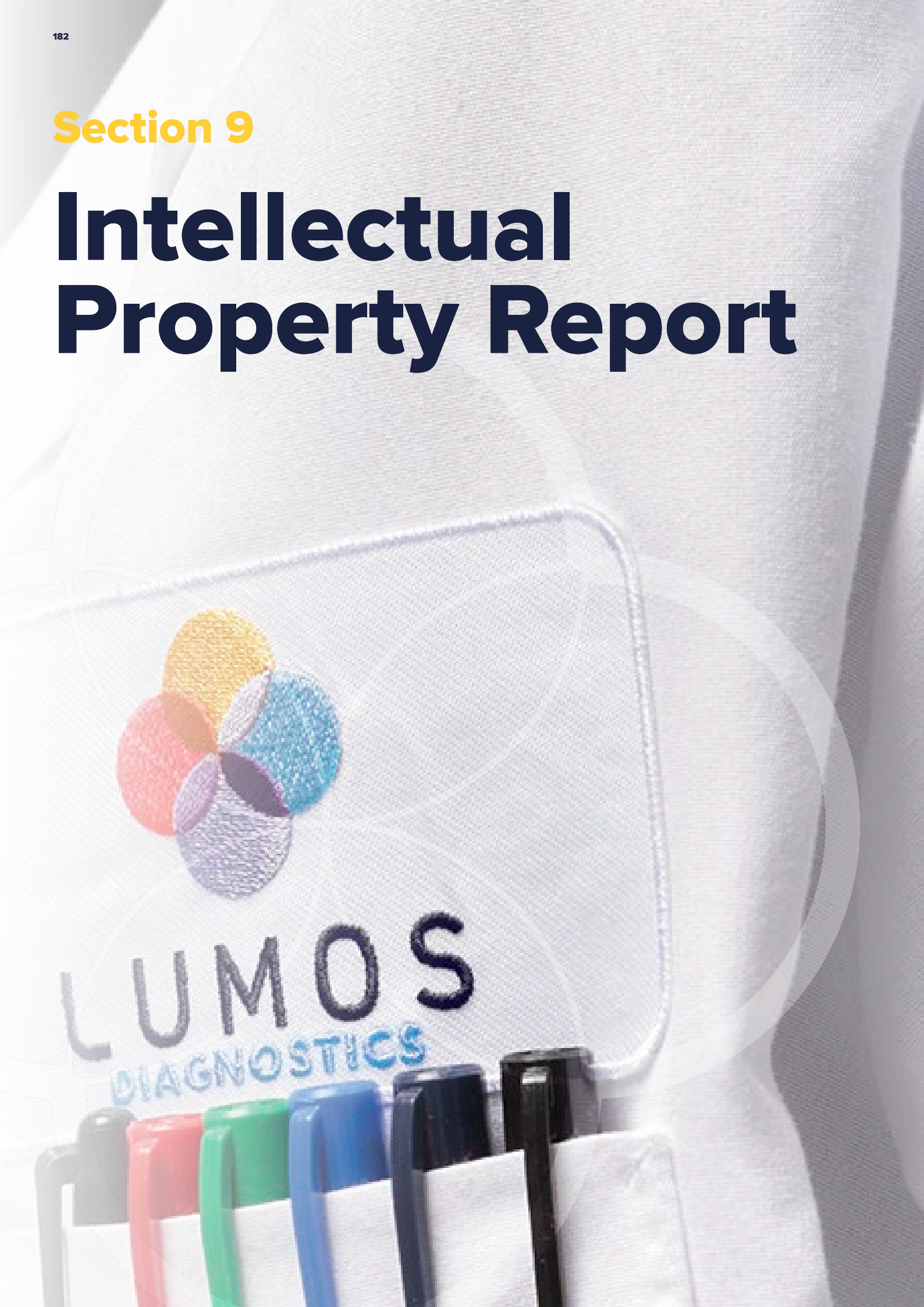
BDO Corporate Finance and its related entities hold Professional Indemnity insurance for the purpose of compensating retail clients for loss or damage suffered because of breaches of relevant obligations by BDO Corporate Finance or its representatives under Chapter 7 of the Corporations Act 2001. These arrangements and the level of cover held by BDO Corporate Finance satisfy the requirements of section 912B of the Corporations Act 2001.

CONTACT DETAILS

You may provide us with instructions using the details set out at the top of this FSG or by emailing - cf.ecp@bdo.com.au

Section 9

Intellectual Property Report



Allens
Patent & Trade Mark Attorneys
Deutsche Bank Place
Corner Hunter and Phillip Streets
Sydney NSW 2000 Australia
T +61 2 9230 4000
F +61 2 9230 5333

GPO Box 50
Sydney NSW 2001 Australia
DX 105 Sydney

www.allens.com.au

ABN 59 727 365 753

Allens › ‹ Linklaters

2 June 2021

The Directors
Lumos Diagnostics Holdings Ltd
Level 4, 96-100 Albert Road
South Melbourne VIC 3205

Dear Sirs

Intellectual Property Report

1 Background and Scope

Allens Patent & Trade Mark Attorneys (***Allens***) has been instructed by Lumos Diagnostics Holdings Ltd. (***Lumos***) to prepare this Report for inclusion in a Prospectus to be issued by Lumos.

Allens is informed that Lumos specialises in rapid and complete point-of-care diagnostic test solutions and offers customised assay development and manufacturing services for point-of-care tests and proprietary digital reader platforms. Lumos also directly develops, manufactures and commercializes proprietary, Lumos-branded point-of-care tests that target infectious and inflammatory diseases. Lumos' current portfolio of tests includes FebriDx® and CoviDx™. FebriDx® is an all-in-one, disposable, 10-minute, fingerstick blood test that differentiates viral from bacterial acute respiratory infections. CoviDx™ is a rapid and easy-to-use test for the detection of antibodies to SARS-CoV-2 virus in patients suspected of a history of COVID-19 infection.

Allens has been instructed to provide the details and status of patent and trade mark matters in the intellectual property portfolio referred to in this Report.

The Report is current as at 2 June 2021. Allens is not aware of any material changes expected to occur to the status of the matters outlined below, except where indicated.

2 Overview of Intellectual Property (IP) Protection

Intellectual Property (**IP**) includes patents, registered designs, trade marks, copyright, plant breeder's rights, and know how or trade secrets.

2.1 Patents

(a) What is a patent?

A patent is a monopoly granted by a government for a standard period of up to 20 years. A patent provides an enforceable legal right to prevent others from exploiting an invention, which may be a product, device, system, substance, process or method, in the country of grant.

For an invention to be patentable, it must be novel, involve an inventive step (not obvious) and useful at the time of filing the initial patent application for that invention. At 18 months from the filing date of the initial patent application, the detailed description of the invention is published.

In order to secure patent protection, a patent application is filed with the patent office in each country of interest, the application is considered under the patent laws of that country, and a patent will be issued if the application meets the patentability criteria of that country.

After a patent expires or lapses, anyone can then use the invention.

(b) Patent validity

The grant of a patent does not guarantee validity and a patent may be challenged by third parties at a patent office, by re-examination in some countries, or through the courts by revocation proceedings.

The grant of a valid patent does not mean that the invention may be exploited in a given country without infringing third party IP rights in that country.

(c) Patent infringement

The owner of a patent has the exclusive right to prevent others from making, selling, importing or otherwise using the patented invention for the life of the patent.

Patent infringement occurs when someone makes, hires, uses, imports or sells the patented invention, or a product made by a patented method, or offers to do any of these things, within the country covered by the patent without the permission of the owner of the patent.

(d) Renewal fees

Patent applications and patents are subject to payment of renewal fees over the life of the patent in order to maintain patent rights. If the renewal fees are not paid then the application or patent may lapse.

Allens has determined that at the time of this Report there are no renewal fees payable in respect of Lumos' patent portfolio.

2.2 International Conventions

Australia is a signatory to a number of international conventions which relate to intellectual property. Many of these conventions are administered by the World Intellectual Property Organisation (WIPO), which is an agency of the United Nations. Some of the more important conventions are listed below.

(a) Paris Convention

The substantive provisions of the Paris Convention fall into three main categories: national treatment, right of priority, common rules.

Under the provisions on national treatment, the Convention provides that, as regards the protection of industrial property, each Contracting State must grant the same protection to nationals of other Contracting States that it grants to its own nationals. Nationals of non-Contracting States are also entitled to national treatment under the Convention if they are domiciled or have a real and effective industrial or commercial establishment in a Contracting State.

The Convention provides for the right of priority in the case of patents (and utility models where they exist), marks and industrial designs. This right means that, on the basis of a regular first application filed in one of the Contracting States, the applicant may, within a certain period of time (12 months for patents and utility models; 6 months for industrial designs and marks), apply for protection in any of the other Contracting States. These subsequent applications will be regarded as if they had been filed on the same day as the first application. In other words, they will have priority (hence the

expression "right of priority") over applications filed by others during said period of time for the same invention, utility model, mark or industrial design. Moreover, these subsequent applications, being based on the first application, will not be affected by any event that takes place in the interval, such as the publication of an invention or the sale of articles bearing a mark or incorporating an industrial design. One of the great practical advantages of this provision is that applicants seeking protection in several countries are not required to present all of their applications at the same time but have 6 or 12 months to decide in which countries they wish to seek protection, and to organize with due care the steps necessary for securing protection.

The Convention lays down a few common rules that all Contracting States must follow. The most important are:

(i) Patents

Patents granted in different Contracting States for the same invention are independent of each other: the granting of a patent in one Contracting State does not oblige other Contracting States to grant a patent; a patent cannot be refused, annulled or terminated in any Contracting State on the ground that it has been refused or annulled or has terminated in any other Contracting State.

The inventor has the right to be named as such in the patent.

(ii) Marks

The Paris Convention does not regulate the conditions for the filing and registration of marks which are determined in each Contracting State by domestic law. Consequently, no application for the registration of a mark filed by a national of a Contracting State may be refused, nor may a registration be invalidated, on the ground that filing, registration or renewal has not been effected in the country of origin. The registration of a mark obtained in one Contracting State is independent of its possible registration in any other country, including the country of origin; consequently, the lapse or annulment of the registration of a mark in one Contracting State will not affect the validity of the registration in other Contracting States.

Where a mark has been duly registered in the country of origin, it must, on request, be accepted for filing and protected in its original form in the other Contracting States. Nevertheless, registration may be refused in well-defined cases, such as where the mark would infringe the acquired rights of third parties; where it is devoid of distinctive character; where it is contrary to morality or public order; or where it is of such a nature as to be liable to deceive the public.

If, in any Contracting State, the use of a registered mark is compulsory, the registration cannot be cancelled for non-use until after a reasonable period, and then only if the owner cannot justify this inaction.

Each Contracting State must refuse registration and prohibit the use of marks that constitute a reproduction, imitation or translation, liable to create confusion, of a mark used for identical and similar goods and considered by the competent authority of that State to be well known in that State and to already belong to a person entitled to the benefits of the Convention.

(iii) Industrial Designs.

Industrial designs must be protected in each Contracting State, and protection may not be forfeited on the ground that articles incorporating the design are not manufactured in that State.

(b) Patent Cooperation Treaty (PCT)

The Patent Cooperation Treaty enables applicants to seek patent protection for an invention simultaneously in each of a large number of countries by filing an 'international' patent application.

Such an application may be filed by anyone who is a national or resident of a PCT contracting state.

The filing of a PCT application automatically designates all PCT contracting states. The effect of the international application in each designated state is the same as if a national patent application had been filed with the national patent office in that state.

The practical advantage of using the PCT system is that the effective filing date and associated fees for each of the designated countries can be deferred by a further 18 or 19 months (country dependent) from the initial 12 month priority deadline available under the Paris Convention.

An application is in the 'international phase' from that date on which the PCT application is filed until such time that national applications (or in the case of the European Patent Convention, regional applications) are filed. Once the national and/or regional applications are filed, the application is in the 'national phase'.

(i) International Search Report

The PCT is subjected to an 'international search'. The international search is carried out by one of the major patent offices and results in an international search report (ISR) which includes a listing of published documents that may affect patentability of the invention claimed in the international application.

(ii) Written opinion/international preliminary report on patentability (IPRP)

In addition to the ISR, a preliminary and non-binding, written opinion on whether the invention appears to meet patentability criteria in light of the search report results is issued.

The ISR and written opinion are communicated to the applicant who, after evaluating their content, may decide to withdraw the application, if for example, the content of the ISR and opinion suggest that the granting of patents is unlikely. Alternatively, the applicant may decide to amend the claims in the application to address any issues raised in the opinion.

The applicant may respond to the written opinion by filing a request for “international preliminary examination”. The response may include amendments to the application, for example, in order to more clearly distinguish the invention from the disclosures made in documents identified in the search report. The result of the preliminary examination is an 'International Preliminary Report on Patentability' (IPRP) which contains, a preliminary and non-binding opinion on the patentability of the claimed invention.

The international search and written opinion are intended to provide a preliminary and non-binding opinion only on patentability of the claimed invention, and are not intended to indicate whether commercial exploitation of the applicant’s invention may infringe the rights of others.

(c) European Patent Convention (EPC)

The European Patent Convention (EPC) provides a legal framework for granting of European patents via a single harmonized procedure before the European Patent Office. A single patent application is filed at the European Patent Office in one language, the invention is searched and examined, and a patent is ultimately granted. The European patent is than validated and maintained in one or more EP states of interest.

The EPC covers: Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco,

Malta, The Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom.

(d) National patents

There is no such thing as a 'global' or 'worldwide patent'. In order to obtain protection for an invention, whether in Australia or overseas, a national patent application must be filed in each jurisdiction of interest.

Most national patent offices will conduct their own comprehensive search and examination to determine whether the application meets the national requirements for patentability. Such search and examination may result in objections being raised. If an objection raised by a national patent office cannot be overcome by amendment to the claims and/or by argument, the application will be refused.

The grant of a patent in one country does not guarantee the grant of a patent for the same invention in another country. Similarly, a challenge to the validity of a patent must generally be made in the country of interest. It is only on the grant of a patent in a given country that the patentee will have enforceable rights in that country for the invention defined in the claims of the granted patent.

(e) Overview of the patenting process

The patenting process involves a number of steps. The typical first step is to file a provisional patent application. A provisional patent application establishes a first 'priority date' for the invention described in the application and provides a period of 12 months within which the invention may be further developed before filing a complete patent application. A provisional patent application is not examined, lapses after a period of 12 months, and is only published if it is the subject of a priority claim in a complete application.

In order to maintain the priority date established by the provisional patent application, a complete application must be filed before the end of the 12 month period. Where patent protection is required in number of countries, the complete application may be a PCT application pursuant to the Patent Cooperation Treaty described above. The PCT application defers the national application filing deadline in countries which are a signatory to the PCT for a further 18 or 19 months.

After the international phase of the PCT application which involves the international search and written opinion as described above, the 'national phase' (or 'regional phase' in the case of the EPC), is entered in the countries of interest. Once the national phase is entered, each application proceeds to examination before the respective national patent office to determine whether the application meets the national requirements for patentability.

In some situations, a PCT application is not filed and complete applications are filed before the end of the 12 month period directly in the countries of interest under the Paris Convention as described above.

2.3 Trade Marks

(a) What is a trade mark?

A trade mark is a sign used to distinguish the goods and services of one trader from those of another.

A registered trade mark is a right that is granted in a given country or region for a sign such as letter, number, word, phrase, sound, smell, shape, logo, picture and/or aspect of packaging. A registered trade mark is legally enforceable and gives the owner exclusive rights to commercially use, licence or sell the trade mark for the goods and services in the country or region in which it is registered.

A trade mark can be used prior to seeking registration. In some countries, the first person to register the trade mark has the legal rights to the trade mark in that country, even if it has been previously used by another party.

Rights in an unregistered trade mark only arise where a substantial reputation has been developed in the relevant trade mark by use of the trade mark in a given geographical area.

(b) Trade mark renewal

A trade mark is registered initially for 10 years and, if continued to be used for the goods or services in the country of the registration, can be maintained indefinitely by payment of periodic renewal fees (usually every 10 years) in the country of registration.

(c) Trade mark infringement

To establish trade mark infringement it is necessary to establish that the potentially infringing trade mark is being used on the same or similar goods or services for which the trade mark is registered and the alleged infringer's brand or trade mark is sufficiently similar to the registered trade mark to cause confusion in the market place regarding the origin of the product.

(d) Madrid Protocol

An application for international registration (an “international application”) may be filed by a national of a country which is party to the Madrid Agreement or the Madrid Protocol. The one application, based on a home country registration, can be filed designating one or more countries of the Madrid Agreement.

International registration has several advantages for the owner of the trade mark. After registering the mark in the home country, or filing an application for registration, there is only the need to file one international application, in one language, and pay one fee instead of filing separately in the trade mark offices of the various contracting parties in different languages and paying a separate fee in each office.

A further important advantage is that changes subsequent to registration, such as a change in the name or address of the holder, or a change (total or partial) in ownership or a limitation of the list of goods and services may be recorded with effect for several designated contracting parties through a single simple procedural step and the payment of a single fee. Moreover, there is only one expiry date and only one registration to renew.

(e) Overview of trade mark process

An application to register a trade mark is filed at a national trade mark office providing a copy of the trade mark together with a description of the goods and or services for which the trade mark will be used. These goods or services fall into one or more International Classes (1 to 45).

The application is examined to ensure that the trade mark sought is adapted to distinguish the goods or services, is not the same or similar to other trade marks registered for the same of similar goods or services. It the trade mark meets the registration criteria, the application will be allowed, published and open to opposition by third parties, then registered for an initial 10 years.

Foreign trade mark applications may be filed within 6 months to claim priority from the first application, or filed at any time as the business or commercialization efforts expand to other countries or regions.

3 Lumos Patent Portfolio

Annexure 1 to this Report provides details of the patent applications relevant to the Lumos patent portfolio.

As shown in Annexure 1, the patent portfolio covers multiple inventions covered by numerous patents and patent applications, an overview of which is as follows. The overview should not be taken to provide definitive position as to the claim scope of any patent or patent application but serves to provide a general description of the technologies described and claimed in each patent family.

Allens makes no comment on the validity of any patent in the portfolio and no inference in relation to the validity of any such patent should be drawn from this Report.

3.1 Patent families 1-7: FebriDx®

These patent families cover various aspects of the FebriDx® technology which is a rapid, point-of-care test that uses a fingerstick blood sample to provide clinicians with a simple, fast, and easy-to-use assessment of a patient's immune response to an acute respiratory infection. Specifically the patents cover lateral flow assays that detect and differentiates between viral and bacterial infections by detecting markers such as the bacterial marker CRP, or the viral marker MxA.

(a) Family 1: Based on PCT/US2014/019771, titled 'Method and Device For Combined Detection Of Viral And Bacterial Infections', in the name of Rapid Diagnostic Screening, Inc

The assay devices covered by this family are lateral flow devices for detecting an analyte (such as CRP or MxA) in a sample. The device is a dual use two strip sample analysis device that includes a first lateral flow chromatographic test strip to detect MxA and a low level of C-reactive protein and a second lateral flow chromatographic test strip to detect high levels of C-reactive protein.

This family also covers methods of using the devices to determine if an infection is bacterial and/or viral. The methods utilise a patient sample (typically a fingerstick blood sample) to determine if the patient has a bacterial and/or viral infection.

The assay device has a sample compressor region having a reagent zone comprising a reagent specific to CRP (such as an antibody) and another reagent zone having a reagent specific to MxA (again, typically an antibody). The sample passes over these zones and any CRP and/or MxA forms a complex with their respective reagents. The complexes move through the device into chromatographic test strip that has a detection zone comprising 'binding partners' specific for each CRP or MxA. The binding partners are typically antibodies specific for the antibodies in the CRP or MxA complexes and which are further conjugated to or green latex beads or red colloidal gold particles, respectively. In the presence of the MxA complexes a natural cross linking of the colloidal gold takes place and one sees the clumping of the red colloidal gold particles. This process is antigen-dependent and fairly rapid, occurring generally within a minute or two and allowing visualisation of the complex. The same phenomenon takes place for the CRP complexes with the green colloidal latex beads.

(b) Family 2: Based on PCT/US2014/019773, Multiplanar Lateral Flow Assay with Diverting Zone', in the name of Rapid Diagnostic Screening, Inc

This family covers lateral flow devices that includes a sample compressor, a chromatographic test strip and a diverting zone. Methods of using the devices for detecting an analyte (or target) in a sample are also covered. The analyte-containing sample is collected directly from a patient and preferably undergoes no prior treatment. The sample is applied to a chromatographic carrier and in multi-planar configurations for point of care tests one or more binding partners of the analyte in question is usually delivered from a different plane. The binding partner is made to come in contact with the sample by means of a sample compressor. Compression aids in combining the binding partner and the sample. The sample compressor is separate from the sample analysis device. The sample compressor is not part of the flow path on the test strip. As a result, the transfer of the conjugate and the sample to the test strip, is initiated using pressure, not flow or capillary action. After the sample compressor is applied, if necessary there may be a time lapse before applying a

running buffer. This time lapse between sample application and the initiation of the testing by the flow can be up to 24 hours or many days depending on the stability of the analyte.

The diverting zone can be a barrier, gap or ditch that diverts the flow through the sample analysis device into a separate plane. This increases the interaction between the reagents on the sample compressor and both the reagents and the sample on the sample analysis device. In addition, the barrier completely blocks flow until the sample compressor is brought down to create a "bridge" that redirects the flow into the plane that comprise the compressor and then returns the flow to the sample analysis device where the barrier ends. Since the liquid has to flow through the compressor, it collects any reagents (including the binding partner) located on the compressor pad as it travels.

As for family 1, the test strip comprises 'binding partners' to from complexes with 'analytes', typically the binding partners are antibodies or antibody complexes specific for an analyte such CRP or MxA.

(c) Family 3: Based on PCT/US2009/057775, titled 'Method and Device For Combined Detection of Viral And Bacterial Infections', in the name of Rapid Diagnostic Screening, Inc

This family covers an early version of the FebriDx technology.

The devices covered by these patents can take the form of test strips having a sample application zone for applying a sample to the device, a reagent zone, and a detection zone. The reagent zone includes a reagent specific to CRP (such as an antibody) and another reagent zone having a reagent specific to MxA (again, typically an antibody). The sample passes over the reagent zones and any CRP and/or MxA forms a complex with their respective reagents. The complexes move through the reagent zone and into a detection zone comprising 'binding partners' specific for each CRP or MxA. The binding partners are typically antibodies specific for the antibodies in the CRP or MxA complexes and which are further conjugated to, for example, green latex beads or red colloidal gold particles, respectively. In the presence of the MxA complexes a natural cross linking of the colloidal gold takes place and one sees the clumping of the red colloidal gold particles. The same phenomenon takes place for the CRP complexes with the green colloidal latex beads. The use of other visible indicators is possible.

The methods utilise a patient sample (typically a fingerstick blood sample) to determine if the patient has a bacterial and/or viral infection. The methods use the devices and require application of the sample to the application zone, optionally with a lysis agent.

(d) Family 4: Based on PCT/US2010/058827, titled 'Multiplanar Lateral Flow Assay with Sample Compressor', in the name of Rapid Diagnostic Screening, Inc

This family covers lateral flow devices that includes a sample compressor and a chromatographic test strip and methods of using the devices for detecting an analyte (or target) in a sample. The analyte-containing sample is collected directly from a patient and preferably undergoes no prior treatment. The sample is applied to a chromatographic carrier and in multi-planar configurations for point of care tests one or more binding partners of the analyte in question is usually delivered from a different plane. The binding partner is made to come in contact with the sample by means of a sample compressor. Compression aids in combining the binding partner and the sample. The sample compressor is separate from the sample analysis device. The sample compressor is not part of the flow path on the test strip. As a result, the transfer of the conjugate and the sample to the test strip, is initiated using pressure, not flow or capillary action. After the sample compressor is applied, if necessary there may be a time lapse before applying a running buffer. This time lapse between sample application and the initiation of the testing by the flow can be up to 24 hours or many days depending on the stability of the analyte.

(e) Family 5: Based on PCT/US2016/058031, titled 'Improved Methods and Devices for Accurate Diagnosis of Infections', in the name of Rapid Pathogen Screening, Inc.

This family covers methods and devices for detecting MxA, IFIT proteins, other viral host markers, C-reactive protein, procalcitonin, and/or other bacterial host markers which may be used on any test platform such as lateral flow devices, ELISA, fluorescence, or chemiluminescence. The methods assist in the rapid differentiation of viral and bacterial infections, the differentiation of colonization and active infection, and to better diagnose microbiologically unconfirmed patients.

The methods identify clinically significant infections by choosing a threshold significantly above baseline values seen in the normal population and based on the relative values of biomarkers such as MxA and CRP, and can assist in the rapid differentiation between viral and bacterial infections and/or between active infection and colonization. The methods utilise a multiplexed pattern of results consisting of medical decision point (e.g. colonisation or infection) reflected by thresholds for low CRP, high CRP, MxA, serology, and levels of atypical bacteria together provides a sensitive and specific way to identify an immune response to a viral and/or bacterial infection.

(f) Family 6: US 63/038,490, titled 'C-terminally truncated MXA for use in diagnostics', in the name of Rapid Pathogen Screening, Inc.

This family consists of a single US patent application (US 63/038,490) filed on 12 June 2020. Further applications (such as PCT application) may be filed from this application by 12 June 2021. Alternatively, this application may mature into a US patent.

This family is directed to a diagnostic assay using a buffer system which contains high salt concentrations in combination with surfactants and chemicals to increase protein solubility, to create a C-terminally truncated MxA or functional equivalent of a truncated MxA, which increases overall MxA solubility, minimizes aggregation, allows for a high degree of MxA bioavailability, and quantitation for the diagnostic assay.

The claims are currently directed to a method of analysing a sample for MxA using a diagnostic assay and a method of analysing a nasopharygeal or orpharyngeal sample for mRNA or DNA for MxA using a nucleic acid amplification method, in combination with other mRNA or DNA, such as other viral pathogen RNA or DNA. The methods can be used to detect viruses such as influenza A, influenza B, respiratory syncytial virus, SARS-CoV-2, rhinovirus, parainfluenzavirus, metapneumovirus, and adenovirus.

(g) Family 7: Based on PCT/JP2007/071344 titled 'Method of immunoassay of component to be measured' in the name of Kyowa Medex Co., Ltd.

This family covers immunoassay methods for cellular detecting targets or analytes (such as MxA) in a blood sample, particularly intracellular targets and those induced by cytokines. The methods avoid the problem of haemoglobin interference in the conventional immunoassay process.

The immunoassay methods involve reacting the target with its cognate antibody in the presence of a bile acid derivative. The bile acid derivative has an amphoteric or non-ionic surfactant function and is distinct from any bile acid derivative that is inherently contained in the sample. The amount of the resulting immune complex of the target and its cognate antibody can then be determined.

This family also covers a method of suppressing the interference of haemoglobin in an immunoassay which involves the same steps, that is reacting the target with its cognate antibody in the presence of a bile acid derivative, as the immunoassay methods.

(i) Licence from Kyowa

Allens is informed that Lumos has licenced this patent family from Kyowa Medex Co., Ltd. Allens makes no comment on the license and no inference in relation to the license should be drawn from this Report.

3.2 Patent Families 8 and 9: Nucleic Acids

These patent families covers method of detecting at least one target double stranded nucleic acid in a sample.

(a) Family 8: Based on PCT/US2010/058822 titled 'Lateral flow assays', in the name of Rapid Pathogen Screening, Inc.

This family consists of a single US patent (US 9,121,849) which claims a test strip and kits containing the strip. The test strip is suitable for assays where the analyte to be detected does not bind directly to an immobilized binding partner in the test zone of the strip. Instead, the analyte preferably interacts with one or more analyte binding partners in other zones on the strip. At least one of the analyte binding partners includes a first tag that forms a complex with a second immobilized tag in the test zone.

The test strip has at least one detection zone comprising at least one test zone, a sample application zone for applying the sample to the test strip, and at least one mobile tagged nucleic acid reagent comprising a plurality of nucleic acid sequences complementary to a first portion of a sequence of the target nucleic acid. The test strip also comprises at least one tag portion comprising a first tag, wherein the mobile tagged nucleic acid reagent does not include a detectable label and wherein the mobile tagged nucleic acid reagent is loaded in a reagent zone. There is also at least one second immobilized tag that binds to the first tag, wherein the immobilized tag is immobilized in a test zone on the test strip. The strip also includes a running buffer that has a dye that binds to double stranded nucleic acids. When the sample, the mobile tagged nucleic acid reagent, and the immobilized tag are all loaded on the test strip the sample encounters the mobile tagged nucleic acid reagent and the immobilized tag and the target nucleic acid in the sample can be detected.

(i) Licence to Quidel Germany GmbH

Allens is informed that Lumos has licenced some aspects of the technology covered by this patent family to Quidel Germany GmbH, in particular these relate to the InflammaDry and AdenoPlus products and not the technology Lumos is presently commercialising. Allens makes no comment on the license and no inference in relation to the license should be drawn from this Report.

(b) Family 9: Based on PCT/US2009/050645 titled 'Lateral Flow Nucleic Acid Detector (NAC)' in the name of Rapid Pathogen Screening, Inc.

This family covers point-of-care assays which include at least one target nucleic acid binding in a multiplex structure with at least one sequence in a partner nucleic acid associated with a label, due to complementary base pairings between at least one sequence in the target nucleic acid and at least one sequence in the partner nucleic acid.

In particular, the methods involve detecting at least one target double stranded nucleic acid in a sample in which the target double stranded nucleic acid is partially opened into a first single strand and a second single strand, exposing the sample to at least one first complex located on a chromatographic test strip, and exposing the sample to at least one second complex located on the chromatographic test strip. The first complex being at least one first nucleic acid sequence associated with at least one label and complementary to a portion of a sequence of the first single strand of the target nucleic acid. The first complex is loaded in a first complex application zone. The second complex being at least one second nucleic acid sequence associated with at least one immobilization agent. At completion of the assay, when the target double stranded nucleic acid is present in the sample, the first complex, the target nucleic acid and the second complex are immobilized in the test zone of the chromatographic test strip.

3.3 Family 10: Reader Activation.
Based on AU 2018100803, titled 'Activation apparatus and method for an assay device', in the name of Lumos Diagnostics IP Pty Ltd

This family consists of a single Australian innovation patent (AU 2018100803) which relates to an activation apparatus for an electronic assay device. In one form the device has a sample port at one end and at the other end there is a formation adapted to associate with and operate a printed circuit board (PCB) 'detection circuit'. The activation apparatus, as a whole, can be removed from the sample port and/or the PCB detection circuit to activate the PCB detection circuit and allow access to the sample port.

In another form, the activation apparatus includes a sample port cover at one end, and an insert at another end which is adapted to isolate a PCB detection circuit from a power source of the PCB detection circuit. The activation apparatus as a whole can be removed from the sample port and/or the PCB detection circuit to activate the PCB circuit and allow access to the sample port.

The patent also covers a method of activating an electronic assay device by covering a sample port of the assay device and isolating a PCB detection circuit of the assay device from a power source of the PCB detection circuit with an integral strip of material and then removing the material from the assay device to activate the PCB circuit and allow access to the sample port prior to applying a sample to the assay device.

3.4 Family 11: Single/Multi-Use Reader.
Based on PCT/AU2019/000090 titled 'Lateral flow assay devices and method of use', in the name of Lumos Diagnostics IP Pty Ltd

This family of applications relates to an electronic assay test reader for reading a lateral flow test strip which has a development area comprising a test background region and at least one test result line. The electronic assay test reader is suited to read a lateral flow test strip which has a development area comprising a test background region and one or more test result lines. The electronic assay test reader includes a cassette for retaining the test strip and a carrier adapted to retain the cassette but also allow the cassette to be removed. There is an illumination LED(s) associated with the cassette and the carrier. A light guide is present to direct light emitted or reflected from a selected portion of the development area of the test strip to a sensor. The proportion the test result line relative to the proportion of test background region in the selected portion of the development area of the test strip is maximized.

3.5 Family 12: Nplex Detector Reader.
Based on PCT/AU2015/050708 titled 'A portable *in-vitro* diagnostic detector and apparatus', in the name of Lumos Diagnostics Pty Ltd

This family of applications is directed to a portable in-vitro (PIV) diagnostic detector operable to perform a fluorescence assay on a sample in one or more detection chambers of a cartridge.

The PIV diagnostic detectors comprises a first optical module which includes an LED light source that can emit substantially monochromatic light to illuminate a detection zone associated with at least one detection chamber. The detectors also comprise an excitation filter interposed between the LED light source and the detection zone. There is also a light detector that operates to detect fluorescent light emitted by an excited fluorescent label associated with the sample and to measure an intensity of the fluoresced light, the first optical module is configured such that a longitudinal axis of the light source extends at an oblique angle with respect to a longitudinal axis of the light detector. There is an emission filter interposed between the light detector and said detection zone. The (PIV) diagnostic detector further comprises a microprocessor that can process the measured intensity of the fluoresced light to determine whether an analyte is present in the sample.

3.6 Family 13: Nplex Camera Reader.
Based on PCT/AU2016/050965, titled 'Device for reading an IVD assay' in the name of Lumos Diagnostics IP Pty Ltd.

This family of applications is directed to a system for reading fluorescent-labelled diagnostic assays for in-vitro diagnostic applications.

The system comprises a receiving member that can receive a fluorescent-labelled diagnostic assay cartridge carrying a fluorescent-labelled diagnostic assay. There is at least one excitation module configured to illuminate the diagnostic assay when the diagnostic assay cartridge is placed in the receiving member, and a camera module for capturing an image of the illuminated diagnostic assay placed in the receiving member. The system has a processor for receiving the captured image from the camera module and determining whether or not a target analyte was present in the diagnostic assay captured by the camera module. The memory firmware includes a brightness compensation module that can adjust the intensity of an image of a diagnostic cartridge captured by the camera module in order to emulate a uniform field of illumination over the diagnostic cartridge. The brightness compensation module can also adjust the intensity of the captured image based on an illumination compensation look-up table.

The family also covers an apparatus for reading fluorescent-labelled lateral flow diagnostic assays for *in-vitro* diagnostic applications. The apparatus comprises a member adapted to receive a fluorescent-labelled lateral flow diagnostic assay cartridge carrying a fluorescent-labelled diagnostic assay, at least two excitation modules counter-disposed at an oblique angle to the receiving member and configured to illuminate the diagnostic cartridge when the diagnostic assay is placed in the receiving member. There is also a camera module for capturing an image of the illuminated diagnostic assay placed in the receiving member.

3.7 Patent families 14-21: Other Technologies

The Lumos patent portfolio comprises various other technologies that are described in the following subsections.

(a) Family 14: based on US 61/481,907, titled 'Methods And Devices For Using Mucolytic Agents Including N-Acetyl Cysteine (NAC)' in the name of Rapid Pathogen Screening, Inc.

This family of applications are directed to devices and methods which incorporate mucolytic agents into a point-of-care testing device. The sample is loaded into the device and travels until it encounters one or more lysis agents and/or mucolytic agents. The mucolytic agent is preferably pre-loaded onto the collection device. The mucolytic agent can be localised between a sample application zone and a conjugate zone. In embodiments with a sample compressor, one or more mucolytic agents may be pre-loaded and dried on the sample compressor, the sample collector, in various locations on the test strip, or in the running buffer.

This family of applications has multiple claims to devices, methods, and test strips comprising a mucolytic agent. There are also claims to a method of performing mucolysis of a sample on a lateral flow chromatography test strip.

(i) Licence to Quidel Germany GmbH

Allens is informed that Lumos has licenced some aspects of the technology covered by this patent family to Quidel Germany GmbH, in particular these relate to the InflammaDry and AdenoPlus products and not the technology Lumos is presently commercialising. Allens makes no comment on the license and no inference in relation to the license should be drawn from this Report.

(b) Family 15: Based on PCT/US2020/065911 titled 'Selective White Blood Cell Lysis For Immunoassay Systems', in the name of Rapid Pathogen Screening, Inc

This family consists of a single PCT application (PCT/US2020/065911) which claims priority to US provisional patent application number 62/949,958.

This family covers a test strip with an absorbent pad for selective white blood cell (WBC) lysis and release of WBC contents, and a blood separation pad to withhold red blood cells (RBC). This allows for rapid and accurate results to be seen at early time points due to the lack of red color interference caused by background red heme color of red blood cells. The removal of the red color interference enhances both visual and digital interpretation of test strips, such as in an immunoassay test. The test strip enhances the detection of both intracellular proteins of WBCs and extracellular proteins of RBCs simultaneously such as MxA and CRP, MxA and PCT, MxA and HNL, and MxA and IL-6, MxA and myeloid cells (sTREM-1), MxA and angiopoietin 2, MxA and vascular endothelial growth factor (VEGF) or its soluble vascular endothelial growth factor receptor-1 (sVEGFR1), MxA and heparin binding protein (HBP) or other combinations.

In particular, the test strip comprises an absorbent pad for receiving a blood sample for testing and selectively lysing at least white blood cells of the blood sample. The blood separation pad is adjacent to and overlapping with the absorbent pad and withholds intact red blood cells or removes heme from any lysed red blood cells of the blood sample. A conjugate pad is adjacent to and overlapping with the blood separation pad and contains biomarkers for binding to intracellular proteins of the white blood cells and extracellular proteins of the red blood cells within the blood sample. There is also a membrane pad adjacent to and overlapping with the conjugate pad for indicating results of the presence of intracellular proteins of the white blood cells and extracellular proteins of the red blood cells within the blood sample. The sample flows from the absorbent pad, to the blood separation pad, to the conjugate pad and to the membrane pad where the results are discernible in ten minutes or less.

(c) Family 16: Based on PCT/US2012/047321 titled 'Enzymatic Cleavage Based Lateral Flow Assays' in the name of Rapid Pathogen Screening, Inc

This family consists of a single US patent (no 9,212,386) which covers assay systems for detecting a target enzyme include an anchored or trapped peptide complex.

The systems include peptides engineered to have one or more enzyme cleavage sites and are used to identify the presence of one or more enzymes in a sample. The assay systems therefore require no antibodies. The peptide complex includes an anchor particle immobilized on a sample analysis device or trapped in a reaction receptacle. The receptacle includes a filter, a peptide with at least one enzyme cleavage site for a target enzyme and bound to the anchor particle, at least one detectable label, and at least one first tag bound to the peptide on a side of the enzyme cleavage site opposite the anchor particle. When the target enzyme is present in the sample, the enzyme cleaves the peptide at the enzyme cleavage site, permitting the cleaved peptide to reach the test zone of a sample analysis device such that the first tag binds to the immobilized second tag and a signal is detected at the test zone.

(i) Licence to Quidel Germany GmbH

Allens is informed that Lumos has licenced some aspects of the technology covered by this patent family to Quidel Germany GmbH, in particular these relate to the InflammaDry and AdenoPlus products and not the technology Lumos is presently commercialising. Allens makes no comment on the license and no inference in relation to the license should be drawn from this Report.

(d) Family 17: Based on US 61/536,740 titled 'Lateral Flow Assays With Time Delayed Components' in the name of Rapid Pathogen Screening, Inc.

This family consists of a single US patent (no 9,068,981) which covers a lateral flow device that includes one or more enhancement elements that bind the sandwich of analyte and its binding partner to increase signal detection in a test zone.

Specifically, the lateral flow device includes a test strip comprising a sample application zone and a test zone, a first conjugate comprising a first binding partner for the analyte and a label, a second binding partner for the analyte capable of being immobilized in the test zone and at least one encapsulated enhancement element. The analyte, the conjugate, and the second binding partner form a sandwich which is immobilized in the test zone when the analyte is present. The encapsulated enhancement element binds to the sandwich after being released from encapsulation to increase a detection signal in the test zone.

The patent also covers methods of using the device to enhance a detection signal.

(i) Licence to Quidel Germany GmbH

Allens is informed that Lumos has licenced some aspects of the technology covered by this patent family to Quidel Germany GmbH, in particular these relate to the InflammaDry and AdenoPlus products and not the technology Lumos is presently commercialising. Allens makes no comment on the license and no inference in relation to the license should be drawn from this Report.

(e) Family 18: Based on US 8,445,293 titled 'Method to Increase Specificity and/or Accuracy of Lateral Flow Immunoassays', in the name of Rapid Pathogen Screening, Inc.

This family consists of two US patents (8,445,293 and 9,250,236) covering methods and devices for preventing interfering substances from affecting the accuracy of a lateral flow immunoassay.

One method comprises collecting a sample with a sample collection system having a mobile capturing reagent, applying the sample and the mobile capturing reagent to a sample application zone of a lateral flow chromatographic test strip. If an interfering substance is present in the sample it is captured by the mobile capturing reagent to separate the interfering substance from the analyte which can then be detected on the lateral flow chromatographic test strip.

Another method involves applying the sample to an application zone of a lateral flow chromatographic test strip and laterally eluting at least one mobile capturing reagent located in a capturing zone which is located upstream of the sample application zone on the lateral flow chromatographic test strip. The mobile capturing reagent travels downstream to encounter the sample. If an interfering substance is present in the sample it is captured by the mobile capturing reagent to separate the interfering substance from the analyte which can then be detected on the lateral flow chromatographic test strip which comprises at least one test zone comprising at least one detection reagent, wherein the detection reagent complexes with and immobilizes the analyte or an antibody against the analyte at the test zone and wherein the detection zone is located downstream of the sample application zone.

The patents also cover a lateral flow chromatographic test strip. These test strips include an application zone to receive the sample and a reagent zone comprising at least one first reagent which interacts with an analyte in the sample to form a first complex. There is also a capturing zone comprising at least one mobile capturing reagent that interacts with an interfering substance in the sample to separate the interfering substance from the analyte. The capturing zone is located upstream of the application zone. A detection zone located downstream of the application zone comprises a second reagent that complexes with and immobilizes the analyte at the test zone.

(f) Family 19: Based on PCT/US2009/046848 titled 'Combined visual/fluorescence analyte detection test', in the name of Rapid Pathogen Screening, Inc.

This family is directed to enhancing the sensitivity of visually read lateral flow immunoassays by adding a small quantity of fluorescing dye or fluorescing latex bead conjugates to the initial conjugate material. Typically, when the visible spectrum test line can be seen the test result is observed and recorded. However, in the case where the result is indeterminate, a light of an appropriate spectrum, such as a UV, visible, or infrared spectrum, is cast on the test line to excite and fluoresce the fluorescing latex beads which are bound in the test line in true positive tests to enhance the visible color at the test line.

Specifically, this family covers a method of running an assay on a sample which involves transferring the sample to a sample analysis device which comprises a plurality of labels visible to an unaided eye and a plurality of fluorescing elements. The labels and the fluorescing elements are each coupled with at least one specific binding partner for a target in the sample. The samples are analysed for the presence of at least one target. The analysis comprises determining if a label is visible to the unaided eye at a test zone of the sample analysis device and if the visibility of the label is indeterminate, casting a fluorescent light source on the test zone to determine whether a result is positive using fluorescence.

(i) Licence to Quidel Germany GmbH

Allens is informed that Lumos has licenced some aspects of the technology covered by this patent family to Quidel Germany GmbH, in particular these relate to the InflammaDry and AdenoPlus products and not the technology Lumos is presently commercialising. Allens makes no comment on the license and no inference in relation to the license should be drawn from this Report..

(g) Family 20: US 8,614,101 titled 'In situ lysis of cells in lateral flow immunoassays', in the name of Rapid Pathogen Screening, Inc.

This family consists of US 8,614,101 which describes techniques for incorporating lysis agents into a point-of-care testing device, such as a chromatography test strip or other lateral flow immunoassay device, so that cell lysis is not conducted as a separate step.

Specifically, the patent covers methods for detecting a target in a sample by applying a sample to a sample application zone of an analysis device, applying an elution medium comprising a lysis agent to the sample analysis device to transfer the sample from the sample application zone to a detection zone. During the transfer the sample encounters the lysis agent such that the sample is lysed prior to reaching the detection zone. The sample is then analysed for the presence of the target by detecting a signal from the labeled binding partner in the detection zone. The sample application zone and the detection zone are on a chromatographic test strip. The chromatographic test strip further comprises a conjugate zone comprising a labeled binding partner that is able to migrate with the elution medium. When the labeled binding partner encounters the sample while the sample is being transferred from the sample application zone to the detection zone it binds to the target when the target is present in the sample. The chromatographic test strip further comprises a lysis zone that comprises another lysis agent.

(i) Licence to Quidel Germany GmbH

Allens is informed that Lumos has licenced some aspects of the technology covered by this patent family to Quidel Germany GmbH, in particular these relate to the InflammaDry and AdenoPlus products and not the technology Lumos is presently commercialising. Allens makes no comment on the license and no inference in relation to the license should be drawn from this Report.

(h) Family 21: PCT/US2021/029953 titled 'Method and device for detection of severe acute respiratory syndrome coronavirus 2 using MXA proteins' in the name of Rapid Pathogen Screening, Inc.

This family consists of a single PCT application (PCT/US2021/029953) which claims priority to US provisional patent applications, numbers 63/017,648 and 63/017,653.

The application covers methods for determining whether an infection is viral or viral positive for SARS-CoV-2 using MxA and immunoglobulins for SARS-CoV-2. The method can be used to detect respiratory viruses such as influenza A, influenza B, SARS, SARS-CoV-2 or respiratory syncytial virus. The applications additionally include using CRP, procalcitonin to confirm bacterial infection and/or coinfection. There are also claims directed to detecting a bacterial and/or viral marker using a first and a second lateral flow test with the first lateral test having reagent zones using a bacterial host biomarker and a second reagent zone using immunoglobulins for SARS-CoV-2. The bacterial host biomarker can be CRP, procalcitonin, IL-6 or human neutrophile lipocalin.

4 Trade Marks

Annexure 2 to this Report provides details of the trade marks relevant to the Lumos trade mark portfolio.

4.1 Word Mark: RPS, in the name of Rapid Pathogen Screening, Inc

This mark is registered in the USA, Australia, Brazil, Canada, Israel, and Japan for goods in class 005 with a description of “test strips for diagnostic antigen or antibody determinations for medical use”.

This mark is in the name of Rapid Pathogen Screening, Inc.

4.2 Word Mark: RIGHT DIAGNOSIS RIGHT TREATMENT RIGHT NOW, in the name of Rapid Pathogen Screening, Inc

The mark is registered in the USA for goods in class 001 with the description 'diagnostic preparations, reagents, and assays for medical research use; diagnostic kits consisting primarily of preparations, reagents, and assays for medical research use', and goods in class 005 for 'medical diagnostic preparations, reagents, and assays for testing of body fluids; medical diagnostic kits consisting primarily of preparations, reagents, and assays for testing of body fluids'.

4.3 Word Mark: FEBRIDX, in the name of Rapid Pathogen Screening, Inc

The mark is registered in the US and Ecuador for goods in class 005 with the description 'diagnostic preparations for medical purposes, namely, diagnostic testing preparations for detecting an immune response to infection'.

4.4 Word Mark: STEWART SHIPP, in the name of Rapid Pathogen Screening, Inc

The text mark for STEWART SHIPP is pending in the USA for goods in class 025 with the description 'athletic apparel, namely, shirts, pants, jackets, footwear, hats and caps, athletic uniforms'.

4.5 Stewart Shipp logo:  , in the name of Rapid Pathogen Screening, Inc

The side view of the logo is registered in the USA for services in class 035 with the description 'promoting antibiotics stewardship'.

4.6 Stewart Shipp logo:  , in the name of Rapid Pathogen Screening, Inc

The front view of the logo is registered in the USA for services in class 035 with the description 'promoting antibiotics stewardship'.

4.7 Word Mark: COVIDX, in the name of Rapid Pathogen Screening, Inc

This mark is pending in the USA for goods in class 005 with the description 'medical diagnostic test strips for measuring, testing, and analyzing blood and other bodily fluids'.

4.8 Word Mark: COV-ID, in the name of Rapid Pathogen Screening, Inc

This mark is pending in the USA for goods in class 005 with the description 'medical diagnostic test strips for measuring, testing, and analysing blood and other bodily fluids'.

4.9 Word Mark: URIDX, in the name of Rapid Pathogen Screening, Inc

The mark is pending in the US for goods in class 005 with the description 'medical diagnostic test strips for measuring, testing, and analyzing blood and other bodily fluids'.

4.10 Word Mark: InnateDX, in the name of Lumos Diagnostics, Inc

The mark is registered in the USA under multiple classes. In class 005 it is registered for goods and services with the description 'medical diagnostic test strips for measuring, testing and analyzing blood and other bodily fluids'. In class 010 it is registered for goods and services with the description 'medical diagnostic instruments for the analysis of body fluids.' In class 042 it is registered for goods and services with the description 'research and development in the field of medical devices and reagents for diagnostics'. In class 044 it is registered for services with the description 'providing an internet website for medical professionals and medical patients featuring medical information from remote locations via devices that feed information to the website that is processed, exchanged and accessed in real-time by users.'

4.11 Word Mark: SEPSIDX, in the name of Rapid Pathogen Screening, Inc

This mark is pending in the USA for goods in class 005 with the description 'Diagnostic preparations for medical purposes; Medical diagnostic test strips for measuring, testing, and analyzing blood and other bodily fluids' and goods in class 010 with the description 'Medical diagnostic instruments for the analysis of body fluids'

4.12 Word Mark: VIRIDX, in the name of Rapid Pathogen Screening, Inc

The mark is pending in the US for goods in class 005 with the description 'Diagnostic preparations for medical purposes; Medical diagnostic test strips for measuring, testing, and analyzing blood and

other bodily fluids' and goods in class 010 with the description 'Medical diagnostic instruments for the analysis of body fluids'

5 Limitations and Disclaimers

5.1 Search Limitations

Prior art (or 'novelty') searches conducted by various patent offices to determine whether a patent should be granted are limited to the time periods and the geographical areas covered. Thus, databases used in searching may not include older published documents and may not cover certain jurisdictions. Moreover, searches cannot locate documents which have not been published at the time of conducting the search. In most countries, publication of a patent application does not occur until 18 months from the earliest priority date. Delays between official publication and the implementation of information onto the relevant databases can also occur.

All searches are limited to the accuracy and scope of the databases searched together with the search criteria adopted. Accordingly, whilst the searches conducted by various patent offices provide a reasonable indicator of patentability prospects, these and other factors make it not possible to guarantee that every relevant prior art record has been identified and considered. Accordingly, any conclusions drawn regarding the validity of claims in a patent based on patent office searches should be regarded as indicative rather than conclusive in nature.

No search can be considered as entirely conclusive or exhaustive as some forms of prior art such as public use, oral disclosures, prior commercial exploitation and prior publication in non-patent literature, cannot be searched systematically.

The commercialization or secret use of an invention that is subject of a patent application can affect the patentability of the invention and the validity of any patent granted on the invention. Such commercialization or secret use is unlikely to be identified by documentary searches of publicly accessible databases.

The views expressed in relation to relevance of prior art cited in various patent office searching and examination reports are based on the relevant patent document classification attributed in such reports.

Searching may not disclose other matters relevant to validity including, for example, matters relevant to obviousness or inventive step.

Examination and search reports in one country are not binding in other countries.

5.2 Duty of Disclosure

In some jurisdictions there is a duty to disclose certain information, such as examination reports from other patent offices or prior art known to the applicant or its agents, to the relevant patent office while an application is pending. Failure to disclose this information in accordance with these obligations may adversely affect the validity or enforceability of the relevant patent.

5.3 Grant of Patent Provides No Guarantee of Validity

Grant of a patent by a national patent office provides an indication rather than a guarantee of its validity. In most jurisdictions, a patent application is subject to substantive examination prior to grant. Although this process confers an initial presumption of validity, in most countries that 'presumption' carries no binding legal weight and a patent may be challenged at any time after grant by way of revocation proceedings undertaken in a court of competent jurisdiction. In some countries a granted patent may be subjected to re-examination by the relevant patent office,

particularly if relevant prior art is identified that was not considered during the initial examination of the application.

5.4 Grant of Patent Provides No Guarantee of Non-Infringement

Grant of a patent provides no guarantee that the patentee is entitled to commercially exploit the patented invention. For example, the working of an invention, even if validly patented, may nevertheless infringe an earlier patent or other intellectual property rights in the country of exploitation.

5.5 Entitlement to Priority

In order for an invention disclosed in a patent to be entitled to the priority date of a corresponding provisional application, the provisional application must disclose the invention in a manner that is clear enough and complete enough for the invention to be performed by a skilled person. Similar provisions apply in other jurisdictions. Subject matter not so disclosed is not entitled to the claim to priority which may affect patentability of an invention or validity of any patent that may be granted in respect of the invention.

5.6 Scope of Claims May Vary During Examination

It may be possible, and it is often necessary, during examination of a patent application to define the invention more specifically by amendment of the claims to distinguish the invention over relevant prior art or to meet national claiming requirements. Accordingly, there may be variations in the claims between countries reflecting in part different national examination procedures and threshold patentability requirements. Such amendments may affect the scope and hence the commercial significance of the resultant patent protection.

5.7 Enforcement of Patent Rights

Upon grant of a patent, the patentee may initiate infringement proceedings against an alleged infringer of the patent. In many jurisdictions, damages for infringement may be awarded for infringements occurring from the date of publication of the patent specification, provided certain criteria are met.

5.8 Changes to Patent Law

From time to time the statutory basis governing patents in particular jurisdictions may be amended by the relevant authority, typically the government of that jurisdiction. In addition, the practical effect of the statute may evolve by development of case law, that is, by the interpretation of the statute by the relevant courts.

5.9 Reliance on Information

The preparation of this Report has included access to and reliance on information contained in publicly available databases relevant to the patents and patent applications in Annexure 1. Allens is not responsible for the accuracy of information available in public databases and cannot guarantee the accuracy of those databases.

6 Allens' Interest

Allens is engaged by Lumos solely in relation to the preparation of this Report and is not directly or indirectly involved in the prosecution of patent or trade marks set out in Annexures 1 and 2.

Section 9
Intellectual Property Report

Allens › ‹ Linklaters

7 Consent

Consent for the inclusion of this Report in a Prospectus to be issued by Lumos, in the form in which it now appears, has been granted by Allens and has not been revoked as at the date of this Report.

Yours sincerely

Linda Govenlock, PhD
Partner
Allens Patent & Trade Mark Attorneys
Linda.Govenlock@allens.com.au
T +61 2 9230 5163

Attach

Tony Shaw, PhD
Principal Patent Attorney
Allens Patent & Trade Mark Attorneys
Tony.Shaw@allens.com.au
T +61 2 9230 4622

Annexure 1
Lumos Patent Portfolio

1. Method and Device For Combined Detection Of Viral And Bacterial Infections (PCT/US2014/019771)

Region	Filing Date	Number	Status
Australia	3 Mar 2014	2014226173	Granted
Australia	3 Mar 2014	2020233741	Pending
Brazil	3 Mar 2014	BR1120150211992	Pending
Europe	3 Mar 2014	2909331	Granted. Validated in the Netherlands, Spain, France, Great Britain, Ireland, Germany, Denmark, Switzerland and Lichtenstein, Italy
Europe	21 May 2019	3591397	Pending
Hong Kong	27 Feb 2016	1214308	Granted
Hong Kong	22 Jun 2020	42020009775.6	Pending
Canada	3 Mar 2014	2,897,494	Pending
USA	8 Mar 2016	8,962,260	Granted
USA	7 Mar 2013	8,815,609	Granted
USA	25 May 2016	10,379,121	Granted
USA	2 Dec 2015	10,408,835	Granted
USA	18 May 2010	9,910,036	Granted
USA	8 Feb 2013	9,372,192	Granted
USA	19 Dec 2014	9,933,423	Granted
USA	6 Aug 2019	16/532,855	Pending
Japan	3 Mar 2014	6521525	Granted
Japan	3 Mar 2014	2019080579	Pending
Japan	3 Mar 2014	2021011320	Pending
Korea	3 Mar 2014	10-2015-7027376	Granted
Korea	3 Mar 2014	10-2021-7002397	Pending

2. Multiplanar Lateral Flow Assay with Diverting Zone (PCT/US2014/019773)

Region	Filing Date	Number	Status
USA	7 Mar 2013	8,815,609	Granted
Canada	3 Mar 2014	2,875,495	Pending
Europe	3 Mar 2014	2906947	Granted. Validated in Turkey, Sweden, Norway, Netherlands, United Kingdom, France, Finland, Spain, Denmark, Germany, Switzerland and Lichtenstein
Hong Kong	3 Mar 2014	16101859.0	Pending
Korea	3 Mar 2014	10-2130186	Granted
Japan	3 Mar 2014	6293797	Granted

3. Method and Device For Combined Detection Of Viral And Bacterial Infections (PCT/US2009/057775)

Region	Filing Date	Number	Status
Europe	22 Sep 2009	2335072	Granted. Validated in Spain, France, Great Britain, Ireland, Italy, Germany
Japan	22 Sep 2009	5859854	Granted

4. Multiplanar Lateral Flow Assay with Sample Compressor (PCT/US2010/058827)

Region	Filing Date	Number	Status
USA	2 Dec 2010	8,609,433	Granted
USA	17 Mar 2014	9,939,434	Granted
Europe	3 Dec 2010	2507632	Granted Validated in Austria, Switzerland and Lichtenstein, Germany, Spain, France, Italy, United Kingdom
Australia	3 Dec 2010	2010325893	Granted
Brazil	3 Dec 2010	1120120123424	Granted
Canada	3 Dec 2010	2,780,751	Granted
Japan	3 Dec 2010	5855572	Granted
Russia	3 Dec 2010	2564911	Granted

5. Improved Methods and Devices for Accurate Diagnosis of Infections (PCT/US2016/058031)

Region	Filing Date	Number	Status
USA	2 Feb 2016	10,808,287	Granted
USA	14 Sep 2014	17/020,628	Pending
Europe	21 Oct 2016	16858264.1	Pending
Australia	21 Oct 2016	2016342268	Pending
Canada	21 Oct 2016	3041458	Pending
Hong Kong	21 Oct 2016	19119787.0	Pending

6. C-terminally truncated MXA for use in diagnostics (US 63/038,490)

Region	Filing Date	Number	Status
USA	12 Jun 2020	63/038,490	Pending

7. Method of immunoassay of component to be measured (PCT/JP2007/071344)

Region	Filing Date	Number	Status
USA	1 Nov 2007	8,043,822	Granted
USA	1 Nov 2007	8,257,935	Granted
Canada	1 Nov 2007	2,668,001	Granted
Europe	1 Nov 2007	2085728	Granted

8. Lateral flow assays (PCT/US2010/058822)

Region	Filing Date	Number	Status
USA	8 Mar 2013	9,121,849	Granted

9. Lateral Flow Nucleic Acid Detector (NAC) (PCT/US2009/050645)

Region	Filing Date	Number	Status
USA	14 Jul 2009	8,669,052	Granted
USA	25 Jun 2012	8,822,151	Granted
Japan	15 Jul 2009	5948056	Granted

10. Activation apparatus and method for an assay device

Region	Filing Date	Number	Status
Australia	15 Jun 2018	2018100803	Granted Innovation Patent

Section 9
Intellectual Property Report

11. Lateral flow assay devices and method of use (PCT/AU2019/000090)

Region	Filing Date	Number	Status
USA	29 Jul 2019	17/263,799	Pending
Europe	29 Jul 2019	19841261.1	Pending
Australia	29 Jul 2019	2019310186	Pending
Singapore	29 Jul 2019	11202100840S	Pending
Korea	29 Jul 2019	1020217006188	Pending

12. A portable in-vitro diagnostic detector and apparatus (PCT/AU2015/050708)

Region	Filing Date	Number	Status
Europe	13 Nov 2015	15859371	Pending
USA	13 Nov 2015	15526324	Pending

13. Device for reading an IVD assay (PCT/AU2016/050965)

Region	Filing Date	Number	Status
Australia	14 Oct 2016	2016340039	Pending
Europe	14 Oct 2016	16854649.7	Pending
India	14 Oct 2016	201837007184.00	Pending
Canada	14 Oct 2016	2997627	Pending
USA	14 Oct 2016	10,768,113	Granted
USA	14 Oct 2016	10,379,049	Granted
Japan	14 Oct 2016	2018517335	Pending
China	14 Oct 2016	201680059964.00	Pending

14. Methods And Devices For Using Mucolytic Agents Including N-Acetyl Cysteine (NAC) (US 61/481,907)

Region	Filing Date	Number	Status
USA	3 May 2012	9,797,898	Granted
USA	3 May 2014	9,804,155	Granted
USA	30 Oct 2017	15/797,915	Allowed
USA	4 April 2021	17/225,605	Pending

15. Selective white blood cell lysis for immunoassay systems (PCT/US2020/065911)

Region	Filing Date	Number	Status
International	18 Dec 2020	PCT/US2020/065911	Pending

16. Enzymatic Cleavage Based Lateral Flow Assays (PCT/US2012/047321)

Region	Filing Date	Number	Status
USA	19 Jul 2012	9,212,386	Granted

17. Lateral Flow Assays With Time Delayed Components (US 61/536,740)

Region	Filing Date	Number	Status
USA	19 Sep 2012	9,068,981	Granted

18. Method to Increase Specificity and/or Accuracy of Lateral Flow Immunoassays

Region	Filing Date	Number	Status
USA	29 Sep 2009	9,250,236	Granted
USA	13 Mar 2013	8,445,293	Granted

19. Combined visual/fluorescence analyte detection test (PCT/US2009/046848)

Region	Filing Date	Number	Status
USA	10 Jun 2009	8,470,608	Granted

20. In situ lysis of cells in lateral flow immunoassays (US 61/098,935)

Region	Filing Date	Number	Status
USA	14 Jul 2009	8,614,101	Granted

21. Method and device for detection of severe acute respiratory syndrome coronavirus 2 using MXA proteins (PCT/US2021/029953)

Region	Filing Date	Number	Status
International	29 Apr 2021	PCT/US2021/029953	Pending

Annexure 2
Lumos Trade Mark Portfolio

1. Word Mark: RPS

Region	Filing Date	Number	Status	Class
USA	4 Aug 2006	76664198	Registered	005
Australia	25 Jan 2007	1157793	Registered	005
Brazil	5 Feb 2007	828958858	Registered	005
Canada	26 Jan 2007	1332971	Registered	005
Europe	25 Jan 2007	5666854	Registered	005
Israel	28 Jan 2007	197264	Registered	005
Japan	30 Jan 2007	5053758	Registered	005

2. Word Mark: RIGHT DIAGNOSIS RIGHT TREATMENT RIGHT NOW

Region	Filing Date	Number	Status	Class
USA	3 Aug 2009	4,002,986	Registered	001 005

3. Word Mark: FEBRIDX

Region	Filing Date	Number	Status	Class
USA	2 Feb 2013	4837134	Registered	005
Ecuador	26 Mar 2013	011690881	Registered	005

4. Word Mark: STEWART SHIPP

Region	Filing Date	Number	Status	Class
USA	6 Aug 2020	6332555	Registered	025
Europe	26 Mar 2013	011690881	Registered	025

5. Stewart Shipp logo: 

Region	Filing Date	Number	Status	Class
USA	6 Aug 2020	6300254	Registered	035

6. Stewart Shipp logo:

Region	Filing Date	Number	Status	Class
USA	6 Aug 2020	6300277	Registered	035

7. Word Mark: COVIDX

Region	Filing Date	Number	Status	Class
USA	13 May 2020	88913775	Pending	005

8. Word Mark: COV-ID

Region	Filing Date	Number	Status	Class
USA	13 May 2020	88913760	Pending	005

9. Word Mark: URIDX

Region	Filing Date	Number	Status	Class
USA	13 May 2020	88913744	Pending	005

10. Word Mark: INNATEDX

Region	Filing Date	Number	Status	Class
USA	4 May 2020	88900469	Registered	005 010 042 044

11. Word Mark: SEPSIDX

Region	Filing Date	Number	Status	Class
USA	1 Apr 2021	90618361	Pending	005 010

12. Word Mark: VIRIDX

Region	Filing Date	Number	Status	Class
USA	31 Mar 2021	90615484	Pending	005 010

Section 10

Additional Information

10.1. Registration

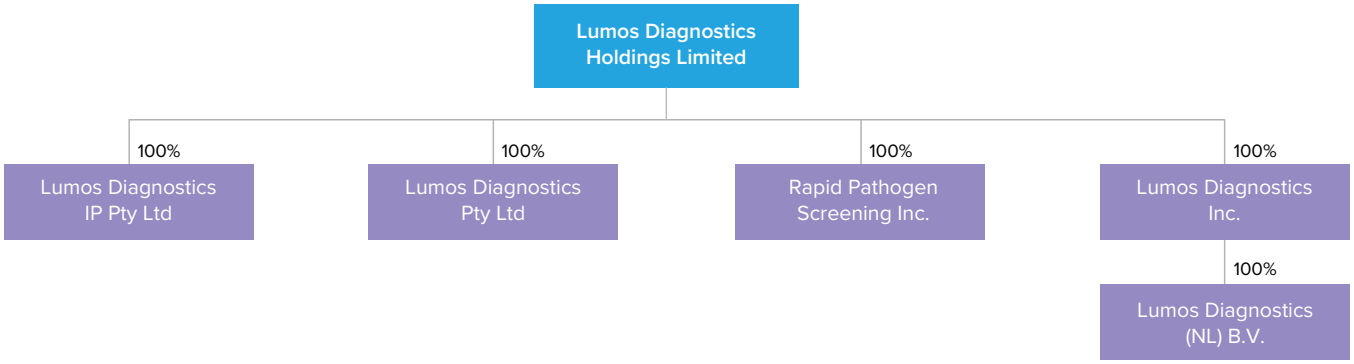
The Company was registered in South Australia on 7 December 2018 and converted to a public company on 13 April 2021. Lumos Diagnostics SaleCo Limited was registered in New South Wales on 18 May 2021.

10.2. Corporate structure

10.2.1. Corporate structure chart

Figure 10.1 represents the corporate structure of the Group as at the Prospectus Date.

Figure 10.1: Corporate structure.



10.2.2. Lumos entities

The Company has five wholly owned subsidiary companies. A brief description of the activities of the Company and each of its subsidiaries is included at Table 10.1.

Table 10.1: Summary of activities of Lumos entities

Name	Place/Date of Incorporation	Summary of activities at the Prospectus Date
Lumos Diagnostics Holdings Limited (Company)	South Australia 7 December 2018	Holding company for the Group
Lumos Diagnostics Pty Ltd	Victoria 25 September 2012	Australian sales and operations
Lumos Diagnostics IP Pty Ltd	South Australia 7 December 2018	Owner of Australian IP (reader platform)
Lumos Diagnostics, Inc.	Delaware 30 May 2017	U.S. sales and operations
Rapid Pathogen Screening, Inc	Delaware 5 January 2004	Owner of FebriDx assets and IP
Lumos Diagnostics (NL) B.V.	Amsterdam 8 November 2019	European entity, currently dormant

Section 10
Additional Information

10.3. Capital structure

The capital structure of the Company as at the Prospectus Date and as at Completion is summarised in Section 6.3.

As at the Prospectus Date, Lumos has 26,268,610 Shares, 12,465,497 Options (including 261,834 Options which Robert Sambursky exercised before the Prospectus Date and which will convert into Shares prior to Completion as described in Section 6.3), 60,922,336 Preference Shares and $25,261,094 of Pre-IPO Convertible Notes on issue. Terms of Shares and Options are described in Sections 7.11 and 6.4.6 respectively. The Preference Shares will convert into Shares on Completion (on a 1 for 1 basis). The Pre-IPO Convertible Notes have an aggregate face value of $25,261,094. Interest on the notes accrues daily at 10% per annum, with the first interest payment date expected on Completion. The number of Shares that the Pre-IPO Convertible Notes convert into is calculated as (the aggregate face value plus accrued interest) divided by the conversion price (being in the context of the offer a pre-money market capitalisation cap of $110 million). Shares on issue following conversion of the Preference Shares and Pre-IPO Convertible Notes will rank equally with other Shares.

On Completion, the Company will have on issue 150,152,413 Shares and 12,203,663 Options (as described in Section 6.3) assuming Completion occurs on 29 June 2021. The exact number of Shares to be on issue at Completion will depend on the date Completion occurs. This is because, as noted above, the number of Shares that Pre-IPO Convertible Notes convert into is determined by reference to the aggregate face value and interest accrued in respect of those notes at the date the number of those Shares is calculated. For this purpose, the Prospectus assumes that Completion occurs on 29 June 2021 and that therefore 32,561,467 Shares will be issued on conversion of the Pre-IPO Convertible Notes. If Completion occurs on a different date, and the number of Shares to be on issue at Completion varies from that indicated in this Prospectus, Lumos will publish that number of Shares to ASX at the time of Listing.

10.4. Sales of Shares by SaleCo

SaleCo, a special purpose vehicle, has been established to facilitate the sale of existing Shares by the Selling Shareholders.

Each of the Selling Shareholders has entered into a Sale Deed in favour of SaleCo under which the relevant Selling Shareholder has agreed to sell to SaleCo some or all of their Shares, which will be sold by SaleCo into the Offer, free from encumbrances and third party rights.

The Shares which SaleCo acquires from the Selling Shareholders will be transferred to successful applicants at the Offer Price. The price payable by SaleCo for these Shares is the Offer Price. The Company will also issue Shares to successful applicants under the Offer.

SaleCo has no material assets, liabilities or operations other than its interests in and obligations under the Underwriting Agreement and the deeds described above. The sole shareholder of SaleCo is Melanie Leydin (holding one share) and the directors of SaleCo are Sam Lanyon, Bronwyn Le Grice and Catherine Robson.

Lumos has agreed to provide such resources and support as are necessary to enable SaleCo to discharge its functions in relation to the Offer and has indemnified SaleCo in respect of costs of the Offer. Lumos has indemnified SaleCo and the shareholders and officers of SaleCo for any loss which they may incur as a consequence of the Offer.

10.5. Participation in issues of securities

Except as described in this Prospectus, Lumos has not granted, or proposed to grant, any rights to any person, or to any class of person, to participate in an issue of Lumos' securities.

10.6. Underwriting Agreement

The Offer is being underwritten by the Lead Manager pursuant to an underwriting agreement, dated on or about the Prospectus Date, between the Lead Manager, Lumos and SaleCo (**Underwriting Agreement**). Under the Underwriting Agreement, the Joint Lead Managers have agreed to arrange, manage and underwrite the Offer.

10.6.1. Commissions, fees and expenses

Lumos must pay to the Joint Lead Managers, in equal proportions, in accordance with the Underwriting Agreement an underwriting and management fee equal to:

- 2.5% of Offer proceeds (up to a maximum of $5m) from funds received or arranged by Lumos (such as under the Priority Offer); and
- 5.0% of other Offer proceeds.

Planet Innovation has agreed to pay the Joint Lead Managers the underwriting and management fee equal to 5% in respect of Offer proceeds received by Lumos in connection with the sale of Shares by SaleCo. Lumos has agreed to reimburse the Joint Lead Managers for reasonable costs and expenses incurred by the Joint Lead Managers in relation to the Offer. Lumos has authorised the Joint Lead Managers to pay any fees of Brokers out of fees payable to them (except as otherwise agreed by Lumos), with the Joint Lead Mangers to be responsible for payment of Broker fees of the relevant Broker firm allocation.

10.6.2. Termination events

A Joint Lead Manager may terminate the Underwriting Agreement, at any time after the date of the Underwriting Agreement and before 10:00am on the date for Settlement, or at any other time earlier as specified below, by notice to the Lumos or SaleCo and the other Joint Lead Manager if any of the following events occur:

- a Joint Lead Manager forms the view (acting reasonably) that:
  - there is a material omission from the Prospectus or any supplementary Prospectus of material required by the Corporations Act to be included;
  - the Prospectus or any supplementary Prospectus contains a material statement which is untrue, inaccurate or misleading or deceptive;
  - the Prospectus or any supplementary Prospectus is likely to mislead or deceive (whether by inclusion or omission) in a material respect; or
  - the Prospectus or any supplementary Prospectus does not contain all material information required to comply with all applicable laws;
- Lumos and SaleCo issues or, in the reasonable opinion of the Joint Lead Managers is required to issue, a supplementary Prospectus because of the operation of section 719(1) of the Corporations Act;
- at any time the S&P/ASX 300 index falls to a level that is 90% or less of the level of that index as at the close of trading on the date of this agreement and closes at or below that 90% level on 2 consecutive business days prior to the Settlement Date, or on the business day prior to the Settlement Date;
- a voluntary escrow agreement (other than in respect of an escrowed securityholder under the Priority Offer) is withdrawn, varied, terminated, rescinded, altered or amended, breached or failed to be complied with or void or voidable or is unable to, or likely to be unable to, be performed;
- a Sale Deed is withdrawn, varied, terminated, rescinded, altered or amended, breached or failed to be complied with or void or voidable or is not performed in accordance with its terms;
- unconditional approval is refused or not granted, or approval is granted subject to conditions other than customary conditions, to:
  - Lumos' admission to the official list of ASX on or before 10.00am on the Settlement Date; or
  - the quotation of the Shares on ASX or for the Shares to be traded through CHESS on or before the quotation date,

  or if granted, the approval is subsequently withdrawn, qualified (other than by customary conditions) or withheld;
- any of the following notifications are made in respect of the Offer or offer documents, pathfinder or public information:
- ASIC issues an order (including an interim order) under sections 739 or 1324B of the Corporations Act and any such inquiry or hearing is not withdrawn within 2 business days or if it is made within 2 business days of the Settlement Date it has not been withdrawn by 10:00am on the Settlement Date;
- ASIC holds a hearing under section 739(2) of the Corporations Act;
  - an application is made by ASIC for an order under Part 9.5 in relation to the Offer, an offer document, the pathfinder or public information or ASIC commences any investigation or hearing under Part 3 of the ASIC Act in relation to the Offer, an offer document, the pathfinder or public information, and any such application inquiry or hearing is not withdrawn within 2 business days or if it is made within 2 business days of the Settlement Date it has not been withdrawn by 10:00 am on the Settlement Date;
  - any other governmental agency commences any investigation or hearing in relation to any offer document, the pathfinder or public information, and any such investigation or hearing is not withdrawn within 2 business days or if it is made within 2 business days of the Settlement Date it has not been withdrawn by 10:00 am on the Settlement Date;
  - any person who has previously consented to the inclusion of its name in the Prospectus (or any supplementary Prospectus) (other than the terminating Joint Lead Manager) withdraws that consent; or
  - any person gives a notice under section 730 of the Corporations Act in relation to the Prospectus (other than the terminating Joint Lead Managers);
- Lumos or SaleCo withdraws the Prospectus or the Offer or all or any part of the Offer or indicates that it does not intend to proceed with the Offer or any part of it;

- an event specified in the timetable up to and including the Settlement Date is delayed by more than one business day (other than any delay caused solely by the Joint Lead Managers or any delay agreed between the Company and the Joint Lead Managers or a delay as a result of an extension of the exposure period by ASIC);
- Lumos is prevented from allotting and issuing the new Shares, or SaleCo is prevented from transferring the sale Shares, by applicable laws, an order of a court of competent jurisdiction or a governmental authority, within the time required by the timetable (as may be amended in accordance with this agreement), offer documents, applicable laws and the Listing Rules;
- any financial forecast that appears in the Prospectus is not based on reasonable grounds (including having regard to ASIC Regulatory Guide 170), or becomes incapable of being met or, in the reasonable opinion of the Joint Lead Managers, is unlikely to be met in the projected time;
- any of the following occur:
  - Lumos or any other Group member, or a director (or proposed director) or officer of Lumosor any other Group member, engages, or any governmental agency commences any claim, proceedings or public action alleging that they have engaged, in any fraudulent conduct or activity or is charged with an indictable offence relating to any financial or corporate matter, whether or not in connection with the Offer; or
  - any director (or proposed director) of Lumos or any other Group member is disqualified from managing a corporation under Part 2D.6 of the Corporations Act;
- a Group member is or becomes Insolvent or there is an act or omission which is likely to result in a Group member becoming Insolvent;
- a specified contract referred to in sections 3.2.3, 3.6.5.2 and 6.7 of the Prospectus is:
  - withdrawn, terminated or rescinded; or
  - found to be void or voidable;
- Lumos or SaleCo does not provide a closing certificate as and when required by this agreement;
- there is an event or occurrence, including any statute, order, rule, regulation, directive or request (including one compliance with which is in accordance with the general practice of persons to whom the directive or request is addressed) of any governmental agency which makes it illegal for the Joint Lead Managers to satisfy an obligation under this Agreement, or to market, promote or settle the Offer;
- Lumos:
  - alters the issued capital of Lumos or a Group member, other than as contemplated in the Prospectus; or
  - disposes or attempts to dispose of a substantial part of the business or property of the Group,
  - without the prior written consent of the Joint Lead Managers (such consent not to be unreasonably withheld or delayed);
- if a regulatory body withdraws, revokes or amends any regulatory approvals required for Lumos or SaleCo to perform their obligations under this agreement, such that Lumos or SaleCo is rendered unable to perform its obligations under this agreement or the transactions contemplated by the offer documents; or
- a change in the board of Directors, chief executive officer or chief financial officer of Lumos or SaleCo is announced or occurs.

10.6.3. Termination events subject to materiality

A Joint Lead Manager may terminate the Underwriting Agreement, at any time after the date of the Underwriting Agreement and before 10:00am on the date for Settlement under the Offer by notice to the other parties, if any of the following events occur and the Joint Lead Manager has reasonable grounds to believe the event: (a) has had or is likely to have a material adverse effect: (i) on the success of the Offer; (ii) on the ability of the Joint Lead Manager to settle the Offer; (iii) the willingness of persons to apply for, or settle obligations to subscribe for, Securities under the Offer; or (b) has, or is likely to, give rise to a liability of the Joint Lead Manager or its affiliates under, or give rise to or result in, a contravention by the Joint Lead Manager or its affiliates, of, any applicable law:

- an offer document (other than the Prospectus) or public information:
  - contains a statement which is untrue, inaccurate, misleading or deceptive or likely to mislead or deceive (whether by inclusion or omission); or
  - does not contain all information required to comply with all applicable laws;
- the due diligence report is, or becomes, false, misleading or deceptive, or likely to mislead or deceive, in each case including by way of omission;
- any information supplied (including any information supplied prior to the date of this agreement) by or on behalf of a Group member to the Joint Lead Managers (and where information has been supplemented, or supplied in draft and then in final form, in its final form as at the Lodgement Date) in respect of the Offer or the Group is, or becomes, misleading or deceptive, or is likely to mislead or deceive (including by omission);

- an event occurs which gives rise to, or is likely to give rise to:
  - an adverse change in the assets, liabilities, financial position or performance, profits, losses or prospects of the Group from those disclosed in the Prospectus lodged with ASIC on the Lodgement Date; or
  - an adverse change in the nature of the business conducted by the Group as disclosed in the Prospectus lodged with ASIC on the Lodgement Date;
- a statement in any closing certificate is false, misleading, inaccurate or untrue or incorrect;
- there occurs a new circumstance that has arisen after the Prospectus was lodged with ASIC that would have been required to be included in the Prospectus if it had arisen before lodgement with ASIC;
- an offer document includes any expression of opinion, belief, intention or expectation which is not based on reasonable grounds (including having regard to ASIC Regulatory Guide 170), taken as a whole;
- there is introduced, or there is a public announcement of a proposal to introduce, a new applicable law or regulation or policy of a governmental agency (other than a law, regulation or policy which has been announced before the date of this agreement);
- there is a contravention by Lumos, SaleCo or any other Group member of the Corporations Act, the Competition and Consumer Act 2010 (Cth), the Australian Securities and Investments Commission Act 2001, its constitution, the Listing Rules or any other applicable law;
- in relation to the specified contracts referred to in sections 3.2.3, 3.6.5.2 and 6.7 of the Prospectus:
  - if any of the obligations of the relevant parties under any of the contracts that are material to the making of an informed investment decision in relation to the Shares or any of the specified contracts referred to in sections 3.2.3, 3.6.5.2 and 6.7 of the Prospectus are not capable of being performed in accordance with their terms; or
  - if all or any part of a specified contracts referred to in sections 3.2.3, 3.6.5.2 and 6.7 of the Prospectus is breached, altered or amended;
- a representation or warranty contained in this agreement on the part of the Company or SaleCo is breached, becomes not true or correct or is not performed, where the pathfinder or public information contains a statement that is not true or correct and this is rectified, with the prior written consent of the Joint Lead Managers, in the Prospectus;
- Lumos or SaleCo defaults on one or more of its undertakings or obligations under this agreement;
- any of the following occurs:
  - the commencement of legal proceedings against Lumos or SaleCo or any of its directors in their capacity as a director; or
  - any governmental agency commences any enquiry or public action against Lumos or another Group member or any of their respective directors in their capacity as a director of Lumos or another Group member (as applicable), or announces that it intends to take action;
- hostilities not existing at the date of this agreement commence (whether war has been declared or not) or a major escalation in existing hostilities occurs (whether war has been declared or not) involving any one or more of Australia, the United States, the United Kingdom, Japan, any member of the European Union, North Korea, South Korea, Singapore, Hong Kong or China, or the declaration by any of these countries of a national emergency (other than in relation to COVID-19 or as already existing prior to entry into this agreement) or an escalation in an existing national emergency (other than in relation to COVID-19), or a significant terrorist attack is perpetrated on any of those countries or any diplomatic, military, commercial or political establishment of any of those countries elsewhere in the world; or
- any of the following occurs:
  - a general moratorium on commercial banking activities in Australia, the United States, the United Kingdom, Singapore, Hong Kong or any member of the European Union is declared by the relevant central banking authority in any of those countries, or there is a material disruption in commercial banking or security settlement or clearance services in any of those countries;
  - any adverse disruption or change (or any escalation thereof) to the existing financial markets or political conditions or currency controls of Australia, the United States, the United Kingdom, Singapore, Hong Kong or any member of the European Union or the international financial markets, or any development involving a prospective change in the financial markets or political conditions or currency controls in any of those countries; or
  - trading in all securities quoted or listed on ASX, the London Stock Exchange, the Hong Kong Stock Exchange or the New York Stock Exchange is suspended or limited in a material respect for 1 day on which that exchange is open for trading.

10.6.4. Indemnity and guarantee

Subject to certain exclusions relating to, among other things, gross negligence, recklessness, fraud or wilful misconduct by an indemnified party, Lumos agrees to keep the Joint Lead Managers and certain affiliated parties indemnified from losses suffered in connection with the Offer.

10.6.5. Conditions, warranties, undertakings and other terms

The Underwriting Agreement contains certain standard representations, warranties and undertakings by Lumos to the Joint Lead Managers (as well as common conditions precedent).

The representations and warranties given by Lumos include but are not limited to matters such as power and authorisations, compliance with applicable laws and ASX Listing Rules, financial information, information contained in the offer documents, the conduct of the Offer and the due diligence process, litigation, data privacy, encumbrances, internal controls and insurance.

Lumos provides undertakings under the Underwriting Agreement which include but are not limited to notifications of breach of any obligation, representation, warranty or undertaking or non-satisfaction of any condition given by it under the Underwriting Agreement that it will not, during the period following the date of the Underwriting Agreement until 180 days after Shares have been issued (or transferred) under the Offer, issue any Shares or Securities without the consent of the Joint Lead Managers, subject to certain exceptions.

10.7. Consent to be named and inclusion of statement and disclaimers of responsibility

10.7.1. Consenting parties

Each of the parties listed below (each a consenting party) and each of their respective related bodies corporate, shareholders and affiliates and their respective officers, directors, employees, partners, affiliates, agents and advisers, to the maximum extent permitted by law, expressly disclaims all liabilities (including, without limitation, any liability arising out of fault or negligence for any direct, indirect, consequential or contingent loss or damage) in respect of, makes no representations or warranties regarding, and takes no responsibility for, any statements in or omissions from this Prospectus, other than in the case of a consenting party the reference to its name in the form and context in which it is named and a statement or report included in this Prospectus with its consent as specified below. Each of the above expressly disclaims any fiduciary relationship with any investor in the Offer. .

Each of the consenting parties has given and has not, before the lodgement of this Prospectus with ASIC, withdrawn its written consent to be named in this Prospectus in the form and context in which it is named.

- MarketsandMarkets;
- Clayton Utz;
- Foley Lardner;
- Wilsons Corporate Finance Limited;
- Bell Potter Securities Limited;
- Blackpeak Capital;
- Computershare Investor Services Pty Limited;
- BDO;
- BDO Tax;
- Allens Patent & Trademark Attorneys;
- William Buck; and
- Frazier & Deeter.

BDO has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to be named as the Investigating Accountant in the form and context in which it is named and to the inclusion in this Prospectus of its Independent Limited Assurance Report set out in Section 8.

Allens Patent & Trademark Attorneys has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to be named as patent & trademark attorneys in the form and context in which it is named and to the inclusion in this Prospectus of its Intellectual Property Report set out in Section 9.

Each of William Buck and Frazier & Deeter has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to be named in this Prospectus as auditor in the form and context in which it is named. Neither of William Buck or Frazier & Deeter has not authorised or caused the issue of this Prospectus and does not make or purport to make any statement in the Prospectus.

MarketsandMarkets has given, and has not withdrawn prior to the lodgement of this Prospectus with ASIC, its written consent to the inclusion in this Prospectus of the data and other information and statements attributed to it in this Prospectus in the form and context in which they are included, and takes no responsibility for any other statements in this Prospectus.

Computershare Investor Services Pty Limited has given and, as at the date hereof, has not withdrawn, its written consent to be named as Share Registrar in the form and context in which it is named. Computershare Investor Services Pty Limited has had no involvement in the preparation of any part of the Prospectus other than being named as Share Registrar to the Company. Computershare Investor Services Pty Limited has not authorised or caused the issue of, and expressly disclaims and takes no responsibility for, any part of the Prospectus.

10.7.2. Non-consenting parties

Lumos has included statements in this Prospectus made by, attributed to or based on statements made by the following parties:

- Ajit Singh, How covid-19 is accelerating the threat of antimicrobial resistance, The BMJ, published on May 2020;
- American Associates, Ben-Gurion University, Quick test to diagnose bacterial or viral infection, ScienceDaily, published on July 2011;
- Australian Government Department of Health, Overview of supplying therapeutic goods in Australia, published on August 2020;
- Benjamin Mullish and Horace Williams, Clostridium difficile infection and antibiotic-associated diarrhoea, Clinical Medicine (London, England) vol. 18(3), published on June 2018;
- Benjamin Plackett, No money for new drugs, Nature vol. 586, published October 2020;
- Biosensis homepage, available at www.biosensis.com/;
- Brian Krans, A Blood Test That Can Tell If You Have a Virus or a Bacterial Infection, published on March 2019;
- C.L. Ventola, The antibiotic resistance crisis: part 1: causes and threats, P & T : a peer-reviewed journal for formulary management vol. 40(4), published on April 2015;
- Centers for Disease Control and Prevention, 1 in 3 antibiotic prescriptions unnecessary, published on May 2016;
- Centres for Disease Control and Prevention, Antibiotic resistance threats in the United States, published on December 2019;
- Centres for Disease Control and Prevention, Antibiotic resistance threats in the United States, published on December 2019;
- Centres for Disease Control and Prevention, Waived Testing, 2021, Waived Tests, published January 2021;
- Chief Public Health Officer of Canada, Preserving Antibiotics, Spotlight Report, published on June 2019;
- Christopher Price and Andrew John, Will COVID-19 be the coming of age for point-of-care testing?, BMJ Innovations 2021 vol. 7, published on December 2020;
- DiaSorin, DiaSorin announces its strategic collaboration with Lumos Diagnostics, published on April 2021;
- Duke Education, Genomic Test Accurately Sorts Viral vs. Bacterial Infections, published on September 2013;
- Ellume, Covid-19 Response, available at www.ellumehealth.com/covid19-response/;
- European Commission, CE marking, published April 2021;
- European Commission, Digital health technologies addressing the pandemic, accessed on April 2021;
- European Commission, Medical Device - Sector, accessed at <ec.europa.eu/health/md_sector/overview_en>;
- Fablo D'Arti et al, Targets for the reduction of antibiotic use in humans in the TATFAR partner countries, Euro Serveill vol. 24(28), published on July 2019;
- Filippo Lagi et al, Use of the FebriDx point-of-care test for the exclusion of SARS-CoV-2 diagnosis in a population with acute respiratory infection during the second (COVID-19) wave in Italy, International Journal of Infectious Disease, published on April 2021;
- Government of Canada, Testing devices for COVID-19, published February 2021;
- Hamish Houston et al, Use of the FebriDx point-of-care assay as part of a triage algorithm for medical admissions with possible COVID-19, BMJ, published January 2021;
- HealthyChildren.org, Tips For Treating Viruses, Fungi, and Parasites, published on November 2011;
- Inflammatix, Pipeline, available at www.inflammatix.com/inflammatix-tests/#pipeline;
- J.E. Schneider et al, Application of a simple point of care test to reduce UK healthcare costs and adverse events in outpatient acute respiratory infections, Journal of Medical Economics vol. 23(7), published on April 2020;

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Additional Information

- Jim O'Neill, Antimicrobial Resistance: tackling a crisis for the health and wealth of nations/the Review on Antimicrobial Resistance, Wellcome Collection, published on December 2014;
- Katie Kalvaitis, Penicillin: An accidental discovery changed the course of medicine, Penicillin: An accidental discovery changed the course of medicine, published on August 2008;
- Kevin Young and Ralph Tricomi, LFI Rapid Diagnostics: Onshoring Strategies for Supply-Chain Stability, published on December 2020;
- LightDeck, Mbio Diagnostics Announces Rebrand to LightDeck Diagnostics, published on October 2020;
- Lumira Ventures homepage, available at www.lumiraventures.com/;
- M.L. Martinez et al, An approach to antibiotic treatment in patients with sepsis, Journal of thoracic disease vol. 13(3), published on March 2020;
- Martin Blaser et al, Accounting for variation in and overuse of antibiotics among humans, BioEssays, published on October 2020;
- Martin Chenal, The other pandemic: Once-treatable diseases are growing resistant to antibiotics, published on January 2021;
- Medical Learning Network, Medicare Physician Fee Schedule (MPFS) Booklet, published on March 2021;
- Medicines and Healthcare products Regulatory Agency, In vitro diagnostic medical devices: guidance on legislation, published on January 2021;
- MedTech Europe, The transition to a new regulatory framework for in vitro diagnostic medical devices in the EU; European Commission, Medical Device Sector, published May 2018;
- MeMed, What is MeMed BV, available at <https://www.me-med.com/memed-bv>; BioWorld, MeMed secures Ce mark for new POC blood test, published on June 2020;
- MeMed, What is MeMed BV, available at www.me-med.com/memed-bv;
- Miles Davidson, FebriDx® Point-of-Care Testing to Guide Antibiotic Therapy, published on August 2017.
- Ministry of Health NZ, Therapeutic products regulatory regime, published on December 2019;
- N. Shehab et al, US Emergency Department Visits for Outpatient Adverse Drug Events, 2013-2014. JAMA vol. 316(20);
- Nathan I Shapiro et al, A prospective, multi-centre United States clinical trial to determine accuracy of FebriDx point-of-care testing for acute upper respiratory infections with and without a confirmed fever, Annals of Medicine, vol 50(5), published on May 2018;
- National Institute for Health and Care Excellence, FebriDx for C-reactive protein and myxovirus resistance protein A testing, published on August 2020;
- Nawazish Karim et al, Utility of the FebriDx® point-of-care test for rapid triage and identification of possible coronavirus disease 2019 (COVID-19), IJCP, published on September 2020;
- NHS, Antibiotics side effects, published on May 2019;
- Nicky Phillips, The coronavirus is here to stay – here's what that means, published on February 2021;
- OraSure, 2019 Annual Report;
- Oxford Ummunotec, Oxford Immunotec Announces Food and Drug Administration (FDA) Clearance of the T-SPOT®.TB Test for Use in Pediatrics Over the Age of Two, published on September 2020;
- Patricia Sweeney, Improving Appropriate Antibiotic Use For Common Clinical Conditions in Urgent Care, The Journal of Urgent Care Medicine, published on June 2017;
- Peter Luppa, Point-of-care testing at the interface of emerging technologies and new clinical applications, Journal of Laboratory Medicine vol. 44(2), published on April 2020;
- Porooshat Dadgostar, Antimicrobial Resistance: Implications and Costs, Infection and drug resistance vol. 12 3903-3910, published on December 2019;
- Qiagen, Financial Report 2019 - Performance Review;
- Reed Sutton et al, An overview of clinical decision support systems: benefits, risks, and strategies for success, Nature Partner Journals vol. 3, published on February 2020;
- Rob Sambursky and Nathan Shapiro, Evaluation of a combined MxA and CRP point of care immunoassay to identify viral and or bacterial immune response in patients with acute febrile respiratory infection, European Clinical Respiratory Journal vol. 2, published on December 2015;
- Robert Trevethan, Sensitivity, Specificity, and Predictive Values: Foundations, Pliabilities, and Pitfalls in Research and Practice, Frontiers in public health vol. 5, published on November 2017;

- Shashank Patil, POCTED: Use of Point of care Test Devices in Emergency Department, ICU Management & Practice vol. 16(3), published 2016;
- Tamar Barlam et al, Unnecessary Antibiotics for Acute Respiratory Tract Infections: Association With Care Setting and Patient Demographics, Open forum infectious diseases vol. 3(1), published on February 2016;
- The Pew Charitable Trusts, Antibiotic Use in Outpatient Settings, published on May 2016;
- Tristan W Clark et al, Diagnostic accuracy of the FebriDx host response point-of-care test in patients hospitalised with suspected COVID-19, The Journal of Infection vol. 81(4), published October 2020;
- U.S. Department of Health & Human Services, U.S. National Action Plan for Combating Antibiotic – Resistant Bacteria (National Action Plan), published October 2020;
- U.S. Food & Drug Administration, Premarket Notification 510(k), published March 2020;
- UK Government, Regulating medical devices in the UK, published on December 2020;
- UK Government, The UK's five-year national action plan, published January 2019;
- UK Government, Using the UKCA marking, published on February 2021;
- University of Rochester Medical Center, New tool to distinguish between viral, bacterial infections, ScienceDaily, published on July 2017;
- Victorian State Government Department of Health, Antibiotics resistant bacteria, published on March 2017;
- W.A. Adedeji, The Treasure Called Antibiotics, Annals of Ibadan postgraduate medicine vol. 14(2), published December 2016;
- Wesley H Self et al, Diagnostic Accuracy of FebriDx: A Rapid Test to Detect Immune Responses to Viral and Bacterial, Journal of Clinical Medicine vol. 6(10), published on October 2017;
- WHO, Medicines reimbursement policies in Europe, published on March 2018; and
- Xavier Onrubia, A pilot evaluation of the FebriDx test in an outpatient pediatric clinic, published on March 2020.

The inclusion of statements made by, attributed to or based on statements made by these parties has not been consented to by the relevant party for the purpose of section 729 of the Corporations Act (other than as made by Rob Sambursky in respect of which he has consented) and are included in this Prospectus by Lumos on the basis of ASIC Corporations (Consents to Statements) Instrument 2016/72 relief from the Corporations Act for statements used from books, journals or comparable publications.

10.8. Description of syndicate

The Joint Lead Managers of the Offer are Wilsons Corporate Finance Limited and Bell Potter Securities Limited.

10.9. Regulatory relief

10.9.1. ASIC Relief

Lumos has applied to ASIC for a modification of Section 707 of the Corporations Act to the extent necessary to permit the Shares that will be issued on exercise of Options granted before the Prospectus Date to be able to be sold within 12 months of issue without the requirement for a future disclosure document to be prepared in connection with that sale.

10.9.2. ASX waivers

Lumos has obtained from ASX in principle advice that, in respect of ASX Listing Rule 9.1.3, the relevant restrictions in Appendix 9B of the ASX Listing Rules do not apply to Lumos as it has a track record of revenue acceptable to ASX.

10.10. Australian corporate regulation

As a company incorporated in Australia, Lumos is already subject to, and will further be subject to on listing on the ASX, a number of corporate laws and regulations, including the Corporations Act, Australian Securities and Investment Commission Act 2001 (Commonwealth) (**ASIC Act**) and ASX Listing Rules. ASIC is an independent Australian Government body and regulates corporates, markets, financial services and consumer credit. ASIC is empowered under the ASIC Act and regulates corporate conduct via that Act and other legislation/regulations including the Corporations Act and works closely with the ASX to ensure compliance with the Corporations Act and market integrity rules. The ASX is obliged to notify ASIC of various matters, including suspected contraventions of relevant laws and rules. ASIC has a number of enforcement powers including investigating actual and suspected breaches of the law and compulsory information gathering powers.

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Additional Information

As a listed entity, Lumos will be subject to the takeover provisions in Chapter 6 of the Corporations Act, which restrict acquisitions of shares in listed companies if the acquirer's (or another party's) voting power would increase to above 20%, or would increase from a starting point that is above 20% and below 90%, unless certain exceptions apply. The Corporations Act also imposes notification requirements on persons having voting power of 5% or more in the Company.

Lumos is also subject to the Foreign Acquisitions and Takeovers Act 1975 (Cth) (**FATA**), which applies to acquisitions of shares and voting power in a company of 20% or more by a single foreign person and its associates (substantial interest), or 40% or more by two or more unassociated foreign persons and their associates (aggregate substantial interest). Where a foreign person holds a substantial interest in Lumos or foreign persons hold an aggregate substantial interest in Lumos, Lumos itself will be a "foreign person" for the purposes of the FATA.

Where an acquisition of a substantial interest or an aggregate substantial interest meets certain criteria, the acquisition may not occur unless notice of it has been given to the Federal Treasurer and the Federal Treasurer has either stated that there is no objection to the proposed acquisition in terms of the Australian Federal Government's Foreign Investment Policy (**FATA Policy**) or a statutory period has expired without the Federal Treasurer objecting. An acquisition of a substantial interest or an aggregate substantial interest meeting certain criteria may also lead to divestment orders unless a process of notification, and either a statement of non-objection or expiry of a statutory period without objection, has occurred.

In addition, in accordance with the FATA, acquisitions of a direct interest in an Australian company by foreign governments and their related entities must be notified to the Foreign Investment Review Board for approval, irrespective of value. According to the FATA Policy, a "direct interest" will typically include any investment of 10% or more of the shares (or other securities or equivalent economic interest or voting power) in an Australian company but may also include investment of less than 10% where the investor obtains the ability to influence, participate or control the target investment.

10.11. Taxation considerations

The comments in this Section 10.11 provide a general outline of Australian tax issues for Australian tax resident Shareholders who acquire Shares under this Prospectus and that hold Shares in Lumos on capital account for Australian income tax purposes. The categories of Shareholders considered in this summary are limited to individuals, companies (other than life insurance companies), trusts, partnerships and complying superannuation funds that hold their shares on capital account.

This summary does not consider the consequences for foreign resident Shareholders, insurance companies, banks, Shareholders that hold their shares on revenue account or carry on a business of trading in shares, Shareholders who are exempt from Australian tax, or Shareholders who are subject to the Taxation of Financial Arrangements rules contained in Division 230 of the Income Tax Assessment Act 1997.

The summary in this Section is general in nature and is non exhaustive of all Australian tax consequences that could apply in all circumstances of any given Shareholder. The individual circumstances of each Shareholder may affect the taxation implications of the investment of the Shareholder.

It is recommended that all Shareholders consult their own independent tax advisers regarding the income tax (including capital gains tax), stamp duty and GST consequences of acquiring, owning and disposing of Shares, having regard to their specific circumstances.

The summary in this Section is based on the relevant Australian tax law in force, established interpretations of that law and understanding of the practice of the relevant tax authority at the time of issue of this Prospectus. The summary does not take into account the tax law of countries other than Australia.

Tax laws are complex and subject to ongoing change. The tax consequences discussed in these summaries do not take into account or anticipate any changes in law (by legislation or judicial decision) or any changes in the administrative practice or interpretation by the relevant authorities. If there is a change, including a change having retrospective effect, the income tax, stamp duty and GST consequences should be reconsidered by Shareholders in light of the changes. The precise implications of ownership or disposal of the Shares will depend upon each Shareholder's specific circumstances.

This summary does not constitute financial product advice as defined in the Corporations Act.

10.11.1. Company Status and Financial Year

The Company has a balance date of 30 June. The Company is a tax resident of Australia and subject to income tax at the standard corporate tax rate of 30% (subject to the base rate entity rules which may give rise to a lower corporate tax rate).

10.11.2. Dividends paid on Shares

Dividends may be paid to Shareholders by Lumos. Lumos may attach 'franking credits' to such dividends. Franking credits broadly represent the extent to which a dividend is paid by Lumos out of profits that have been subject to Australian income tax. It is possible for a dividend to be fully franked, partly franked or unfranked. The dividend should be included in each Shareholder's assessable income for the relevant year of income.

It should be noted that the concept of a dividend for Australian income tax purposes is very broad and can include payments that are made in respect of such things as off-market share buy-backs.

To the extent that franking credits are attached to a dividend, Australian tax resident Shareholders should include in their assessable income an amount equal to the franking credits (in addition to the dividend paid) in the income year in which the dividend is paid or credited.

Australian tax resident Shareholders should be entitled to a tax offset equal to the franking credits attached to the dividend so long as they are a "qualified person". A "qualified person" is a Shareholder who, in broad terms, hold Shares in Lumos "at risk" for a period of more than 45 days within a period beginning on the day after the date on which the Shareholder acquired the Shares and ending on the 45th day after the date on which the Shares became "ex dividend". An individual may also be a "qualified person" where their total franking credit entitlement in the relevant income year is below $5,000 for the relevant year.

In some cases, an amount of a tax offset not applied against an Australian tax resident Shareholder's tax liability can be refunded to that Shareholder. Whether this is available depends on the particular circumstances of the Shareholder, including their entity type.

Shareholders who are not tax residents of Australia should generally be subject to Australian dividend withholding tax with respect of any unfranked dividends paid by the Company. Prima facie, the dividend withholding tax rate imposed is at 30%, however this rate may be reduced where the shareholder is a tax resident of a country that has a double tax treaty with Australia.

Dividends paid which are fully franked are exempt from Australian dividend withholding tax.

10.11.3. Australian Capital gains tax (CGT) implications for Australian tax resident Shareholders on a disposal of Shares

Australian tax resident Shareholders who hold their Shares on capital account will be required to consider the impact of the Australian CGT provisions in respect of the disposal of their shares. A capital gain will arise where the capital proceeds on disposal exceed the cost base of the share (broadly, the cost base is the amount paid to acquire the share plus any (non-tax deductible) transaction costs incurred in relation to the acquisition or disposal of the shares). In the case of an arm's length on-market sale, the capital proceeds should be the total amount of the money and property received from the sale of the shares. A CGT discount may be applied against the capital gain (after first deducting any available capital losses, see below) where the Shareholder is an individual, complying superannuation entity or trustee, and the Shares have been held for more than 12 months prior to the CGT event. Where the CGT discount applies, any capital gain arising to individuals and entities acting as Trustees (other than a trust that is a complying superannuation entity) may be reduced by one-half after offsetting current year or prior year capital losses. For a complying superannuation entity, any capital gain may be reduced by one-third, after offsetting current year or prior year capital losses.

Where the Shareholder is the trustee of a trust that has held the Shares for more than 12 months before disposal, the CGT discount may flow through to the beneficiaries of the trust if those beneficiaries are not companies. Shareholders that are trustees should seek specific advice regarding the tax consequences of distributions to beneficiaries who may qualify for discounted capital gains.

A capital loss will be realised where the reduced cost base of the share (the reduced cost base is determined by a similar (although not identical) calculation to the cost base) exceeds the capital proceeds from disposal. Capital losses may only be offset against capital gains realised by the Shareholder in the same income year or future income years, subject to certain loss recoupment tests being satisfied. Capital losses cannot be offset against other forms of assessable income.

10.11.4. Australian Capital gains tax (CGT) implications for foreign tax resident Shareholders on a disposal of Shares

Prima facie, foreign tax residents are not subject to Australian CGT.

However, foreign tax resident Shareholders may make a capital gain on the disposal of taxable Australian property (including shares). For tax purposes, the Shares will only be considered taxable Australian property where broadly:

- The foreign tax resident Shareholder owns an interest of 10% or more in Lumos; and
- More than 50% of the value of Lumos relates to taxable Australian real property (i.e. Australian land or buildings).

On the basis that the value of Lumos is unlikely to be generated mostly from Australian real property interests, it is unlikely that the Shares would be considered taxable Australian property. As such, foreign tax resident Shareholders who acquire and subsequently dispose of their Shares are unlikely to be subject to Australian tax on any gains from the disposal of the Shares. At the same time, any capital loss cannot be utilised by the foreign tax resident Shareholder to reduce their Australian tax liability (if any).

10.11.5. Withholding Tax

Resident Shareholders may, if they choose, notify Lumos of their tax file number (TFN), ABN, or a relevant exemption from withholding tax with respect to dividends.

In the event that Lumos is not so notified, Australian tax may be required to be deducted at the maximum marginal tax rate plus the Medicare levy from the cash amount of the unfranked portion (if any) of the dividends. No amount is required to be deducted by Lumos in respect of fully franked dividends. The rate of withholding tax is currently 47%.

Lumos is required to withhold and remit to the ATO such tax until such time as the relevant TFN, ABN or exemption notification is given to Lumos. Shareholders will be able to claim a tax credit/rebate (as applicable) in respect of any tax withheld on the dividends in their individual income tax returns.

A Shareholder that holds Shares as part of an enterprise may quote their ABN instead of their TFN. Foreign tax resident shareholders are not required to comply with the above requirement.

10.11.6. Stamp Duty

Shareholders should not be liable for stamp duty in respect of their initial subscription of Shares on the basis that Lumos does not hold any relevant interests in real property. Under current stamp duty legislation, no stamp duty should ordinarily be payable by Shareholders on any subsequent transfer of Shares whilst the Company remains listed on the ASX.

Shareholders should seek their own advice as to the impact of stamp duty in their own particular circumstances.

10.12. Dividend reinvestment plan

On Completion, the Company will not have a dividend reinvestment plan. It may elect to implement one in the future.

10.13. Selling restrictions

This document does not constitute an offer of Shares in any jurisdiction in which it would be unlawful. In particular, this Prospectus may not be distributed to any person, and the Shares may not be offered or sold in any country outside of Australia, except as set out in Appendix B.

10.14. Costs of the Offer

The costs of the Offer are expected to be $4.7m (pre GST) (refer to Section 6.4.1). These costs will be borne by Lumos from the proceeds of the Offer and existing funds.

10.15. Privacy

Lumos, SaleCo and the Share Registry on Lumos' behalf, collect, hold and use your personal information to process your application, service your needs as a Shareholder, provide facilities and services that you request and carry out appropriate administration. Once you have become a Shareholder, the Corporations Act requires information about you (including your

name, address and details of the Shares you hold) to be included in the Shareholder register. This information must continue to be included in the Shareholder register even if you cease to be a Shareholder. If you do not provide all the information requested in the Application Form, your Application Form may not be able to be processed.

Lumos, SaleCo and the Share Registry may disclose your personal information for purposes related to your investment to their agents and service providers including the following: the Share Registry for ongoing administration of the Shareholder register; the Joint Lead Managers in order to assess your application; printers and other companies for the purpose of preparation and administration of documents and for handling mail; market research companies for the purpose of analysing Lumos' shareholder base and for product development and planning; and legal and accounting firms, auditors, management consultants and other advisers for the purpose of administering, and advising on, the Shares and for associated actions.

You may request access to your personal information held by the Share Registry on Lumos' behalf, by contacting the Share Registry. You will generally be provided access to your personal information (subject to some exceptions permitted by law), but you may be required to pay a reasonable charge to the Share Registry for access. Lumos aims to ensure that the personal information it retains about you is accurate, complete and up to date. To assist with this, please contact the Share Registry if any of the details you have provided change. In accordance with the requirements of the Corporations Act, information on the Shareholder register will be accessible by members of the public.

If you have any concerns or queries about the way your personal information is managed by Lumos, please contact us by phone on 1300 850 505, by email to web.queries@computershare.com.au or write to Yarra Falls, Computershare Investor Services Pty Ltd, 452 Johnston Street, Abbotsford VIC 3067.

The Share Registry's complete privacy policy is available at the Share Registry's website, www.computershare.com/au/privacy. Further details about the Share Registry's privacy policy including how to access and correct your personal information, and information on the privacy complaints handling procedure, may also be emailed to the Privacy Officer at privacy@computershare.com.au.

Lumos' privacy policy is available on its website https://lumosdiagnostics.com/. The privacy policy contains information about how you can gain access to or seek correction of personal information that Lumos holds about you.

10.16. Contract summaries

Summaries of contracts set out in this Prospectus (including the summary of the Underwriting Agreement set out in Section 10.6) are included for the information of potential investors but do not purport to be complete and are qualified by the text of the contracts themseves.

10.17. Photographs and diagrams

Photographs and diagrams used in this Prospectus that do not have descriptions are for illustration only and should not be interpreted to mean that any person shown in them endorses this Prospectus or its contents or that the assets shown in them are owned by Lumos. Diagrams used in this Prospectus are illustrative only and may not be drawn to scale. Unless otherwise stated, all data contained in charts, graphs and tables is based on information available at the Prospectus Date.

10.18. Governing law

This Prospectus, the Offer and the contracts that arise from the acceptance of the applications and bids under this Prospectus are governed by the laws applicable in New South Wales, Australia and each applicant submits to the exclusive jurisdiction of the courts of New South Wales, Australia.

10.19. Expiry date

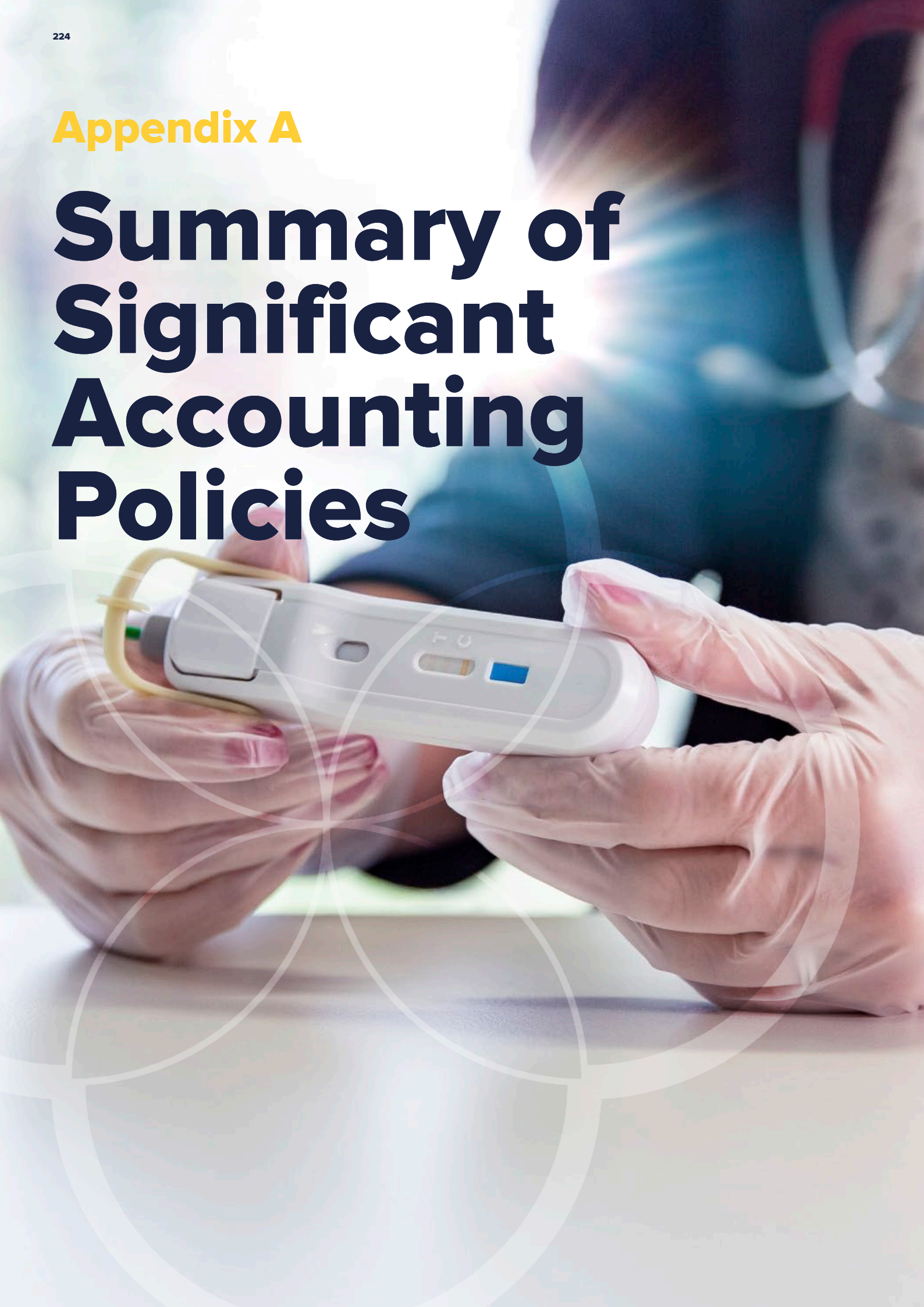
No Shares will be offered on the basis of this Prospectus after the Expiry Date.

10.20. Statement of Directors and SaleCo Directors

This Prospectus is authorised by each Director of Lumos and of SaleCo. Each Director has consented to the lodgement of this Prospectus with ASIC and the issuance of this Prospectus, and has not withdrawn that consent.

Appendix A

Summary of Significant Accounting Policies



The principal accounting policies adopted in the preparation of the Financial Information are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

Basis of preparation

This Financial Information have been prepared in accordance with Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') and the Corporations Act 2001, as appropriate for for-profit oriented entities. This Financial Information also comply with International Financial Reporting Standards as issued by the International Accounting Standards Board ('IASB').

Historical cost convention

The Financial Information has been prepared under the historical cost convention.

Critical accounting estimates

The preparation of the financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the consolidated entity's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed further below.

Revenue recognition

The consolidated entity recognises revenue as follows:

Revenue from contracts with customers

Revenue is recognised at an amount that reflects the consideration to which the consolidated entity is expected to be entitled in exchange for transferring goods or services to a customer. For each contract with a customer, the consolidated entity: identifies the contract with a customer; identifies the performance obligations in the contract; determines the transaction price which takes into account estimates of variable consideration and the time value of money; allocates the transaction price to the separate performance obligations on the basis of the relative stand-alone selling price of each distinct good or service to be delivered; and recognises revenue when or as each performance obligation is satisfied in a manner that depicts the transfer to the customer of the goods or services promised.

Variable consideration within the transaction price, if any, reflects concessions provided to the customer such as discounts, rebates and refunds, any potential bonuses receivable from the customer and any other contingent events. Such estimates are determined using either the 'expected value' or 'most likely amount' method. The measurement of variable consideration is subject to a constraining principle whereby revenue will only be recognised to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. The measurement constraint continues until the uncertainty associated with the variable consideration is subsequently resolved. Amounts received that are subject to the constraining principle are recognised as a refund liability.

Sale of goods

Revenue from the sale of goods is recognised at the point in time when the customer obtains control of the goods, which is generally at the time of delivery.

Rendering of services

Revenue from a contract to provide services is recognised over time as the services are rendered based on either a fixed price or an hourly rate.

Interest

Interest revenue is recognised as interest accrues using the effective interest method. This is a method of calculating the amortised cost of a financial asset and allocating the interest income over the relevant period using the effective interest rate, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the net carrying amount of the financial asset.

Other revenue

Other revenue is recognised when it is received or when the right to receive payment is established.

Appendix A
Summary of Significant Accounting Policies

Income tax

The income tax expense or benefit for the period is the tax payable on that period's taxable income based on the applicable income tax rate for each jurisdiction, adjusted by the changes in deferred tax assets and liabilities attributable to temporary differences, unused tax losses and the adjustment recognised for prior periods, where applicable.

Deferred tax assets and liabilities are recognised for temporary differences at the tax rates expected to be applied when the assets are recovered or liabilities are settled, based on those tax rates that are enacted or substantively enacted, except for:

- When the deferred income tax asset or liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting nor taxable profits; or
- When the taxable temporary difference is associated with interests in subsidiaries, associates or joint ventures, and the timing of the reversal can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax assets are recognised for deductible temporary differences and unused tax losses only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

The carrying amount of recognised and unrecognised deferred tax assets are reviewed at each reporting date. Deferred tax assets recognised are reduced to the extent that it is no longer probable that future taxable profits will be available for the carrying amount to be recovered. Previously unrecognised deferred tax assets are recognised to the extent that it is probable that there are future taxable profits available to recover the asset.

Deferred tax assets and liabilities are offset only where there is a legally enforceable right to offset current tax assets against current tax liabilities and deferred tax assets against deferred tax liabilities; and they relate to the same taxable authority on either the same taxable entity or different taxable entities which intend to settle simultaneously.

Inventories

Raw materials, work in progress and finished goods are stated at the lower of cost and net realisable value on a 'first in first out' basis. Cost comprises of direct materials and delivery costs, direct labour, import duties and other taxes, an appropriate proportion of variable and fixed overhead expenditure based on normal operating capacity, and, where applicable, transfers from cash flow hedging reserves in equity. Costs of purchased inventory are determined after deducting rebates and discounts received or receivable.

Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

Investments and other financial assets

Investments and other financial assets are initially measured at fair value. Transaction costs are included as part of the initial measurement, except for financial assets at fair value through profit or loss. Such assets are subsequently measured at either amortised cost or fair value depending on their classification. Classification is determined based on both the business model within which such assets are held and the contractual cash flow characteristics of the financial asset unless an accounting mismatch is being avoided.

Financial assets are derecognised when the rights to receive cash flows have expired or have been transferred and the consolidated entity has transferred substantially all the risks and rewards of ownership. When there is no reasonable expectation of recovering part or all of a financial asset, its carrying value is written off.

Financial assets at fair value through other comprehensive income

Financial assets at fair value through other comprehensive income include equity investments which the consolidated entity intends to hold for the foreseeable future and has irrevocably elected to classify them as such upon initial recognition.

Impairment of financial assets

The consolidated entity recognises a loss allowance for expected credit losses on financial assets which are either measured at amortised cost or fair value through other comprehensive income. The measurement of the loss allowance depends upon the consolidated entity's assessment at the end of each reporting period as to whether the financial instrument's credit risk has increased significantly since initial recognition, based on reasonable and supportable information that is available, without undue cost or effort to obtain.

Where there has not been a significant increase in exposure to credit risk since initial recognition, a 12 month expected credit loss allowance is estimated. This represents a portion of the asset's lifetime expected credit losses that is attributable to a default event that is possible within the next 12 months. Where a financial asset has become credit impaired or where it is determined that credit risk has increased significantly, the loss allowance is based on the asset's lifetime expected credit losses. The amount of expected credit loss recognised is measured on the basis of the probability weighted present value of anticipated cash shortfalls over the life of the instrument discounted at the original effective interest rate.

For financial assets mandatorily measured at fair value through other comprehensive income, the loss allowance is recognised in other comprehensive income with a corresponding expense through profit or loss. In all other cases, the loss allowance reduces the asset's carrying value with a corresponding expense through profit or loss.

Right-of-use assets

A right-of-use asset is recognised at the commencement date of a lease. The right-of-use asset is measured at cost, which comprises the initial amount of the lease liability, adjusted for, as applicable, any lease payments made at or before the commencement date net of any lease incentives received, any initial direct costs incurred, and, except where included in the cost of inventories, an estimate of costs expected to be incurred for dismantling and removing the underlying asset, and restoring the site or asset.

Right-of-use assets are depreciated on a straight-line basis over the unexpired period of the lease or the estimated useful life of the asset, whichever is the shorter. Where the consolidated entity expects to obtain ownership of the leased asset at the end of the lease term, the depreciation is over its estimated useful life. Right-of use assets are subject to impairment or adjusted for any remeasurement of lease liabilities.

The consolidated entity has elected not to recognise a right-of-use asset and corresponding lease liability for short-term leases with terms of 12 months or less and leases of low-value assets. Lease payments on these assets are expensed to profit or loss as incurred.

Intangible assets

Intangible assets acquired as part of a business combination, other than goodwill, are initially measured at their fair value at the date of the acquisition. Intangible assets acquired separately are initially recognised at cost. Indefinite life intangible assets are not amortised and are subsequently measured at cost less any impairment. Finite life intangible assets are subsequently measured at cost less amortisation and any impairment. The gains or losses recognised in profit or loss arising from the derecognition of intangible assets are measured as the difference between net disposal proceeds and the carrying amount of the intangible asset. The method and useful lives of finite life intangible assets are reviewed annually. Changes in the expected pattern of consumption or useful life are accounted for prospectively by changing the amortisation method or period.

Goodwill

Goodwill arises on the acquisition of a business. Goodwill is not amortised. Instead, goodwill is tested annually for impairment, or more frequently if events or changes in circumstances indicate that it might be impaired, and is carried at cost less accumulated impairment losses. Impairment losses on goodwill are taken to profit or loss and are not subsequently reversed.

Research and development

Research costs are expensed in the period in which they are incurred. Development costs are capitalised when it is probable that the project will be a success considering its commercial and technical feasibility; the consolidated entity is able to use or sell the asset; the consolidated entity has sufficient resources and intent to complete the development; and its costs can be measured reliably. Capitalised development costs are amortised on a straight-line basis over the period of their expected benefit, being their finite life of 10 years from commencement of the project entering into service.

Intellectual property

In general intellectual property is not amortised and tested annually for impairment.

Appendix A
Summary of Significant Accounting Policies

Impairment of non-financial assets

Goodwill and other intangible assets that have an indefinite useful life are not subject to amortisation and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. Other non-financial assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount.

Recoverable amount is the higher of an asset's fair value less costs of disposal and value-in-use. The value-in-use is the present value of the estimated future cash flows relating to the asset using a pre-tax discount rate specific to the asset or cash-generating unit to which the asset belongs. Assets that do not have independent cash flows are grouped together to form a cash-generating unit.

Borrowings

Loans and borrowings are initially recognised at the fair value of the consideration received, net of transaction costs. They are subsequently measured at amortised cost using the effective interest method.

The component of the convertible notes that exhibits characteristics of a liability is recognised as a liability in the statement of financial position, net of transaction costs.

On the issue of the convertible notes the fair value of the liability component is determined using a market rate for an equivalent non-convertible bond and this amount is carried as a non-current liability on the amortised cost basis until extinguished on conversion or redemption. The increase in the liability due to the passage of time is recognised as a finance cost. The remainder of the proceeds are allocated to the conversion option that is recognised and included in shareholders equity as a convertible note reserve, net of transaction costs. The carrying amount of the conversion option is not remeasured in the subsequent years. The corresponding interest on convertible notes is expensed to profit or loss.

Lease liabilities

A lease liability is recognised at the commencement date of a lease. The lease liability is initially recognised at the present value of the lease payments to be made over the term of the lease, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the consolidated entity's incremental borrowing rate. Lease payments comprise of fixed payments less any lease incentives receivable, variable lease payments that depend on an index or a rate, amounts expected to be paid under residual value guarantees, exercise price of a purchase option when the exercise of the option is reasonably certain to occur, and any anticipated termination penalties. The variable lease payments that do not depend on an index or a rate are expensed in the period in which they are incurred.

Lease liabilities are measured at amortised cost using the effective interest method. The carrying amounts are remeasured if there is a change in the following: future lease payments arising from a change in an index or a rate used; residual guarantee; lease term; certainty of a purchase option and termination penalties. When a lease liability is remeasured, an adjustment is made to the corresponding right-of use asset, or to profit or loss if the carrying amount of the right-of-use asset is fully written down.

Finance costs

Finance costs attributable to qualifying assets are capitalised as part of the asset. All other finance costs are expensed in the period in which they are incurred.

Employee benefits

Short-term employee benefits

Liabilities for wages and salaries, including non-monetary benefits, annual leave and long service leave expected to be settled wholly within 12 months of the reporting date are measured at the amounts expected to be paid when the liabilities are settled.

Other long-term wemployee benefits

The liability for annual leave and long service leave not expected to be settled within 12 months of the reporting date are measured at the present value of expected future payments to be made in respect of services provided by employees up to the reporting date using the projected unit credit method. Consideration is given to expected future wage and salary levels, experience of employee departures and periods of service. Expected future payments are discounted using market yields at the reporting date on high quality corporate bonds with terms to maturity and currency that match, as closely as possible, the estimated future cash outflows.

Share-based payments

Equity-settled and cash-settled share-based compensation benefits are provided to employees.

Equity-settled transactions are awards of shares, or options over shares that are provided to employees in exchange for the rendering of services. Cash-settled transactions are awards of cash for the exchange of services, where the amount of cash is determined by reference to the share price.

The cost of equity-settled transactions are measured at fair value on grant date. Fair value is independently determined using either the Binomial or Black-Scholes option pricing model that takes into account the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk free interest rate for the term of the option, together with non-vesting conditions that do not determine whether the consolidated entity receives the services that entitle the employees to receive payment. No account is taken of any other vesting conditions.

The cost of equity-settled transactions are recognised as an expense with a corresponding increase in equity over the vesting period. The cumulative charge to profit or loss is calculated based on the grant date fair value of the award, the best estimate of the number of awards that are likely to vest and the expired portion of the vesting period. The amount recognised in profit or loss for the period is the cumulative amount calculated at each reporting date less amounts already recognised in previous periods.

The cost of cash-settled transactions is initially, and at each reporting date until vested, determined by applying either the Binomial or Black-Scholes option pricing model, taking into consideration the terms and conditions on which the award was granted. The cumulative charge to profit or loss until settlement of the liability is calculated as follows:

- during the vesting period, the liability at each reporting date is the fair value of the award at that date multiplied by the expired portion of the vesting period.
- from the end of the vesting period until settlement of the award, the liability is the full fair value of the liability at the reporting date.

All changes in the liability are recognised in profit or loss. The ultimate cost of cash-settled transactions is the cash paid to settle the liability.

Market conditions are taken into consideration in determining fair value. Therefore any awards subject to market conditions are considered to vest irrespective of whether or not that market condition has been met, provided all other conditions are satisfied.

If equity-settled awards are modified, as a minimum an expense is recognised as if the modification has not been made. An additional expense is recognised, over the remaining vesting period, for any modification that increases the total fair value of the share-based compensation benefit as at the date of modification.

If the non-vesting condition is within the control of the consolidated entity or employee, the failure to satisfy the condition is treated as a cancellation. If the condition is not within the control of the consolidated entity or employee and is not satisfied during the vesting period, any remaining expense for the award is recognised over the remaining vesting period, unless the award is forfeited.

If equity-settled awards are cancelled, it is treated as if it has vested on the date of cancellation, and any remaining expense is recognised immediately. If a new replacement award is substituted for the cancelled award, the cancelled and new award is treated as if they were a modification.

Appendix A
Summary of Significant Accounting Policies

Fair value measurement

When an asset or liability, financial or non-financial, is measured at fair value for recognition or disclosure purposes, the fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date; and assumes that the transaction will take place either: in the principal market; or in the absence of a principal market, in the most advantageous market.

Fair value is measured using the assumptions that market participants would use when pricing the asset or liability, assuming they act in their economic best interests. For non-financial assets, the fair value measurement is based on its highest and best use. Valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, are used, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

Issued capital

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

Business combinations

The acquisition method of accounting is used to account for business combinations regardless of whether equity instruments or other assets are acquired.

The consideration transferred is the sum of the acquisition-date fair values of the assets transferred, equity instruments issued or liabilities incurred by the acquirer to former owners of the acquiree and the amount of any non-controlling interest in the acquiree. For each business combination, the non-controlling interest in the acquiree is measured at either fair value or at the proportionate share of the acquiree's identifiable net assets. All acquisition costs are expensed as incurred to profit or loss.

On the acquisition of a business, the consolidated entity assesses the financial assets acquired and liabilities assumed for appropriate classification and designation in accordance with the contractual terms, economic conditions, the consolidated entity's operating or accounting policies and other pertinent conditions in existence at the acquisition-date.

Where the business combination is achieved in stages, the consolidated entity remeasures its previously held equity interest in the acquiree at the acquisition-date fair value and the difference between the fair value and the previous carrying amount is recognised in profit or loss.

Contingent consideration to be transferred by the acquirer is recognised at the acquisition-date fair value. Subsequent changes in the fair value of the contingent consideration classified as an asset or liability is recognised in profit or loss. Contingent consideration classified as equity is not remeasured and its subsequent settlement is accounted for within equity.

The difference between the acquisition-date fair value of assets acquired, liabilities assumed and any non-controlling interest in the acquiree and the fair value of the consideration transferred and the fair value of any pre-existing investment in the acquiree is recognised as goodwill. If the consideration transferred and the pre-existing fair value is less than the fair value of the identifiable net assets acquired, being a bargain purchase to the acquirer, the difference is recognised as a gain directly in profit or loss by the acquirer on the acquisition-date, but only after a reassessment of the identification and measurement of the net assets acquired, the non-controlling interest in the acquiree, if any, the consideration transferred and the acquirer's previously held equity interest in the acquirer.

Business combinations are initially accounted for on a provisional basis. The acquirer retrospectively adjusts the provisional amounts recognised and also recognises additional assets or liabilities during the measurement period, based on new information obtained about the facts and circumstances that existed at the acquisition-date. The measurement period ends on either the earlier of (i) 12 months from the date of the acquisition or (ii) when the acquirer receives all the information possible to determine fair value.

Government grants

Government grants relating to costs are deferred and recognised in profit or loss over the period necessary to match them with the costs that they are intended to compensate.

During the June 2020 financial year, the Group received grants from the US Federal Government as part of the Pay-check Protection Program (PPP). As at 30 June 2020, the grant received was recognised in the Statement of Profit of Loss and Other Comprehensive income as the funds received meet the criteria for recognition under *AASB 120 – Accounting for government grants*. The grant has been recognised as other income.

Appendix B

Foreign Selling Restrictions

Appendix B
Foreign Selling Restrictions

This document does not constitute an offer of Shares in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

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"). No action has been taken in Hong Kong to authorise or register this document or to permit the distribution of this document or any documents issued in connection with it. Accordingly, the Shares have not been and will not 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 Shares 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 Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted Shares 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 Shares are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than 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 Shares 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 Shares, may not be issued, circulated or distributed, nor may the Shares 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 XIII of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), or as otherwise pursuant to, and in accordance with the conditions of any other applicable provisions of the SFA.

This document has been given to you on the basis that you are (i) an "institutional investor" (as defined in the SFA) or (ii) an "accredited investor" (as defined in the SFA). If you are not an investor falling within one of these categories, 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 Shares being subsequently offered for sale to any other party. There are on-sale restrictions in Singapore that may be applicable to investors who acquire Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

United Kingdom

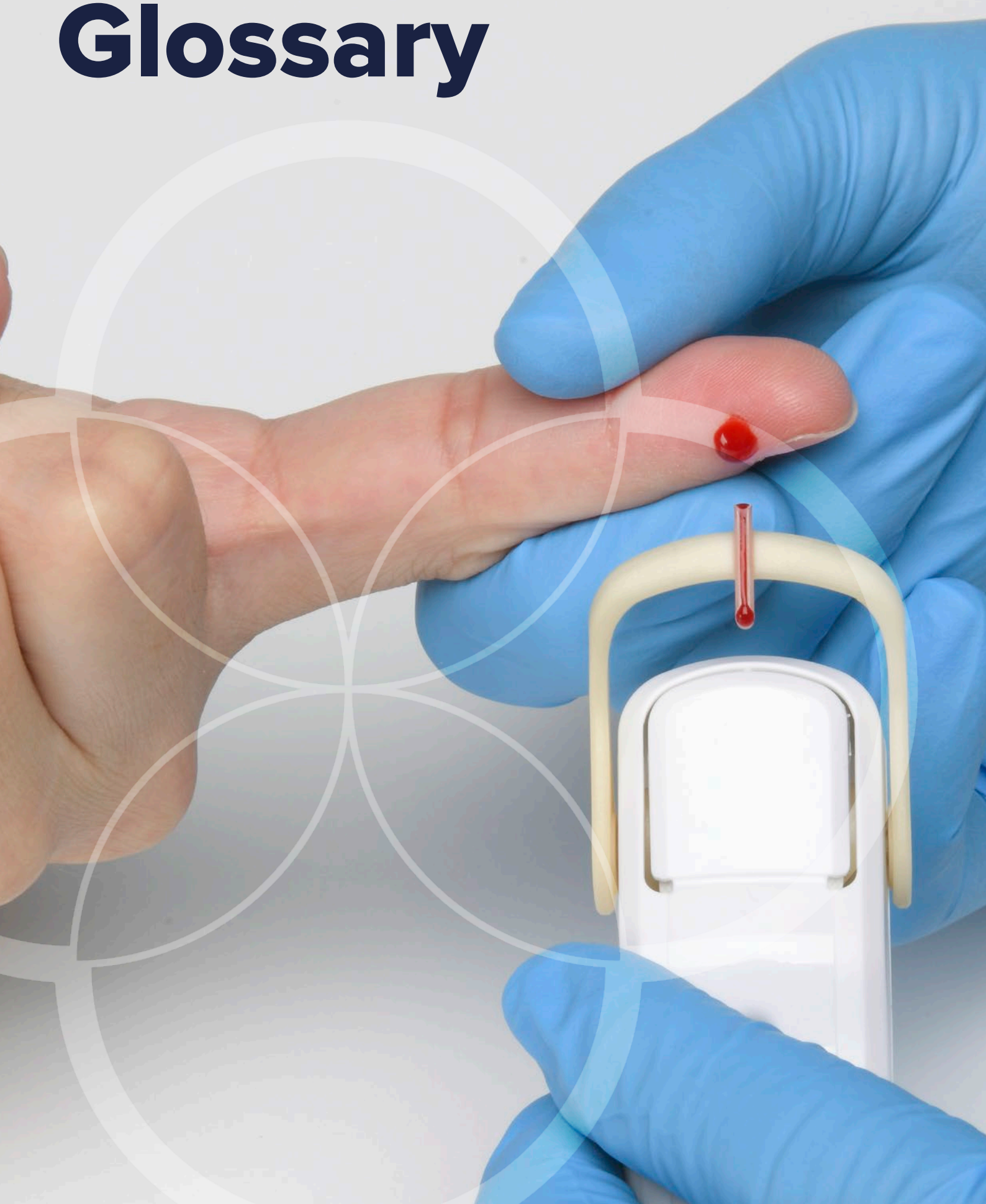
Neither this document nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the Shares.

The Shares 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 Shares 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



Term	Description
$ or AUD	Australian Dollars
1H20 and 1H21	Financial half-years endings 31 December 2019 and 31 December 2020, respectively
2019 Convertible Notes	Convertible notes issued by the Company in March 2019 which converted into Preference Shares in November 2019
510(k) clearance	Clearance granted by the FDA if the submitted data establishes that the proposed medical device is "substantially equivalent" to a legally marketed existing Class I or Class II medical device or to a Class III medical device (under the FDCA) for which the FDA has not required pre-market approval. Refer to section 2.7.
AAS	Australian Accounting Standards
AASB	Australian Accounting Standards Board
AASB 15	Accounting standard published by the AASB titled AASB 15 *Revenue from Contracts with Customers*
AASB 16	Accounting standard published by the AASB titled AASB 16 *Leases*
AASB 117	Accounting standard published by the AASB titled AASB 117 *Leases*
AASB 138	Accounting standard published by the AASB titled AASB 138 *Intangible Assets*
ABN	Australian Business Number
ACN	Australian Company Number
AGM	Annual general meeting
AMR	Anti-microbial resistance
Amended Planet Innovation MSA	Planet Innovation MSA as amended and with effect from 1 July 2021
Application	Application to subscribe for, or acquire, Shares offered under the Prospectus
Application Form	The application form attached to or accompanying this Prospectus (including the electronic form provided by an online application facility)
ARI	Acute respiratory infection
ARTI	Acute respiratory tract infections
ARTG	Australian Register of Therapeutic Goods
ASIC	Australian Securities and Investments Commission
ASIC Act	*Australian Securities and Investments Commission Act 2001* (Commonwealth)
ASX	ASX Limited ACN 008 624 691 or the Australian Securities Exchange operated by it (as the context requires)

Glossary

Term	Description
ASX Listing Rules	The official listing rules of the ASX, as amended, modified or waived from time to time
ASX Recommendations	The fourth edition of the Corporate Governance Principles and Recommendations issued by the ASX Corporate Governance Council
ASX Settlement	ASX Settlement Pty Limited ACN 008 504 532
ASX Settlement Operating Rules	The operating rules of ASX Settlement
ATO	Australian Taxation Office
Atomo	Atomo Diagnostics Limited ACN 142 925 684
Audit and Risk Management Committee	Refer to Section 6.6.4.1
BDO	BDO Corporate Finance (East Coast) Pty Ltd ACN 050 038 170
BDO Tax	BDO Services Pty Limited ACN 134 242 434
Blackpeak Capital	Blackpeak Capital Pty Ltd ACN 601 350 841
Board or **Board of Directors**	The board of Directors of the Company
Board Charter	Refer to Section 6.6.3
Board Committees	Committees established by the Board, including the Audit and Risk Management Committee, and Remuneration and Nomination Committee
Bookbuild	The process through which Institutional Investors may be invited to bid under the Institutional Offer as described in Section 7.5
Brexit	Legislative changes introduced as part of the United Kingdom's exit from the EU
Broker	Any ASX participating organisation appointed to act as a broker to the Offer
Broker Firm Offer	The offer of Shares under this Prospectus to eligible Australian resident retail clients of Brokers as described in Section 7.3
Business day	Any weekday that is not a public holiday in the state of New South Wales, Australia
CAGR	Compound Annual Growth Rate
CDC	United States Centers for Diseases Control and Prevention
CEO	Chief Executive Officer
CE Mark	European designation that demonstrates a medical device conforms to the 'essential requirements' set forth in the product's applicable directives
CGT	Capital gains tax

Term	Description
CHESS	ASX's Clearing House Electronic Subregister System
CLIA	Clinical Laboratory Improvement Amendments 1988
CMS	Centers for Medicare and Medicaid Services
Code	U.S. Internal Revenue Code
Commercial Services	Lumos' commercial services business division, as described in Section 3.6
Company	Lumos Diagnostics Holdings Limited ACN 630 476 970
Completion	The completion of the Offer, being the date on which Shares are issued or transferred to successful applicants in accordance with the terms of the Offer
Constitution	The constitution of the Company
Corporations Act	*Corporations Act 2001* (Commonwealth)
COVID-19	The infectious disease caused by the coronavirus, SARS-CoV-2, a respiratory pathogen, declared a pandemic by the World Health Organisation on 11 March 2020. Where the context refers to the impact of COVID-19, the expression includes the impact of various governmental or regulatory responses to COVID-19
Crucible Investments	Crucible Investments Pty Ltd ACN 627 552 461
CRP	C-reactive protein, a general or non-specific marker for inflammation and infection
D&A	Depreciation and amortisation
DiaSorin	DiaSorin S.p.A (Fiscal Code and Subscription to Vercelli Companies Register no 13144290155)
Director	Each of the directors of the Company and/or SaleCo (as the context requires) from time to time
EBIT	Earnings before interest and tax
EBITDA	Earnings before interest, tax, depreciation and amortisation
EBITDA margin	EBITDA expressed as a percentage of revenue. Refer to Section 4.2.4
EMR	Electronic Medical Record
Escrowed Shareholders	Shareholders that have entered into a voluntary escrow deed with the Company in relation to their escrowed Shares, as described in Section 6.5
EU	European Union
EUA	Emergency use authorisation
Existing Planet Innovation MSA	Planet Innovation MSA in effect from 1 April 2019 to 30 June 2021

Glossary

Term	Description
Existing Securityholders	Holders of Shares, Preference Shares, Pre-IPO Convertible Notes or Option at the Prospectus Date
Expiry Date	13 months after the Prospectus Date
Exposure Period	The seven day period commencing on the date of lodgement of the Prospectus with ASIC, which may be extended by ASIC for up to an additional seven days, during which an Application must not be accepted
FATA	Foreign Acquisitions and Takeovers Act 1975 (Cth)
FATA Policy	Australian Federal Government's Foreign Investment Policy
FDA	U.S. Food and Drug Administration
FDCA	The Federal Food, Drug, and Cosmetic Act
FebriDx®	Lumos' proprietary POC diagnostic test for rapid bacterial versus viral detection
Financial Information	Together, the Historical Financial Information and Forecast Financial Information as described in Section 4.1
Forecast Financial Information	Together, the Statutory Forecast Financial Information and the Pro Forma Forecast Financial Information as described in Section 4.1
Forecast Period	Financial year ending 30 June 2021 (FY21F)
Frazier & Deeter	Frazier & Deeter, LLC.
FTE	Full time equivalent
FY19 and FY20	Historical financial years ended 30 June 2019 and 30 June 2020, respectively
FY21F	Forecast financial year ending 30 June 2021
GDPR	General Data Protection Regulation (European Union)
General and Administrative expense or **G&A**	Refer to Section 4.8.6.2
Group	Lumos Diagnostics Holdings Limited and its subsidiaries
GP	General Practitioner
GST	Australian goods and services tax
HIN	Holder Identification Number
HIPAA	Health Insurance Portability and Accountability Act of 1996
Historical Financial Information	Together, the Statutory Historical Financial Information and the Pro Forma Historical Financial Information as described in Section 4.1

Term	Description
Historical Period	FY19, FY20, 1H20, 1H21
HIV	Human immunodeficiency virus
HR	Human resources
IASB	International Accounting Standards Board
IFRS	International Financial Reporting Standards
Independent Limited Assurance Investigating Accountants Reports	The reports prepared by the Investigating Accountant, as provided in this Prospectus contained in Section 8
Investigating Accountant	BDO
IVDD	In vitro diagnostic device
IVDR	In vitro diagnostic medical devices regulation
Joint Lead Managers	Wilsons Corporate Finance Limited ACN 057 547 323 and Bell Potter Securities Limited ACN 006 390 722
KPI	Key performance indicator
Leydin Freyer	Leydin Freyer Corporate Pty Ltd ACN 115 051 897
LFA	Lateral flow assay
Listing	Admission of the Company to the Official List and quotation of the Shares on the ASX
LTI	Long-term incentive
Lumos	Lumos Diagnostics Holdings Limited ACN 630 476 970 and where the context permits, the business of Lumos and other members of the Group
Lumos Diagnostics IP Pty Ltd	Lumos Diagnostics IP Pty Ltd ACN 630 477 324
Lumos Diagnostics Pty Ltd	Lumos Diagnostics Pty Ltd ACN 160 497 076
m	million
MDD	Medical Device Directives (EU)
MDR	Medical devices regulation
MDSAP	Medical Device Single Audit Program
Medicare	National health insurance program in the United States, administered by CMS
MHRA	Medicines and Healthcare products Regulatory Agency (Great Britain)

Glossary

Term	Description
MSA	Master Services Agreement
MxA	Myxovirus resistance protein A, a marker specific for viral infections
New Lumos LTIP	The new Lumos long term incentive plan referred to in Section 6.4.6
NHS	The United Kingdom's National Health Service
Notified Body	an organisation designated by an EU country that assesses the conformity of certain products with the requirements set out in the applicable legislation before being placed on the EU market.
NPAT	Net profit/(loss) after taxation
NPV	Negative Predictive Value
Non-executive Director	A member of the Board who does not form part of the Company's management
Non-IFRS financial measures	Measures to manage and report on its business that are not recognised under AAS or IFRS. Refer to Section 4.2.4.
Non-Statutory Information	Information, measures and ratios to manage and report on performance which are prepared on a basis that is not in accordance with all relevant accounting standards
Offer	The offer of Shares under this Prospectus, including the Institutional Offer, the Broker Firm Offer and the Priority Offer
Offer Information Line	1300 040 690 between 8:30am to 5:00pm (Sydney time) Monday to Friday (excluding public holidays)
Offer Period	The period from the opening date to the closing date of the Broker Firm Offer
Offer Price	A$1.25 per Share
Official List	The official list of entities that the ASX has admitted to, and not removed, from listing
Options	Options (each over 1 Shares) on issue on the Prospectus Date and on Completion.
Optionholders	Holders of Options
OTC	Over-the-counter
PIPL	Planet Innovation Pty Ltd ACN 137 428 141
Planet Innovation	Planet Innovation Holdings Limited ACN 152 424 916
Planet Innovation MSAs	The Existing Planet Innovation MSA or the New Planet Innovation MSA
Products	Lumos' products business division, as described in Sections 3.4 and 3.5
POC	Point-of-care
PPP	Paycheck Projection Program of the U.S. Small Business Administration, made available to U.S. companies to help retain staff through the COVID-19 pandemic

Term	Description
PPP grant	Funds received by Lumos subsidiaries under the PPP. Refer to Sections 5.1.11, 4.3.2, 4.4.2 and 4.5.1, including for risks in relation to the PPP grant
Pre-IPO Convertible Notes	Convertible notes issued by the Company in September 2020 as described in Section 10.3
Preference Shares	Preferences shares in the Company which will convert to Shares on Completion on a one-for-one basis
Priority Offer	The offer of Shares to persons who have received an invitation from the Company to participate in the Offer as described in Section 7.4
Privacy Act	*Privacy Act 1988* (Commonwealth)
Pro Forma Forecast Cash Flows	Pro forma forecast consolidated statement of cash flows for FY21F
Pro Forma Forecast Financial Information	Pro Forma Forecast Results and Pro Forma Forecast Cash Flows
Pro Forma Forecast Income Statement	Pro forma forecast income statement for FY21F
Pro Forma Forecast Results	Pro forma forecast consolidated statement of profit or loss for FY21F
Pro Forma Historical Cash Flows	Pro forma historical consolidated statements of cash flows for FY19, FY20, 1H20 and 1H21
Pro Forma Historical Financial Information	Pro Forma Historical Results, Pro Forma Historical Cash Flows, and Pro Forma Historical Statement of Financial Position
Pro Forma Historical Results	*Pro forma historical consolidated statements of profit or loss for FY19, FY20, 1H20 and 1H21*
Pro Forma Historical Statement of Financial Position	Pro forma historical Results statement of financial position as at 31 December 2020
Prospectus	This document dated Monday 7 June 2021 and any replacement or supplementary prospectus in relation to this document
Prospectus Date	The date on which this Prospectus was lodged with ASIC, being Monday 7 June 2021
Remuneration and Nomination Committee	Refer to Section 6.6.4.2
R&D	Research and development
RPS	Rapid Pathogen Screening, Inc., a subsidiary of the Company
RPS Acquisition	Acquisition by the Company of 100% of Rapid Pathogen Screening Inc (RPS) via a share purchase agreement on 22 May 2019

Glossary

Term	Description
RPS Diagnostics	RPS Diagnostics, Inc, a Shareholder
Sale Deeds	The sale deeds under which SaleCo acquires Shares from the Selling Shareholders as referred to in Section 10.4
SaleCo	Lumos Diagnostics SaleCo Limited ACN 650 279 511
Selling Shareholders	Shareholders who sell Shares through SaleCo
Senior Leadership Team	Members of management listed in Table 6.2 in Section 6.2 (also referred to as Management).
Settlement	The Settlement in respect of the Shares which are the subject of the Offer occurring under the Underwriting Agreement
Share Registry	Computershare Investor Services Pty Limited ACN 078 279 277
Shareholder	The registered holder of one or more Shares
Shares	Fully paid ordinary shares in the capital of the Company
SRN	Securityholder Reference Number
Statutory Forecast Cash Flows	Statutory forecast consolidated statement of cash flows for FY21F
Statutory Forecast Financial Information	Statutory forecast consolidated statement of profit or loss and statutory forecast consolidated statement of cash flows
Statutory Forecast Results	Statutory forecast consolidated statement of profit or loss for FY21F
Statutory Historical Cash Flows	Statutory historical consolidated statements cash flows for FY19, FY20, 1H20 and 1H21
Statutory Historical Financial Information	Statutory historical consolidated statement of profit or loss, statutory historical consolidated statements of financial performance and statutory historical consolidated statements of cash flows
Statutory Historical Results	Statutory historical consolidated statements of profit or loss for FY19, FY20, 1H20 and 1H21
Statutory Historical Statement of Financial Position	Statutory historical consolidated statement of financial position as at 31 December 2020
STI	Short-term incentive
Sydney time	The official time in Sydney, Australia
TFN	Tax file number
TGA	Therapeutic Goods Association (Australia)

Term	Description
UKCA	United Kingdom Conformity Assessed
Underwriting Agreement	The underwriting agreement (as amended or supplemented) entered into between the Joint Lead Managers, the Company and SaleCo dated 4 June 2021
U.S. or **United States**	United States of America, its territories and possessions, any State of the United States of America and the District of Columbia
U.S. Participants	Participants under the New Lumos LTIP who are citizens or residents of the United States of America or otherwise subject to the Code
U.S. PTO	United States Patent and Trademark Office
U.S. Securities Act	The U.S. Securities Act of 1933, as amended
US$ or USD	United States Dollars
VP	Vice president
WHO	World Health Organisation
William Buck	William Buck Audit (Vic) Pty Ltd ACN 116 151 136
You	The investors under this Prospectus, and **Your** has the corresponding meaning

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Corporate Directory

Company's registered office

Lumos Diagnostics Holdings Limited
Level 4, 100 Albert Road
South Melbourne., VIC 3205

SaleCo's registered office

Lumos Diagnostics SaleCo Limited
Level 4, 100 Albert Road
South Melbourne, VIC 3205

Joint Lead Managers and Underwriter

Wilsons Corporate Finance Limited
Level 32, Governor Macquarie Tower
1 Farrer Place
Sydney, New South Wales 2000

Bell Potter Securities Limited
Level 38, Aurora Place
88 Phillip St
Sydney NSW 2000

Australian Legal Adviser

Clayton Utz
Level 15, 1 Bligh Street
Sydney, New South Wales 2000

Financial adviser

Blackpeak Capital
40-42 Young Street
Sydney, New South Wales 2000

Investigating Accountant

BDO Corporate Finance (East Coast) Pty Ltd
11/1 Margaret St, Sydney NSW 2000
Sydney, New South Wales 2000

Tax Advisor

BDO Services Pty Limited
11/1 Margaret St, Sydney NSW 2000
Sydney, New South Wales 2000

Auditors

William Buck
Level 20, 181 William Street
Melbourne VIC 3000

Share Registry

Computershare Investor Services Pty Limited
Yarra Falls, 452 Johnston Street
ABBOTSFORD VIC 3067 Australia

LUMOS
DIAGNOSTICS

Lumos Diagnostics Holdings Limited

ACN 630 476 970

Enquiries:

(within Australia) 1300 040 690
(outside Australia) +61 3 9415 4100

Broker Firm Offer Application Form

This is an Application Form for ordinary shares (**Shares**) in Lumos Diagnostics Holdings Limited ACN 630 476 970 under the Broker Firm Offer on the terms set out in the Prospectus dated Monday, 7 June 2021 (**Prospectus**). This Application Form is important and should be read in conjunction with the Prospectus. This Application Form and you Application Monies must be received by your Broker by the deadline set out in their offer to you.

If you are in doubt as to how to deal with it, please contact your stockbroker, accountant or other professional advisor without delay. You should read the Prospectus carefully before completing this Application Form. The Corporations Act prohibits any person from passing on this Application Form (whether in paper or electronic form) unless it is attached to or accompanies a complete and unaltered copy of the Prospectus (whether in paper or electronic form).

A **I/we apply for**

Shares at $1.25 per Share or such lesser number of Shares which may be allocated to me/us.

B **I/we lodge full Application Monies**

$.

C **Individual/Joint applications - refer to naming standards overleaf for correct forms of registrable title(s)**

Title or Company Name Given Name(s) Surname

Joint Applicant 2 or Account Designation

Joint Applicant 3 or Account Designation

D **Enter the postal address - include State and Postcode**

Unit Street Number Street Name or PO Box/Other information

City/Suburb/Town State Postcode

E **Enter your contact details**

Contact Name

Telephone Number - Business Hours

( )

F **CHESS Participant**

Holder Identification Number (HIN)

X

Please note that if you supply a CHESS HIN but the name and address details on your form do not correspond exactly with the registration details held at CHESS, your Application will be deemed to be made without the CHESS HIN, and any Shares issued as a result of the Offer will be held on the issuer sponsored subregister.

G **Payment details - Please follow the payment instructions provided to you. If paying by cheque, provide your cheque details below.**

Drawer	Cheque Number	BSB Number	Account Number	Amount of cheque
				$

Cheques should be drawn according to the instructions provided by your Broker.

By submitting this Application Form:

- I/we declare that this Application is complete and lodged according to the Prospectus and the declarations/statements on the reverse of this Application Form,
- I/we declare that all details and statements made by me/us (including the declaration on the reverse of this Application Form) are complete and accurate, and
- I/we agree to be bound by the Constitution of Lumos Diagnostics Holdings Limited.

See overleaf for completion guidelines ➔

How to complete this Application Form

A **Number of Shares applied for**
Enter the number of Shares you wish to apply for. The Application must be for a minimum of 1,600 Shares ($2,000.00). There is no maximum value of Shares that may be applied for under the Broker Firm Offer.

B **Application Monies**
Enter the amount of Application Monies. To calculate the amount, multiply the number of Shares applied for in Step A by the issue price of $1.25.

C **Applicant Name(s)**
Enter the full name you wish to appear on the statement of shareholding. This must be either your own name or the name of a company. Up to 3 joint Applicants may register. You should refer to the table below for the correct forms of registrable title. Applications using the wrong form of names may be rejected. Clearing House Electronic Subregister System (CHESS) participants should complete their name identically to that presently registered in the CHESS system.

D **Postal Address**
Enter your postal address for all correspondence. All communications to you from the Registry will be mailed to the person(s) and address as shown. For joint Applicants, only one address can be entered.

E **Contact Details**
Enter your contact details. These are not compulsory but will assist us if we need to contact you regarding this Application.

F **CHESS**
Lumos Diagnostics Holdings Limited will apply to the ASX to participate in CHESS, operated by ASX Settlement Pty Limited, a wholly owned subsidiary of ASX Limited. If you are a CHESS participant (or are sponsored by a CHESS participant) and you wish to hold Shares issued to you under this Application on the CHESS Subregister, enter your CHESS HIN. Otherwise, leave this section blank and on issue, you will be sponsored by Lumos Diagnostics Holdings Limited and allocated a Securityholder Reference Number (SRN).

G **Payment**
You should ask your Broker for information about how and when to lodge this Application Form, and lodge this Application Form and your payment with your Broker in accordance with their instructions.

Before completing the Application Form the Applicant(s) should read the Prospectus to which this Application Form relates. By lodging the Application Form, the Applicant agrees that this Application for Shares in Lumos Diagnostics Holdings Limited is upon and subject to the terms of the Prospectus and the Constitution of Lumos Diagnostics Holdings Limited, agrees to take any number of Shares that may be issued to the Applicant(s) pursuant to the Prospectus and declares that all details and statements made are complete and accurate. It is not necessary to sign the Application Form.

Lodgement of Application

The Broker Firm Offer is expected to open on 15 June 2021 and close on 23 June 2021. Lumos Diagnostics Holdings Limited and the Joint Lead Managers may elect to extend the Broker Firm offer. If you have been contacted by your Broker regarding the Broker Firm Offer, you should ask your Broker for information about how and when to lodge this Application Form. Generally, you will lodge this Application Form and payment with your Broker in accordance with their instructions. Do NOT lodge this Application Form with the Registry. Your Broker must receive your completed Application Form and Application Monies in time to arrange settlement on your behalf by the Closing Date for the Broker Firm Offer. You should allow sufficient time for this to occur.

Privacy Notice

The personal information you provide on this form is collected by CIS, as registrar for the securities issuer (the issuer), for the purpose of maintaining registers of securityholders, facilitating distribution payments and other corporate actions and communications. In addition, the issuer may authorise us on their behalf to send you marketing material or include such material in a corporate communication. You may elect not to receive marketing material by contacting CIS using the details provided overleaf or emailing privacy@computershare.com.au. We may be required to collect your personal information under the Corporations Act 2001 (Cth) and ASX Settlement Operating Rules. We may disclose your personal information to our related bodies corporate and to other individuals or companies who assist us in supplying our services or who perform functions on our behalf, to the issuer for whom we maintain securities registers or to third parties upon direction by the issuer where related to the issuer's administration of your securityholding, or as otherwise required or authorised by law. Some of these recipients may be located outside Australia, including in the following countries: Canada, India, New Zealand, the Philippines, the United Kingdom and the United States of America. For further details, including how to access and correct your personal information, and information on our privacy complaints handling procedure, please contact our Privacy Officer at privacy@computershare.com.au or see our Privacy Policy at http://www.computershare.com/au.

Correct forms of registrable title(s)

Note that ONLY legal entities are allowed to hold Shares. Application Forms must be in the name(s) of a natural person(s), companies or other legal entities acceptable to the issuer. At least one full given name and the surname is required for each natural person. Application Forms cannot be completed by persons less than 18 years of age. Examples of the correct form of registrable title are set out below.

Type of Investor	Correct Form of Registration	Incorrect Form of Registration
Individual: use given names in full, not initials	Mr John Alfred Smith	JA Smith
Company: use the company's full title, not abbreviations	ABC Pty Ltd	ABC P/L or ABC Co
Joint Holdings: use full and complete names	Mr Peter Robert Williams & Ms Louise Susan Williams	Peter Robert & Louise S Williams
Trusts: use the trustee(s) personal name(s)	Mrs Susan Jane Smith <Sue Smith Family A/C>	Sue Smith Family Trust
Deceased Estates: use the executor(s) personal name(s)	Ms Jane Mary Smith & Mr Frank William Smith <Est John Smith A/C>	Estate of late John Smith or John Smith Deceased
Minor (a person under the age of 18): use the name of a responsible adult with an appropriate designation	Mr John Alfred Smith <Peter Smith A/C>	Master Peter Smith
Partnerships: use the partners personal names	Mr John Robert Smith & Mr Michael John Smith <John Smith and Son A/C>	John Smith and Son
Long Names	Mr John William Alexander Robertson-Smith	Mr John W A Robertson-Smith
Clubs/Unincorporated Bodies/Business Names: use office bearer(s) personal name(s)	Mr Michael Peter Smith <ABC Tennis Association A/C>	ABC Tennis Association
Superannuation Funds: use the name of the trustee of the fund	Jane Smith Pty Ltd <Super Fund A/C>	Jane Smith Pty Ltd Superannuation Fund