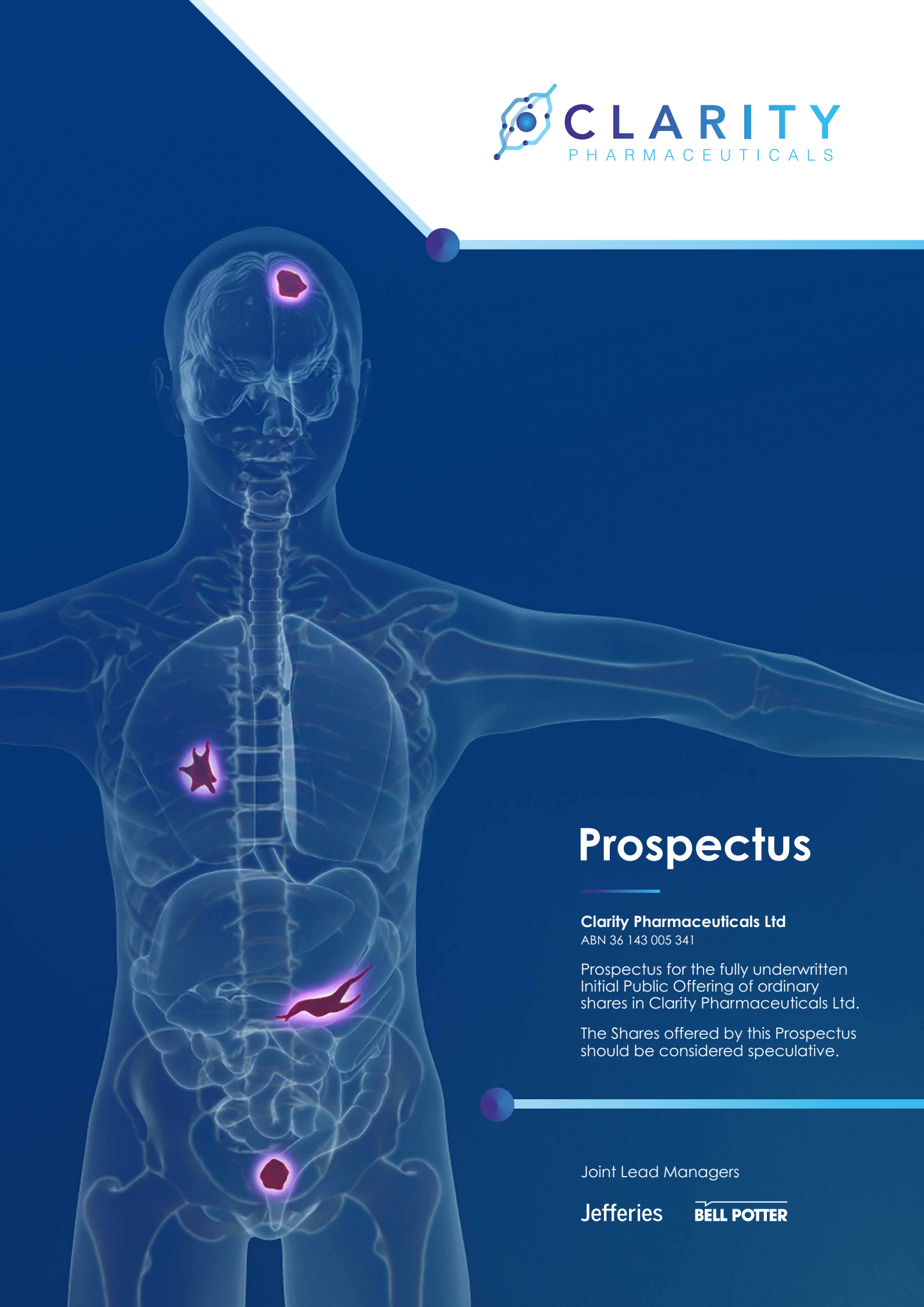
CLARITY
PHARMACEUTICALS



Prospectus

Clarity Pharmaceuticals Ltd
ABN 36 143 005 341

Prospectus for the fully underwritten Initial Public Offering of ordinary shares in Clarity Pharmaceuticals Ltd.

The Shares offered by this Prospectus should be considered speculative.

Joint Lead Managers

Jefferies BELL POTTER

Important Information

The Offer

This Prospectus is issued by Clarity Pharmaceuticals Ltd ABN 36 143 005 341 (**Company** or **Clarity**) for the purposes of Chapter 6D of the *Corporations Act 2001* (Cth) (**Corporations Act**). The offer contained in this Prospectus is an initial public offering to acquire fully paid ordinary shares (**Shares**) in the Company (**Offer**).

Lodgement and listing

This Prospectus is dated 16 July 2021 (**Prospectus Date**) and a copy was lodged with the Australian Securities and Investments Commission (**ASIC**) on that date.

The Company will apply to the Australian Securities Exchange (**ASX**) for admission of the Company to the Official List and quotation of its Shares on ASX within seven days of the Prospectus Date (which is expected to be under the ticker code "CU6"). The fact that the ASX may admit the Company to the Official List is not to be taken in any way as an indication of the merits of the Shares, the Offer or the Company.

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

Expiry date

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

Not investment advice

The information in this Prospectus is not investment or financial product advice and does not take into account your investment objectives, financial circumstances, tax position or particular needs. This Prospectus should not be construed as financial, taxation, legal or other advice.

The Company is not licensed to provide financial product advice in respect of its securities or any other financial products.

It is important that you read this Prospectus carefully in its entirety and seek professional advice where necessary before deciding whether to invest in the Company. In particular, you should consider risk factors that could affect the performance of the Company and other information in this Prospectus. Some of the key risks you should consider are set out in Section 5 "Key Risks". You should carefully consider these risks in light of your personal circumstances (including your investment objectives, financial circumstances and tax position) and seek professional guidance from your stockbroker, accountant, lawyer or other professional adviser before deciding whether to invest in the Company. There may be risk factors in addition to these that should be considered in light of your personal circumstances.

Except as required by law, and only to the extent required, no person named in this Prospectus, nor any other person, warrants or guarantees the performance of the Company or the repayment of capital by the Company or any return on investment made pursuant to this Prospectus.

This Prospectus includes information regarding the past performance of the Company. You should be aware that past performance is not indicative of future performance.

No person is authorised to give any information or to make any representation in connection with the Offer that is not contained in this Prospectus. Any information not so contained may not be relied upon as having been authorised by the Company, the Lead Managers, the Directors or any other person in connection with the Offer. You should rely only on information contained in this Prospectus when deciding whether to invest in Shares.

Financial information presentation

Section 4 sets out in detail the financial information referred to in this Prospectus and the basis of preparation of that information.

The financial information included in Section 4 has been prepared in accordance with the recognition and measurement principles prescribed in Australian Accounting Standards (**AAS**) adopted by the Australian Accounting Standards Board (**AASB**), which are consistent with the International Financial Reporting Standards (**IFRS**) as issued by the International Accounting Standards Board, and the accounting policies of the Company.

All financial amounts contained in this Prospectus are expressed in Australian dollars and are rounded to the nearest $1,000 (unless otherwise stated). Any discrepancies between totals and sums of components in tables and figures contained in this Prospectus are due to rounding. Tables and figures contained in this Prospectus have not been amended by the Company to correct immaterial summation differences that may arise from this rounding convention.

The financial information in this Prospectus should be read in conjunction with, and is qualified by reference to, the information contained in Section 4. Where financial information and metrics represent pro forma amounts, they have been labelled "pro forma".

No forecast financial information

Given the fact that the Company is in an early stage of development, there are significant uncertainties associated with forecasting the future revenues and expenses of the Company. On this basis, the Directors believe that there is no reasonable basis for the inclusion of financial forecasts in this Prospectus.

Disclaimer and forward looking statements

This Prospectus contains forward-looking statements that are identified by words such as "may", "could", "believes", "estimates", "expects", "intends", "plans", "considers", "assume", "anticipate", "should", "outlook", "forecasts", "target", "goal" and other similar words that involve known or unknown risks and uncertainties. Forward-looking statements speak only as at the Prospectus Date and include statements about the Company's expectations regarding the performance of the Company's business and its plans, strategies, prospects and outlook.

Any forward-looking statements involve known and unknown risks, uncertainties, assumptions and other important factors that could cause actual results, performance, events or outcomes to differ materially from the results, performance, events or outcomes expressed or anticipated in these statements, many of which are beyond the control of the Company and the Directors. Such forward-looking statements are based on an assessment of present economic and operating conditions and a number of best estimate assumptions regarding future events and actions that, as at the Prospectus Date, are expected to take place. The forward-looking statements should be read in conjunction with, and are qualified by reference to, the risk factors set out in Section 5 and other information contained in this Prospectus.

The Directors 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 such forward-looking statements. Except where required by law, the Company does not intend 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. You should, however, review the information and the risks that the Company describes in those reports to be filed by the Company with ASX after the Prospectus Date.

Bell Potter Securities Limited (ACN 006 390 772) and Jefferies (Australia) Pty Ltd (ABN 76 623 059 898) have acted as Joint Lead Managers to the Offer and have not authorised, permitted or caused the issue or lodgement, submission, dispatch or provision of this Prospectus and there is no statement in this Prospectus which is based on any statement made by any Joint Lead Manager or by any of their respective affiliates or related bodies corporate (as defined in the Corporations Act), or any of their respective officers, directors, employees, partners, advisers or agents (each a **Limited Party**). To the maximum extent permitted by law, each Limited Party expressly disclaims all liabilities in respect of, makes no representations regarding, and takes no responsibility for, any part of this Prospectus (other than, in respect of the Joint Lead Managers, references to their name) and makes no representation or warranty as to the currency, accuracy, reliability or completeness of this Prospectus.

Market and industry information

This Prospectus contains certain statistics, data and other information relating to markets, market sizes and other industry data pertaining to the Company's industry (**Industry Data**). Unless otherwise stated, the Industry Data has been obtained from publicly available data and sources. The Industry Data has not been independently prepared or verified and neither the Company nor the Joint Lead Managers can assure you as to its accuracy or the accuracy of the underlying assumptions used to estimate such Industry Data. The Company's estimates on industry size and related matters involve risks and uncertainties that are subject to change based on various factors, including those described in the risk factors set out in Section 5. Investors should note that market data and statistics are inherently predictive and subject to uncertainty and not necessarily reflective of actual market conditions. In addition to Industry Data, this Prospectus uses third-party data, estimates and projections. There is no assurance that any third-party data, estimates or projections contained in this Prospectus can be achieved. The Company has not independently verified such information. Estimates involve risks and uncertainties and are subject to change based on various factors including those described in the risk factors set out in Section 5.

No offering where offering would be illegal

This Prospectus does not constitute an offer or invitation to apply for Shares in any place 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 outside Australia (including in electronic form) may be restricted by law and persons who come into possession of this Prospectus outside Australia must observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws.

This Prospectus may only be distributed in the United States to Institutional Investors by registered US broker-dealers of the Joint Lead Managers and only if this Prospectus is accompanied by the US Offering Circular. The Shares being offered pursuant to this Prospectus have not been registered under the US Securities Act of 1933, as amended (**US Securities Act**) and may not be offered or sold in the United States except in a transaction exempt from, or not subject to, registration under the US Securities Act and applicable US state securities laws. See Section 7.8 for more details on selling restrictions that apply to the Offer and sale of Shares to Institutional Investors in jurisdictions outside Australia.

Important Information continued

Exposure period

The Corporations Act prohibits the Company from processing applications to subscribe for Shares under this Prospectus (**Applications**) during the seven day period after the Prospectus Date (**Exposure Period**). The Exposure Period may be extended by ASIC by up to a further seven days, being an Exposure Period of up to a total of 14 days. The purpose of the Exposure Period is to enable the Prospectus to be examined by market participants prior to the raising of funds under the Offer. Applications received during the Exposure Period will not be processed until after the expiry of the Exposure Period. No preference will be conferred on Applications received during the Exposure Period.

Prospectus availability

During the Offer Period, a paper copy of this Prospectus will be available for Australian residents free of charge by contacting the Clarity Offer Information Line on 1800 645 237 (within Australia) or +61 1800 645 237 (outside Australia) between 8.30am and 5.30pm (Sydney time), Monday to Friday (Business Days only).

The Prospectus is also available in electronic form at the Offer website, https://events.miraqle.com/clarity-ipo.

The Offer constituted by this Prospectus in electronic form is available only to persons within Australia and is not available to persons in other jurisdictions. Persons who access the electronic version of this Prospectus must ensure that they download and read the entire Prospectus. If you are unsure about the completeness of this Prospectus received electronically, or a printed copy of it, you should contact the Company.

Applications

Applications for Shares under this Prospectus may only be made during the Offer Period and on the appropriate application form (**Application Form**) attached to, or accompanying, this Prospectus in its paper copy form, or in its electronic form, which must be downloaded in its entirety from the Offer website at https://events.miraqle.com/clarity-ipo. By submitting an Application, you represent and warrant that you were given access to this Prospectus, together with an Application Form. The Corporations Act prohibits any person from passing on to another person the Application Form unless it is attached to, or accompanied by, the complete and unaltered version of this Prospectus.

No cooling-off rights

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

Defined terms and time

Some of the terms and abbreviations used in this Prospectus have defined meanings. These are capitalised and defined in the Glossary in Section 11 of this Prospectus. Unless otherwise stated or implied, a reference to a time is a reference to Sydney time.

Currency

Unless otherwise noted in this Prospectus, all references to "$", "A$" or "dollars" are to Australian dollars. References to "US$" or "USD" are to United States dollars.

Timetable

Notwithstanding any provision of this Prospectus, the Company may, from time to time and without giving any notice, abridge or further abridge, extend or further extend any period or vary or further vary any date referred to in this Prospectus and for such period or to such later date as the Company thinks fit, whether or not the period to be extended has expired, or the date to be varied has passed.

Privacy

By filling out the Application Form to apply for Shares, you are providing personal information to the Company through its service provider, the Share Registry, which is contracted by the Company to manage Applications. The Company, and the Share Registry on its behalf, collects, holds and uses that personal information in order to process your Application, service your needs as a Shareholder, provide facilities and services that you request and carry out appropriate administration. If you do not provide the information requested in the Application Form, the Company 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 in the Share register. In accordance with the requirements of the Corporations Act, information on the Share register may be accessible by members of the public. Your name and details must continue to be included in the Share register for a period of seven years after you cease to be a Shareholder.

The personal information may also be provided to the Company's agents and service providers on the basis that they deal with such information in accordance with the Company's privacy policy. The Company's 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. The types of agents and service providers that may be provided with your personal information and the circumstances in which your personal information may be shared are:

- the Share Registry for ongoing administration of the Share register;
- the Joint Lead Managers in order to assess your Application;
- brokers for the purpose of providing their services;
- printers and other companies for the purposes of preparation and distribution of statements and for handling mail;

- market research companies for the purpose of analysing the Company's shareholder base; and
- legal and accounting firms, auditors, contractors, consultants and other advisers for the purpose of administering, and advising on, the Shares and for associated actions.

Information contained in the Company's Share register is also used to facilitate corporate communications (including the Company's financial results, annual reports and other information that the Company may wish to communicate to its Shareholders) and compliance by the Company with legal and regulatory requirements.

Under the *Privacy Act 1988* (Cth), Applicants may request access to their personal information held by or on behalf of the Company by contacting the Company's registered office or the Share Registry as set out in the Corporate Directory. You may be required to pay a reasonable charge to the Share Registry in order to access your personal information. Applicants can obtain a copy of the Company's privacy policy by visiting the Company's website (www.claritypharmaceuticals.com). By submitting an Application, you agree that the Company and the Share Registry may communicate with you in electronic form or contact you by telephone in relation to the Offer.

Company website

Any references to documents included on the Company's website at www.claritypharmaceuticals.com are provided for convenience only and none of the documents or other information on the Company's website are incorporated by reference into this Prospectus.

Photographs, diagrams and trademarks

Photographs and diagrams used in this Prospectus which do not have descriptions are for illustration or design purposes only and should not be interpreted to mean that any person shown in them endorses the Prospectus or its contents or that the assets shown in them are owned by the Company.

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.

This Prospectus also includes trademarks, trade names and service marks that are the property of other organisations. Unless indicated, the Company does not purport to own this property.

Third party publications

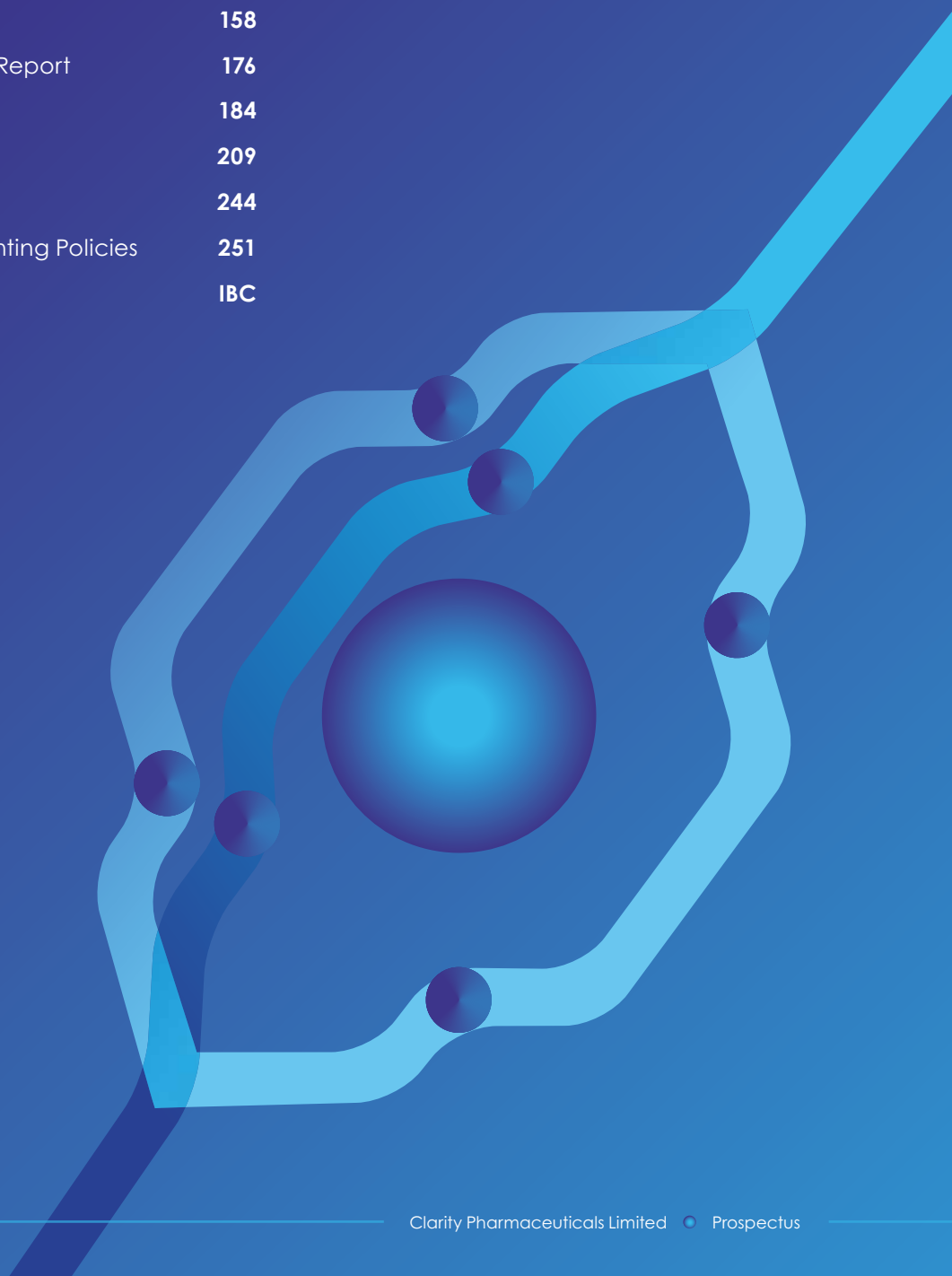
This Prospectus includes statements from books, journals and comparable publications that are not specific to, and have no connection with, the Company. Except where indicated otherwise, the authors of these books, journals and comparable publications have not provided their consent for these statements to be included in this Prospectus, and the Company is relying upon ASIC Corporations (Consents to Statements) Instrument 2016/72 for the inclusion of these statements in this Prospectus without that consent having been obtained.

Further queries

Call the Clarity Offer Information Line on 1800 645 237 (within Australia) or +61 1800 645 237 (outside Australia) between 8.30am and 5.30pm (Sydney time), Monday to Friday (Business Days only) if you require assistance to complete the Application Form, require additional copies of this Prospectus or have any questions in relation to the Offer.

If you are unclear in relation to any matter or are uncertain as to whether acquiring Shares in the Company is a suitable investment for you, you should seek professional advice from your accountant, financial adviser, tax adviser, lawyer or other independent and qualified professional adviser before deciding whether or not to invest in the Company.

Contents



Key Offer Information

Key dates	
Prospectus Date	Friday, 16 July 2021
Opening Date for the Retail Offer	Tuesday, 3 August 2021
Closing Date for the Retail Offer	Tuesday, 10 August 2021
Settlement of Offer	Friday, 20 August 2021
Allotment of Shares (Completion of the Offer)	Monday, 23 August 2021
Expected commencement of trading of Shares on ASX on a normal settlement basis	Wednesday, 25 August 2021
Expected dispatch of holding statements (and any refund payments if applicable)	Wednesday, 25 August 2021

Dates may change

This timetable is indicative only and may change without notice. Unless otherwise indicated, all times are stated in Sydney time. Clarity, 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 the ASX Listing Rules and the Corporations Act, to close the Offer early, to extend a closing date, or 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 notifying any recipient of this Prospectus or Applicant. Offers may be made and may be open for acceptances under this Prospectus either generally or in particular cases, including until Completion or, subject to the Corporations Act, thereafter, at the discretion of the Directors.

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. Investors are encouraged to submit their Applications as soon as possible after the Offer opens.

How to Invest

Applications for Shares under this Prospectus may only be made during the Offer Period by completing and lodging an Application Form. Instructions on how to apply for Shares are set out in Section 7 and on the back of the Application Form.

Questions

Please call the Clarity Offer Information Line on 1800 645 237 (within Australia) or +61 1800 645 237 (outside Australia) between 8.30am and 5.30pm (Sydney time), Monday to Friday (Business Days only) if you require assistance to complete the Application Form, require additional copies of this Prospectus or have any questions in relation to the Offer.

If you are unclear in relation to any matter or are uncertain as to whether acquiring Shares in the Company is a suitable investment for you, you should seek professional advice from your accountant, financial adviser, tax adviser, lawyer or other independent and qualified professional adviser before deciding whether or not to invest in the Company.

References to “we”, “us”, “our” and Clarity

Where used in this Prospectus, the expressions “we”, “us”, “our”, “the Company” and “Clarity” refer to Clarity Pharmaceuticals Ltd and/or its subsidiaries as the context requires.

Key Offer Information continued

Key Offer details	
Offer Price	$1.40 per share
Gross proceeds from the Offer	$92 million
Total number of Shares offered under the Offer	65.7 million
Total number of Shares on issue as at the Prospectus Date	190.4 million
Total number of Options on issue as at the Prospectus Date	51.1 million
Total number of Shares on issue on Completion of the Offer (on an undiluted basis)[1]	256.1 million
Total number of Options on issue on Completion of the Offer[2]	51.1 million
Total number of Shares on issue on Completion of the Offer (on a fully diluted basis, excluding the China Grand Options*)[3]	281.7 million
Indicative market capitalisation at the Offer Price (on an undiluted basis)[4]	$358.6 million
Indicative market capitalisation at the Offer Price (on a fully diluted basis, excluding the China Grand Options*)[5]	$394.3 million
Pro forma Net Cash as at the Prospectus Date[6]	$104.2 million
Enterprise Value at the Offer Price (on a fully diluted basis, excluding the China Grand Options*)[7]	$290.1 million

* The China Grand Options have been excluded from these figures due to the fact that the ability of China Grand to exercise any of the China Grand Options is, at the Prospectus Date, uncertain as the vesting of those options is conditional on not only the Listing of the Company and the quotation of its Shares on ASX but also the Company and China Grand being able to agree the terms of the licence agreement referred to in Section 10.7.4.

1. This number assumes that none of the 51,088,812 Options on issue at the Prospectus Date are exercised prior to Completion. Further details regarding the terms of the Options are provided in Section 10.7.
2. This number assumes that none of the 51,088,812 Options on issue at the Prospectus Date are exercised prior to Completion. Further details regarding the terms of the Options are provided in Section 10.7.
3. This number assumes all of the 51,088,812 Options on issue at the Prospectus Date (but excluding the China Grand Options, being 25,543,912 of those Options) have been exercised, and all of the Shares the subject of those Options have been issued.
4. Calculated as the total number of Shares on issue at Completion (on an undiluted basis i.e. assuming none of the 51,088,812 Options on issue at the Prospectus Date have been exercised) multiplied by the Offer Price. The Shares may not trade at the Offer Price after Listing. If the Shares trade below the Offer Price after Listing, then the market capitalisation may be lower.
5. Calculated as the total number of Shares on issue at Completion (on a fully diluted basis i.e. assuming all of the 51,088,812 Options on issue at the Prospectus Date (but excluding the China Grand Options, being 25,543,912 of those Options) have been exercised) multiplied by the Offer Price. The Shares may not trade at the Offer Price after Listing. If the Shares trade below the Offer Price after Listing, then the market capitalisation may be lower.
6. Represents pro forma net cash as at the Prospectus Date, including existing cash reserves of $17.6 million, plus $92.0 million gross proceeds from the Offer, less $5.4m costs associated with the Offer (excluding GST).
7. Enterprise value is calculated as the market capitalisation at the Offer Price (on a fully diluted basis i.e. assuming all of the 51,088,812 Options on issue at the Prospectus Date (but excluding the China Grand Options, being 25,543,912 of those Options) have been exercised), minus pro forma net cash of $104.2 million as at the Prospectus Date. Refer to Section 4 for more detail.

Chairperson's Letter

Dear Investor,

On behalf of the Directors of Clarity Pharmaceuticals Ltd (**Clarity**), I am pleased to invite you to consider becoming a shareholder of Clarity.

Clarity is an Australian-based clinical stage radiopharmaceutical company that is developing next-generation products to address the growing need for the use of radiopharmaceuticals in the diagnosis and therapy of cancers in children and adults. Clarity's proprietary SAR Technology platform employs the "perfect pairing" of copper radioisotopes (copper-64 for diagnosis and copper-67 for therapy), with the aim of achieving superior imaging and highly precise and accurate therapy. With this technology perfectly suited to Targeted Copper Theranostics (TCT), Clarity is seeking to address the current manufacturing and logistical limitations associated with the use of existing radiopharmaceuticals within the global oncology market.

Clarity is an Australian science-industry collaboration success story, with the company originally being founded in 2010 with licenses of intellectual property from The University of Melbourne and the Australian Nuclear Science and Technology Organisation. Clarity has maintained a strong relationship with these organisations as we have progressed our products into the clinic.

Clarity's first clinical product, SARTATE™, entered a first-in-human Phase I trial in 2015, which demonstrated the technology's ability to target and visualise the cancer of trial patients. This diagnostic study provided Clarity with sufficient data to commence a therapeutic trial of SARTATE™ in children with neuroblastoma, a devastating childhood cancer, with a goal of developing treatments with enhanced diagnosis and more positive therapeutic outcomes for these kids. The diagnostic and theranostic trials of SARTATE™ helped to validate Clarity's SAR Technology as a TCT platform and paved the way for the clinical development of two additional products, SAR-Bombesin and SAR-bisPSMA, for the management and treatment of breast and prostate cancers. We will continue this broad ranging approach by further rolling out our Discovery Program with new products and for additional cancer indications in pursuit of our ultimate goal of improving the treatment of children and adults with cancer.

In building our product range since our inception, we have created a robust intellectual property portfolio in respect of our platform, pipeline and clinical-stage products, details of which are set out in Section 9 of this Prospectus. Clarity is led by a management team and Board who possess a diverse range of skills and expertise, together with extensive experience in the radiopharmaceutical market. Alongside the management team and Board, Clarity has a Scientific Advisory Board, which consists of key opinion leaders who have significant research and clinical experience in global radiopharmaceuticals.

Under this Prospectus Clarity is offering 65.7 million Shares at $1.40 per Share to raise gross proceeds of $92 million.

This Prospectus contains detailed information about the Offer, the intellectual property owned by Clarity and the key risks associated with an investment in Clarity and the industry within which it operates. The risk factors that could affect Clarity's business, financial condition and results of operations, including macro-economic and market conditions and risks related to the COVID-19 pandemic, together with the key risks associated with investing in Clarity, are outlined in Section 5 of this Prospectus. I strongly encourage you to read this Prospectus carefully in its entirety before making your investment decision.

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

Yours sincerely

Dr Alan Taylor
Chairperson
Clarity Pharmaceuticals Ltd

01

Investment Overview

01 Investment Overview

1.1. Overview of Clarity and its business model

Topic	Summary	For more information
Who is Clarity?	Clarity is a clinical stage radiopharmaceutical company developing next-generation products to address the growing need for the use of radiopharmaceuticals in oncology. Clarity is a global leader in Targeted Copper Theranostics (**TCT**), developed with its proprietary SAR Technology platform. TCT are the next-generation disruptive platform in radiopharmaceuticals that employ the "perfect pairing" of copper-64 (^{64}Cu) and copper-67 (^{67}Cu) for diagnosis and therapy. TCT deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers, as well as providing supply and logistical advantages over current theranostics. TCT provide a highly efficacious, scalable, and cost-effective way to expand radiopharmaceuticals into the global oncology market. Clarity was incorporated on 8 April 2010 and is headquartered in Sydney, Australia and has subsidiaries in Belgium and the US. As it is a clinical stage company, Clarity does not currently generate any revenue.	**Sections 2.5.3, 3.1, 5.2.1, 5.2.21 and 10.1**
What is Clarity's history?	Clarity was founded in 2010 with licenses to intellectual property from The University of Melbourne and the Australian Nuclear Science and Technology Organisation. The Company completed its first capital raising in early 2011, and through this funding and by leveraging Australian Government grants it began developing the technology toward clinical products. Clarity started to grow its team in 2013 through engaging employees and advisers with commercial and clinical experience and continued to raise capital to achieve its goals. Clarity's first clinical product, SARTATE™, entered a first-in-human Phase I trial in 2015, which demonstrated the technology's ability to target and visualise the cancer of trial patients. This result has enabled the rollout of a pipeline of products, which include SAR-Bombesin and SAR-bisPSMA. Clarity continued to raise capital with a A$10 million equity raising in 2019 and a A$25 million equity raising in 2020 from sophisticated and professional investors. This has led to the expansion of the team with world class experience and subsequently the translation of its three lead products into clinical development.	**Section 3.1.1**
What industry does Clarity operate in?	Clarity operates in the pharmaceutical industry with a focus on the global oncology and radiopharmaceutical markets.	**Section 2.1**
What is Clarity's proprietary technology?	Clarity's proprietary SAR Technology platform can be used to develop a range of theranostic radiopharmaceuticals that target different types of cancer. At the heart of Clarity's theranostic SAR Technology platform is a highly specific and highly stable bifunctional cage (chelator) that retains copper isotopes within it and prevents their leakage into the body. The cage is linked to a targeting molecule, which finds and binds tumour specific receptors on cancer cells. Together with the targeting molecule and the isotope, the technology enables the development of radiopharmaceuticals for diagnosis and therapy in oncology.	**Section 3.2.1**

01 Investment Overview continued

Topic	Summary	For more information
What are Clarity's existing products and what are they used for?	Clarity's current pipeline of products in clinical and preclinical stages include: • **SARTATE™ Neuroblastoma:** for the treatment of neuroblastoma, Phase I/IIa (see Section 3.5.1.1); • **SARTATE™ NETs:** for the diagnosis of neuroendocrine tumours (NETs), Phase II (see Section 3.5.1.2); • **SAR-Bombesin:** a pan-cancer treatment product, including for the treatment of breast cancer and prostate cancer, Phase I (see Section 3.5.2); and • **SAR-bisPSMA:** for the treatment of prostate cancer, Phase I/IIa; for the diagnosis of prostate cancer, Phase I (see Section 3.5.3).	**Section 3.1**
What is Clarity's strategy?	Clarity is developing products for both rare and large indications of cancer, thereby positioning the products to take advantage of the high unmet needs that currently exist in respect of the medical treatment used for these types of cancer. Clarity's focus in the development process is on high quality clinical sites and experienced investigators. The Company is targeting the lucrative US market for first product approvals.	**Section 3.3**
What is Clarity's intellectual property coverage?	Clarity has an extensive patent portfolio generated from a patent strategy designed to cover its SAR Technology platform and its radiopharmaceutical products as well as a 'Discovery Program' focused on developing new products and new intellectual property for a range of indications of cancer (see further information on the 'Discovery Program' in Section 3.6). Clarity works closely with experienced patent attorneys at the patent firm Davies Collison Cave (**DCC**) and their overseas associates to protect its IP in accordance with the patent strategy. DCC has prepared an independent intellectual property report, which is contained in Section 9.	**Sections 3.6, 3.8 and 9**
Who manufactures Clarity's products?	Clarity works with outsourced commercial development manufacturing organisations (CDMOs) which produce the quality and volume of products required for the Company's clinical trials.	**Section 3.7.1**
What are Clarity's key costs?	**Operating expenses** which relate to all indirect expenditure that is not attributable to the Company's research and development activities. These expenses include legal fees, corporate advisory costs, indirect employee costs, administration costs, travel costs, occupancy costs, and patent costs (including costs of application for patents as well as patent protection). **Research & development expenses** which represent costs for employees, contractors, materials and other expenditure associated with the Clarity Group's research & development programs. **Share based payments** represent the non-cash expense attributed to vested options and the expenses to date for options that have not yet vested (as the expense is spread over the vesting period). The options have been issued to key management personnel, employees and non-employees of the Clarity Group as well as advisers.	**Section 4.5**

Topic	Summary	For more information
How will Clarity fund its operations?	Clarity expects that it will have sufficient cash to fund its medium term operational requirements and business objectives as a result of the funds raised under the Offer as stated in this Prospectus and discussed in Section 7.1.3 (Sources and Uses of Funds).	**Section 4.7.3**
Why are there no financial forecasts in the Prospectus?	Given the fact that the Company is in an early stage of development, there are significant uncertainties associated with forecasting the future revenues and expenses of the Company. On this basis, the Directors believe that there is no reasonable basis for the inclusion of financial forecasts in this Prospectus.	**N/A**
How does Clarity generate revenue?	As at the Prospectus Date, the Company does not generate revenue and does not have a product that is capable of generating revenue without completing further clinical trials and obtaining regulatory approvals.	**Section 5.2.1**
What is Clarity's dividend policy?	The Company has never paid a dividend and the Directors have no current intention of declaring or paying any dividends in the foreseeable future. The Directors will review this policy as appropriate and the declaration and amount of any dividends will be determined by, and at the sole discretion of, the Board.	**Section 4.10**

1.2 Key features of the industry in which Clarity operates

Topic	Summary	For more information
What are diagnostic and therapeutic radiopharmaceuticals and what are they used for?	Radiopharmaceuticals utilise the radiation emitted by different radioisotopes to allow diagnosis and treatment of disease. Diagnostic radiopharmaceuticals allow visualisation of the sites of disease in the body by utilising special equipment, such as Single Photon Emission Computed Tomography (SPECT) cameras and Positron Emission Tomography (PET) cameras for imaging. Therapeutic radiopharmaceuticals use a more powerful radioisotope which has the ability to kill cancer cells.	**Section 2.4**
What is theranostics?	Theranostics is the combination of both **thera**peutic and diag**nostic** radiopharmaceuticals in the one platform. It is considered the next-generation of "Precision Therapy" in cancer care.	**Section 2.5**

Topic	Summary	For more information
What is the development pathway for radiopharmaceutical products in the US?	The process of developing a radiopharmaceutical candidate is divided into several phases, each used to investigate different aspects of the drug product candidate. After the discovery and development process, a pharmaceutical company will pursue preclinical research for a drug, in which it aims to gather detailed information on dosing and toxicity.[8] Once preclinical research is complete and the decision has been made to pursue testing in humans, the developers design clinical studies and consider what they wish to achieve at each of the three stages of clinical research. Before clinical research begins in the US, the developers must submit an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA).[9] In the United States, Clarity has two open IND applications that received clearance to proceed to clinical trials from the FDA, one for $^{64/67}$Cu SARTATE™ and one for $^{64/67}$Cu SAR-bisPSMA. A Phase I/IIa trial of $^{64/67}$Cu SARTATE™ in children with neuroblastoma commenced in 2020 and is continuing. A Phase I/IIa trial of $^{64/67}$Cu SAR-bisPSMA is due to start in July 2021.	**Sections 2.6.2, 3.3 and 3.5**
What types of cancer do Clarity's products address?	**Prostate Cancer** Prostate cancer is a cancer that forms in the cells of the prostate. Prostate cancer is the second most common cancer in men and the fifth leading cause of cancer death in men worldwide. **Breast Cancer** Breast cancer is a cancer that forms in the cells of the breasts. Breast cancer is the most common cancer, and the most common cause of cancer death in females worldwide. **Neuroblastoma** Neuroblastoma is a cancer that develops from immature nerve cells found in several areas of the body. Neuroblastoma most commonly arises in and around the adrenal glands (a gland that sits atop the kidneys). This cancer occurs most often in infants and young children, usually in children younger than 5 years old. It is rarely found in people older than 10 years. **Neuroendocrine Tumours** Neuroendocrine tumours (NETs) are a type of tumour that arises from body cells called neuroendocrine cells. Neuroendocrine cells are naturally found within most organs of the body, including the thymus, liver, pancreas, ovaries, prostate and kidneys.	**Section 2.7**

8. FDA <https://www.fda.gov/patients/drug-development-process/step-2-preclinical-research>.
9. See Code of Federal Regulations Title 21, Volume 5 (Revised as of April 1, 2020), Part 312, Section 312.20 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312>.

1.3. Key strengths

Topic	Summary	For more information
Global leader in copper theranostics	Clarity is a global leader in Targeted Copper Theranostics (**TCT**), developed with its proprietary SAR Technology platform. TCT are the next-generation disruptive platform in radiopharmaceuticals that employ the "perfect pairing" of copper-64 (^{64}Cu) and copper-67 (^{67}Cu) for diagnosis and therapy. TCT deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers, as well as providing supply and logistical advantages over current theranostics. TCT provide a highly efficacious, scalable, and cost-effective way to expand radiopharmaceuticals into the global oncology market.	**Section 3.1**
Diverse asset portfolio addressing both large and orphan market opportunities across diagnostics and therapies	Clarity has a diverse range of products in clinical trials which address both large indications (prostate cancer and breast cancer) as well as rare and orphan indications (neuroendocrine tumours (NETs) and neuroblastoma) of cancer. Rare and orphan indications allow Clarity to develop products where there is significant unmet medical need, and the regulatory agencies, such as FDA in the US, provide benefits and regulatory incentives for companies developing these products. At the same time, these products can allow a premium on pricing. Large indications (e.g. prostate cancer) allow faster recruitment into clinical trials due to a larger patient pool and there is significant opportunity to sell higher volumes of products once they are approved due to the greater incidence.	**Section 2.7 and 3.1**
Broad and robust patent position – multiple patent families across all products and in all major markets	Clarity has an extensive patent portfolio generated from a patent strategy designed to cover its SAR Technology platform and its radiopharmaceutical products as well as a 'Discovery Program' focused on developing new products and new intellectual property for a range of indications of cancer (see further information on the 'Discovery Program' in Section 3.6). Clarity's current patent portfolio covers a broad range of countries and major markets, including the United States, Australia, Europe, Japan, China, Canada, Singapore, Malaysia, South Korea, Russia, Mexico and India. Originating from pioneering work at the Australian National University, The University of Melbourne and the Australian Nuclear Science and Technology Organisation, Clarity has expanded its patent base, protecting its proprietary SAR Technology platform, existing products, Discovery Program pipeline, manufacturing and processes.	**Sections 3.6 and 3.8**
Rich Discovery Program enabled by the SAR Technology platform	The versatility of the SAR Technology platform enables Clarity to pursue a Discovery Program focused on developing new products and new intellectual property for a range of indications of cancer.	**Sections 3.1 and 3.6**
Highly experienced management team and Board	Clarity is led by a highly experienced management team and Board with significant years of active involvement in the radiopharmaceutical market. Alongside the management team and Board, Clarity has a Scientific Advisory Board, which consists of global thought leaders with extensive capabilities, expertise and experience in developing radiopharmaceutical products.	**Sections 6.1, 6.2 and 6.3**

Topic	Summary	For more information
Supply and manufacturing of copper radioisotopes provides an advantage in the commercialisation phase	The supply of, and manufacturing process utilised in the production of copper radioisotopes give Clarity an advantage in the commercialisation phase of its theranostic products. This advantage primarily relates to the fact that the production of copper-64 occurs on existing cyclotrons (the infrastructure for which is well established worldwide). The 12.7 hour half-life of copper-64 permits central manufacturing and regional distribution whereas competing isotopes used for diagnostic imaging, like gallium-68, are short lived and therefore present logistical constraints for distribution. The production of copper-67 employs electron accelerators. By contrast, the production of the isotopes utilised by the Company's competitors, specifically lutetium-177, is reliant on a small number of nuclear reactors globally.	**Section 3.7.1**
Strong focus on the US regulatory pathways to approval with a theranostic IND in place and ongoing US clinical trials	Clarity's main focus is on the US regulatory approval pathway. The Company currently has two open Investigational New Drug (**IND**) applications that have received clearance to proceed to clinical trials from the FDA for its theranostic SARTATE™ and SAR-bisPSMA products. SARTATE™ has been granted two Orphan Drug Designations (**ODDs**) and two Rare Paediatric Disease Designations (**RPDDs**) from the FDA for the management and treatment of neuroblastoma. If Clarity is able to achieve successful US FDA New Drug Applications for SARTATE™ in neuroblastoma, these may give Clarity access to two tradeable Priority Review Vouchers (**PRVs**), although there can be no guarantee that these PRVs will be able to be accessed. A PRV speeds up the timeline that the FDA commits to the review of a drug application, which is significant for companies with blockbuster products who seek to buy PRVs to accelerate approvals and shorten the time to market (if ultimately approved) and thereby potentially boosting their sales.	**Section 2.6.4 and 3.1**

1.4. Key risks

There are a number of risks that may affect the Company's financial performance, financial position, cash flows, distributions, growth prospects and share price. The following table is a summary of key risks to which the Company is exposed. Further details about these and other specific and general risks associated with an investment in the Company are set out in Section 5. An investment in the Shares offered under this Prospectus should be considered as speculative and investors should consider the risk factors described below, including the additional risks set out in Section 5, before making an investment decision.

Topic	Summary	For more information
Speculative nature of investment	As at the Prospectus Date, the Company does not generate revenue and, without completing further clinical trials and obtaining additional regulatory approvals, does not have a product that is capable of generating revenue. The Company will need to successfully develop and commercialise its products in order to generate revenue and to become, and then remain, profitable. In order to do so, the Company will need to successfully complete clinical trials for the Company's products and obtain all relevant regulatory approvals from regulatory bodies in the United States, together with other relevant jurisdictions, such as Europe, for those product candidates and for the manufacturing, marketing and sale of the Company's products in these jurisdictions. As at the Prospectus Date, the Company is only at the preliminary stage of these activities and there is no guarantee that the Company will succeed in these activities. Should the Company be successful in these ventures, there is still a risk that the Company may never generate enough revenue to achieve profitability or declare any dividends.	**Section 5.2.1**
Success of clinical trials is not guaranteed	The Company's ability to generate revenue and become, and remain, profitable will largely depend on whether the Company's clinical trials are successful and whether the Company is able to demonstrate, through these clinical trials, that the Company's products are suitable for commercialisation. Clarity seeks to minimise its clinical trial risk by using targeted diagnostic products as part of its clinical trial process to select patients who are likely to respond to treatment with its therapeutic products. However, the success of the Company's clinical trials and the development of the Company's products, and therefore the Company's ability to generate revenue, is not guaranteed.	**Section 5.2.2**
The Company may not obtain the required regulatory approvals	The Company will need to obtain ongoing approvals from the FDA in the US, the TGA in Australia and the EMA in Europe in order to run its studies and clinical trials in those jurisdictions. The Company will also need new approvals from these regulators in order to further develop its products and, at a later stage, to distribute and market its products in each of the US, Australia and Europe respectively. In addition, the Company will require approvals from equivalent regulatory authorities in other countries should the Company wish to conduct clinical trials or commercialise its products in those jurisdictions. The Company has two open Investigational New Drugs (**INDs**) applications that received clearance to proceed to clinical trials from the FDA and has received approvals from the FDA for two Orphan Drug Designations (**ODD**) and two Rare Paediatric Disease Designations (**RPDD**). There is no guarantee that the Company will continue to receive the regulatory approvals that are necessary for the Company to run studies and clinical trials or to commercialise its products (including the INDs, OODs and RPDDs referred to above) in any jurisdiction. Whether the Company successfully obtains these regulatory approvals is, ultimately, outside of the Company's control and dependent on the decisions of the regulatory bodies in each relevant jurisdiction. If the Company does not receive the regulatory approvals that are required, the Company will not be able to commercialise its products or generate revenue in the relevant jurisdictions, which may have a material adverse impact on Shareholder returns.	**Section 5.2.3**

Topic	Summary	For more information
Competitive industry	Clarity is operating in the pharmaceutical industry with a focus on the global oncology and radiopharmaceutical markets, which are both competitive and subject to rapid and significant technological change. The Board considers that the Company has, as at the Prospectus Date, a competitive advantage in these markets for its products due to the versatility of the SAR Technology platform that enables the Company to pursue its Discovery Program that is focused on developing new products and intellectual property for various indications of cancer. However, these circumstances may change over time as there is always a risk of new entrants to the market, and the risk that an existing radiopharmaceutical company or another company within the markets may disrupt the Company's business operations and anticipated market share. The Company cannot predict the timing and scale of new competitors that may emerge.	**Section 5.2.4**
Clarity requires effective protection and maintenance of its intellectual property	The Company currently has title to a number of key patents and patent applications in respect of the technology that forms the basis of a number of its product candidates. The success of the Company is therefore partly dependent on the Company's ability to continue to obtain and maintain commercially beneficial patents and to protect its intellectual property. The risks that the Company faces with respect to the patents and patent applications that it owns, and any future patents/patent applications that may be acquired or licensed, include but are not limited to the following: • patent applications that are lodged by the Company may not result in granted patents; • the Company may experience delays in obtaining the grant of patents; • any request by the Company to obtain an extension to the term of a patent may not be granted or, if it is granted, the patent may be granted on the condition that revisions to the patent are imposed; • the patents that are granted to the Company may not necessarily protect the Company's commercial activities; • the patents that the Company owns or licences may be challenged at any time; • other entities may independently develop similar, duplicate or alternative technologies to those of the Company; • other entities may design workarounds to the Company's technology; • other entities may own intellectual property that is relevant to the Company's technology or activities; and • the value of the Company's intellectual property rights may diminish if a patent is not granted with respect to any patent application. Additionally, any information that is contained in the patent application will be publicly available information and as a result will not be subject to any confidentiality restrictions.	**Section 5.2.5**

Topic	Summary	For more information
Clarity requires effective protection and maintenance of its intellectual property (continued)	The degree of protection that the Company may have with respect to its intellectual property rights is uncertain and subject to the risks detailed above as well as other potential unanticipated risks. In addition, the Company's intellectual property rights may be subject to change as laws and regulations relating to the scope and validity of patents continues to evolve. These and other risks set out in Section 5.2.5 may materially and adversely impact the Company's planned future revenue, margins and profitability and reduce the value of an investment in the Shares.	**Section 5.2.5**
Reliance on key suppliers, contract development and manufacturing organisations and logistics partners	As the Company does not have its own facilities from which to manufacture its products (including the materials required for its products), it relies on third parties for the supply of the critical materials that are necessary for the manufacture of its product candidates. These third parties include suppliers of radioisotopes, consumable and vial suppliers, suppliers of certain precursor elements of radiopharmaceuticals and sterility subcontractors. If these third parties are no longer able to provide such materials or services to the Company, the Company may be required to seek alternative suppliers which may cause delays to its clinical trial programs. Copper-64 (^{64}Cu) is a critical material necessary for the manufacture of the Company's product candidates. The Company's existing supply of ^{64}Cu is sufficient for the Company's current clinical trials program and the Company is expanding its network of ^{64}Cu suppliers to produce industrial levels of ^{64}Cu for its diagnostic products for commercial supply. However, if the Company does not receive a sufficient supply of ^{64}Cu on an ongoing basis, this could have an adverse impact on commercialisation of its products and its ability to earn revenue. Further specific details on these risks are detailed in Section 5.2.6. Copper-67 (^{67}Cu) is also a critical material necessary for the manufacture of the Company's product candidates. The existing supply of ^{67}Cu is sufficient for the Company's current clinical trials program and the Company has entered into supply agreements to produce industrial levels of ^{67}Cu for its therapeutic pipeline and commercialisation. However, if the Company does not receive a sufficient supply of ^{67}Cu on an ongoing basis, this could have an adverse impact on commercialisation of its products and its ability to earn revenue from its therapeutic radiopharmaceutical products. Further specific details on these risks are detailed in Section 5.2.7.	**Sections 5.2.6 and 5.2.7**
Risk of failing to keep up with advances in radiopharmaceuticals	The Company is in the process of developing a number of innovative diagnostic imaging and therapeutic products that seek to improve the efficacy, safety, ease of use and cost-effectiveness of treatment for patients and the oncology market more broadly. In order for the Company to succeed in this pursuit, both in the short and long term, the Company will need to continuously adapt to changes and advances in the radiopharmaceutical market. In particular, it will be necessary for the Company to adapt to new technologies and anticipate and satisfy customer and patient needs. If the Company is unable to continuously innovate and develop new products or product candidates, adapt to changing technologies or anticipate changes in patient and customer needs, the Company's products may become obsolete which could have a material adverse effect on the Company's business and financial position.	**Section 5.2.8**

Topic	Summary	For more information
Lack of acceptance of radiopharmaceuticals by the medical community	The success of the Company is largely dependent on whether the medical community accepts and embraces the use of radiopharmaceutical products and treatments. If there are any adverse results in the clinical trials of the Company's product candidates or in the clinical trials of the Company's competitors that are developing similar products, or any negative publicity with respect to the safety or efficacy of radiopharmaceutical products and treatments, this could result in the Company's products not being accepted or used by the medical community or the general public. This may have a material adverse effect on the Company's business and financial position.	**Section 5.2.9**
Development program may be delayed	There may be delays in achieving critical milestones set by the Company. These include completing clinical trials, obtaining regulatory or reimbursement approvals, establishing commercial manufacturing, and commencing product launch and sales. If the Company experiences any material delays, this may have a material adverse effect on the Company's business and financial position.	**Section 5.2.10**
Risk associated with the use of radiopharmaceuticals	The Company deals with radiopharmaceutical products that use radioactive materials, which generate medical and other regulated wastes. There are a number of risks associated with the use, possession and disposal of these materials and waste products, including physical injury and accidental environmental contamination. The storage, design and manufacturing processes for these radioactive materials may not entirely eliminate the risk of employees of the Company and others being exposed to radiation and radioactive materials. There is a risk that, at times, the Company may need to alter its storage and manufacturing processes in order to remain in compliance with radio-protection laws in the jurisdictions in which the Company operates. The Company is unable to completely eliminate all risk of accidental contamination or injury from these materials and waste products. Consequently, the Company is at risk of being held liable for any damages or losses that are suffered as a result of an accidental contamination or the injury to an employee or other person, and these damages could fall outside, or exceed the limits of, the Company's current insurance coverage. If this was to occur it may adversely impact the Company's financial position, business operations and reputation.	**Section 5.2.11**
The pricing of the Company's products may be subject to external factors	In Australia, and also in various overseas jurisdictions, the price of medicinal products and technologies is often regulated or influenced by government authorities, health insurers and other healthcare providers. In particular, these bodies often determine whether a customer or patient will receive a reimbursement or subsidy for the cost of their medicine or medical treatment. Accordingly, if the Company is successfully able to sell its products to the market, the pricing of the Company's products will be influenced by these external factors, including the cost of healthcare and the level of reimbursement or subsidy available to customers or patients that use the Company's products. As the pricing of the Company's products will be subject to these external factors, there is no guarantee that the Company will achieve its targeted price for the sale of its products. If the level of reimbursement available to customers or patients is less than anticipated, this may also negatively impact the profitability of the Company's products and therefore the Company's financial position.	**Section 5.2.12**

Topic	Summary	For more information
Anticipated future expenses may be incorrect	In determining the use of funds under the Offer, the Company has considered the expenses that it anticipates it will incur. A number of these anticipated expenses relate to the engagement of third party suppliers, manufacturers and other service providers with whom the Company has not yet entered into contractual arrangements. As the Company is not yet party to any contractual agreement with those third parties, there is a risk that the Company may not be able to source the required supplies, manufacturing and services at the cost that it anticipates incurring. As a result, there is a risk that the anticipated future expenses of the Company may be incorrect and more than anticipated, and the Company will be required to adjust its use of funds raised under the Offer accordingly. This may have a material adverse effect on the Company's business and financial position.	**Section 5.2.13**
Reliance on key personnel	The Company is heavily reliant on the capabilities of its key management personnel who have extensive experience in, and knowledge of, the Company's technology, its business and the market in which it operates. In particular, the loss of one or more of each of the executive directors, being Alan Taylor and Colin Biggin, or any other key executives or management, and any delay in sourcing their replacement, may adversely impact the ability of the Company to implement and expand its business and achieve its growth strategies. There is no guarantee that the Company will be able to retain its key management personnel or, in the event that their employment is terminated, be able to replace them in a timely manner with qualified individuals who have the necessary skills and expertise. This could have a material adverse impact on the Company's business, operating or financial performance. In addition to the Company's key management personnel, the Company is also reliant on attracting and retaining qualified scientific and technical personnel who are experts in the radiopharmaceutical field. If the Company fails to attract or retain these key employees or contractors, the Company's business, including its research and development programs, could be adversely affected, which may in turn impact the Company's future product success and financial prospects. Additionally, as there is significant demand in the oncology and radiopharmaceutical markets for expert qualified scientific and technical personnel, there is a likelihood that the Company's labour costs will need to increase in order to continue to attract and retain these personnel.	**Section 5.2.14**
Product liability	Due to the innovative nature of the Company's products, the Company is exposed to the risk of product liability claims arising from defective products or products that are no longer viable, even where the Company has received prior regulatory approval. If the Company is subject to any product liability claims, this could result in the removal of regulatory approvals that the Company may have obtained. In addition, the Company may also incur unanticipated costs as a result of product liability claims, which may exceed or not be covered by the Company's insurance coverage.	**Section 5.2.15**

Topic	Summary	For more information
COVID-19	Events related to COVID-19 have resulted in significant market volatility. There is continued uncertainty as to the ongoing and future response of governments and authorities globally, and a further Australian economic downturn is possible. As a result, the full impact of COVID-19 on consumer behaviour, manufacturers, suppliers, employees and the Company are not fully known. Given this, the impact of COVID-19 could potentially be materially adverse to the Company's current operational, and potential future financial, performance. It is possible that disruptions related to COVID-19 may impact the ability of the Company's suppliers and CDMOs to maintain timely product supply for the Company's clinical trials. It is also possible that clinical sites for the Company's trials will experience COVID-19 related disruptions, which could impact their ability to recruit and treat patients in line with forecasts. Further, any government or industry measures in response to COVID-19 may materially adversely affect the Company's operations and are likely to be beyond the Company's control.	**Sections 5.2.16 and 5.2.17**
Supply chain	Factors outside the control of the Company, for example COVID-19, may have a material adverse impact on the Company's supply chain. Restrictions on the manufacturing of copper-64 (^{64}Cu) and copper-67 (^{67}Cu) may restrict the ability of the Company to conduct clinical trials and other operations that are key to its business model such as research. This may materially impact the ability of the Company to meet its proposed development timetable and adversely impact the price of the Shares.	**Section 5.2.18**
Information technology and cybersecurity	The Company's business requires information technology systems in order to support and perform key functions and achieve business objectives. The information technology systems that are used by the Company are vulnerable to interruption or damage from: • loss of power; • failure of computer systems; • telecommunications or data network failures; • improper operation of the information technology systems by employees or others; • loss of data; • computer viruses; • cyber threats (including but not limited to malware, ransomware, phishing and Distributed denial of service (DdoS) attacks); and • natural disasters, terrorist attacks or other events outside of the control of the Company. The Company retains a specialist information technology (**IT**) managed services firm to maintain processes and controls over its IT environment. Notwithstanding the remedial measures in place, any interruption or damage to the Company's IT systems could directly or indirectly impact the Company's ability to conduct its business and may result in the Company incurring unforeseen costs in order to take corrective measures, obtain or rebuild lost data or respond to regulatory inquiries or actions that may stem from a data breach.	**Section 5.2.19**

Topic	Summary	For more information
Loss or misuse of personal information	The Company utilises confidential and other sensitive information that is stored within its IT systems and networks. The Company has in place a range of security measures over these systems and networks. The Company places reliance on the security of those IT systems to ensure that this proprietary and confidential data is stored, processed and transmitted securely across systems and networks. The Company is at risk of these IT systems being exposed to security and privacy incidents, breaches, acts of theft or vandalism, misplaced or lost data, programming errors, human errors and other general cybersecurity risks. A security breach or incident that involves the loss, exploitation or otherwise unauthorised disclosure or use of any confidential or sensitive information, whether by the Company or a third party, could have a materially negative effect on the Company's reputation, financial condition, cash flows, or results of operations. If any of these events occur, it may result in interruptions, delays, a corruption or loss of data, potential liability and regulatory action, potential liability under security and privacy laws or a discontinuance of the availability of IT systems. All could have a significant negative effect on the Company's financial performance, business operations and reputation.	**Section 5.2.20**
Foreign operations	The Company has a subsidiary that is incorporated in Belgium and another subsidiary that is incorporated in the US. The Company may also conduct activities in other overseas jurisdictions from time to time. As a result, the Company is exposed to various laws and regulations that it must consider and comply with in the relevant jurisdictions. If the Company does not always receive foreign legal advice in the jurisdictions within which it operates, the Company may be exposed to risks with respect to its asset ownership, labour practices, contract enforcement, changes in the relevant legal and regulatory structures and other issues that could arise in foreign jurisdictions in which the Company operates (for example, government and regulatory authority practices).	**Section 5.2.21**
Liquidity risk and escrow arrangements	As a result of the compulsory escrow requirements contained in Chapter 9 of the ASX Listing Rules and the voluntary escrow arrangements that have been entered into by certain Existing Shareholders with the Company, it is expected, subject to ASX confirmation, that approximately 155,355,708 of the Shares on issue in the Company as at Completion[10] (representing 60.65% of the Shares on issue as at Completion) will be subject to escrow restrictions from Listing including 76,680,986 Shares (representing approximately 29.94% of the Shares on issue as at Completion) for a period of 24 months. It is expected that the remaining 78,674,722 Shares (representing approximately 30.72% of the Shares on issue as at Completion) will be released from escrow during the course of the initial six month period from Listing. Following release from escrow, Shares held by these Shareholders (referred to as Escrowed Shareholders) will be freely tradeable on the ASX. A significant sale by an Escrowed Shareholder of its Shares following their release from escrow (or a perception that such sale has occurred or might occur), could also adversely affect the price of Shares.	**Section 5.3.1**

10. Assumes 256,132,546 Shares on issue as at Completion and no Options have been exercised.

Topic	Summary	For more information
Liquidity risk and escrow arrangements (continued)	There also can be no guarantee that an active market in the Shares will develop or continue, or that the market price of the Shares will increase. If a market does not develop or is not sustained, it may be difficult for investors to sell their Shares. Furthermore, the market price for Shares may fall or be made more volatile because of a relatively low volume of trading. When trading volume is low, significant price movements can be caused by trading a relatively small number of Shares (including, for example, a sale of Shares recently released from escrow). If illiquidity arises, there is a risk that Shareholders will be unable to realise their investment in the Company when they wish to do so.	**Section 5.3.1**
Risk of Shareholder dilution	The Company currently has 51,088,812 Options on issue as at the Prospectus Date, representing approximately 26.83% of the undiluted share capital of the Company as at the Prospectus Date and will represent approximately 19.95% of the undiluted share capital of the Company as at Completion. If all of these Options are exercised, Shareholders' interests may be significantly diluted. The Company may also in the future issue additional Options to eligible participants either under the Equity Incentive Plan or otherwise to third parties or additional Shares under fundraisings that the Company may undertake. If additional Options are issued and they are subsequently exercised by the relevant option holders or additional Shares are issued under a fundraising, Shareholders' interests may be significantly diluted and they may also experience a loss in value of their Shares.	**Section 5.3.2**
Risk of non-exercise of options	The Company will have 51,088,812 Options on issue as at Completion (assuming no Options are exercised prior to Completion). As all of the Options on issue are exercisable at the sole discretion of the option holder once they become exercisable, there is no guarantee that any Options will ever be exercised. In addition, the Company Options and Adviser Options allow them to be exercised pursuant to a cashless exercise mechanism as detailed in Section 6.4.2.6, which means that no funds are received by the Company where this mechanism is utilised by an option holder. In relation to the China Grand Options, while there is no cashless exercise mechanism that may be utilised by China Grand, the China Grand Options will only vest and be capable of exercise by China Grand if the relevant vesting condition is satisfied (i.e. the Company has been admitted to the Official List and its Shares have been admitted to quotation on the ASX and the Company has also entered into a licence agreement with China Grand in respect of the territory of Greater China) prior to the China Grand Options Expiry Date set out in Section 10.7.4. As a result, there is no guarantee that the China Grand Options will vest before the China Grand Options Expiry Date and, even if they do vest, there is no obligation on China Grand to exercise any of the China Grand Options. Accordingly, the Company may never receive any funds from the China Grand Options. If no or only limited funds are received by the Company from the exercise of any Options, this would impact the Company's potential future cash reserves. The Board, however, believes that the Company's current cash reserves plus the net proceeds of the Offer will be sufficient to fund the Company's stated business objectives.	**Section 5.3.3**

1.5. Key financial information

Topic	Summary	For more information
What is Clarity's key financial information?		Sections 4.5 and 4.7

Historical statement of profit and loss and other comprehensive income

The table below presents the summary historical consolidated statement of profit and loss and other comprehensive income for the years ended 30 June 2019 and 30 June 2020 and the six months ended 31 December 2020 (with six months ended 31 December 2019 comparative information). Further discussion regarding the summarised historical consolidated statement of operations is set out in Section 4.

	Audited	Audited	Reviewed	Reviewed
A$'000	Year ended 30 June 2019	Year ended 30 June 2020	Six months ended 31 December 2020	Six months ended 31 December 2019
Other income	**2,643**	**2,839**	**1,382**	**1,210**
Operating expenses	(1,757)	(4,598)	(2,642)	(2,108)
Research & Development	(4,107)	(4,037)	(2,441)	(1,885)
Share based payments	(522)	(1,194)	(1,171)	(565)
Depreciation	(22)	(17)	(7)	(9)
Net Interest income	81	53	25	59
Net Loss After Tax	**(3,684)**	**(6,954)**	**(4,855)**	**(3,296)**
Total comprehensive loss	**(3,676)**	**(6,953)**	**(4,858)**	**(3,295)**

Pro forma statement of financial position

The table below sets out the summarised historical and pro forma consolidated statement of financial position as at 31 December 2020. Details of the pro forma statement of financial position, including the pro forma adjustments are set out in Section 4.

	Reviewed	Pro forma
A$'000	As at 31 December 2020	
Total current assets	**26,585**	**113,368**
Total non current assets	107	107
Total assets	**26,692**	**113,475**
Total current liabilities	1,927	1,927
Total non current liabilities	90	90
Total liabilities	**2,016**	**2,016**
Net assets	**24,675**	**111,458**
Total equity	**24,675**	**111,458**

1.6. Board and management team

Topic	Summary	For more information
Who are the Directors of Clarity?	**Dr Alan Taylor, PhD** *(Executive Chairperson)* Dr Taylor joined the Board in November 2013 as Executive Chairperson. Dr Taylor has been instrumental in the growth of the Company and has been heavily involved in all areas of the Company's business. Dr Taylor has approximately 15 years of investment banking experience focused predominantly on the life sciences sector, and has significant expertise in capital raisings, mergers and acquisitions, and general corporate advisory. Prior to joining Clarity, Dr Taylor was an Executive Director of Inteq Limited, a boutique Australian investment bank. **Dr Colin Biggin, PhD** *(Managing Director and CEO)* Dr Biggin joined the Board in October 2019 as Managing Director and CEO after playing an instrumental role in enhancing and designing the Company's product development and clinical programmes since he first joined the Company in January 2017. Dr Biggin has over 15 years of radiopharmaceutical development and commercialisation experience. Dr Biggin previously served with Algeta ASA during the development and commercialisation of its product Xofigo® (radium-223 dichloride) for metastatic prostate cancer, which was approved by the FDA in 2013. Prior to joining the Company, Dr Biggin also consulted to a range of biotech and large pharmaceutical companies developing radiopharmaceuticals. **Ms Rosanne Robinson** *(Non-Executive Director)* Ms Robinson joined the Board in October 2010 as a Non-Executive Director. Ms Robinson brings extensive experience in the nuclear field and a range of commercial expertise to the Company and has over 25 years of experience in both governance and management roles in public and private companies and government. Ms Robinson is the General Manager of Business Development at Australian Nuclear Science and Technology Organisation. Ms Robinson's in-depth knowledge of the nuclear medicine industry provides the Company with a clear vision across the dynamics of, and most recent changes in, the sector. **Dr Chris Roberts, PhD** *(Non-Executive Director)* Dr Roberts joined the Board in March 2016 as a Non-Executive Director. Dr Roberts has over 40 years of experience in the medical innovation space and has served on the boards of a number of ASX-listed companies during his career. Dr Roberts was previously the CEO of ASX-listed company Cochlear Limited and Chairman of ASX-listed company Sirtex Medical Ltd. Dr Roberts was also Executive Vice-President and a director of the dual-listed (ASX and NYSE) company ResMed Inc., a global sleep disorder treatment company. Dr Roberts is Chairman of the ASX-listed company Oncosil Ltd.	**Section 6.1.1**

Topic	Summary	For more information
Who are the Directors of Clarity? (continued)	**Dr Thomas Ramdahl, PhD** *(Non-Executive Director)* Dr Ramdahl joined the Board in March 2019 as a Non-Executive Director. Dr Ramdahl is a pharmaceutical executive with over 20 years of clinical and development experience. In 2001, he became President and the first CEO of Algeta ASA. When Dr Ramdahl joined Algeta, he was one of six employees and he played an instrumental role in its success, serving in several senior positions within the company through to and post the acquisition of Algeta by Bayer AG in 2014 for US$2.9 billion. Dr Ramdahl has authored more than 40 publications and is a co-inventor of several patents. Dr Ramdahl currently serves as Chairman of Precirix (Belgium) and AppSens AS (Norway). **Dr Gillies O'Bryan-Tear, MBBS FRCP** *(Non-Executive Director)* Dr O'Bryan-Tear joined the Board in April 2019 as a Non-Executive Director. Dr O'Bryan-Tear has over 30 years of experience in the pharmaceutical industry in clinical development, medical management and commercial roles. He has held senior leadership roles in large and small pharmaceutical and biotech companies in the US and Europe and has been involved in multiple product approvals. He was previously the Chief Medical Officer of Algeta ASA. Dr O'Bryan-Tear has been an adviser to several US and European biotech companies and is a member of the Scientific Advisory Boards of Audentes, Inc. (US) and Fusion Pharmaceuticals Inc. (Canada). **Mr Robert Thomas** *(Proposed Non-Executive Director)* It is proposed that Mr Thomas will join the Board upon Listing as a Non-Executive Director. Mr Thomas has a strong background in financial services and capital markets and has considerable expertise in mergers & acquisitions and capital markets including advising on the IPOs of the Commonwealth Bank of Australia and Qantas. Mr Thomas is the former CEO of County NatWest Securities and the former CEO (and then Chairman) of Citi Corporate and Investment Bank Australasia. Mr Thomas has also held the position of Chairman at Australian Wealth Management Ltd (ultimately IOOF Ltd), TAL (Australia's largest life insurance company) and the previously ASX-listed company HeartWare® International Inc. Mr Thomas is the Chairman of AusBio Ltd, Grahger Retail Securities Pty Ltd and ASX-listed Starpharma Holdings Limited, and is a non-executive director of Biotron Limited and O'Connell Street Associates. He is a past non-executive director of Reva Medical Inc. and Virgin Australia.	**Section 6.1.1**

Topic	Summary	For more information
Who are the members of Clarity's senior executive team?	**Dr Alan Taylor, PhD** *(Executive Chairperson)* Refer to Directors of Clarity above. **Dr Colin Biggin, PhD** *(Managing Director and CEO)* Refer to Directors of Clarity above. **Dr Matt Harris, PhD, MBA** *(Chief Scientific Officer)* Dr Harris is the founder, former CEO (2010-2019) and currently Chief Scientific Officer of the Company. Dr Harris has approximately 20 years of combined experience in cancer research, nuclear medicine and business and has a PhD in cancer research from the Australian National University. Dr Harris brings expertise in biotechnology, radiopharmaceuticals, academic research and investment to the Company and focuses on developing the technology behind the Company's products. **Ms Michelle Parker** *(Director of Clinical Operations)* Ms Parker joined the Company in June 2018 and is the Company's Director of Clinical Operations. Ms Parker has over 20 years of experience spanning across nuclear medicine/PET and pharmaceutical industries both in Australia and internationally. Prior to joining the Company, Ms Parker held the position of Head of International Clinical Research Operations at Novartis Australia, a global pharmaceutical company, leading a multi-disciplinary, high performing team of over 35 associates responsible for end-to-end clinical trial execution. **Dr Mike Ironside, PhD** *(Director of Operations)* Dr Ironside joined the Company in June 2020 and is the Company's Director of Operations. Dr Ironside has over 25 years of experience in senior roles in the global pharmaceutical industry, including key positions in Europe, US and Asia at contract development and manufacturing organisations (CDMOs) including Hovione FarmaCiencia SA and Albany Molecular Research Inc. (AMRI), as well as in the pharmaceutical and biotech sector at GlaxoSmithKline plc, Anacor Pharmaceuticals, Inc. and Biosignal, Inc. During his career, Dr Ironside has contributed to the development of more than a dozen approved drugs including Alosetron, Viracept, Vyvanse, Tavaborole and Zejula.	**Section 6.2**

Topic	Summary	For more information
Who are the members of Clarity's senior executive team? (continued)	**Mr Shaemus Gleason** *(Executive Vice President – US Operations)* Mr Gleason joined the Company in May 2021 and is the Company's Executive Vice President of US Operations. Mr Gleason has over 13 years of experience spanning across all facets of targeted radionuclide therapies and diagnostic radiopharmaceuticals. Prior to joining the Company, Mr Gleason was a member of the oncology strategy business unit at Bayer/ Algeta where he was responsible for the technical operations in their phase I targeted alpha therapy development globally. Prior to this, he held a leadership role on the US commercial organisation supporting a marketed product Xofigo® (radium-223 dichloride) for metastatic prostate cancer. **Dr Jennifer Rosenthal, PhD** *(Director of Quality and Regulatory Affairs)* Dr Rosenthal joined the Company in October 2019 and is the Company's Director of Quality and Regulatory Affairs. Dr Rosenthal has over 20 years of management experience in the biotechnology industry, serving in senior director and executive level roles with an oncology focus. She has successfully developed strategy, and managed teams and projects in the areas of regulatory affairs (agencies include US Food and Drug Administration, European Medicines Agency and Australian Therapeutic Goods Administration), clinical trials, quality assurance and intellectual property. **Mr Robert Vickery** *(Chief Financial Officer and Company Secretary)* Mr Vickery joined the Company in July 2019 and is the Company's Chief Financial Officer and Company Secretary. Mr Vickery is a finance executive with over 30 years of experience and has had extensive involvement in life sciences and early stage businesses. Prior to joining the Company, Mr Vickery led the finance function at the previously ASX-listed company, Viralytics Limited, and was a key member of the due diligence target team during the trade sale negotiations and due diligence process with the purchaser of the company (Merck & Co), liaising with legal and investment banking teams, as well as leading the finance, IT and HR integration efforts post acquisition.	**Section 6.2**

1.7. Significant interests of key people and related party transactions

Topic	Summary	For more information
Who are the existing shareholders and what will be their interest in the Company before and after Completion?	The shareholdings of the Existing Shareholders on the Prospectus Date and immediately following Completion of the Offer (excluding any Shares applied for under the Offer and on an undiluted basis i.e. assuming no Options have been exercised) are set out in the table below.	**Section 7.1.4**

	Shareholding as at the Prospectus Date		Shareholding following Completion	
Shareholder	**Shares**	**%**	**Shares**	**%**
TM Ventures Pty Ltd[i]	18,788,460	9.9%	18,788,460	7.3%
Dr Roberts[ii]	17,911,280	9.4%	17,911,280	7.0%
Dr Taylor[iii]	14,066,660	7.4%	14,066,660	5.5%
Charles Morgan[iv]	12,330,220	6.5%	12,330,220	4.8%
GenesisCare Ventures Pty Ltd	10,362,700	5.4%	10,362,700	4.0%
Dr Biggin	419,100	0.2%	419,100	0.2%
Directors[v]	930,000	0.5%	930,000	0.4%
Other senior management	8,775,800	4.6%	8,775,800	3.4%
Other Existing Shareholders	106,834,040	56.1%	106,834,040	41.7%
Investors under the Offer	–	–	65,714,286	25.7%
Total	**190,418,260**	**100%**	**256,132,546**	**100%**

(i) Dr Harris, current Chief Scientific Officer of the Company and former CEO, is a director and shareholder of TM Ventures Pty Ltd. Dr Harris is also a director of Boorris Pty Ltd ATF Boorris Trust and a beneficiary under that trust (whose shareholding in the Company is noted in Section 10.8).

(ii) Dr Roberts holds all of his Shares through the Robwill Trust (Dr Roberts is a director and shareholder of the trustee and a beneficiary of the family trust).

(iii) Dr Taylor holds all of his interests in Shares through the Taylor Family Trust and persons connected to the Taylor Family Trust.

(iv) Mr Morgan is also a shareholder of TM Ventures Pty Ltd (see Section 10.8).

(v) Including the Proposed Director but excluding Dr Roberts, Dr Taylor and Dr Biggin.

Investors under the Offer will hold in aggregate 65,714,286 Shares immediately following Completion (assuming Existing Shareholders do not acquire any Shares under the Offer).

Topic	Summary	For more information
Who are the existing Option holders and what will be their interest in the Company before and after Completion?	The Options held by Option holders of the Company as at the Prospectus Date and immediately following Completion of the Offer (assuming none of these Options are exercised prior to Completion) are set out in the table below.	**Section 7.1.4**

	Prospectus Date		Completion	
Option holder	**Options**	**%**	**Options**	**%**
Company Options	24,626,680	48.2%	24,626,680	48.2%
Adviser Options	918,220	1.8%	918,220	1.8%
China Grand Options	25,543,912	50.0%	25,543,912	50.0%
Investors under the Offer	–	–	–	–

Topic	Summary	For more information
What significant benefits are payable to Directors and other persons connected with the Company or the Offer and what interests do they hold?	For Shares expected to be held by Directors on Completion (excluding any Shares that Directors acquire under the Offer), refer to Section 6.4.2.5 and the table below.	**Sections 6.4.2.5 and 6.4.2.6**

	Interests held at the Prospectus Date		Interests held at Completion	
Director	**Shares**	**Options**	**Shares**	**Options**
Dr Taylor[i]	14,066,660	2,800,000	14,066,660	2,800,000
Dr Biggin	419,100	5,600,000	419,100	5,600,000
Dr Roberts[ii]	17,911,280	200,000	17,911,280	200,000
Ms Robinson	–	200,000	–	200,000
Dr Ramdahl	–	600,000	–	600,000
Dr O'Bryan Tear	–	900,000	–	900,000
Mr Thomas	930,000	–	930,000	–

(i) Dr Taylor holds all of his interests in Shares through the Taylor Family Trust and persons connected to the Taylor Family Trust.

(ii) Dr Roberts holds all of his Shares through the Robwill Trust (Dr Roberts is a director and shareholder of the trustee and a beneficiary of the family trust).

Directors and senior management are entitled to receive the remuneration and fees disclosed in Section 6.4.2 and are entitled to participate in the incentive arrangements described in Section 6.5.

Advisers and other service providers are entitled to fees for services and have other interests as disclosed in Section 6.4.1.

Topic	Summary	For more information
Will any Shares or Options be subject to restrictions on disposal following Completion?	Although the escrow position is subject to ASX review, as a result of the below mentioned mandatory and voluntary escrow restrictions, it is anticipated that, subject to ASX confirmation, approximately 155,355,708 of the Shares on issue in the Company as at Completion[11] (representing 60.65% of the Shares on issue as at Completion) will be subject to escrow restrictions from Listing. **Mandatory Escrow** At the Completion of the Offer, it is expected that approximately 89,559,154 Shares (representing approximately 34.97% of the Shares on issue at Completion[12]) will be mandatorily escrowed from Listing for varying periods with 76,680,986 Shares being escrowed for a period of 24 months (representing approximately 29.94% of the Shares on issue at Completion[13]) and the remaining 12,878,168 Shares being released from escrow during the course of the initial six month period from Listing. It is also expected that 14,218,220 Options will be mandatorily escrowed (representing 27.83% of all Options on issue at Completion[14]) for a period of 24 months from Listing. **Voluntary Escrow** In addition, certain Existing Shareholders of the Company have also agreed to voluntarily escrow their Shares, and have entered into voluntary escrow deeds under which they will be restricted from dealing in a specified number of Shares held by them for a period of six months from Listing. A total of 65,796,554 Shares held by these Existing Shareholders will be voluntarily escrowed (representing 25.69% of the Shares on issue at Completion[15]) for this six month period. No Options will be voluntarily escrowed.	**Section 10.4**

11. Assumes 256,132,546 Shares on issue as at Completion and no Options have been exercised.
12. Assumes 256,132,546 Shares on issue as at Completion and no Options have been exercised.
13. Assumes 256,132,546 Shares on issue as at Completion and no Options have been exercised.
14. Assumes 51,088,812 Options on issue as at Completion and no Options have been exercised.
15. Assumes 256,132,546 Shares on issue as at Completion and no Options have been exercised.

Topic	Summary	For more information
Are there any related party transactions?	The Company has entered into the following related party transactions with the Directors and the Proposed Director on arms' length terms: • letters of appointment with each of its Non-Executive Directors and the Proposed Director (refer to Section 6.4.2.1 for details); • employment agreements with its Executive Directors (refer to Section 6.4.2.8 for details); • deeds of indemnity, insurance and access with each of its Directors and the Proposed Director (refer to Section 6.4.2.4 for details); and • a Consulting Services Agreement with O'Bryan-Tear Consulting Ltd, an entity controlled by Dr O'Bryan-Tear, pursuant to which Dr O'Bryan Tear provides consulting services to the Company for a consulting fee of US$30,000 per annum. The Consulting Services Agreement commenced on 1 August 2018 and is due to expire on 31 December 2021. In addition, Ms Robinson is the General Manager of Business Development at ANSTO. ANSTO holds 3,599,920 Shares (representing 1.89% of the undiluted issued share capital of the Company as at the Prospectus Date[16]) and is a supplier of research services to the Company. Approximately $65,000 was paid to ANSTO by the Company in FY2020. ANSTO is not considered a related party of the Company as Ms Robinson does not hold a position of control over ANSTO.	**Section 6.7**

1.8. Overview of the Offer

Topic	Summary	For more information
Who is the issuer of this Prospectus?	Clarity Pharmaceuticals Ltd ABN 36 143 005 341 (which is expected to have the ASX ticker code "CU6").	**Section 7**
What is the Offer?	This Prospectus relates to an initial public offering of new Shares to be issued by the Company at an Offer Price of $1.40 per Share. A total of 65.7 million Shares will be available under the Offer. These Shares will be available for investors under the Broker Firm Offer, the Institutional Offer and the Priority Offer. The Offer is expected to raise gross proceeds of approximately $92 million from the issue of new Shares by the Company and for the Company's benefit.	**Section 7.1**

16. Assumes 190,418,260 Shares being on issue at the Prospectus Date and that no Options have been exercised.

01 Investment Overview continued

<table>
<tr><th>Topic</th><th>Summary</th><th>For more information</th></tr>
<tr><td>Why is the Offer being conducted?</td><td>The purpose of the Offer is to:
support the Company's growth strategy, as further detailed in this Prospectus, by advancing and funding the clinical development of its three lead products, $^{64/67}$Cu SARTATE™, $^{64/67}$Cu SAR-Bombesin and $^{64/67}$Cu SAR-bisPSMA, through their respective phases of clinical trials in Australia and the US;
provide funding and financial flexibility for general corporate purposes;
assist with future growth opportunities;
broaden Clarity's shareholder base and provide a liquid market for Shares;
provide Clarity with access to the public equity capital markets, in order to improve its financial flexibility to pursue further growth opportunities and take advantage of the associated benefit of creating an increased profile that arises from being listed on the ASX; and
pay transaction costs associated with the Listing and this Prospectus.</td><td>Section 7.1.2</td></tr>
<tr><td>What are the sources and uses of the proceeds of the Offer?</td><td>The Offer is expected to raise gross proceeds of approximately $92 million.

<table><tr><th>Sources of funds</th><th>A$ million</th></tr><tr><td>Gross cash proceeds received by Clarity under the Offer from the issue of Shares</td><td>$92.0</td></tr><tr><td>Existing cash reserves as at the Prospectus Date</td><td>$17.6</td></tr><tr><td>Total sources</td><td>$109.60</td></tr></table>
<table><tr><th>Uses of funds</th><th>A$ million</th></tr><tr><td>Pre-Clinical</td><td>$2.7</td></tr><tr><td>Clinical</td><td>$84.0</td></tr><tr><td>Regulatory</td><td>$5.7</td></tr><tr><td>Patents</td><td>$1.4</td></tr><tr><td>Corporate</td><td>$10.4</td></tr><tr><td>Costs associated with the Offer[i]</td><td>$5.4</td></tr><tr><td>Total uses</td><td>$109.6</td></tr></table>
(i) Excluding GST.</td><td>Section 7.1.3</td></tr>
<tr><td>What is the consideration payable for the Shares?</td><td>Successful Applicants under the Offer will pay the Offer Price, being $1.40 per Share.</td><td>Section 7.2</td></tr>
</table>

Topic	Summary	For more information
Will the Shares be quoted on ASX?	The Company will apply to the ASX for admission to the Official List and quotation of its Shares on the ASX under the ticker code 'CU6'. The application for admission will be made no later than seven days after the Prospectus Date. Completion of the Offer is conditional on the ASX approving the admission 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 will be refunded without interest as soon as practicable in accordance with the requirements of the Corporations Act. Clarity will be required to comply with the ASX Listing Rules, subject to any waivers obtained by it from time to time. The ASX takes no responsibility for this Prospectus or the investment to which it relates. The fact that the ASX may admit Clarity to the Official List is not to be taken as an indication of the merits of Clarity, the Offer, or the Shares offered under this Prospectus.	**Section 7.10.1**
How is the Offer structured?	The Offer comprises the following components: • The **Retail Offer**, comprising: – The **Broker Firm Offer**, which is an offer to Australian resident retail clients of Brokers who have received a firm allocation of Shares from their Broker (see Section 7.3); – The **Priority Offer**, which is open to selected investors in Australia nominated by the Company (see Section 7.4); and • The **Institutional Offer**, which consists of an offer to Institutional Investors in Australia and other Permitted Jurisdictions (see Section 7.7).	**Section 7.1.1**
Is the Offer underwritten?	The Joint Lead Managers have fully underwritten the Offer pursuant to the Underwriting Agreement.	**Section 10.11.1**
What is the allocation policy?	The allocation of Shares between the Institutional Offer and Retail Offer (including the Broker Firm Offer and the Priority Offer) was determined by agreement between the Company and the Joint Lead Managers, having regard to the allocation policies outlined in Sections 7.3.4, 7.4.4 and 7.7.2.	**Sections 7.3.4, 7.4.4 and 7.7.2**
Is there any brokerage, commission or stamp duty payable by Applicants?	No brokerage, commission or stamp duty is payable by Applicants on the acquisition of Shares under the Offer. See Section 10.11.1 for details of various fees payable by Clarity to the Joint Lead Managers and by the Joint Lead Managers to certain Brokers (on behalf of the Company).	**Sections 7.2 and 10.11.1**
Are there any tax considerations for Australian investors?	Yes. Refer to Section 10.16 and note that 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.	**Section 10.16**

Topic	Summary	For more information
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 or about Wednesday, 25 August 2021. Refunds (without interest) to Applicants who make an Application and are scaled back (or otherwise receive Shares having a lesser value than the amount of Application Monies they have paid) will be made as soon as possible after Completion of the Offer.	**Section 7.2**
How can I apply?	Applicants under the Broker Firm Offer should contact their Broker to request a Prospectus and Broker Firm Offer Application Form. Applicants under the Priority Offer may apply for Shares by following the instructions in their personalised invitation to participate in the Priority Offer. To the extent permitted by law, an Application by an Applicant may not be varied and is irrevocable.	**Sections 7.3.2 and 7.4.2**
Where can I find more information about this Prospectus or the Offer?	All enquiries in relation to this Prospectus should be directed to the Clarity Offer Information Line on 1800 645 237 (within Australia) or +61 1800 645 237 (outside Australia) between 8.30am to 5.30pm (Sydney time), Monday to Friday (Business Days only) if you require assistance to complete the Application Form, require additional copies of this Prospectus or have any questions in relation to the Offer. 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 stockbroker, solicitor, accountant, financial adviser or other independent professional adviser before deciding whether to invest.	**Section 7.2**
Can the Offer be withdrawn?	Yes. The Company reserves the right not to proceed with the Offer at any time before the allocation of Shares to Successful Applicants. If the Offer does not proceed to Completion, Application Monies will be refunded. No interest will be paid on any Application Monies refunded as a result of the withdrawal of the Offer.	**Section 7.9**

02

Industry Overview

02 Industry Overview

2.1. Introduction

Clarity is a clinical stage radiopharmaceutical company focused on the diagnosis and therapy of cancer in children and adults. Clarity operates in the pharmaceutical industry with a focus on the global oncology and radiopharmaceutical markets.

This Section covers five key topics:

1. an overview of cancer, cancer diagnosis and therapy;
2. the field of radiopharmaceuticals;
3. an overview of theranostics and the pairing of radioisotopes;
4. the key regulatory processes relevant to Clarity and its portfolio of products; and
5. an overview of the indications of cancer which Clarity is currently targeting with its products.

The market data and analysis in this Section primarily focuses on the United States of America (**US**). The US accounts for a significant portion of global expenditure in oncology, making it the leading region for the development and commercialisation of new forms of cancer diagnosis and treatment.

2.2. An introduction to cancer

2.2.1. Cancer[17]

Cancer is the result of cell mutation causing unregulated cell growth and encompasses a collection of related diseases. Cancer can occur almost anywhere in the human body, and cells that continue to multiply in an uncontrolled way can form growths, known as tumours. Tumours can be benign (noncancerous growths) or malignant (cancerous growths).

When left unchecked, the unregulated cells can spread to nearby organs. Cancer may spread regionally, forming a lesion, or through the blood or lymph system to distant parts of the body, where it may form new tumours. This spread to distant parts of the body is known as "metastasis".

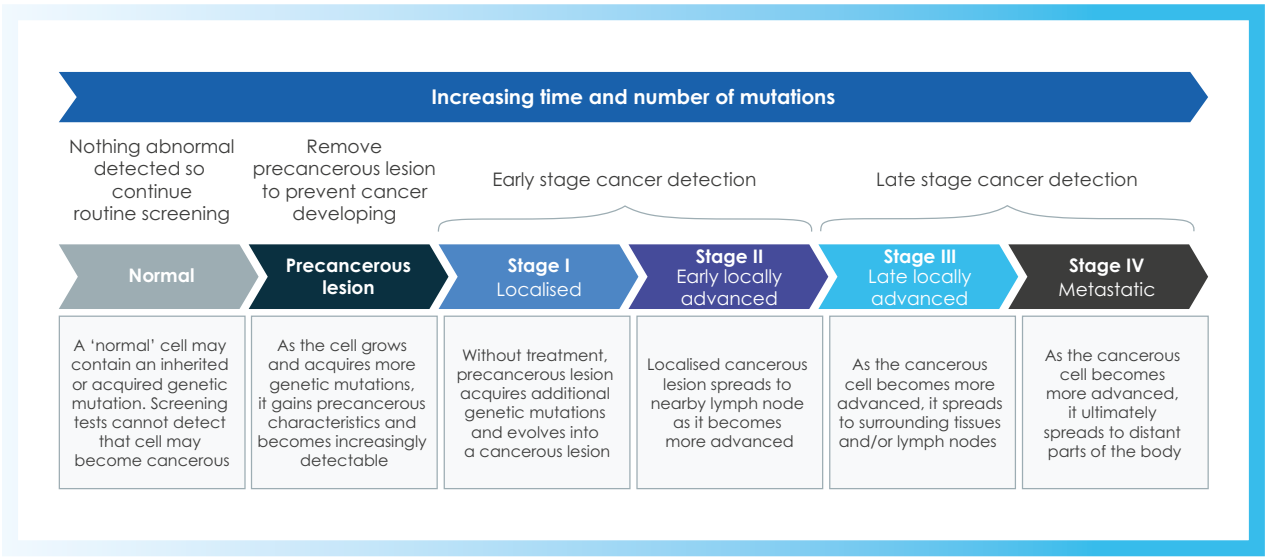
The transformation of normal cells into tumour cells is a multi-stage process that generally progresses from a pre-cancerous lesion to a malignant tumour. These changes are the result of the interaction between a person's genetic factors and three categories of external agents, being:

- physical carcinogens: such as ultraviolet and ionising radiation;
- chemical carcinogens: such as asbestos, components of tobacco smoke, aflatoxin (a food contaminant), and arsenic (a drinking water contaminant); and
- biological carcinogens: such as infections from certain viruses, bacteria, or parasites.

Over time, cancer cells spread and continue to mutate. At diagnosis, cancer can be categorised into four stages according to its size, location and spread to other parts of the body, as outlined in Figure 1.

17. World Health Organization <https://www.who.int/news-room/fact-sheets/detail/cancer>.

Figure 1: Stages of cancer[18]



2.2.2. The societal impact of cancer

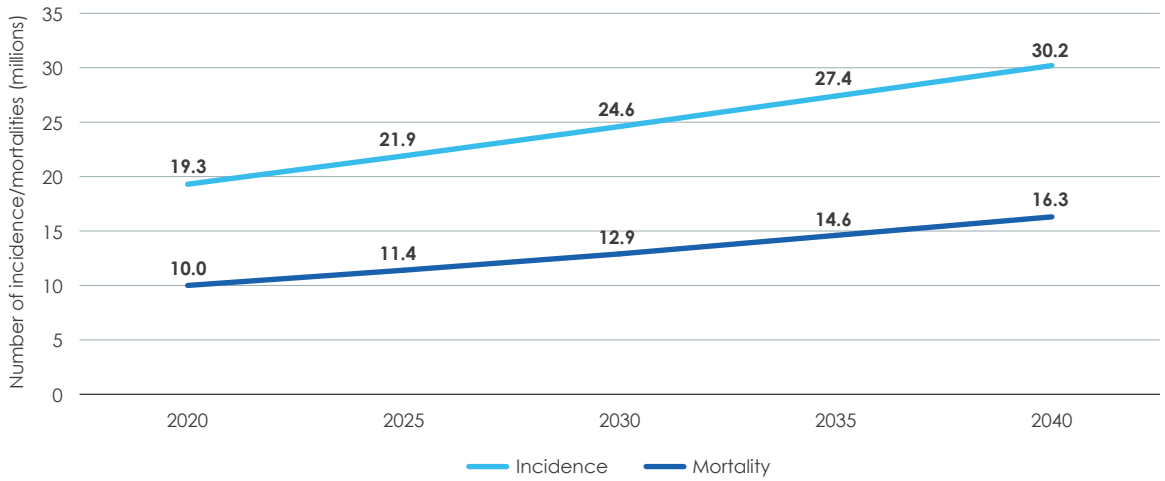
Cancer is a leading cause of death worldwide[19]. As shown in Figure 2, cancer caused approximately 10.0 million deaths globally in 2020 and this is due to rise to approximately 16.3 million deaths per annum by 2040 (63% increase). New cancer cases are expected to rise from 19.3 million globally in 2020 to 30.2 million by 2040 (56% increase).

In the US in 2021, there will be an estimated 1.9 million new cases of cancer diagnosed and 608,570 cancer deaths.[20] New cases of cancer in the US are forecast to rise to 3.1 million per annum by 2040[21]. The growth in new cases of cancer being diagnosed is driven by several factors:

- an ageing population, with people in the US aged 65 or over expected to increase from 54 million in 2020 to 80 million in 2040[22];
- various environmental, lifestyle and social factors such as obesity and smoking; and
- advancements in new technology to identify and diagnose new forms of cancer which were previously undiagnosed.

18. American Association for Cancer Research Cancer Progress Report 2020, <https://cancerprogressreport.aacr.org/progress/cpr19-contents/cpr19-screening-for-early-detection/>.
19. World Health Organization <https://www.who.int/news-room/fact-sheets/detail/cancer>.
20. <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2021.html>.
21. <https://gco.iarc.fr/tomorrow/en/dataviz/trends>.
22. Urban Institute, <https://www.urban.org/policy-centers/cross-center-initiatives/program-retirement-policy/projects/data-warehouse/what-future-holds/us-population-aging>.

Figure 2: Estimated number of cancer incidence cases and deaths from 2020 – 2040[23]



2.2.3. The economic impact of cancer

The economic impact of cancer is significant and is expected to continue to increase. The costs of cancer are both direct and indirect:

- **Direct medical costs:** total of all healthcare expenditure; and
- **Indirect costs:** such as lost earnings due to missed work from illness or premature death.

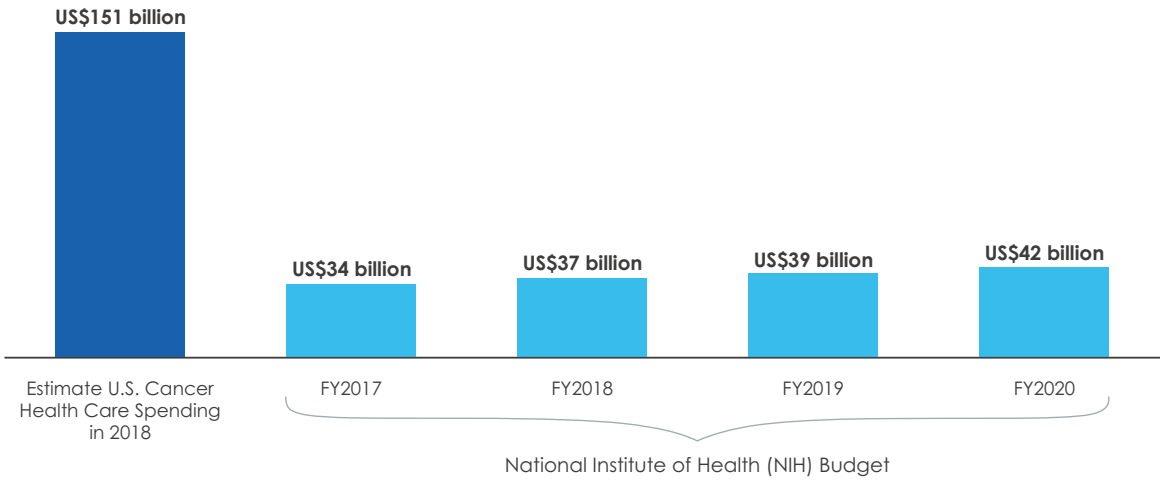
Cancer-related direct medical costs in the US were US$183 billion in 2015 and are projected to increase to US$246 billion by 2030[24]. The average cost of new medicines continues to grow and was estimated at US$149,000 per average patient treatment year in 2018[25].

Despite the growing number of cancer drugs on the market, there is still a significant unmet need for more efficacious cancer treatments.

Figure 3 shows the direct cost of treating cancer is significantly above the National Institute of Health (NIH) budget in the US.

23. <https://gco.iarc.fr/tomorrow/en/dataviz/trends>.
24. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf>.
25. <https://www.iqvia.com/insights/the-iqvia-institute/reports/global-oncology-trends-2019>.

Figure 3: The direct costs of cancer care in the United States[26]



Indirect cancer care costs include lost income due to time away from work during cancer treatment and recovery. In 2015, research showed the overall lost earnings related to cancer was US$94.4 billion, and the average lost earnings per cancer death was an estimated US$191,900.[27]

2.3. Cancer care

Cancer care involves both diagnosing and treating cancer. This Section provides an overview of the key methods by which cancer is currently diagnosed and treated. The oncology market comprises those companies which are involved in either, or both, the diagnosis and treatment of cancer. Clarity is developing and trialling both diagnostic and therapeutic products.

2.3.1. Cancer diagnosis[28,29]

There are four main ways to diagnose cancer, and often a combination of these approaches is used to assess the type, location and size of the cancer, as outlined in Table 1.

26. American Association for Cancer Research Cancer Progress Report 2020.
27. American Cancer Society (2019). The costs of cancer in 2015: 8.7 million years of life and $94 billion in lost earnings: New analysis identifies which cancers and which states are associated with the greatest cost. ScienceDaily. Retrieved October 31, 2019 from <www.sciencedaily.com/releases/2019/07/190705102948.htm>.
28. <https://www.mayoclinic.org/diseases-conditions/cancer/diagnosis-treatment/drc-20370594#:~:text=Imaging%20tests%20used%20in%20diagnosing,for%20testing %20in%20the%20laboratory>.
29. <https://www.cancer.gov/about-cancer/diagnosis-staging/diagnosis#lab-tests>.

Table 1: Types of cancer diagnosis

Type of diagnosis	Description
Physical Examination	Cancer may be identified through a physical examination in which doctors look for lumps on the body which indicate the presence of cancer. Abnormalities like changes in skin colour or the enlargement of organs may indicate the presence of cancer.
Laboratory Testing	A number of laboratory tests may be performed to identify abnormalities which may indicate the presence of cancer. There are a wide variety of tests used, requiring either a sample of blood, urine, other bodily fluid or tissue. Different tests may be used for different types of cancer.
Imaging	Imaging is a non-invasive method of diagnosing cancer. Through a series of imaging techniques, doctors can examine bones and internal organs for the presence of cancerous cells/tumours. A variety of tests may be used, including computerised tomography (CT) scans, bone scans, single photon emission computed tomography (SPECT) scans, positron emission tomography (PET) scans, magnetic resonance imaging (MRI) and others. SPECT and PET scans both involve the use of radioactive tracers. The tracers are liquid substances accumulating in tumour tissue after injection that release low levels of radiation which can be picked-up by these specialist imaging equipment.[30] As cancerous cells may absorb more or less of the tracer than normal tissues, it can be used to visualise where the cancer is located since there will be increased cell activity and tracer uptake (or reduced uptake compared to normal tissue depending on what tracer is used).[31] In cancer patients, these scans aim to determine the biology and/or stage of the cancer, and are used to help determine an appropriate treatment. Clarity's radiopharmaceutical diagnostic products fall within this category. These are discussed in Section 3.5.
Biopsy	A biopsy is a surgical procedure in which a sample of the cancerous cells is collected for testing in a laboratory. The collection can happen in a number of ways and is often dependent on the type of cancer and its location. The test aims to determine the biology and/or stage of the cancer and is used to help determine an appropriate treatment.

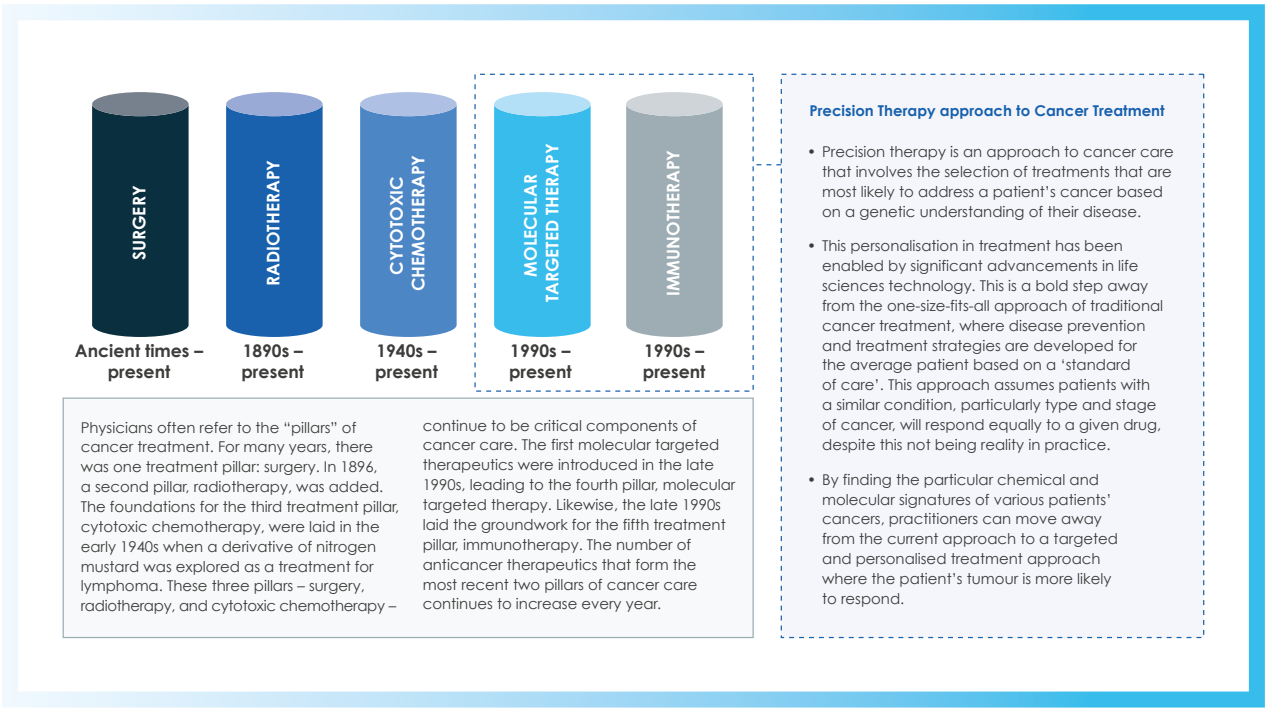
2.3.2. Cancer treatment

There are several factors that influence a cancer treatment regimen including the type, size and stage of the cancer in addition to individual patient factors such as age and overall health status.

There are five key pillars in cancer treatment, which may be used together or in isolation, namely surgery, radiotherapy, chemotherapy, molecular targeted therapy and immunotherapy, as shown in Figure 4. Depending on the case, treatment may aim for complete cancer removal, regional control of the cancer, prevention of future metastases and improving the patient's quality of life and long-term chances of survival.

30. <https://www.nibib.nih.gov/science-education/science-topics/nuclear-medicine>.
31. <https://www.cancer.org/treatment/understanding-your-diagnosis/tests/nuclear-medicine-scans-for-cancer.html#:~:text=These%20scans%20use%20liquid%20substances,the%20tracer%20than%20normal%20tissues>.

Figure 4: The pillars of cancer treatment[32]



2.3.2.1. Treatment via surgery

Surgery has been a mainstay of cancer treatment and is often performed with an intent to remove all cancerous tissue. In the circumstance where the cancerous tissue cannot be fully removed, surgery can be effective in reducing the size of the tumours. This process is known as tumour debulking. Tumour debulking may also increase the chance that other cancer treatment methods are successful. However, surgery is often not enough to totally remove a cancer or stop it spreading throughout the body.

2.3.2.2. Treatment via radiotherapy

Radiation therapy (radiotherapy) uses high-energy radiation to control and eliminate cancer. Various types of radiation may be used, including x-rays, high-energy beams, gamma rays, electron beams or heavy ions (most commonly protons). Radiotherapy destroys cancerous cells by damaging the cell DNA with the intent to destroy or injure cancer cells so they cannot continue to grow and multiply. Typically, high dose radiation is applied to a tumour while attempting to minimise exposure to healthy surrounding cells.

Radiotherapy can be used for localised cancers or cancers that have spread, but it is typically used to destroy cancerous cells in one part of the body. It is also used in a variety of treatment settings, including destroying residual cancerous cells following surgery, palliatively to reduce pain and control symptoms when cure is not possible, or to reduce tumour size or growth prior to surgery.

The most common form of radiotherapy is external beam radiation therapy (EBRT), which delivers several beams of high-energy x-rays to the tumour from outside the body. A newer technology is intensity-modulated radiation therapy (IMRT), which delivers the highest dose of radiation to the target while sparing surrounding healthy tissue[33]. Another class of radiotherapy is hadron therapies, such as proton therapy, which utilise a beam of protons to irradiate cancers.

32. American Association for Cancer Research Cancer Progress Report 2020, amended by Clarity Management.
33. Mayo Clinic <https://www.mayoclinic.org/tests-procedures/external-beam-radiation-for-prostate-cancer/about/pac-20384743>.

2.3.2.3. Treatment via chemotherapy

Chemotherapy uses chemically formulated pharmaceuticals that inhibit a cell's ability to divide and multiply. As cancer cells often divide faster than normal cells, they are particularly sensitive to chemotherapy drugs.

Other rapidly dividing normal healthy cells such as hair follicles, blood cells, and cells inside the mouth and bowel are also sensitive to chemotherapy. As a result, chemotherapy can cause severe side effects that negatively impact the patient's quality of life, some of which persist beyond treatment.[34]

Chemotherapies are delivered intravenously or orally and are typically administered in courses with rest periods in between each dose. Chemotherapy is used to treat cancer throughout the whole body, which makes it a valuable tool for the treatment of cancer that has metastasised. Chemotherapies are used in a variety of treatment settings, including reducing the size of a tumour, relieving symptoms or controlling cancer growth.

2.3.2.4. Treatment via Molecular Targeted Therapy

Molecular Targeted Therapies treat cancer by targeting molecules that control how cancer cells grow, divide and spread.[35] Most Molecular Targeted Therapies are small-molecule drugs or monoclonal antibodies.[36]

Small-molecule drugs are small enough to enter cells easily, so they are used for targets that are inside cells.[37] The targets are normally enzymes and proteins that control the growth of cancer cells.[38]

Monoclonal antibodies, also known as therapeutic antibodies, are proteins produced in a laboratory.[39] These proteins are designed to attach to specific targets found on cancer cells. Some monoclonal antibodies mark cancer cells so that they will be better seen and destroyed by the immune system overlapping with "Immunotherapy" (refer Section 2.3.2.5),[40] some directly stop cancer cells from growing or cause them to self-destruct, and others carry toxins to cancer cells.[41]

Molecular Targeted Therapy is a personalised approach to cancer treatment as the molecular targets of cancers may be known, unknown or different within different individuals.[42] The process of identifying the correct cancer pathology and selecting the right treatment requires close work with pathologists.[43] For this reason, Molecular Targeted Therapy is regarded as the key foundation of "Precision Therapy".

2.3.2.5. Treatment via immunotherapy

Immunotherapies are a significant recent advancement in cancer treatment. Immunotherapy works by educating the immune system to recognise and kill cancer cells in the same way it fights bacterial and viral infections. Immunotherapy works by recognising and targeting a specific protein that is only found on cancer cells.

Clarity's therapeutic products

Clarity's radiopharmaceutical therapeutic products fit uniquely into two of the five pillars of cancer treatment. They can be thought of as a combination of Molecular Targeted Therapy and radiotherapy as they involve the use of molecular targeted drugs linked to radioisotopes. The former binds specific proteins on cancer cells, which assists with achieving accurate targeting of cancerous tissue, while radioisotopes attached to them deliver radiation which aims to kill the cancer in a localised manner.

34. American Association for Cancer Research <http://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/chemotherapy-side-effects.html>.
35. <https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies>.
36. National Institute of Biomedical Imaging and Bioengineering (NIBIB) <https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/targeted-therapies-fact-sheet>.
37. <https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies>.
38. <https://www.cancer.org.au/cancer-information/treatment/targeted-therapy>.
39. <https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies>.
40. National Institute of Biomedical Imaging and Bioengineering (NIBIB). <https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/targeted-therapies-fact-sheet>.
41. <https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies>.
42. <https://www.pennmedicine.org/cancer/navigating-cancer-care/treatment-types/targeted-therapy>.
43. <https://www.pennmedicine.org/cancer/navigating-cancer-care/treatment-types/targeted-therapy>.

2.3.2.6. Combination of cancer treatments

While the types of cancer therapies discussed above have had some success in treating cancer on their own, in practice the most effective way to treat cancer is to use several methods in combination. For example, using surgery can remove the bulk of the cancer cells from a solid tumour in a patient, but would be unlikely to entirely remove tumours that have spread. Further treatment with immunotherapy, chemotherapy, radiotherapy or Molecular Targeted Therapy can be used to eliminate the cancer cells that could not be removed with surgery. Most types of cancer therapies are employed together to effectively treat a patient rather than being used on their own.

2.4. Radiopharmaceuticals[44]

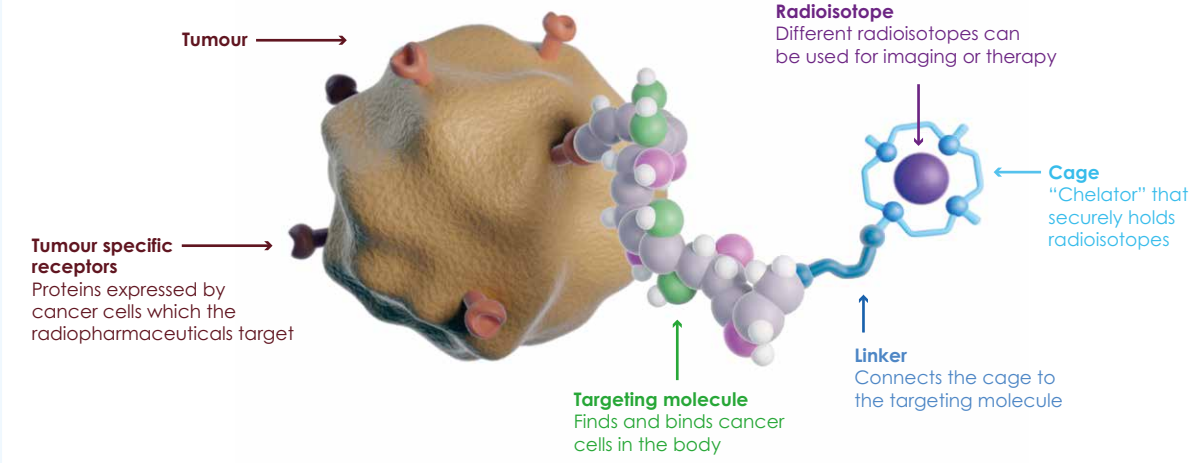
2.4.1. Introduction to targeted radiopharmaceuticals

Radiopharmaceuticals utilise the radiation emitted by different radioisotopes to allow diagnosis and treatment of disease. Diagnostic radiopharmaceuticals allow visualisation of the sites of disease in the body by utilising special equipment, such as Single Photon Emission Computed Tomography (SPECT) cameras and PET cameras for imaging. Therapeutic radiopharmaceuticals use a more powerful radioisotope which has the ability to kill the cancer cells.

To create targeted radiopharmaceuticals that employ radiometals, radioisotopes need to be held in a special cage (otherwise known as a chelator) which is connected to a targeting molecule using a linker (see Figure 5). The targeting molecules can either be a biological targeting molecule such as a peptide or an antibody, or a small molecule of chemical origin, which bind to specific receptors on cancer cells. The targeting molecule is the part that delivers the radioisotope to the disease site. Typically, targeting molecules used in radiopharmaceuticals bind to receptors that are present at high levels on the disease site, but are not present, or present at low levels, on healthy tissues. This approach allows for the maximisation of effectiveness whilst minimising side effects of the treatment.

There are many target receptors that have been discovered on cancer cells with some receptors being specific to certain cancers and others found on a range of cancers. Different radiopharmaceuticals are developed to target different receptors. For example, Clarity has three lead radiopharmaceutical products that target three distinct receptors and a range of cancer indications.

Figure 5: The targeting of tumours with radiopharmaceutical products



44. National Institute of Biomedical Imaging and Bioengineering (NIBIB) <https://www.nibib.nih.gov/science-education/science-topics/nuclear-medicine>.

Once a radiopharmaceutical product is administered into the human body intravenously, the targeting molecule finds and binds specific receptors on cancer cells, accumulating at the tumour site, whilst the radioisotope attached emits radiation, helping to visualise the cancer via an imaging scan or to kill the cancer cells with a therapeutic radioisotope (see Figure 6).

Figure 6: A targeted radiopharmaceutical accumulates at cancer sites and emits radiation

2.4.2. Growth of radiopharmaceuticals in the US

The radiopharmaceuticals market is expected to grow strongly over the next 20 years. Two of the main reasons for this expected growth are:

- Expansion of the user base who can prescribe radiopharmaceuticals
- Positive US reimbursement environment

Expansion of the user base who can prescribe radiopharmaceuticals

One of the reasons for the growth in this oncology sector is the rising number of radiopharmaceuticals in development from a very low base. It is also due to the increasing acceptance and broader use of radiopharmaceuticals by oncologists.

Traditionally, radiopharmaceuticals were predominately administered by nuclear medicine physicians. Since 2008, however, radiation oncologists can also become certified to administer radiopharmaceuticals.[45] Despite this change, radiopharmaceuticals are not commonly administered in an oncologist's practice due to challenges with the current generation of products including product supply issues and the investment required in infrastructure and personnel.[46] These are the issues that Clarity is looking to address by implementing central manufacturing and broad distribution of its range of products.

45. § 35.396 Training For The Parenteral Administration Of Unsealed Byproduct Material Requiring A Written Directive. | NRC.gov, <https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0396.html>.
46. Meeting of the Advisory Committee on the Medical Uses of Isotopes, Monday, July 16, 2018, full transcript page 62.

In this context, an important development has been that the US Nuclear Regulatory Commission is considering transformative changes to allow medical oncologists and urologists to also administer radiopharmaceuticals to patients[47]. If this change was to be made, it would increase the number of physicians who could prescribe radiopharmaceuticals to their cancer patients and Clarity believes that this would assist in increasing the market size and opportunities for its products.

Positive US reimbursement environment

The Centre for Medicare & Medicaid Services in the US is considering capping the cost of certain drugs and procedures. Radiopharmaceuticals are specifically exempt from the proposed Most Favoured Nation pricing model[48], which would make them a preferable service line for oncologists to offer. Should this exemption be implemented, Clarity believes that it should assist in facilitating private practices to utilise new radiopharmaceuticals, especially ready-to-use centrally manufactured products, such as those being developed by Clarity (see Section 3.7 for more information on the manufacturing and supply advantages of Clarity's products).

2.4.3. Radioisotopes

Radioisotopes (also known as radionuclides) are unstable atoms that contain an excess of either neutrons or protons. In order to become more stable, they emit radiation from the atom. The radiation may be emitted in the form of alpha particles, beta minus particles, beta plus particles or gamma rays which are described further in Table 2.

Radioisotopes that emit alpha particles and beta minus particles are used as therapeutic radioisotopes, whilst radioisotopes that emit beta plus particles and gamma rays are used in diagnostic applications.

Table 2: Types of radioisotopes

Type of radiation	Symbol	Use in radiopharmaceuticals	Example radioisotopes
Alpha particles	α	alpha therapy	Actinium-225 (^{225}Ac) Radium-223 (^{223}Ra)
Beta minus particles	$\beta-$	beta therapy	Copper-67 (^{67}Cu) Lutetium-177 (^{177}Lu)
Beta plus particles	$\beta+$	PET imaging	Copper-64 (^{64}Cu) Gallium-68 (^{68}Ga)
Gamma rays	γ	SPECT/planar imaging	Indium-111 (^{111}In) Technetium-99m (^{99m}Tc)

2.4.4. Diagnostic radiopharmaceuticals

Diagnostic radiopharmaceutical products contain different radioisotopes and targeting molecules depending on the purpose of a scan and the disease that is being diagnosed. The targeted accumulation of the product creates a visual map of the patient's disease inside the body through using PET and SPECT imaging, providing important information about tumour size, location, spread and metabolic activity as outlined below in Section 2.4.4.1. It is highly useful in initial diagnosis, monitoring the progression of the disease and examining the response to a range of treatments, including surgery and chemotherapy.

47. Rulemaking plan for training and experience requirements for unsealed byproduct material – SECY-20-0005 January 13, 2020.
48. Federal Register: Most Favored Nation (MFN) Model. A Rule by the Centers for Medicare & Medicaid Services on 11/27/2020. <https://www.federalregister.gov/documents/2020/11/27/2020-26037/most-favored-nation-mfn-model>.

2.4.4.1. Imaging instruments in diagnostic radiopharmaceuticals

SPECT and PET are two common imaging modalities in nuclear medicine, as outlined in Table 3. The information gathered from SPECT and PET scans, which show how the radiopharmaceuticals are metabolised in a patient's body, is used in conjunction with other imaging techniques, such as Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) scans, which take images of the body's structure, tissues and organs.

The combination of PET-CT and SPECT-CT provide a co-registered image of the patient combined with the location of the radiopharmaceutical and allows clinicians to visualise where the drug goes in the body via a 3D model on a screen. This provides valuable clinical data for cancer diagnosis, such as seeing the extent of the patient's disease and monitoring the spread of the cancer throughout the body.

Table 3: Nuclear medicine imaging techniques[49]

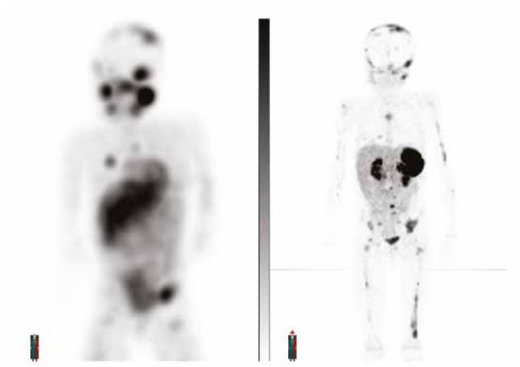
Imaging technique	Description
Single Photon Emission Computed Tomography (SPECT)[50]	• A three-dimensional nuclear medicine imaging technique combining the information gained from scintigraphy (gamma scan) • Allows the distribution of the radionuclide to be displayed in a three-dimensional manner offering better detail, contrast and spatial information than planar nuclear imaging alone • SPECT scans measure gamma ray emissions from the tracers that have been injected into the body • Less expensive than PET, but gives poorer contrast and spatial resolution compared to PET
Positron Emission Tomography (PET)[51]	• Modern non-invasive three-dimensional imaging technique for quantification of radioactivity in vivo • Involves the intravenous injection of a positron-emitting radiopharmaceutical, waiting to allow for systemic distribution, and then scanning for detection and quantification of patterns of radiopharmaceutical accumulation in the body • More expensive than SPECT but gives better contrast and spatial resolution compared to SPECT

PET represents a significant advancement in nuclear medicine imaging quality

The physical properties of positrons used in PET imaging allow for better quality contrast and spatial resolution compared to SPECT, as shown in Figure 7.

49. <https://www.nibib.nih.gov/science-education/science-topics/nuclear-medicine>.
50. <https://radiopaedia.org/articles/single-photon-emission-computed-tomography-spect?lang=us>.
51. <https://radiopaedia.org/articles/positron-emission-tomography?lang=us>.

Figure 7: ^{123}I MIBG SPECT scan compared to PET scan of Clarity's ^{64}Cu SARTATE™ product



SPECT scan
^{123}I MIBG
Current Standard of Care

PET scan
^{64}Cu SARTATE™
Clarity's product

2.4.4.2. Radioisotopes in diagnostic radiopharmaceuticals

The advantages and limitations of most commonly used diagnostic radioisotopes are outlined in Table 4 below.

Table 4: Advantages and limitations of most commonly used diagnostic radioisotopes

Diagnostic radioisotope	Advantages	Disadvantages
Gallium-68 (^{68}Ga) *Refer to Table 7 for further detail*	• PET agent (see Section 2.4.4.1 for more details) • Available to sites without a cyclotron by eluting from Ge-68/Ga-68 generators	• Half-life of ~1 hour creates supply and manufacturing challenges • Requires high-cost generators for production • In-house production at the treatment sites and elution process can create additional radiation safety compliance concerns
Iodine-123 (^{123}I)	• Cheaper and easier to access than ^{124}I • ^{123}I labelled diagnostic products can be used as a companion diagnostic with ^{131}I labelled therapeutic products • Patient is administered and imaged on the same day	• Requires a high energy cyclotron for production • SPECT agent (see Section 2.4.4.1 for more details) • Prolonged scan acquisition sessions that increase the time spent in the SPECT scanner • Need for pharmacological thyroid protection • Strict radiation safety requirements due to volatility of iodine

Diagnostic radioisotope	Advantages	Disadvantages
Iodine-124 (^{124}I)	• PET agent (see Section 2.4.4.1 for more details) with greater lesion detection • Favourable supply logistics due to 4.2 day half-life of ^{124}I • Longer half life enables imaging at later time points necessary for tracers with slow pharmacokinetics such as antibodies	• High radiation exposure for diagnostic purposes • The complex decay scheme of ^{124}I results in a relatively poorer image quality compared to ^{18}F and ^{68}Ga based radiopharmaceuticals • Need for pharmacological thyroid protection • Long half-life leads to inconvenience of a next-day imaging schedule, with no option for same-day imaging • Cyclotron-produced ^{124}I-MIBG is not widely available for clinical use, which is accompanied by high costs and limited experience • Strict radiation safety requirements due to volatility of iodine
Fluorine-18 (^{18}F)	• ^{18}F is the most commonly used PET imaging agent (see Section 2.4.4.1 for more details) • Excellent image resolution • Easily produced in a standard cyclotron	• Half-life of <2 hours creates supply and manufacturing challenges • Limited manufacturing bandwidth in certain geographies for significant future growth
Zirconium-89 (^{89}Zr)	• PET imaging agent (see Section 2.4.4.1 for more details) • Half-life that supports centralised manufacture of products (78.4 hours) • Cyclotron produced and relatively low cost	• Not possible to administer and image on the same day due to long half-life, which requires patients to re-visit the hospital for imaging days after administration • Lower image resolution compared to other PET imaging agents • Effective radiation dose to patient is high for a diagnostic scan • Mainly used with antibodies, which makes for high-cost diagnostic agents • Limited number of promising ^{89}Zr-based tracers in clinical use to date

Diagnostic radioisotope	Advantages	Disadvantages
Copper-64 (^{64}Cu) *Refer to Table 7 for further detail*	• PET imaging agent (see Section 2.4.4.1 for more details) • Excellent image resolution • Cyclotron produced in significant volumes at very high purity • Half life of 12.7 hours provides ample time for shipment to central radiopharmacy and delivery of ready to use products to treatment centres • Easily obtained starting material for production (^{64}Ni) • Has a theranostic pairing with ^{67}Cu for therapy • ^{64}Cu based products can be administered and imaged on the same day and also offer the ability to collect multiple images from one hour to 48 hours • ^{64}Cu has a shorter positron range which can result in improved image quality compared to ^{68}Ga	• Historically, the absence of a suitable chelator technology has limited product development for copper-based radiopharmaceuticals, which meant demand for copper radioisotopes was limited, subsequently causing limited supply of these radioisotopes

2.4.4.3. Sensitivity and specificity of diagnostic products

Diagnostic performance of radiopharmaceutical products is assessed based on their specificity and sensitivity. Both require careful analysis in relation to intended applications and their implications for cancer care.

Sensitivity

In diagnostic imaging, sensitivity is the proportion of people with a disease that test positive to it. The higher the sensitivity of a diagnostic agent, the more diseased individuals are correctly identified as diseased, eliminating false negatives. For example, ^{18}F FDG has lower sensitivity than ^{64}Cu SARTATE™ in neuroblastoma, meaning the former might misclassify those with a disease as being healthy.

Specificity

Specificity is the proportion of people without a disease that test negative to it. The higher the specificity of a diagnostic test, the healthier individuals are correctly identified as healthy, eliminating false positives. For example, a ^{99m}Tc MDP bone scan, also called bone scintigraphy, results in "false-positive" findings in staging disease in the skeleton of patients at risk of bone metastases as it indicates the presence of conditions such as arthritis, bone infections and bone trauma, which could be incorrectly identified as metastases.

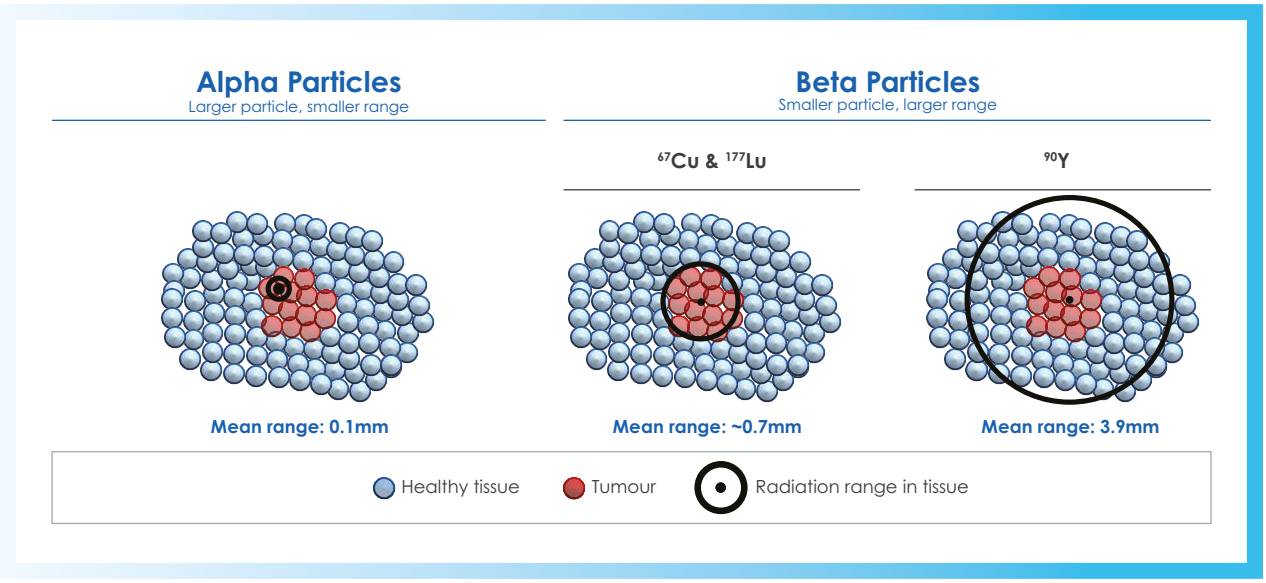
2.4.5. Therapeutic radiopharmaceuticals

Therapeutic radiopharmaceuticals are those which are used to treat cancer by delivering radiation directly to the cancer cells in order to kill them. The aim is to shrink or eradicate the cancers that may have spread throughout the body. Therapeutic radionuclides developed to date can be categorised into two groups: beta minus (beta) emitting and alpha emitting radionuclides.

Beta and alpha emitting radionuclides have different physical properties which create different modes of action in the body. Beta emitters are well established in the field of radionuclide therapy with a range of different radiopharmaceuticals which have been approved by the FDA[52] or reported positive benefits on overall survival in Phase III studies[53]. Clarity is developing ^{67}Cu as its therapeutic isotope, which is a beta emitter. Alpha emitters are a relatively new class of radiopharmaceutical. There is only one approved alpha emitter in the market to date, a drug called Xofigo®, which is a passively targeted radium salt[54].

Alpha particles are relatively heavy particles. Their relative weight gives them a very short range in human tissue and they emit all their energy over this short range. Beta particles are around 8,000 times lighter than alpha particles. They have a longer range in tissue than alpha particles and give off most of their energy at around one third of their maximum range. The range in human tissue of the beta particle depends on the beta energy of the radionuclide. A graphical comparison and average range of alpha and beta particles is shown in Figure 8.

Figure 8: Comparison of alpha and beta particles



52. <FDA https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-certain-digestive-tract-cancers>, <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-rare-adrenal-tumors#:~:text=The%20U.S.%20Food%20and%20Drug,unresectable)%2C%20have%20spread%20beyond%20the>.
53. Novartis <https://www.novartis.com/news/media-releases/novartis-177lu-psma-617-significantly-improves-overall-survival-and-radiographic-progression-free-survival-men-metastatic-castration-resistant-prostate-cancer>.
54. <https://www.prnewswire.com/news-releases/bayer-receives-us-fda-approval-for-xofigo-radium-ra-223-dichloride-injection-as-a-new-treatment-for-castration-resistant-prostate-cancer-with-bone-metastases-207545191>.

2.4.5.1. Alpha emitting radioisotopes

Alpha emitters kill cancer cells through damaging their DNA. Alpha particles have a higher probability of inducing hard to repair DNA double strand breaks compared to beta particles.

However, there are a number of significant limitations associated with targeted radiopharmaceuticals based on alpha particles:

- **Short range:** Alpha particles can only irradiate over a few cell diameters. This may result in them not accessing all the tumour. By the nature of their short range, alpha particles may be more suited to micro-metastatic disease.
- **Recoil effect:** Due to the heavy mass of alpha particles, their emission from the nucleus produces a powerful recoil effect which is 100 times greater than the binding energy of many chelators. This leads to dissociation of the radioisotope from the radiopharmaceutical and could result in off target toxicity.
- **Alpha particles escaping the chelator:** Most alpha emitting radioisotopes have a range of radioactive decay products which allows them to escape the cage of the radiopharmaceutical due to different chemical bonding and accumulate in different parts of the body.
- **Damage to healthy tissue:** Typically, 10% to 20% of an injected product reaches the cancer, and the remaining 80-90% of injected activity is excreted from the body over time. While alpha particles have demonstrated high cell kill in tumours, they can also localise to healthy cells. Because of the alpha emission, they have a greater probability of inducing double strand DNA breaks in healthy organs compared to beta emitters.
- **Late-stage radiation toxicity:** Since the majority of patients who have received alpha particle based radiopharmaceuticals to date were elderly prostate cancer patients, late-stage radiation toxicity from alpha particles has not yet been studied. There may be challenges with the use of alpha particles in younger patient populations due to the potential side effects in normal organs.
- **Radiation safety:** Due to their greater probability of cell kill compared to beta emitters, there is a range of radiation safety issues related to manufacture, distribution, administration and release of products with alpha particle emitters. While alpha emitters might be easier to handle due to their short range of travel, when accidents occur at clinical sites, they carry additional complications for managing occupational exposure.

Currently the only commercial alpha emitter available is Xofigo® (Radium-223 dichloride) developed by Algeta ASA, which was subsequently acquired by Bayer AG. Xofigo® is a simple radium salt, which passively targets osteoblastic (bone) cells, including metastases from prostate cancer that have spread to the bones.

2.4.5.2. Beta emitting radioisotopes

Beta emitters also kill cells by damaging their DNA and from production of free radicals from water contained in the cells they irradiate. A number of beta emitting radiopharmaceuticals have been commercialised as outlined in Table 6. One of the most successful beta emitters is Iodine-131 (^{131}I) which has intrinsic targeting to the thyroid organ and is very efficacious and safe when used to treat hyperthyroidism and thyroid cancer.

There are a number of positive reasons for using beta emitters such as copper-67:

- **Optimal range:** Beta particles from radioisotopes such as copper-67 and lutetium-177 have a long enough range to irradiate many layers of cancer cells in a tumour mass without having too long a range to harm healthy tissue.
- **Chelation:** Beta emitters can be chelated (held in a cage) in order to be contained and linked (conjugated) to targeting molecules to create stable targeted radiopharmaceuticals. In addition, radiolysis from beta emitters, which affects stability, can be adequately managed with formulation strategies.
- **Regulatory:** Beta emitters are available and many have been industrialised and commercialised for decades, setting the basis for regulatory agencies to approve new isotopes.
- **Decay:** Common beta emitters decay to a stable (non-radioactive) nuclide via a simple decay mechanism.
- **Approvals:** There have been multiple approved beta emitting products with market authorisation for decades, setting the basis for regulatory agencies to approve new products.
- **Theranostics:** Ability to create paired theranostic (combined diagnostic and therapy) products with both a therapeutic and imaging isotope counterpart such as copper-64/copper-67, iodine-123/iodine-131 and others.
- **Paediatrics:** There is experience with the use of beta emitters in paediatric medicine, particularly with ^{131}I-MIBG, a drug used to treat neuroblastoma.

The advantages and limitations of common beta emitters are considered in Table 5.

Table 5: Advantages and limitations of select types of beta emitters in targeted therapy (including average range in tissue)

Beta emitter	Average range in tissue	Advantages	Limitations
Lutetium-177 (^{177}Lu) *Refer to Table 8 for further detail*	0.7 mm	• Well established isotope used in cancer treatment • Optimal range in tissue • In addition to beta radiation, ^{177}Lu also emits gamma radiation which enables imaging after therapy	• Currently requires nuclear reactor to produce which leads to regional limitations and intermittent supply disruptions based on reactor schedule • Difficult to increase current global production further as there are only a few nuclear research reactors globally • Long-lived radioactive impurities in c.a. ^{177}Lu • Limited supply of starting material for n.c.a. ^{177}Lu • Relatively long half-life better suited to antibody pharmacokinetics
Yttrium-90 (^{90}Y)	3.9 mm	• Radioactive half-life (2.6 days) well matched to peptide pharmacokinetics • More suited for treating large tumours • Pure β- emitter that is available in high specific activity and purity	• Currently requires nuclear reactor to produce • Long range in tissue can result in off-target irradiation of healthy tissue • No gamma emissions to permit imaging after therapy
Iodine-131 (^{131}I)	0.4 mm	• High availability • Low cost • Highly efficient for treating thyroid tumours • Well established isotope in cancer treatment	• Requires nuclear reactor to produce • High radiation burden to family members and medical personnel • Significant radiation safety restrictions in handling ^{131}I and for patient release • Thyroid protecting medication required • Logistically difficult procedure to treat the patients with ^{131}I based products due to the long half-life of ^{131}I

Beta emitter	Average range in tissue	Advantages	Limitations
Copper-67 (^{67}Cu) *Refer to Table 8 for further detail*	0.7 mm	• Produced on electron accelerators rather than nuclear reactors, which translates into significantly lower capital investment to grow supply • Minimal supply disruptions of the isotope compared to reactor production • Scalable production and abundant starting material • High purity and high specific activity • Optimal beta energy/range in tissue • Optimal half life for therapeutic applications • US domestic supply • In addition to beta radiation, ^{67}Cu also emits gamma radiation which enables imaging after therapy • No long-lived radioactive impurities, unlike c.a ^{177}Lu • Can administer significantly higher activities without the requirement to isolate patients for long periods of time due to radiation safety • Limited competition for ^{67}Cu supply • Has an ideal diagnostic paring with ^{64}Cu	• Historically, the absence of a suitable chelator technology has limited product development for copper-based radiopharmaceuticals, which meant demand for copper radioisotopes was limited, subsequently causing limited supply of these radioisotopes • Investment required for non-US production (EU, APAC)

Table 6: Select beta emitting radiopharmaceuticals that have been commercialised

Trade name	Clinical name	Ownership rights
Bexaar	^{131}I tositumomab	GlaxoSmithKline
Zevalin®	^{90}Y ibritumomab tiuxetan	Spectrum Pharmaceuticals
Lutathera®	^{177}Lu DOTATATE	Advanced Accelerator Applications (AAA), now a subsidiary of Novartis
Azedra®	^{131}I Iobenguane	Lantheus

2.5. Theranostics and radioisotope pairings

2.5.1. Introduction to theranostics

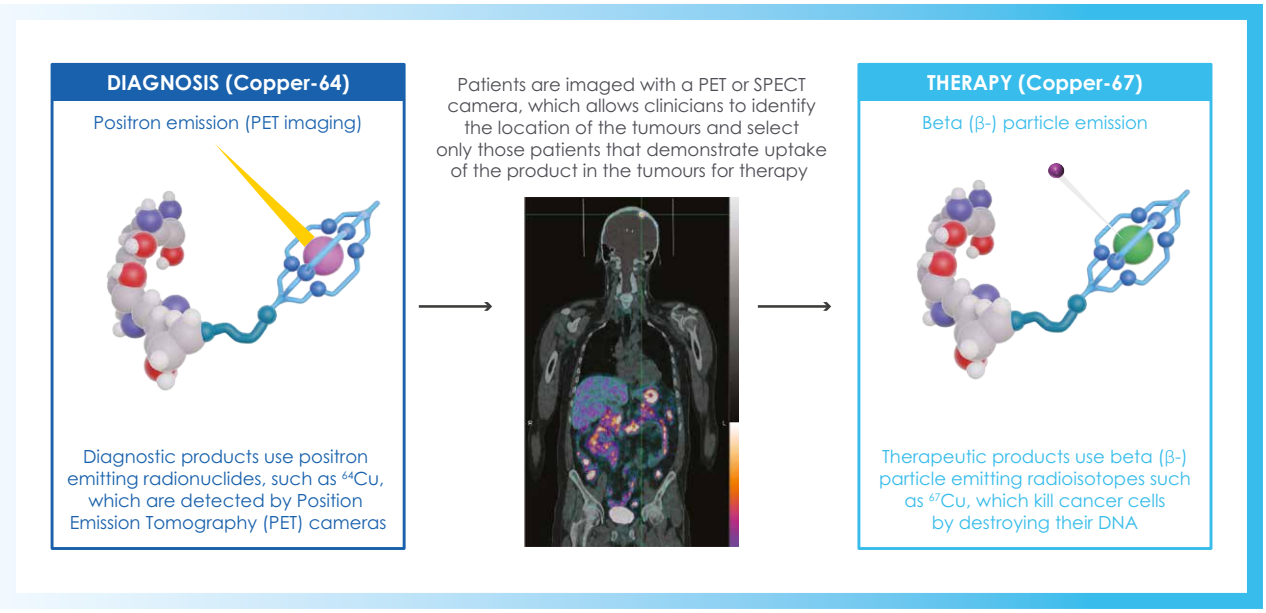
Theranostics is the combination of both **thera**peutic and diag**nostic** radiopharmaceuticals in the one platform. It is considered the next-generation of "Precision Therapy" in cancer care.

In the ideal theranostic pairing, the diagnostic product in the theranostic approach is also called a "companion diagnostic". It is developed to be used in conjunction with a therapeutic drug as a partner "companion" to identify which patients may or may not respond to a particular treatment.

The diagnostic and the therapeutic products target the same receptor on the cancer tumour via the identical targeting molecule used in both products.

Using a companion diagnostic allows practitioners to identify those patients whose cancer expresses the receptors which the therapeutic agent can target and who are most likely to respond to an accompanying therapeutic product. In this way, the therapy is only pursued by the practitioner if the patient is suitable (i.e. the diagnostic product is taken up by the tumour), meaning the probability of an efficacious therapy is greater. The diagnostic is so closely related to the therapeutic that its use becomes a good indicator of the potential of success in therapy as outlined in Figure 9.

Figure 9: The theranostic process: diagnostic imaging followed by therapy



Using a companion diagnostic prior to treatment also allows for more tailored therapeutic dosing regimens and more effective patient outcomes as the imaging data enables the physician to visualise the cancer. This information provides numerous benefits to patient-centred care, enabling "Precision Medicine" benefits, which include:

- the likelihood of a treatment option being successful, based on the specific tumour;
- providing a physician with information to determine an optimal starting dose for treatment and timing of treatment;
- regularly measuring the response to treatment and adjusting the dosage accordingly; and
- providing a physician with information to determine whether selecting alternative treatment options should be considered if the patient has not responded to initial treatment.

These beneficial clinical outcomes can also deliver a paradigm shift in the management of treatment costs and provide compelling health economic outcomes for reimbursement by governments and health insurers, saving both costs to the system (not using drugs which are unlikely to work) and also sparing the patient's time and the side effects inflicted by pursuing ineffective therapies for their cancer. In addition to economic and clinical benefits for the patient, selecting patients that have a higher chance of response to the therapy can potentially increase the chance of product development success.

2.5.2. Theranostic pairing of radioisotopes

The theranostic pairing of radioisotopes refers to using a pair of different radioisotopes in the same drug to diagnose cancer with one type of radioisotope and to treat cancer with a different radioisotope.

To date, the most successful theranostic pairing is gallium-68 (^{68}Ga) for diagnosis and lutetium-177 (^{177}Lu) for therapy, which is driving broad awareness and popularity of this treatment paradigm. However, the characteristics of ^{68}Ga and ^{177}Lu isotopes have significant limitations in the ability to upscale from small cancer indications into larger indications or to roll out into broader clinical practise[55,56].

Current treatment paradigms, such as gallium and lutetium, employ different chemical elements for diagnosis (^{68}Ga, an isotope of gallium) and therapy (^{177}Lu, an isotope of lutetium) and are therefore two chemically different radiopharmaceutical products even when paired together. This can result in differing targeting of each product in the body which directly affects precision. The current standard of care for neuroendocrine tumours (**NETs**) is to use ^{68}Ga DOTATATE (**NETSPOT®**) for imaging and ^{177}Lu DOTATATE (**Lutathera®**) for treatment. The current theranostic approach for prostate cancers that express prostate specific membrane antigen (**PSMA**) is to use two different targeting molecules and two different radioisotopes, ^{68}Ga PSMA-11 for imaging and ^{177}Lu PSMA-617 for treatment.

Favourable characteristics of radioisotopes for large-scale radiopharmaceutical applications include:

- A sufficiently long half-life to allow for:
  - time to synthesise the radiopharmaceutical off-site;
  - point-to-point delivery; and
  - dose administration delays due to fluctuations in clinical workflow.
- Appropriate range of the radiation in tissue to allow for localisation in the cancerous area whilst minimising damage to nearby healthy cells.
- Centralised and efficient clinical-grade manufacturing that is scalable and responsive to fluctuations in end user demands.
- A robust supply chain to minimise supply chain issues that are all too common with current radiopharmaceuticals.

Limitations in the use of traditional pairings, such as gallium-68 and lutetium-177, has presented an opportunity for the broader use of other isotopes in development, including copper, which is the core of Clarity's products.

2.5.3. Targeted Copper Theranostics (TCT)

TCT are the next-generation disruptive platform in radiopharmaceuticals that employ the "perfect pairing" of copper-64 (^{64}Cu) and copper-67 (^{67}Cu) for diagnosis and therapy. TCT deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers, as well as providing supply and logistical advantages over current theranostics. TCT provide a highly efficacious, scalable, and cost-effective way to expand radiopharmaceuticals into the global oncology market.

The term "perfect pairing" relates to the unique characteristics of the two copper isotopes, ^{64}Cu for diagnosis and ^{67}Cu for therapy, which have been discussed in the scientific literature for approximately 25 years. The pairing is well suited for precision medicine due to the unique physical characteristics of each isotope of copper as well as having the "ideal theranostic pair", meaning the same product and same element are used for both diagnosis and therapy.

The physical characteristics of ^{64}Cu and ^{67}Cu position this pairing to compete head-to-head with ^{68}Ga and ^{177}Lu and other isotope pairings.

55. Vogel, W.V., van der Marck, S.C. and Versleijen, M.W.J. Challenges and future options for the production of lutetium-177. European Journal of Nuclear Medicine and Molecular Imaging. 2021 < https://link.springer.com/article/10.1007%2Fs00259-021-05392-2>.
56. <https://link.springer.com/article/10.1007/s00259-021-05392-2>.

Targeted Copper Theranostics (TCT) may enable further expansion of targeted radiopharmaceuticals into global oncology

- TCT offer ready-to-use products which are easier to incorporate into broader clinical practice than currently used first-generation theranostics
- TCT may allow oncologists to maintain their existing patients without further referral to other clinicians
- Receiving ready-to-use products allows access to oncologists without the requirement for additional infrastructure investment at the treatment facilities
- TCT can provide a more reliable supply of large volumes of products which is important to deliver the product volumes required for large cancer indications

Figure 10 shows a comparison between traditional theranostic radioisotope pairing and Targeted Copper Theranostics (**TCT**).

Figure 10: Traditional pairings and Targeted Copper Theranostics (TCT)

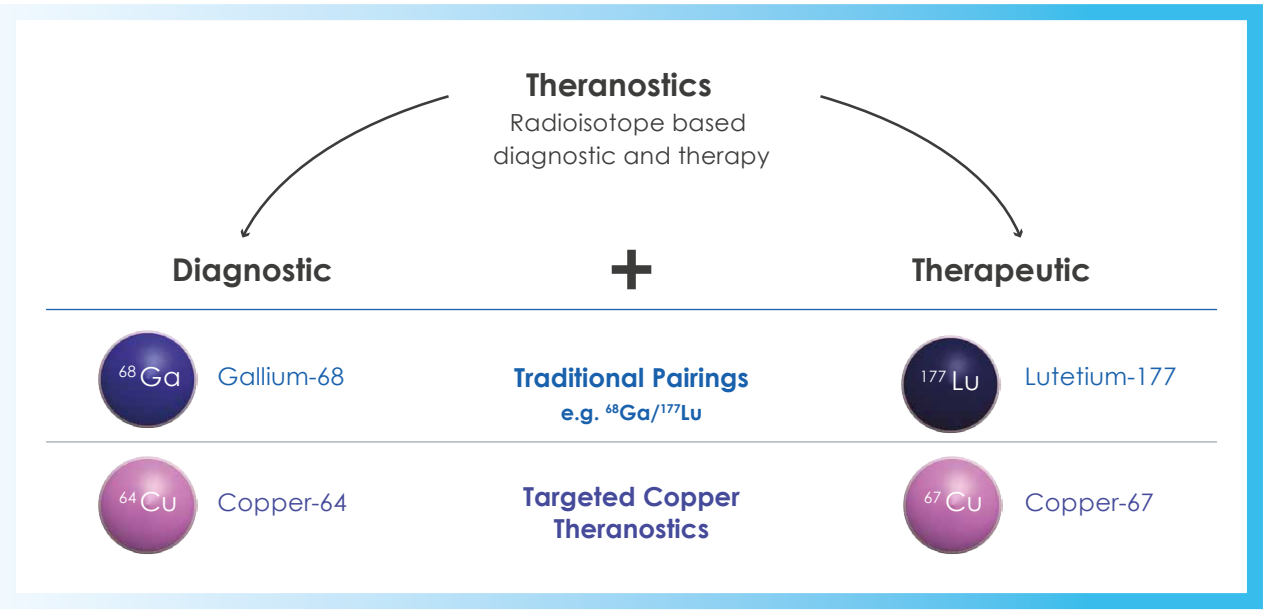


Table 7 outlines they key differences between diagnostic radioisotopes in traditional pairings (gallium-68) and Targeted Copper Theranostics (copper-64).

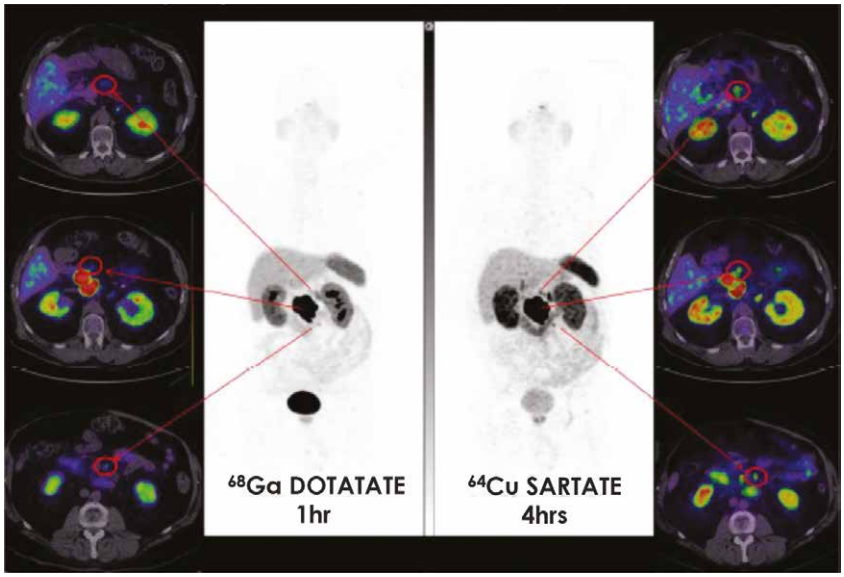
Table 7: Comparison of diagnostic radioisotopes ^{68}Ga and ^{64}Cu

	Traditional Pairings (Gallium-68)	Targeted Copper Theranostics (Copper-64)
Description	^{68}Ga is a positron emitting isotope of gallium that is made through local (typically on-site) elution due to its relatively short half-life and therefore shelf life. Recently approved generators cannot meet this demand due to the low number of manufacturing sites, which results in delivery times of one year or more.	^{64}Cu is a positron and beta emitting isotope of copper that can be produced daily on cyclotrons in significant volume. Due to the 12.7 hour half-life, ^{64}Cu based products can be produced centrally and distributed to treatment centres as a finished drug product with a shelf life of a few days.
Production route	Eluted from on-site germanium-68/ gallium-68 generators, which have a limit on the amount of ^{68}Ga that can be collected per day per generator.	Produced in large batch sizes using biomedical cyclotrons by irradiation of ^{64}Ni. There is already sufficient capacity in the US from a number of manufacturers producing ^{64}Cu weekly as well as the potential to increase supply by utilising cyclotrons that are currently used for the production of ^{18}F.
Manufacturing	Generally, elution has to be done on-site due to the limitation of the ~1 hour half-life of ^{68}Ga. This requires users to have a radiopharmacy facility and the staff to run it. These requirements along with the high cost of generators can be prohibitive outside of large treatment centres who have such specialised facilities and staff. The in-house production and elution process increases radiation safety and compliance obligations as well as high annual disposal costs of the long lived radioactive waste.	Industrial scale ^{64}Cu production on cyclotrons with solid targetry capability creates a high purity product, free from radioactive contaminants and permits central manufacture of large volumes of ready-to-use radiopharmaceuticals.
Radioactive half-life	68 minutes	12.7 hours
Typical shelf-life of formulated products	3-4 hours	>48 hours

	Traditional Pairings (Gallium-68)	Targeted Copper Theranostics (Copper-64)
Key benefits of ^{64}Cu	• ^{64}Cu based products can be manufactured at a central radiopharmacy and distributed broadly • The 12.7 half-life of ^{64}Cu enables increased market access through additional treatment centres and the movement of radiopharmaceuticals into the large oncology space • Easily scalable product supply due to favourable production method and half-life • No requirement for in-hospital radiopharmacy facilities • No risk of generator breakthrough of long lived radioactive material • No requirements for local quality control procedures • No requirements on decommissioning funding liability which can be a requirement for some sites using a Ge-68/Ga-68 generator • No requirement to return generators back to the manufacturer or radioactive waste for long-term storage • Can be administered and imaged on the same day (as with current patient scheduling), but also offers the ability to collect multiple images from one hour to 48 hours (as with flexible patient scheduling) • ^{64}Cu has a shorter positron range which can result in improved image quality compared to ^{68}Ga	
Key limitations of ^{64}Cu	• Historically, the absence of a suitable chelator technology has limited product development for copper-based radiopharmaceuticals, which meant demand for copper radioisotopes was limited, subsequently causing limited supply of these radioisotopes.	

In addition to the benefits outlined in Table 7 above, using targeting agents labelled with ^{64}Cu may allow for better imaging of disease compared to other isotopes as it can detect additional tumours at later time points that may not show in initial scans at early time points. This is because the tumour-bound product will stay in the tumour while the non-bound product is cleared from the body through excretion processes, therefore improving the signal to background ratio when imaging at later time points.

Figure 11: CL01 Trial – Superior lesion detection at 4 hours. High lesion contrast on ^{64}Cu SARTATE™ images at 4 hours (right) better defines regional nodal disease than ^{68}Ga DOTATATE images at 1 hour (left) in patient with large pancreatic primary tumour[57]



Due to the shorter range of the positron emitter from ^{64}Cu compared to ^{68}Ga, it also provides higher resolution images.[58]

For therapeutic applications, ^{177}Lu is produced in a small number of nuclear research reactors globally. It has increased in use due to its optimal range in tissue, similar to ^{67}Cu of 0.7mm. ^{177}Lu has a 6.7 day half-life, which is better suited to the pharmacokinetics of antibodies rather than molecules such as DOTATATE.

^{67}Cu is the longest-lived copper radioisotope and the most suitable for therapeutic applications. Unlike ^{177}Lu, it does not rely on nuclear reactors for production and can be manufactured on e-accelerators. The combination of the half-life and emission profile makes ^{67}Cu a highly attractive radioisotope for cancer therapy with a variety of different targeting molecules. ^{67}Cu has a similar beta emission profile to ^{177}Lu; however, it has a shorter half-life of 2.6 days. The shorter half-life of ^{67}Cu is more suited to the pharmacokinetics of peptides and small molecules and is likely to be safer to off-target organs and allows for more frequent repeat dosing in patients and a decrease in radiation safety requirements, even with higher dosing.

Table 8 outlines the key differences in therapeutic radioisotopes between traditional pairings (lutetium-177 and Targeted Copper Theranostics (copper-67)).

57. Hicks et al., 2019, JNM.
58. Johnbeck, CB et al. Head-to-Head Comparison of ^{64}Cu DOTATATE and ^{68}Ga DOTATOC PET/CT: A Prospective Study of 59 Patients with Neuroendocrine Tumors Journal of Nuclear Medicine March 2017, 58 (3) 451-457; DOI: https://doi.org/10.2967/jnumed.116.180430 <https://jnm.snmjournals.org/content/58/3/451>.

Table 8: Comparison of therapeutic radioisotopes ^{177}Lu and ^{67}Cu

	Traditional Pairings (Lutetium-177)	Targeted Copper Theranostics (Copper-67)
Description	^{177}Lu is a beta emitting radionuclide used in therapy	^{67}Cu is a beta emitting radionuclide used in therapy
Production route	Nuclear reactor	e-accelerator/Rhodotron/alpha beam
Manufacturing	Limited number of nuclear reactors globally produce ^{177}Lu	Current US domestic supply through IAC and future clinical and commercial supply through NorthStar Medical Radioisotopes
Radioactive half-life	6.7 days	2.6 days
Max β-energy	498 keV	577 keV
ϒ energy & yield	208 keV (11%)	185 keV (45%)
Average range in soft tissue	0.7 mm	0.7 mm
Key benefits of ^{67}Cu	• Optimal beta energy/range in tissue/half life • Minimal supply disruptions compared to reactor production which has regional limitations and intermittent supply disruptions based on reactor schedule • US Domestic supply currently available from multiple suppliers • Straightforward purification of ^{67}Cu allows reliable preparation of a high specific activity product • No long-lived radioactive impurities (a problem with c.a. ^{177}Lu) • High specific activity radionuclides may be important from a radiation biology perspective • Shorter half-life compared to ^{177}Lu may allow more administrations with frequent dosing and a more attainable therapeutic window • Can potentially administer higher activities of ^{67}Cu based products than of ^{177}Lu based products without the requirement to isolate patients for long periods of time due to radiation safety • Currently limited competition for ^{67}Cu supply • Is currently available at a lower cost than ^{177}Lu	
Key limitations of ^{67}Cu	• Historically, the absence of a suitable chelator technology has limited product development for copper-based radiopharmaceuticals, which meant demand for copper radioisotopes was limited, subsequently causing limited supply of these radioisotopes • Investment required for non-US production (EU and Asia Pacific)	

2.5.3.1. Major limitation of Targeted Copper Theranostics to date

Unsuitable chelators

Until recently, the application of $^{64}Cu/^{67}Cu$ for diagnostic imaging and therapy has been hindered by the lack of appropriate technology to hold radioisotopes of copper inside the cage and prevent their leakage into the bloodstream with subsequent accumulation in the liver. As a result of the inability of the copper-based products to meet basic drug requirements, the demand for copper radioisotopes was limited, subsequently leading to limited supply of these radioisotopes.

The key requirement for radiopharmaceutical products is high stability of the drug in the body. Many of the common commercially available copper chelators leak copper from the chelator when administered in the body (see Figure 19), making them unsuitable for clinical applications, particularly relevant in therapeutic applications with high activity (meaning a high radiation dose goes to healthy tissue). Once copper leaks out of the chelator, it is no longer bound to the targeting molecule and free copper enters the bloodstream and accumulates in the liver, which may cause side effects in patients, especially in therapeutic applications.

Clarity's SAR Technology has been demonstrated to address this limitation in preclinical and clinical trials to date. This is explored in further detail in Section 3.2. To further address the historically limited supply of copper radioisotopes and create abundant supply for its future clinical demand, Clarity is successfully expanding its collaborations with a number of suppliers, which is discussed in further detail in Section 3.7.

2.6. Government regulation

This Section aims to provide an overview of the key regulatory processes and requirements relevant to Clarity and its portfolio of products. For the reasons noted at the start of Section 2, this section will focus on the US.

2.6.1. Introduction

Radiopharmaceuticals are typically administered intravenously and require a high degree of care during the manufacturing and dispensing stages. Pharmaceutical regulation is mainly concerned with matters including product efficacy, safety, supply chain and purity.

Radiopharmaceuticals are required to conform to the Current Good Manufacturing Practice (cGMP) regulation, and their distinctive nature necessitates that they cater to the requirements of the pharmaceutical and nuclear regulatory bodies.[59] Drug regulatory bodies such as the FDA in the United States, the TGA in Australia and the EMA in Europe regulate the human use of radiopharmaceutical products. The nuclear regulators are responsible for isotope manufacturing and safety (e.g. the US Nuclear Regulatory Commission).

2.6.2. Preclinical studies, Investigational New Drugs (INDs) and the clinical trial process

After the discovery and development process, a pharmaceutical company will pursue preclinical research for a drug, in which it aims to gather detailed information on dosing and toxicity.[60] Once preclinical research is complete and the decision has been made to pursue testing in humans, the developers need to design clinical studies and consider what they wish to achieve at each of the three stages of clinical research. Before clinical research begins in the US, the developers must submit an Investigational New Drug (IND) application with the FDA.[61]

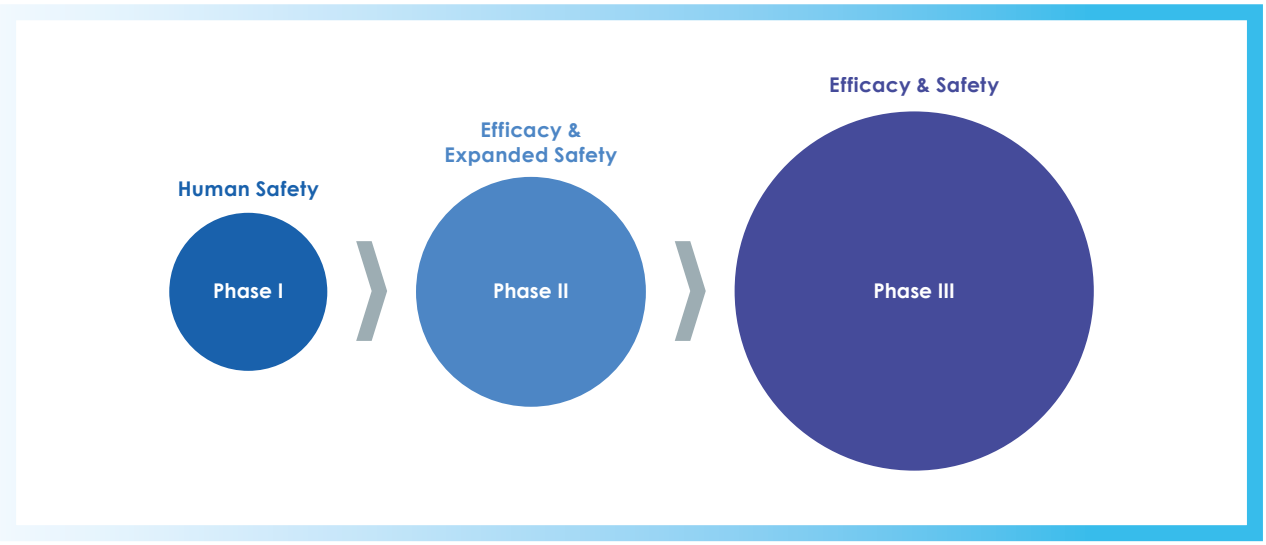
The clinical trial phases

In a similar manner to pharmaceutical companies, radiopharmaceutical companies such as Clarity typically follow a standard clinical trial development pathway. These trials follow a plan or set of rules, known as a protocol, to ensure they measure the right endpoints in the right way with meaningful results. Regulatory agencies usually agree to these protocols in advance and will typically grant approval to commence each stage of the development pathway. The process of developing a radiopharmaceutical candidate is divided into several phases, each used to investigate different aspects of the drug product candidate.

Outlined in Figure 12 are the three key phases of clinical trial development from Phase I to Phase III clinical trials.

59. FDA <https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps>.
60. FDA <https://www.fda.gov/patients/drug-development-process/step-2-preclinical-research>.
61. FDA < https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312>.

Figure 12: Clinical trial phases



2.6.2.1. Phase I: Human safety

Phase I establishes any potential toxicities (safety), how the drug is processed, absorbed and spread through the body. The correct dosage and frequency of the product to be used in the subsequent clinical trials can then be established. In cancer patients, Phase I can give an early efficacy signal.

2.6.2.2. Phase II: Efficacy and expanded safety

Phase II continues to measure safety and also establishes the potential efficacy of the drug candidate by testing how effective it is against a specific type of disease.

2.6.2.3. Phase III: Efficacy and safety in larger patient groups

In Phase III, the drug is compared to medication alternatives already in the pharmaceutical market for its relative performance. Further confirmation of safety and efficacy in the targeted disease is also sought. In this phase, the number of patients varies by the disease and the desired study endpoints. For radiopharmaceutical based therapies, typical Phase III studies may require 400-700 patients to achieve statistically relevant study endpoints.

Phase III is the final phase before the application for marketing of the drug is sent to the authorities and in some cases several Phase III trials may be conducted or required. In limited cases, cancer drugs in development with promising results from Phase II can be enough to receive a marketing approval of a drug product candidate and is often referred to as accelerated approval. Companies that receive such an approval are typically still required to conduct the clinical research program after it has been approved. This accelerated approval may fast track marketing of the drug if the product shows far superior effectiveness at an early stage and if the market lacks a treatment alternative.

2.6.3. Orphan Drug Designation[62]

Regulatory authorities in various jurisdictions may also provide drug products an Orphan Drug Designation (ODD) if the product treats a disease or cancer that affects a small number of people. In the US, this number is in diseases affecting less than 200,000 people.

ODD incentives include protocol assistance, reduced or waived regulatory fees and, in the US, tax credits to the extent of 50% of clinical investigation expenses. Importantly, products with ODD status receive market exclusivity. In the US, market exclusivity is granted for seven years from the time of US FDA approval. Clarity was granted ODDs with the US FDA for its ^{67}Cu SARTATE and ^{64}Cu SARTATE products for the treatment and management of neuroblastoma. Further details on this program are provided in Section 3.5.1.1.

2.6.4. Rare Paediatric Disease Designation and the Priority Review Voucher Program[63]

The US FDA defines a "rare paediatric disease" (RPD) as a serious or life-threatening disease primarily affecting individuals aged 18 years or younger that impacts fewer than 200,000 people in the United States. The RPD program is intended to facilitate development of new drugs and biologics for the prevention and treatment of RPDs. As part of this program, the FDA provides various incentives including the potential for a Priority Review Voucher (**PRV**) to be awarded.

PRVs are awarded to companies following FDA approval of new treatments for diseases with smaller market opportunities, such as paediatric diseases. PRVs are fully tradable and transferrable and can be either used by the receiving company or sold to another drug developer.

A PRV speeds up the timeline that the FDA commits to the review of a drug application, which is significant for companies with blockbuster products who seek to buy PRVs to accelerate approvals and shorten the time to market (if ultimately approved) and thereby potentially boosting their sales. A PRV does not, however, alter the scientific/medical standard for approval, or the quality of evidence required in an application.

Drivers for obtaining a PRV include:

- four months of additional sales due to the reduction in review timeline from ten months to six months, providing significant opportunity for products with large target markets, which could result in greater than several hundred million dollars in additional sales;
- extension of sales under effective patent life with additional four month sales period before generic products can compete; and
- competitive benefits from early entry relative to competitors.

Some of the recent PRV transactions are reflected in the Figure 13 below.

Figure 13: Recent PRV transactions

PRVs have recently been transacted for c.US$100 million			
		Seller	**Buyer**
US$100 million	Jan-21	Rhythm Parmaceuticals	Alexion (owned by AstraZeneca)
US$105 million	Dec-20	mAbs Therapeutics	United Therapeutics
US$98 million	Nov-20	Bayer	Agenx
US$100 million	Jul-20	Lumons Pharma	Merck

62. FDA <https://www.fda.gov/industry/developing-products-rare-diseases-conditions#:~:text=Device%20Exemption%20approvals.-,OOPD%20Programs,recovery%20provisions%20of%20the%20act.>.
63. FDA <https://www.fda.gov/media/90014/download>.

RPDD and potential PRVs in Clarity's Development Program

Clarity has received Rare Paediatric Disease Designations (RPDD) for its SARTATE™ program for both ^{64}Cu SARTATE™ for the management of neuroblastoma and ^{67}Cu SARTATE for the treatment of neuroblastoma. Clarity has two products in development that may be eligible for one PRV each (a total of two PRVs) if the products are approved by the FDA.

Ongoing clinical programs are generating data to support the marketing applications for ^{64}Cu SARTATE™ and ^{67}Cu SARTATE™ in neuroblastoma. The timeframe for the potential approval of ^{64}Cu SARTATE™ for the management of disease may be considerably shorter than for ^{67}Cu SARTATE™ for the treatment of disease.

Clarity is investigating expediated pathways to achieve approval for ^{64}Cu SARTATE™.

2.7. Focus areas in Clarity's portfolio

Clarity's diverse asset portfolio addresses large indications as well as rare and orphan indications.

Rare and orphan indications allow Clarity to develop products where there is significant unmet medical need, and the regulatory agencies, such as FDA in the US, provide benefits and regulatory incentives for companies developing these products. At the same time, these products can allow a premium on pricing. Large indications (e.g. prostate cancer) allow faster recruitment into clinical trials due to a larger patient pool and there is significant opportunity to sell higher volumes of products once they are approved due to the greater incidence.

Figure 14 provides an overview of each of the indications of cancer that Clarity's current portfolio targets. The figure also notes the tumour receptor that Clarity's products target and the percentage of tumours within that incidence of cancer which express that receptor.

Figure 14: Cancers that Clarity is currently focused on

	Pan Cancer (e.g. breast and prostate)	Prostate Cancer	Neuroblastoma (NB)	Neuroendocrine Tumours (NETs)
Incidence	**1 in 8 women will be diagnosed with breast cancer during their lifetime** Breast cancer is the most common cancer in the world and the most common cause of female cancer mortality worldwide	**1 in 8 men will be diagnosed with prostate cancer during their lifetime** Prostate cancer is the 2nd most common cancer in men and the 5th leading cause of cancer mortality in men worldwide	**800 new cases each year in the US and the most common cancer in infants** Neuroblastoma is one of the most aggressive childhood cancers, usually found in infants and children under the age of five	**12,000 people diagnosed each year in the US** NETs are rare types of tumour arising from neuroendocrine cells which are found within most organs of the body, including the liver, pancreas, ovaries and prostate
Receptor	**GRPr** Gastrin releasing peptide receptor	**PSMA** Prostate specific membrane antigen	**SSTR2** Somastostatin receptor 2	**SSTR2** Somastostatin receptor 2
Receptor Expression	**83%** of estrogen receptor (ER) positive breast cancers **75%-100%** of prostate carcinomas	**90%** of metastatic castrate resistant prostate cancers	**84%** of neuroblastomas	**76%** of primary NETs

2.7.1. Neuroblastoma

2.7.1.1. Description and occurrence of cancer

Neuroblastoma is a cancer that develops from immature nerve cells found in several areas of the body. Neuroblastoma most commonly arises in and around the adrenal glands (a gland that sits atop the kidneys). However, neuroblastoma can also develop in other areas of the body, including the neck, chest, or spinal cord, where groups of nerve cells naturally exist.

This cancer occurs most often in infants and young children, usually in children younger than 5 years old, and is rarely found in people older than 10 years.[64] The average age of diagnosis is between 1 and 2 years old. In rare cases, neuroblastoma is detected by ultrasound even before birth. Each year, about 800 children are diagnosed with neuroblastoma in the US.[65] It accounts for 6% of all childhood cancers in the US[66] and approximately 13% of paediatric cancer mortalities[67].

Neuroblastoma is a very complex disease, where patients are classified into low-, intermediate-, and high-risk categories. In general, those with low-risk disease have an excellent chance of survival with minimal therapeutic interventions. The outcome of patients with intermediate-risk disease, who are treated primarily with surgery and chemotherapy, has also improved in recent years. However, patients with high-risk disease, comprising approximately half of all new neuroblastoma cases each year, require treatment with many different types of therapies in order to improve their survival odds. These treatments include surgery, radiotherapy, different types of high-dose chemotherapy, stem cell transplantation, biologic and immunotherapies. Unfortunately, even with this aggressive therapeutic strategy, a significant number of patients will still relapse and eventually die of this disease. The 5-year life expectancy is around 40% to 50% (5-year life expectancy means percent of children alive at least 5 years after the cancer is found). Novel treatments in development are putting an emphasis on targeted therapies which are more "precise" than standard agents, as these treatments have the potential to be more effective and less toxic, leading to further improvement in the survival of patients with neuroblastoma.[68]

Somatostatin receptors are commonly expressed in neuroblastoma. Clarity's ^{64}Cu SARTATE™ and ^{67}Cu SARTATE™ products target the SSTR2 subtype, which is found in approximately 84% of neuroblastomas[69].

2.7.1.2. Standard of care and competitive environment in radiopharmaceuticals

Standard of care

Imaging

The standard of care diagnostic radiopharmaceuticals used in the clinic to diagnose and monitor neuroblastoma include ^{123}I MIBG (registered as Adreview®) and in some cases ^{18}F FDG.

^{123}I MIBG is not a PET imaging agent, but a single-photon emission computed tomography (SPECT) imaging agent. In general, SPECT scans have additional limitations compared to PET scans, such as lower-resolution and limited sensitivity to detect small lesions (see Section 2.4.4.1) as well as a requirement for prolonged sessions in the SPECT scanner needed to acquire an effective scan. These prolonged sessions are a particular disadvantage for small children because it increases the length of time for which they need to be sedated while undergoing the scan. In the case of ^{123}I MIBG specifically, there is additional burden associated with the preparation of patients for the scan. A number of medications (e.g. antihistamines, antihypertensive agents and opioid analgesics) are known to interfere with ^{123}I MIBG and therefore these medications must be avoided for a certain period after the scan. Furthermore, a thyroid-blocking medication is also necessary before the scan in order to protect the thyroid gland from radiation.

64. <https://www.cancer.net/cancer-types/neuroblastoma-childhood/statistics>.
65. <https://www.cancer.net/cancer-types/neuroblastoma-childhood/statistics>.
66. <https://www.cancer.net/cancer-types/neuroblastoma-childhood/statistics>.
67. Maris JM. Recent advances in neuroblastoma. The New England journal of medicine. 2010;362(23):2202-2211. doi:10.1056/NEJMra0804577.
68. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5649635/>.
69. Albers, A. R., M. S. O'Dorisio, D. A. Balster, M. Caprara, P. Gosh, F. Chen, C. Hoeger, et al. 2000. "Somatostatin Receptor Gene Expression in Neuroblastoma." Regulatory Peptides 88 (1–3): 61–73.

^{18}F FDG is a PET imaging agent that is primarily used for patients that are negative on the ^{123}I MIBG scans (a negative scan means that the imaging product was unable to visualise the cancer lesions on the scan). However, due to its lower sensitivity, the role of ^{18}F FDG in the imaging of patients with neuroblastoma remains controversial[70] (see Section 2.4.4.3 for more details on sensitivity of diagnostic tests).

PET imaging is of increasing interest for patients with neuroblastoma. However, currently there are no approved PET products on the market.

Therapy

The standard of care therapeutic radiopharmaceutical for high-risk neuroblastoma is ^{131}I MIBG, although it is not an FDA approved agent for use in patients with neuroblastoma. In the clinic, patients who demonstrate uptake of ^{123}I MIBG in cancer lesions may then be treated with ^{131}I MIBG. From these patients, approximately 36% demonstrate response to treatment (such as shrinkage of the tumours)[71], however, approximately 10% of patients have a ^{123}I MIBG negative scan[72] and therefore are not suited for this treatment.

^{131}I MIBG therapy is an extremely intense and logistically difficult process due to the long half-life of ^{131}I. There are a number of safety precautions that must be followed.[73] Radiation safety requirements often include isolation of the child from carers into specialised rooms for several days, specialised staff, restriction to bed, urinary catheter placement, use of thyroid protecting medication and parental education on radiation safety measures for urinary and stool clean-ups following discharge from the hospital.[74] Short- and medium-term side effects include nausea and vomiting during infusion, pain, elevated liver function tests, suppressed bone marrow production, neutropenia and infections.[75] The long-term side effects include potential development of hypothyroidism which requires thyroid replacement therapy, and possible increased risk of contracting a secondary cancer such as myelodysplastic syndrome and acute myeloid leukemia.[76]

Competitive environment

Imaging

There are a number of PET diagnostic radiopharmaceuticals in development for neuroblastoma (see Table 9 below).

Table 9: Imaging radiopharmaceutical products in development for neuroblastoma

Product in development	Receptor target	Phase of development
^{124}I MIBG	Norepinephrine transporter (NET-1)	Phase I/II
^{18}F MFBG	Norepinephrine transporter (NET-1)	Phase III
^{68}Ga DOTATATE	SSTR2	Phase II
^{68}Ga DOTATOC	SSTR2	Phase II
^{18}F DOPA	Norepinephrine transporter (NET-1)	Phase III

Note: This list of products in development is not comprehensive and is indicative only.

70. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3668791/>.
71. Matthay KK, Yanik G, Messina J, et al. Phase II study on the effect of disease sites, age, and prior therapy on response to iodine-131-metaiodobenzylguanidine therapy in refractory neuroblastoma. J Clin Oncol. Mar 20 2007;25(9):1054-60. doi:10.1200/jco.2006.09.3484.
72. Bleeker G, Tytgat GA, Adam JA, et al. ^{123}I MIBG scintigraphy and ^{18}F FDG-PET imaging for diagnosing neuroblastoma. Cochrane Database Syst Rev. Sep 29 2015;(9):Cd009263. doi:10.1002/14651858.CD009263.pub2.
73. <http://www.danafarberbostonchildrens.org/innovative-approaches/mibg-therapy/what-to-expect-during-mibg-treatment.aspx>.
74. <http://www.danafarberbostonchildrens.org/innovative-approaches/mibg-therapy/what-to-expect-during-mibg-treatment.aspx>.
75. Quach A, Ji L, Mishra V, et al. Thyroid and hepatic function after high-dose 131 I-metaiodobenzylguanidine (131 I-MIBG) therapy for neuroblastoma. Pediatric Blood and Cancer. 2011;56(2):191-201.
76. DuBois et al. Nuclear Med Biol, 35(suppl 1), pps. S35-S48. (2008).

For advantages and limitations of radioisotopes used in the products mentioned above, refer to Table 4 and Table 7 as well as Sections 2.4.4 and 2.5.3.

Therapy

Table 10: Therapeutic radiopharmaceutical products in development for neuroblastoma

Product in development	Phase of development
^{177}Lu DOTATATE	Phase II
^{90}Y DOTATOC	Phase II

Note: This list of products in development is not comprehensive and is indicative only.

For advantages and limitations of radioisotopes used in the products mentioned above, refer to Table 5 and Table 8 as well as Sections 2.4.5 and 2.5.3.

2.7.2. Neuroendocrine tumours

2.7.2.1. Neuroendocrine tumours: description and occurrence of cancer

Neuroendocrine tumours (NETs) are a type of tumour that arises from body cells called neuroendocrine cells. Neuroendocrine cells are naturally found within most organs of the body, including the thymus, liver, pancreas, ovaries, prostate and kidneys. Neuroendocrine tumours can occur anywhere within the body. The most common disease sites are the lungs, appendix, small intestine, rectum and pancreas.[77]

It is estimated that more than 12,000 people in the US are diagnosed with a NET each year, and over 175,000 people in the US are currently living with NETs[78]. The number of people diagnosed with NETs has been steadily rising over the years[79]. This increase is mostly related to improvements in the way NETs are diagnosed, including better imaging tests, and increased awareness of these tumours.[80]

The diagnosis of NETs is based on the evaluation of clinical symptoms, histopathology, blood tests and imaging.[81] Tumours can remain asymptomatic for a long time and despite the advancements in diagnostic methods, there is still a large number of undiagnosed patients. As slow progressing tumours are potentially curable if detected early[82], diagnostic imaging plays a critical role in the diagnosis, staging and selection of treatment[83].

77. <https://www.mayoclinic.org/diseases-conditions/neuroendocrine-tumors/symptoms-causes/syc-20354132>.
78. <https://www.cancer.net/cancer-types/neuroendocrine-tumors/statistics>.
79. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5824320/>.
80. <https://www.cancer.net/cancer-types/neuroendocrine-tumors/statistics>.
81. Raphael, Michael J., David L. Chan, Calvin Law, and Simron Singh. 2017. "Principles of Diagnosis and Management of Neuroendocrine Tumours." CMAJ : Canadian Medical Association Journal 189 (10): E398–404. https://doi.org/10.1503/cmaj.160771.
82. Sundaresan, Sinju, Anthony J. Kang, and Juanita L. Merchant. 2017. "Pathophysiology of Gastric NETs: Role of Gastrin and Menin." Current Gastroenterology Reports 19 (7): 32. https://doi.org/10.1007/s11894-017-0572-y.
83. Bodei, Lisa, Anders Sundin, Mark Kidd, Vikas Prasad, and Irvin M. Modlin. 2015. "The Status of Neuroendocrine Tumor Imaging: From Darkness to Light?" Neuroendocrinology 101 (1): 1–17. https://doi.org/10.1159/000367850.

Due to the rarity and type of symptoms, a delay in diagnosis or misdiagnosis is common. Patients may be seen by multiple specialists and undergo extensive and repetitive testing, leading to varying and potentially conflicting treatment recommendations and contributing to delays in an accurate diagnosis[84]. Disease related symptoms have been reported to persist from 4.5 to 9 years before an accurate diagnosis is made, resulting in a negative impact on the quality of life of NETs patients[85,86]. Due to the delay in diagnosis, about 30-75% of NETs patients have metastases at the time of diagnosis according to US and European cancer registries[87]. In addition to being difficult to diagnose, NETs also represent a complex disease. Treatment options vary, depending largely on the type and stage of the disease. The survival estimates are also highly variable.

Somatostatin receptors (SSTRs) are commonly expressed in NETs[88]. Clarity's ^{64}Cu SARTATE™ product targets the somatostatin receptor subtype 2 (SSTR2), which is found in approximately 76% of all primary NETs[89] (for more detail see section 3.5.3). This type of imaging, which utilises the somatostatin receptors, is often referred to as "somatostatin receptor imaging".

2.7.2.2. Neuroendocrine tumours: standard of care and competitive environment in radiopharmaceuticals

Standard of care

In nuclear medicine imaging, the current standard of care for PET imaging of NETs is ^{18}F FDG and ^{68}Ga DOTATATE (registered as "NETSPOT®"). Other recently approved PET radiopharmaceuticals include ^{68}Ga DOTATOC and ^{64}Cu DOTATATE (registered as "Detectnet™").

^{68}Ga DOTATATE, ^{68}Ga DOTATOC and ^{64}Cu DOTATATE all fall into the category of somatostatin receptor imaging. ^{68}Ga DOTATATE and ^{68}Ga DOTATOC are approved by the FDA for the localisation of somatostatin receptor positive NETs in both adult and paediatric patients. ^{64}Cu DOTATATE is approved for the same patient population, however only for use in adults. Somatostatin imaging is primarily used to look at slow-growing NETs (grades 1 and 2)[90]. For this patient population, this imaging modality is highly sensitive. Apart from the use as a stand-alone diagnostic, somatostatin receptor imaging is also utilised to identify patients that may benefit from somatostatin receptor targeted therapy.

^{18}F FDG is a different category of PET imaging. It is sometimes used for faster-growing NETs (grade 3) or in combination with somatostatin receptor imaging.[91]

Competitive environment

There are several ^{68}Ga- and ^{18}F-based PET diagnostic radiopharmaceuticals in development worldwide. However, there are a number of limitations to the expansion of these products. Firstly, none of the approved PET radiopharmaceuticals or those in development have the potential to image patients beyond a few hours after administration to the patient. In addition, the short half-life of ^{68}Ga based products requires them to be produced on-site, posing a requirement for radiopharmacy facilities in treatment centres where they are used.

84. Singh, Simron, Dan Granberg, Edward Wolin, Richard Warner, Maia Sissons, Teodora Kolarova, Grace Goldstein, Marianne Pavel, Kjell Öberg, and John Leyden. 2016. "Patient-Reported Burden of a Neuroendocrine Tumor (NET) Diagnosis: Results From the First Global Survey of Patients With NETs." Journal of Global Oncology 3 (1): 43–53. https://doi.org/10.1200/JGO.2015.002980.
85. Basuroy, Ron, Catherine Bouvier, John Keith Ramage, Maia Sissons, and Raj Srirajaskanthan. 2018. "Delays and Routes to Diagnosis of Neuroendocrine Tumours." BMC Cancer 18 (November). https://doi.org/10.1186/s12885-018-5057-3.
86. Singh, Simron, Dan Granberg, Edward Wolin, Richard Warner, Maia Sissons, Teodora Kolarova, Grace Goldstein, Marianne Pavel, Kjell Öberg, and John Leyden. 2016. "Patient-Reported Burden of a Neuroendocrine Tumor (NET) Diagnosis: Results From the First Global Survey of Patients With NETs." Journal of Global Oncology 3 (1): 43–53. https://doi.org/10.1200/JGO.2015.002980.
87. Aluri, Vidya, and Joseph S. Dillon. 2017. "Biochemical Testing in Neuroendocrine Tumors." Endocrinology and Metabolism Clinics of North America 46 (3): 669–77.
88. <https://www.researchgate.net/publication/342888432_Clinical_Medicine_Prevention_and_Management_of_Hormonal_Crisis_during_Theragnosis_with_LU-DOTA-TATE_in_Neuroendocrine_Tumors_A_Systematic_Review_and_Approach_Proposal>.
89. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5067972/>.
90. <https://www.cancer.net/cancer-types/neuroendocrine-tumors/diagnosis>.
91. <https://www.cancer.net/cancer-types/neuroendocrine-tumors/diagnosis>.

^{64}Cu based products have a longer half-life and can be produced in volume at a central radiopharmacy and distributed to a number of treatment sites. When combined with a suitable chelator for the copper isotope that does not leak copper in-vivo, ^{64}Cu enables imaging at later time points in addition to imaging at early time points. Imaging at later time points can produce images that are of better quality with a high contrast of diseased-to-healthy tissue and minimal circulating isotope (see Figure 28, Figure 29). Consequently, additional later time point imaging may enable the detection of additional tumours[92]. It is hoped that improved imaging will ultimately allow for earlier diagnosis and improved patient outcomes.

Furthermore, there are widely recognised issues with the supply and availability of ^{68}Ga radioisotope[93], further limiting the competitiveness of ^{68}Ga-based products and opening opportunities for ^{64}Cu based diagnostics (for more detail, see Sections 2.5.3 and 3.7).

Table 11: Imaging radiopharmaceutical products in development for NETs

Product in development	Receptor target	Phase of development
Al^{18}F NOTA-octreotide	SSTR2	Phase II/III
^{68}Ga HA-DOTATATE	SSTR2	Phase II
^{68}Ga NODAGA-E[c(RGDyK)]2	integrin αVβ3	Phase II
^{68}Ga NOTA-AE105	uPAR	Phase II
^{18}F MFBG	Norepinephrine transporter (NET-1)	Phase I/II
^{68}Ga NODAGA-LM3	SSTR2	Phase II
^{68}Ga DOTA-LM3	SSTR2	Phase II
^{68}Ga NODAGA-JR11 (^{68}Ga OPS202)	SSTR2	Phase II

Note: This list of products in development is not comprehensive and is indicative only.

For advantages and limitations of radioisotopes used in the products mentioned above, refer to Table 4 and Table 7 as well as Sections 2.4.4 and 2.5.3.

2.7.3. Breast cancer

2.7.3.1. Breast cancer: description and occurrence of cancer

Breast cancer is cancer that forms in the cells of the breasts. Breast cancer is the most common cancer, and the most common cause of female cancer mortality worldwide.[94] Breast cancer can occur in both men and women, but it is far more common in women. It is estimated that approximately 281,550 people will be diagnosed with breast cancer (accounting for 14.8% of all new cancer cases) and approximately 43,600 people will die of breast cancer (accounting for 7.2% of all cancer deaths) in the US in 2021.[95] Breast cancer is a highly heterogeneous disease and can be classified in different subtypes with distinctive characteristics.

92. Hicks RJ, et al. ^{64}Cu SARTATE PET imaging of patients with neuroendocrine tumours demonstrates high tumor uptake and retention, potentially allowing prospective dosimetry for peptide receptor radionuclide therapy. J Nucl Med. 2019;60(6):777-785.
93. <https://www.auntminnie.com/index.aspx?sec=ser&sub=def&pag=dis&ItemID=121582>.
94. <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660>.
95. <https://seer.cancer.gov/statfacts/html/breast.html>.

Although breast cancer is diagnosed by histology, imaging methods are essential for detection of the disease. Mammography is used for breast cancer screening to help with the diagnosis and, in some cases, this is supplemented with (MRI) or ultrasound.[96,97] Following confirmation of breast cancer, patients will usually undergo a series of additional staging scans to assess the extent of disease which will assist doctors to determine an appropriate treatment plan for patients. These scans may consist of CT, ^{99m}Tc bone scans and PET imaging.[98]

Most patients presenting with breast cancer have disease localised only to the breast or nearby lymph nodes, however, 40% to 50% eventually may develop metastatic disease[99]. Additionally, approximately 20% to 30% of breast cancer patients experience a relapse (return of the cancer after initial successful therapy) with metastatic disease.[100] In the setting of metastatic spread, the prognosis is poor with an overall 5-year life expectancy of 26%.[101]

Accurate staging is thus imperative in optimising treatment regimens. Staging is an effort to determine if the cancer has spread and, if so, to what parts of the body. At present, the standard of imaging for metastatic breast cancer consists of diagnostic CT, bone scanning and PET. There is increasing evidence that PET imaging detects distant metastases with higher sensitivity than conventional imaging.

Treatment goals of metastatic cancer patients focus on relieving symptoms of breast cancer, optimising quality of life, delaying disease progression, and prolonging life expectancy. The decision regarding therapy choice(s) for patients with metastatic breast cancer depends on several factors, including prior therapies that were administered, biological characteristics of the tumour, location of the tumours, and the patient's overall clinical condition. Treatment for metastatic breast cancer usually involves treatment with one or more systemic therapies, such as hormonal therapy, chemotherapy and targeted therapy.[102] Radiotherapy may be used to reduce the size of metastatic breast cancers in some parts of the body and to relieve pain, especially in the bones. Women with hormone receptor-positive (estrogen receptor-positive or progesterone receptor-positive) cancers are often treated first with hormone therapy. This may be combined with a targeted therapy if their cancer cells express hormone receptors. For women who do not have hormone receptors on their breast cancer cells, chemotherapy is the first choice.

A gastrin releasing peptide receptor (GRPr) is commonly expressed in breast cancer. Clarity's ^{64}Cu SAR-Bombesin and ^{67}Cu SAR-Bombesin products target the GRPr, which is found in approximately 83% of estrogen receptor positive breast cancers.[103] Studies have indicated that when the primary tumours express GRPr, metastases originating from these tumours also retain GRPr expression.[104] Retention of the GRPr expression in metastases makes it a promising target for staging and therapy of breast cancer.

2.7.3.2. Breast cancer: standard of care and competitive environment in radiopharmaceuticals

Standard of care

Imaging

Diagnostic radiopharmaceuticals are used for detecting and staging of metastatic disease and are not commonly used to diagnose breast cancer. Approved diagnostic agents that are used for imaging breast cancer include ^{99m}Tc MDP bone scan, ^{18}F FDG, ^{18}F sodium fluoride (^{18}F NaF) and ^{18}F fluoroestradiol (^{18}F FES, registered as Cerianna).

A ^{99m}Tc MDP bone scan, also called bone scintigraphy, is a planar whole body imaging test used to determine whether breast cancer has metastasised to the bones. These scans are commonly undertaken at initial diagnosis, as well during and after treatment. A ^{99m}Tc MDP bone scan can identify areas of physical and chemical changes in bone, such as bone tumours. However, these changes may indicate the presence of conditions such as arthritis, bone infections and bone trauma, resulting in "false-positive" findings. Although planar bone scanning has recognised limitations, such as poor specificity in staging and response assessment, it continues to be the main

96. Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update From the American Cancer Society | Breast Cancer | JAMA | JAMA Network, <https://jamanetwork.com/journals/jama/fullarticle/2463262>.
97. American Cancer Society Guidelines for Breast Screening with MRI as an Adjunct to Mammography - Saslow - 2007 - CA: A Cancer Journal for Clinicians - Wiley Online Library, <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/canjclin.57.2.75>.
98. Breast cancer - Diagnosis and treatment - Mayo Clinic, <https://www.mayoclinic.org/diseases-conditions/breast-cancer/diagnosis-treatment/drc-20352475>.
99. <https://www.mayoclinicproceedings.org/article/S0025-6196(11)62636-0/fulltext>.
100. (EBCTCG) EBCTCG. Effects of chemotherapy and hormonal therapy for early breast cancer on recurrence and 15-year survival: an overview of the randomised trials. The Lancet. 2005;365(9472):1687-1717.
101. Lu J, Steeg PS, Price JE, Krishnamurthy S, Mani SA, Reuben J, et al. Breast cancer metastasis: challenges and opportunities. Cancer Res. 2009;69(12):4951-3.
102. <https://www.canceraustralia.gov.au/affected-cancer/cancer-types/breast-cancer/treatment-options-metastatic-breast-cancer>.
103. <https://jnm.snmjournals.org/content/jnumed/early/2017/03/08/jnumed.116.188011.full.pdf>.
104. Dalm SU, Schrijver WA, Sieuwerts AM, et al. Prospects of Targeting the Gastrin Releasing Peptide Receptor and Somatostatin Receptor 2 for Nuclear Imaging and Therapy in Metastatic Breast Cancer. PloS one. 2017;12(1):e0170536.

method in current clinical practice for staging of the skeleton in patients at risk of bone metastases. There have been reported improvements in sensitivity and specificity (for definitions of these terms please refer to Section 2.4.4.3) for staging of the skeleton with either bone-specific PET/CT tracers, such as ^{18}F NaF, or tumour-specific tracers, such as ^{18}F FDG, although these methods are more costly.

The ^{18}F FDG PET/CT is often recommended when the findings of conventional imaging are suspicious or uncertain. ^{18}F FDG scans can be useful to determine whether the cancer has spread to the lymph nodes or to other parts of the body. ^{99m}Tc MDP bone scan or ^{18}F NaF PET/CT may be bypassed when ^{18}F FDG PET/CT has already detected skeletal metastasis.

Estrogen receptor (ER) expression in breast cancer is associated with a more favourable prognosis when the cancer is treated early, and it is necessary for response to endocrine therapies. Traditionally, ER expression is assessed by in vitro assays on biopsied tumour tissue. However, the FDA recently approved ^{18}F FES for the detection of estrogen receptor-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer. ^{18}F FES, however, is not useful for imaging other receptors that are commonly expressed on breast cancer cells (such as human epidermal growth factor receptor 2 and the progesterone receptor).

Therapy

There are currently no approved radiopharmaceuticals for breast cancer.

Competitive environment

Imaging

Table 12: Imaging radiopharmaceutical products in development for breast cancer

Product in development	Phase of development
^{18}F DPA-714	Phase II
^{18}F FLT	Phase II
^{18}F FFNP	Phase II
^{18}F DCFPyL	Phase II
^{18}F 4FMFES-PET	Phase II
^{18}F FDHT	Phase II
^{68}Ga NeoB	Phase II
^{68}Ga RM2	Phase I/II
^{18}F FSPG	Phase II
^{68}Ga ABY-025	Phase I/II
^{68}Ga NOTA-AE105	Phase II
^{89}Zr trastuzumab	Phase II
^{89}Zr pertuzumab	Phase I

Note: This list of products in development is not comprehensive and is indicative only.

For advantages and limitations of radioisotopes used in the products mentioned above, refer to Table 4 and Table 7 as well as Sections 2.4.4 and 2.5.3.

Therapy

Table 13: Therapeutic radiopharmaceutical products in development for breast cancer

Product in development	Phase of development
^{177}Lu DOTATATE	Phase II
^{177}Lu DOTATOC	Phase II
^{223}Ra dichloride	Phase II

Note: This list of products in development is not comprehensive and is indicative only.

For advantages and limitations of radioisotopes used in the products mentioned above, refer to Table 5 and Table 8 as well as Sections 2.4.5 and 2.5.3.

There are currently no reported clinical trials using GRPr-targeting therapeutic radiopharmaceuticals in development specifically for breast cancer. However, there are early phase safety studies in solid tumours with ^{177}Lu NeoBOMB1 (also called ^{177}Lu-NeoB; e.g. Clinicaltrials.gov entry NCT03872778)[105].

2.7.4. Prostate cancer

2.7.4.1. Prostate cancer: description and occurrence of cancer

Prostate cancer is the second most common cancer in men and the fifth leading cause of cancer death in men worldwide.[106] In the US, about one in eight men will be diagnosed with prostate cancer during his lifetime and about 1 in 41 men will die of prostate cancer.[107] In 2021, the National Cancer Institute estimated 248,530 new cases of prostate cancer (13.1% of all new cancers) in the US with an estimated 34,130 deaths (5.3% of all cancer deaths).[108]

Metastatic castration resistant prostate cancer (mCRPC) is an advanced and lethal form of prostate cancer. The number of people diagnosed with this form of prostate cancer has increased during the past years by 20%.[109] Despite the current availability of life-extending therapies for mCRPC, the majority of men will die of the disease as the median life expectancy is less than three years[110,111] (median life expectancy means that about 50% of patients are expected to be alive at a given timepoint).

Several imaging methods are used in different clinical scenarios with their very own advantages and limitations. Imaging plays a pivotal role in the management of prostate cancer through its non-invasive approach to evaluating the presence and extent of disease. Until recently, imaging of prostate cancer has most commonly been carried out by a combination of MRI, CT and via nuclear medicine bone scans. However, these conventional imaging modalities suffer from limited sensitivity and specificity for the detection of disease (for definitions of these terms please refer to Section 2.4.4.3). This can lead to disease under-staging and the improper selection of treatment. Given the limitations of traditional imaging, the use of PET imaging has been explored to better identify sites of disease. As a result, a number of new PET imaging products have been developed for the imaging of prostate cancer.

The main goal for treating metastatic prostate cancer is to control symptoms and slow progress. Some of the common treatments for mCRPC include chemotherapy, androgen synthesis inhibitors or androgen signal blockers and hormone therapy. Many patients will ultimately receive second line or third line therapies in the course of their treatment. Other treatment options involve immunotherapy and radiation therapy.

105. US National Library of Medicine – <ClinicalTrials.gov>. (Reference: NCT03872778).
106. <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660>.
107. <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>.
108. SEER Cancer Stat Facts: Prostate Cancer. 2019 <https://seer.cancer.gov/statfacts/html/prost.html>.
109. Zafeiriou Z, Jayaram A, Sharp A, de Bono JS. Managing Metastatic Castration Resistant Prostate Cancer in the Pre-chemotherapy Setting: A Changing Approach in the Era of New Targeted Agents. Drugs. 2016;76(4):421-430.
110. Ryan CJ, Smith MR, de Bono JS, et al. Abiraterone in metastatic prostate cancer without previous chemotherapy. N Engl J Med. 2013;368(2):138-148.
111. Barnett CM, Heinrich MC, Lim J, et al. Genetic profiling to determine risk of relapse free survival in high-risk localized prostate cancer. Clinical cancer research : an official journal of the American Association for Cancer Research. 2014;20(5):1306- 1312.

Prostate-specific membrane antigen (**PSMA**) is a transmembrane protein that is commonly expressed in prostate cancer. In the era of personalised medicine, there is an increased interest in the use of PSMA in the theranostic setting. Clarity's ^{64}Cu SAR-bisPSMA and ^{67}Cu SAR-bisPSMA products target PSMA, which is found in approximately 90% of prostate cancers[112]. Consequently, approximately 10% of patients will not be suitable for treatment with PSMA-targeting agents.

GRPR is a receptor that is overexpressed in a number of cancers including prostate, breast, colon, gastric, glioma, pancreatic, small cell lung and non-small cell lung cancer, as well as renal cell cancer.[113,114,115] Clarity's ^{64}Cu SAR-Bombesin and ^{67}Cu SAR-Bombesin products target the GRPR, which is found in approximately 75-100% of prostate cancers.[116,117,118,119,120] This provides an opportunity in the market, especially for patients that are not suitable for PSMA-targeted therapies.

2.7.4.2. Prostate cancer: standard of care and competitive environment in radiopharmaceuticals

Standard of care

Imaging

There are currently several diagnostic radiopharmaceuticals in use that have demonstrated efficacy for cancer detection in various clinical settings. Approved diagnostic radiopharmaceuticals that are commonly used to image prostate cancer include ^{99m}Tc MDP bone scan, ^{18}F FACBC (or ^{18}F Fluciclovine; registered as Axumin®), ^{18}F Sodium Fluoride (NaF), ^{11}C choline, ^{18}F FDG PET and, more recently, the PSMA-based PET radiopharmaceuticals, ^{68}Ga PSMA-11 and ^{18}F DCFPyL (registered as PYLARIFY®).

If prostate cancer spreads to distant parts of the body, it often goes to the bones first. ^{99m}Tc MDP bone scan (or bone scintigraphy) is a whole-body planar imaging test. A bone scan is not particularly effective at finding individual prostate cancer cells, and thus can miss very small tumours. It can detect bone damage or abnormalities that were caused by something other than cancer (e.g. arthritis), resulting in "false-positive" findings that can lead to unnecessary additional testing. Similar to ^{99m}Tc MDP, ^{18}F NaF is used for skeletal imaging of bone metastases but uses PET imaging. It provides diagnostic information superior to that of ^{99m}Tc MDP bone scans due to higher sensitivity and specificity in a wide variety of bone metastasis.[121,122]

Although ^{18}F FDG PET is commonly used in oncology to image different types of cancers, it has only shown limited clinical utility in prostate cancer imaging, with reported sensitivities as low as 37%.[123]

There are also a number of radiopharmaceuticals approved that accumulate in cells based on changes in the cellular metabolism, such as ^{11}C choline and ^{18}F FACBC. However, these changes in cellular metabolism are not specific to cancer cells and therefore these products may visualise non-cancerous tissues as well.

112. Silver DA, Pellicer I, Fair WR, et al. Prostate-specific membrane antigen expression in normal and malignant human tissues. Clin Can Res 1997;3(1):81-85; Kratochwil c, Afshar-Oromieh A, Kopka K, et al. Current status of prostate-specific membrane antigen targeting in nuclear medicine: clinical translation of chelator containing prostate-specific membrane antigen ligands into diagnostics and therapy for prostate cancer. Sem Nuc Med 2016;46(5):405-418; Santoni M, Scarpelli M, Mazzucchelli R, et al. Targeting prostate-specific membrane antigen for personalized therapies in prostate cancer: morphologic and molecular backgrounds and future promises. J Biol Reg Hom Ag 2014;28(4):555-563.
113. Maina, T. and B.A. Nock, From Bench to Bed: New Gastrin-Releasing Peptide Receptor-Directed Radioligands and Their Use in Prostate Cancer. PET Clin, 2017. 12(2): p. 205-217.
114. Kahkonen, E., et al., *In vivo imaging of prostate cancer using [68Ga]-labeled bombesin analog BAY86-7548*. Clin Cancer Res, 2013. **19**(19): p. 5434-43.
115. Mansi, R., et al., Bombesin-Targeted PET of Prostate Cancer. J Nucl Med, 2016. 57(Suppl 3): p. 67S-72S.
116. Markwalder R, Reubi JC. Gastrin-releasing peptide receptors in the human prostate: relation to neoplastic transformation. Cancer research. 1999;59(5):1152-1159.
117. Fleischmann A, Waser B, Reubi JC. High expression of gastrin-releasing peptide receptors in the vascular bed of urinary tract cancers: promising candidates for vascular targeting applications. Endocrine-related cancer. 2009;16(2):623-633.
118. Ananias HJ, van den Heuvel MC, Helfrich W, de Jong IJ. Expression of the gastrin-releasing peptide receptor, the prostate stem cell antigen and the prostate-specific membrane antigen in lymph node and bone metastases of prostate cancer. The Prostate. 2009;69(10):1101-1108.
119. Reubi JC, Wenger S, Schmuckli-Maurer J, Schaer JC, Gugger M. Bombesin receptor subtypes in human cancers: detection with the universal radioligand (125)I-[D-TYR(6), beta-ALA(11), PHE(13), NLE(14)] bombesin(6-14). Clin Cancer Res. 2002;8(4):1139-1146.
120. Sun B, Halmos G, Schally AV, Wang X, Martinez M. Presence of receptors for bombesin/gastrin-releasing peptide and mRNA for three receptor subtypes in human prostate cancers. The Prostate. 2000;42(4):295-303.
121. Ahuja, K, Sotoudeh H, Galgano SJ et al. ^{18}F-Sodium Fluoride PET: History, Technical Feasibility, Mechanism of Action, Normal Biodistribution, and Diagnostic Performance in Bone Metastasis Detection Compared with Other Imaging Modalities. Journal of Nuclear Medicine Technology 2020, 48 (1) 9-16.
122. Mick CG, James T, Hill JD, Williams P, Perry M. Molecular imaging in oncology: ^{18}F-sodium fluoride PET imaging of osseous metastatic disease. AJR. 2014;203:263–271.
123. Minamimoto R, Senda M, Jinnouchi S, Terauchi T, Inoue T. Detection of prostate cancer by an FDG-PET cancer screening program: results from a Japanese nationwide survey. Asia Ocean J Nucl Med Biol. 2014;2(1):19-23.

To improve prostate cancer imaging, PET radiotracers that bind to specific proteins on prostate cancer cells, such as PSMA, have been developed. Recently, the FDA approved two PSMA-based diagnostic radiopharmaceuticals, ^{68}Ga PSMA-11 and ^{18}F DCFPyL. Preliminary evidence indicates that these new PSMA PET products are better at detecting prostate cancer than the previously approved PET products (such as ^{11}C choline and ^{18}F FACBC).[124,125,126] Therefore, PSMA has quickly become the front-runner of the currently available radiopharmaceuticals for imaging of prostate cancer.

At present, ^{68}Ga PSMA-11 is only available locally at two sites, The University of California, Los Angeles in the US, and The University of California, San Francisco in the US, severely limiting its availability for patients not able to attend these institutions for imaging.

In terms of standard of care therapeutic radiopharmaceuticals, radium-223 (registered as Xofigo®), an alpha-particle-emitting radiopharmaceutical, is indicated for the treatment of end-stage mCRPC patients with bone metastases. It has also been shown to help men who have prostate cancer that has spread only to their bones (as opposed to spreading to other organs such as the lungs) to live longer. For these men, radium-223 may be an early part of treatment. For more information about α-particle-emitting radiopharmaceuticals see Section 2.4.5.1

Competitive landscape

Imaging

There are several PET diagnostic radiopharmaceuticals targeting PSMA as well as GRPr currently in development (see table below).

Table 14: Imaging radiopharmaceutical products in development for prostate cancer

Product in development	Receptor target	Phase of development
^{18}F PSMA-1007	PSMA	Phase III
^{68}Ga THP-PSMA (GalliProst™)	PSMA	Phase II
^{68}Ga PSMA-R2	PSMA	Phase II
^{68}Ga PSMA-11	PSMA	Phase III
^{18}F rhPSMA-7.3	PSMA	Phase III
^{68}Ga NeoB	GRPr	Phase II
^{68}Ga RM2	GRPr	Phase II/III

Note: This list of products in development is not comprehensive and is indicative only.

For advantages and limitations of radioisotopes used in the products mentioned above, refer to Table 4 and Table 7 as well as Sections 2.4.4 and 2.5.3.

124. Alonso O, Dos Santos G, Garcia Fontes M, Balter H, Engler H. (68)Ga-PSMA and (11)C-Choline comparison using a tri-modality PET/CT-MRI (3.0 T) system with a dedicated shuttle. European journal of hybrid imaging. 2018;2(1):9.

125. Schwenck J, Rempp H, Reischl G, et al. Comparison of (68)Ga-labelled PSMA-11 and (11)C-choline in the detection of prostate cancer metastases by PET/CT. European journal of nuclear medicine and molecular imaging. 2017;44(1):92-101.

126. Calais J, Ceci F, Eiber M, et al. (18)F-fluciclovine PET-CT and (68)Ga-PSMA-11 PET-CT in patients with early biochemical recurrence after prostatectomy: a prospective, single-centre, single-arm, comparative imaging trial. The Lancet Oncology. 2019;20(9):1286-1294.

Therapy

There are several therapeutic radiopharmaceuticals targeting PSMA as well as GRPR currently in development (see table below).

Table 15: Therapeutic radiopharmaceutical products in development for prostate cancer

Product in development	Receptor target	Phase of development
^{177}Lu PSMA-617	PSMA	Phase III
^{177}Lu PSMA I&T (PNT2002)	PSMA	Phase III
^{177}Lu DOTA-rosopatamab	PSMA	Phase III
^{131}I MIP-1095	PSMA	Phase I
^{225}Ac PSMA-617	PSMA	Phase I
^{225}Ac J591	PSMA	Phase I/II
^{177}Lu PSMA-R2	PSMA	Phase I/II
^{177}Lu RM2	GRPr	Phase I

Note: This list of products in development is not comprehensive and is indicative only.

For advantages and limitations of radioisotopes used in the products mentioned above, refer to Table 5 and Table 8 as well as Sections 2.4.4 and 2.5.3.

^{177}Lu PSMA-617 is currently under clinical investigation for mCRPC. Novartis recently announced the positive results from the Phase III VISION study with ^{177}Lu PSMA-617 and its plan to submit to US and EU health authorities in the second half of 2021. The product has also received breakthrough status from the US FDA. Men who received ^{177}Lu PSMA-617 plus best standard of care had a 38% reduction in risk of death (median overall survival benefit of four months) and a 60% reduction in the risk of radiographic disease progression or death (median radiographic progression-free survival benefit of five months) compared to best standard of care alone.[127]

Besides a published first in human dosimetry study using ^{177}Lu RM2[128], there are currently no reported clinical trials using GRPr-targeting therapeutic radiopharmaceuticals in development specifically for prostate cancer. However, there are early phase safety studies in solid tumours with ^{177}LuNeoBOMB1 (also called ^{177}Lu-NeoB; e.g. see Clinicaltrials.gov entry NCT03872778[129]).

127. <https://www.novartis.com/news/media-releases/novartis-177lu-psma-617-significantly-improves-overall-survival-and-radiographic-progression-free-survival-men-metastatic-castration-resistant-prostate-cancer>.
128. Kurth J, Krause BJ, Schwarzenbock SM, Bergner C, Hakenberg OW, Heuschkel M. First-inhuman dosimetry of gastrin-releasing peptide receptor antagonist [(177)Lu]Lu-RM2: a radiopharmaceutical for the treatment of metastatic castration-resistant prostate cancer. European journal of nuclear medicine and molecular imaging. 2020;47(1):123-135.
129. US National Library of Medicine <ClinicalTrials.gov>. (Reference: NCT03872778).

03

Company Overview

03 Company Overview

3.1. Introduction to Clarity Pharmaceuticals Ltd

Clarity is a clinical stage radiopharmaceutical company developing next-generation products to address the growing need for radiopharmaceuticals in oncology.

Clarity is a global leader in Targeted Copper Theranostics (**TCT**), developed with its proprietary SAR Technology platform.

TCT are the next-generation disruptive platform in radiopharmaceuticals that employ the "perfect pairing" of copper-64 (^{64}Cu) and copper-67 (^{67}Cu) for diagnosis and therapy. TCT deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers, as well as providing supply and logistical advantages over current theranostics. TCT provide a highly efficacious, scalable, and cost-effective way to expand radiopharmaceuticals into the global oncology market.

Clarity has a diverse range of products in clinical trials which address both large indications (prostate cancer and breast cancer) as well as rare and orphan indications (neuroendocrine tumours (NETs) and neuroblastoma) of cancer.

The versatility of the SAR Technology platform enables Clarity to pursue a Discovery Program focused on developing new products and new intellectual property (IP) for a range of indications of cancer. Clarity has a robust IP position with a broad patent portfolio covering its platform, pipeline and products.

Clarity's current pipeline of products in clinical and preclinical stages include:

- **SARTATE™ Neuroblastoma:** for the treatment of neuroblastoma, Phase I/IIa (see Section 3.5.1.1)
- **SARTATE™ NETs:** for the diagnosis of neuroendocrine tumours (NETs), Phase II (see Section 3.5.1.2)
- **SAR-Bombesin:** a pan-cancer treatment product, including for the treatment of breast cancer and prostate cancer, Phase I (see Section 3.5.2)
- **SAR-bisPSMA:** for the treatment of prostate cancer, Phase I/IIa; for the diagnosis of prostate cancer, Phase I (see Section 3.5.3)

Clarity's main focus is on the US regulatory approval pathway. The Company currently has two open Investigational New Drug (IND) applications that have received clearance to proceed to clinical trials from the FDA for its theranostic SARTATE™ and SAR-bisPSMA products. SARTATE™ has been granted two ODDs and two RPDDs from the FDA for the management and treatment of neuroblastoma. If Clarity is able to achieve successful US FDA New Drug Applications for SARTATE™ in neuroblastoma, these may give Clarity access to two tradable Priority Review Vouchers (PRVs) which are further discussed in Section 2.6.4 (although there can be no guarantee that these PRVs will be able to be accessed).

3.1.1. History of Clarity

Clarity was founded in 2010 with licenses to intellectual property from The University of Melbourne and the Australian Nuclear Science and Technology Organisation. The Company completed its first capital raising in early 2011, and through this funding and by leveraging Australian Government grants it began developing the technology toward clinical products. Clarity started to grow its team in 2013 through engaging employees and advisers with commercial and clinical experience and continued to raise capital to achieve its goals.

Clarity's first clinical product, SARTATE™, entered a first-in-human Phase I trial in 2015, which demonstrated the technology's ability to target and visualise the cancer of the trial patients. This result enabled the rollout of a pipeline of products, which include SAR-Bombesin and SAR-bisPSMA. Clarity continued to raise capital with a A$10 million equity raising in 2019 and a A$25 million equity raising in 2020 from sophisticated and professional investors. This has led to the expansion of the team with world class experience and subsequently the translation of its three lead products into clinical development.

3.2. Clarity's proprietary SAR Technology platform

3.2.1. Introduction

Clarity's proprietary SAR Technology platform can be used to develop a range of theranostic radiopharmaceuticals that target different types of cancer. The technology can be employed for diagnostic imaging using (PET) cameras as well as for targeted cancer therapy.

At the heart of Clarity's theranostic SAR Technology platform is a highly specific and highly stable bifunctional cage (chelator) that retains copper isotopes within it and prevents their leakage into the body. The cage is linked to a targeting molecule, which finds and binds tumour specific receptors on cancer cells. Together with the targeting molecule and the isotope, the technology enables the development of radiopharmaceuticals for diagnosis and therapy in oncology.

3.2.2. History of Clarity's SAR Technology

3.2.2.1. Introduction

Clarity's proprietary SAR Technology and Targeted Copper Theranostics (**TCT**) build on a long-term history of scientific and technological progress in the use of radiation to treat disease.

Since the discovery of radioactivity in 1896, scientists, researchers and clinicians have been actively exploring its therapeutic use. In 1941, Dr Saul Hertz treated a patient for the first time with radioactive iodine (radioiodine). Iodine is selectively taken up by the thyroid gland, offering effective treatment for patients with thyroid cancer and is still in clinical use today. Importantly, Dr Hertz was able to image the radioiodine in the patient and confirm its selective uptake in the cancer. The ability to image and treat with radioiodine was the birth of theranostics.

3.2.2.2. The development of Clarity's SAR Technology

The pioneering work that had a direct influence on Clarity's proprietary technology was conducted by a prominent Australian chemist Professor Alan Sargeson (1930-2008) and his team at the Australian National University. They focused on the development of a cage that can hold a metal inside – a "chelator". They called this chelator "sarcophagine", which was a word play on "sarcophagus", i.e. holding copper inside and preventing it from leaking to the body. The name of the chelator, sarcophagine, further gave name to Clarity's proprietary "SAR" Technology.

Professor Sargeson envisioned for the technology to be used in the field of oncology and anticipated the potential role of the new chelator technology as a powerful molecular imaging agent to diagnose disease, evaluate response to treatment and be used as a therapeutic.

Professor Paul Donnelly and his team at the School of Chemistry and Bio21 Institute of Molecular Science and Biotechnology, The University of Melbourne, worked on modifying the original "sarcophagine" chelator to produce bifunctional chelating agents. These agents were called "bifunctional" due to the ability to serve two objectives: a metal binding moiety function and a chemically reactive functional group, enabling the chelator's attachment to a biologic agent.

The developed chelators have the ability to completely encapsulate copper isotopes and demonstrate in vivo thermodynamic stability, kinetic inertness as well as rapid clearance from the body. The research proved to be readily adaptable for large scale manufacture. Clarity holds a robust patent portfolio to protect the sarcophagine technology and the products based on it.

3.2.2.3. Key contributions in the history of radiopharmaceuticals

There are a number of key milestones in the development of theranostics that contribute and allow Clarity to be well positioned in the nuclear medicine market.

^{64}Cu, a diagnostic radioisotope, can be produced on cyclotrons in large volumes. A cyclotron is a particle accelerator which can be used to produce radioactive isotopes for medical applications. There is a significant network of cyclotrons globally due to the success of ^{18}F FDG, a radiolabelled sugar which is taken up by rapidly dividing cells that need energy. This includes muscles and the brain but also cancers. Typically known as the "PET scan", ^{18}F FDG lights up cancers in the body and is now a stalwart of oncology worldwide as a definitive diagnostic across most cancers. The PET scan tells the doctor where the cancers are across the whole body and how many

cancerous tumours there are. This allows the doctor to stage the disease and develop a treatment plan that may include surgery, radiotherapy, chemotherapy or targeted therapy. Importantly for Clarity's products, since ^{18}F FDG was developed in the 1980s and rolled out over the 1990s, the cyclotron and PET camera infrastructure is already imbedded across the world, aiding ^{64}Cu production and ^{64}Cu PET imaging.

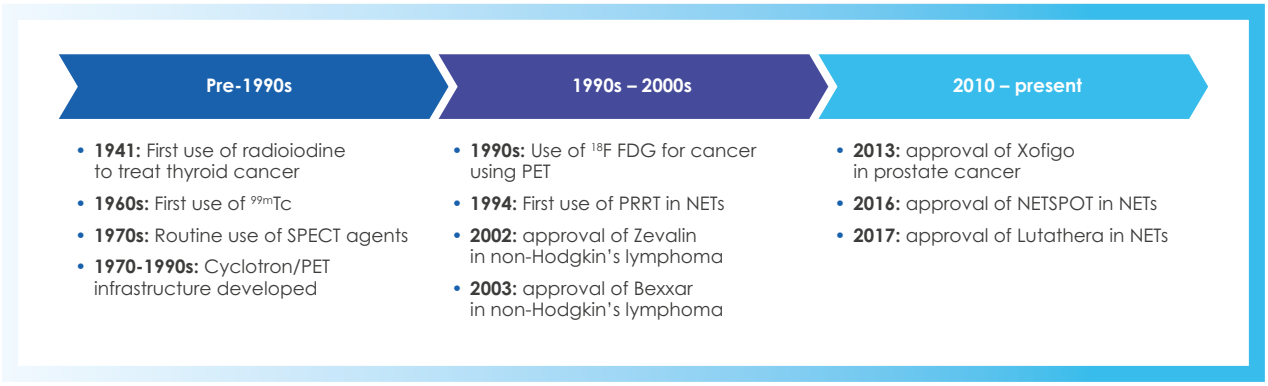
Another major advance was the manufacture of high purity, high specific activity and high yields of ^{67}Cu, which is a therapeutic isotope. Attempts to manufacture ^{67}Cu on nuclear reactors started about 50 years ago, but the purity, specific activity and yields were low and not commercially viable. The development of electron accelerators for use in radiotherapy and industrial applications prompted the development of various ^{67}Cu production methods. The major breakthrough was reported in the ^{68}Zn(γ,p)^{67}Cu reaction which enabled manufacture of high purity and high specific activity ^{67}Cu with scalable processes that can produce high yield.

A key milestone in the development of targeted radiopharmaceuticals was registrations of the first two therapeutic radiopharmaceutical products Zevalin® (2002) and Bexxar (2003) for treatment of non-Hodgkin lymphoma. These were two products based on radiolabelled antibodies that targeted a cancer specific receptor and had a therapeutic isotope attached to the antibodies (termed radioimmunotherapy or RIT). Zevalin® remains in use today.

One of the key events that enabled the development of theranostics was the first use of a targeted radiolabelled peptide in the technique called Peptide Receptor Radionuclide Therapy (PRRT). The first-in-human use of PRRT occurred in 1994 to treat neuroendocrine tumours as ^{18}F FDG had poor uptake in these types of cancer. The first registration of PRRT as a product occurred in 2017 when Advanced Accelerator Applications (AAA, now owned by Novartis) registered Lutathera®. AAA has paved the regulatory pathways for Clarity's lead product SARTATE™ and has helped open the radiopharmaceutical market for subsequent theranostics.

Figure 15 below illustrates the key milestones in the development of radiopharmaceuticals from the birth of theranostics.

Figure 15: Development timeline of radiopharmaceuticals



3.2.3. SAR Technology and products

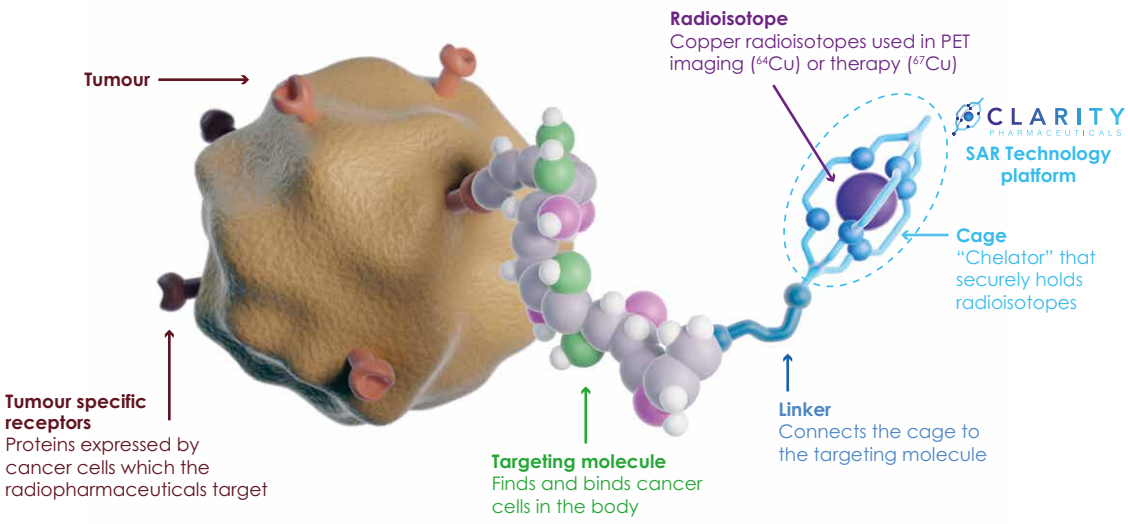
Clarity's SAR Technology securely holds isotopes of copper inside the cage, employing copper-64 (^{64}Cu) for the diagnosis and copper-67 (^{67}Cu) for the treatment of cancer. The isotope is delivered to the cancer site via biological targeting agents, which are linked to the cage carrying the isotope.

The biological targeting agent (targeting molecule) is designed to find and bind/stick to specific proteins on cancer cells. Once the targeting molecule has found the tumour, the radioisotope can act in that location, either emitting radiation to be picked up by an imaging device (diagnostic radioisotope) or by destroying the cancer cells (therapeutic radioisotope).

For Clarity's diagnostic products, a PET scanner is used to essentially "see" where the radiopharmaceutical is in the body. This is used in diagnostics, measuring the extent of the disease, as well as disease progression. It can also be used as a companion diagnostic to a therapy, helping to select patients who are most likely to respond to treatment.

In Clarity's therapeutic products, ^{67}Cu kills cancer cells by causing breaks in their DNA strands. These products are administered intravenously. Figure 16 outlines how Clarity's products and SAR Technology platform work in practice.

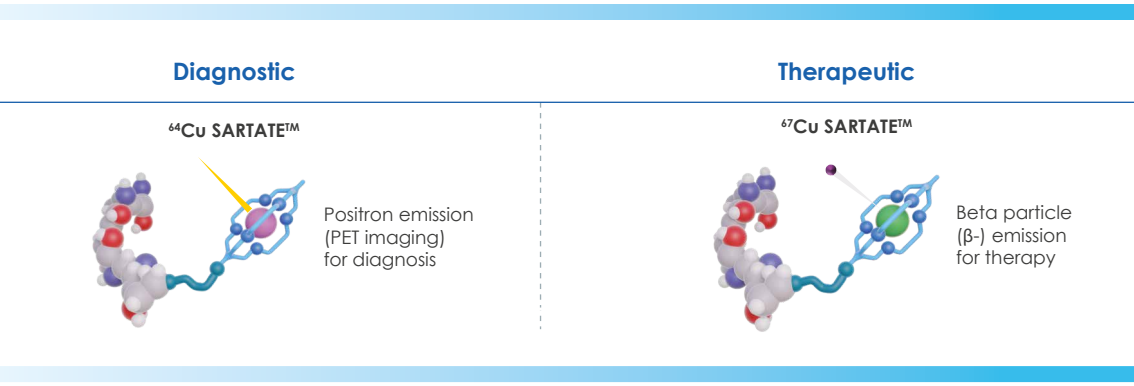
Figure 16: Clarity's SAR Technology in action



3.2.3.1. The sarcophagine chelator

Outlined in Figure 17 is a graphic of Clarity's SAR chelator, bound to a targeting molecule, across both diagnostic and therapeutic products.

Figure 17: Graphic of Clarity's SAR chelator bound to a targeting molecule



As discussed in Section 2.5.3.1, the utilisation of copper radioisotopes has historically been hampered as there were no suitable cages (chelators) that would hold the isotopes inside securely and prevent their leakage into the body when administered to the patients. Clarity's chelator seeks to address this issue.

Clarity's sarcophagine chelators are based on a cage structure which has six points to coordinate the copper metal (see Figure 18). Other cages used in radiopharmaceutical development often have only four points to hold the metal (see Figure 5). This difference and other chemistry characteristics can be attributed to the higher stability of the sarcophagine chelators for copper. Clarity holds a large IP portfolio on the SAR Technology platform which enables their commercial exploitation, whereas most other chelators remain unpatented.

Figure 18 visualises the difference in Clarity's superior chelator compared to other chelators.

Figure 18: Comparison of Clarity's superior chelator vs. other chelators

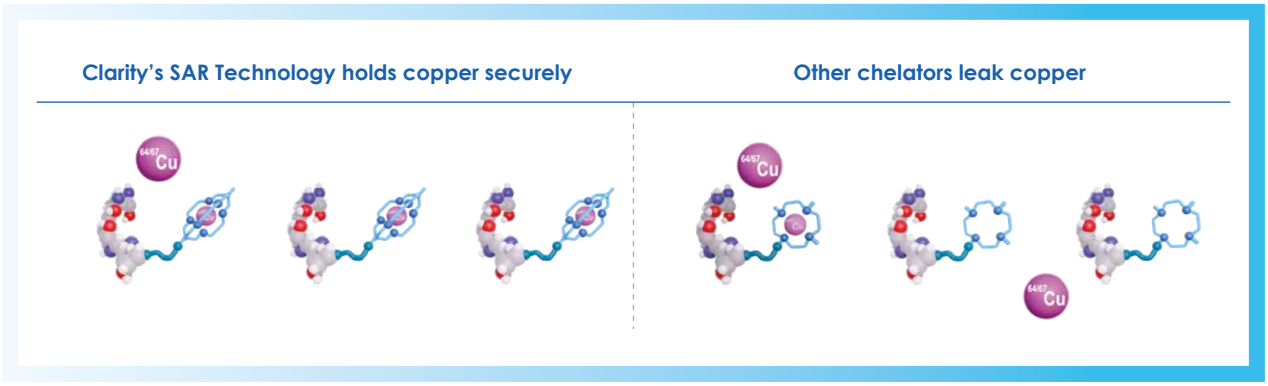


Figure 19 highlights the improvement in clinical outcomes that Clarity's chelator brings. Free ^{64}Cu leaked from the chelator usually accumulates in the liver, presenting background radioactivity on diagnostic scans. The images of ^{64}Cu SARTATE™ highlight that there is a decrease in detected radioactivity in the liver over time, which is indicative that there is minimal free ^{64}Cu in the body as a result of chelator leakage, meaning that there is minimal copper leaking from the product. In comparison, images with ^{64}Cu DOTATATE, which employs a chelator called DOTA, show that there is a constant background in the liver, indicative of the presence of free ^{64}Cu in the liver, meaning there is leakage from the DOTA chelator.

Figure 19: Comparison of Clarity's ^{64}Cu SARTATE™ vs. ^{64}Cu DOTATATE

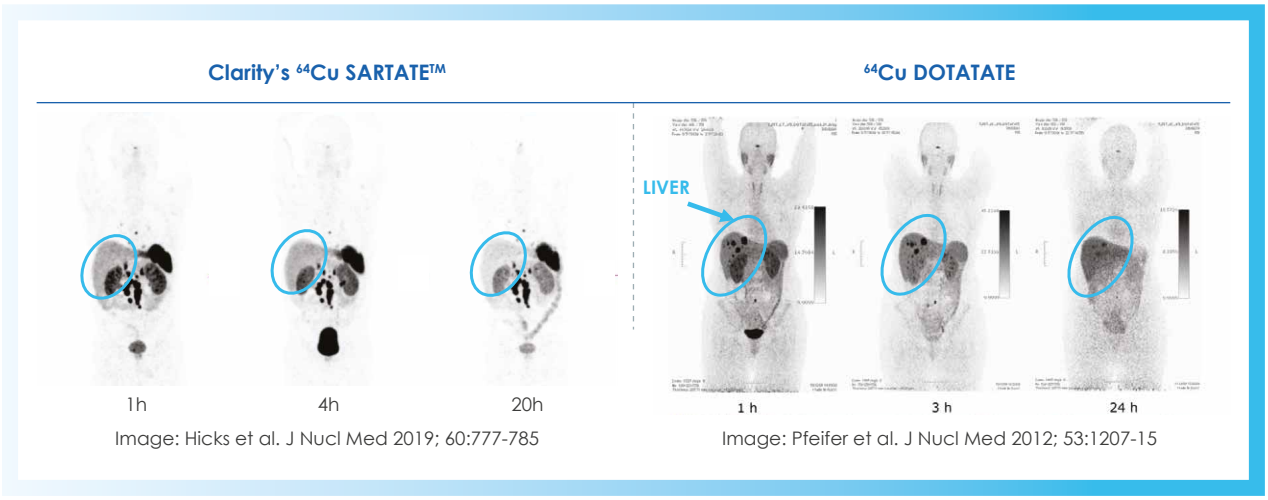


Image: Hicks et al. J Nucl Med 2019; 60:777-785

Image: Pfeifer et al. J Nucl Med 2012; 53:1207-15

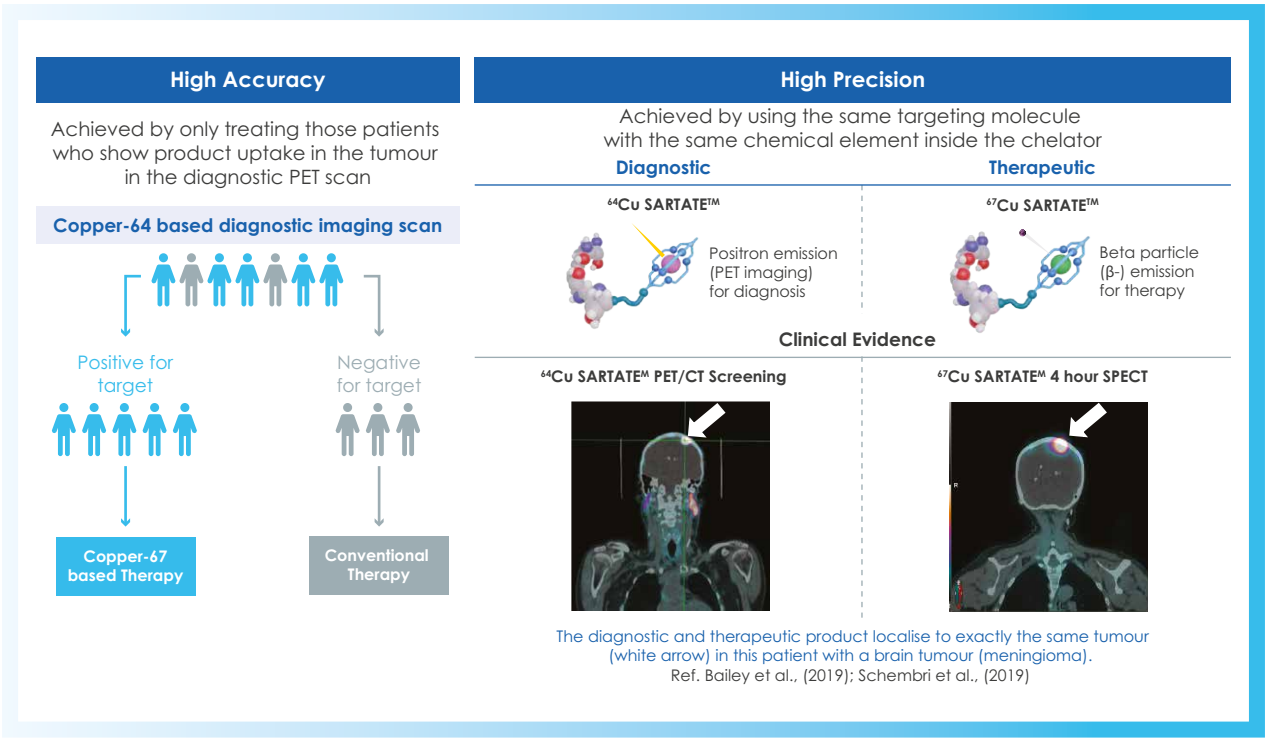
3.2.3.2. Benefits of the SAR Technology platform and copper radioisotopes

High accuracy and high precision

The two key clinical benefits of using copper isotopes are that they provide high accuracy and high precision in diagnosing and treating cancer.

High accuracy can be achieved by only selecting those patients for therapy who show product uptake in the tumours when imaging with a PET scan during the diagnostic stage, an indicator that the product targets the cancer and not healthy tissues, thereby maximising the probability of treatment success. High precision is achieved by using the same targeting molecule with the same chemical element inside the chelator (a different isotope of copper), ensuring both the diagnostic and therapeutic products have identical targeting in vivo as outlined in Figure 20.

Figure 20: High accuracy and high precision



The diagnostic and therapeutic product localise to exactly the same tumour (white arrow) in this patient with a brain tumour (meningioma).
Ref. Bailey et al., (2019); Schembri et al., (2019)

Further clinical benefits

Key advantages of Clarity's SAR Technology platform are outlined in Table 16.

Table 16: Key advantages of Clarity's SAR Technology platform

Advantage	Comments
Greater stability than other chelating agents for binding copper	SAR Technology is considered more stable than other chelating agents for binding copper.[130] Other chelators have resulted in the leakage of copper from the chelator which accumulates in the liver once released into the bloodstream. As a result, using these chelators provides less imaging clarity due to the background in the scan created by free ^{64}Cu. The increased stability of the SAR Technology allows therapeutic applications with ^{67}Cu. The leakage of high activity ^{67}Cu into the body would have significant safety concerns due to off-target therapeutic radiation from free ^{67}Cu at high doses.
Targeting agent's ability to bind to a cancer cell is unaffected	SAR Technology does not affect the targeting agent's ability to bind to a cancer cell, meaning more of the radiopharmaceutical finds the disease site, and does not bind to healthy cells.
High quality diagnostic images	With the diagnostic radioisotope ^{64}Cu, greater stability results in high-quality images with a high contrast of diseased-to-healthy tissue and minimal circulating isotope. Such high-quality images provide clinicians with a powerful tool for diagnosis and help to assist in the making of informed decisions regarding therapeutic development and treatment.
Improved image resolution compared to ^{68}Ga and ^{89}Zr	The shorter positron range of ^{64}Cu gives improvements in image resolution, which is important in the localisation of small tumours.
Minimal side effects from treatment	With the therapeutic radioisotope ^{67}Cu, greater stability results in the therapeutic load being delivered to the tumour site with minimal off-target activity, preventing accumulation in healthy tissues and organs and minimising side effects.
Centralised manufacture of finished drug products	SAR Technology allows the utilisation of copper isotopes in a range of different products. The radioactive half-lives of ^{64}Cu and ^{67}Cu are particularly suited to the centralised manufacturing of finished drug products which allows ready-to-use products to be delivered to a larger base of end users.

130. Di Bartolo, N. et al. (2001). Synthesis of a new cage ligand, SarAr, and its complexation with selected transition metal ions for potential use in radioimaging. J. Chem. Soc., Dalton Trans.2303–2309.

Significant supply and manufacturing advantages

Clarity's SAR Technology is specifically designed for copper, which has substantial supply and manufacturing advantages over other theranostic pairings in the market. See Section 3.7 for further detail.

Flexible platform enabling product development

A key advantage of SAR Technology is that it allows for the development of a range of radiopharmaceutical products by attaching it to various biological targeting agents. Biological targeting agents have been developed to target many different diseases, mostly in oncology but also in cardiology, rheumatology, dermatology, gastroenterology, neurology and others. SAR Technology allows radioisotopes of copper, held securely in a cage, to be linked to these agents. In this way, SAR Technology is a platform technology that enables Clarity to build a pipeline of products by using different biological targeting agents to image and/or treat different diseases.

See Section 3.5 for the range of products Clarity is currently developing and trialling using the SAR Technology platform and Section 3.6 for more detail on Clarity's Discovery Program.

3.3. Clarity's product pipeline

Clarity's clinical development pipeline is underpinned by its proprietary SAR Technology platform that enables highly targeted theranostic radiopharmaceuticals for both the diagnosis (using copper-64) and treatment (using copper-67) of serious diseases. Clarity has a well-developed pipeline of clinical-stage products as outlined in Section 3.5.

Clarity's products are progressing through Phase I and Phase II clinical trials with two open IND applications that received clearance to proceed to clinical trials from the FDA, two RPDDs and two ODDs from the FDA.

Clarity's most advanced product, SARTATE™, is being developed to diagnose and treat an aggressive childhood cancer, neuroblastoma, and is also being developed as a diagnostic for the adult cancer, neuroendocrine tumours (NETs). Clarity successfully completed a first-in-human diagnostic study in NETs and a Phase I/IIa theranostic safety trial in adult patients with a brain cancer called meningioma. These completed trials provided the data to commence SARTATE™'s development as a cancer therapy in a Phase I/IIa theranostic trial of patients with high-risk neuroblastoma in the US. Neuroblastoma is the lead indication for SARTATE™ as both a diagnostic and therapeutic product. Clarity has also continued the diagnostic development of SARTATE™ for NETs in a Phase II diagnostic trial, which is being run in Australia.

With the success of SARTATE™ in early clinical trials providing validation for the SAR Technology platform as a paradigm, Clarity has utilised it to progress two additional products into clinical development, SAR-bisPSMA for prostate cancer and SAR-Bombesin as a pan-cancer product.

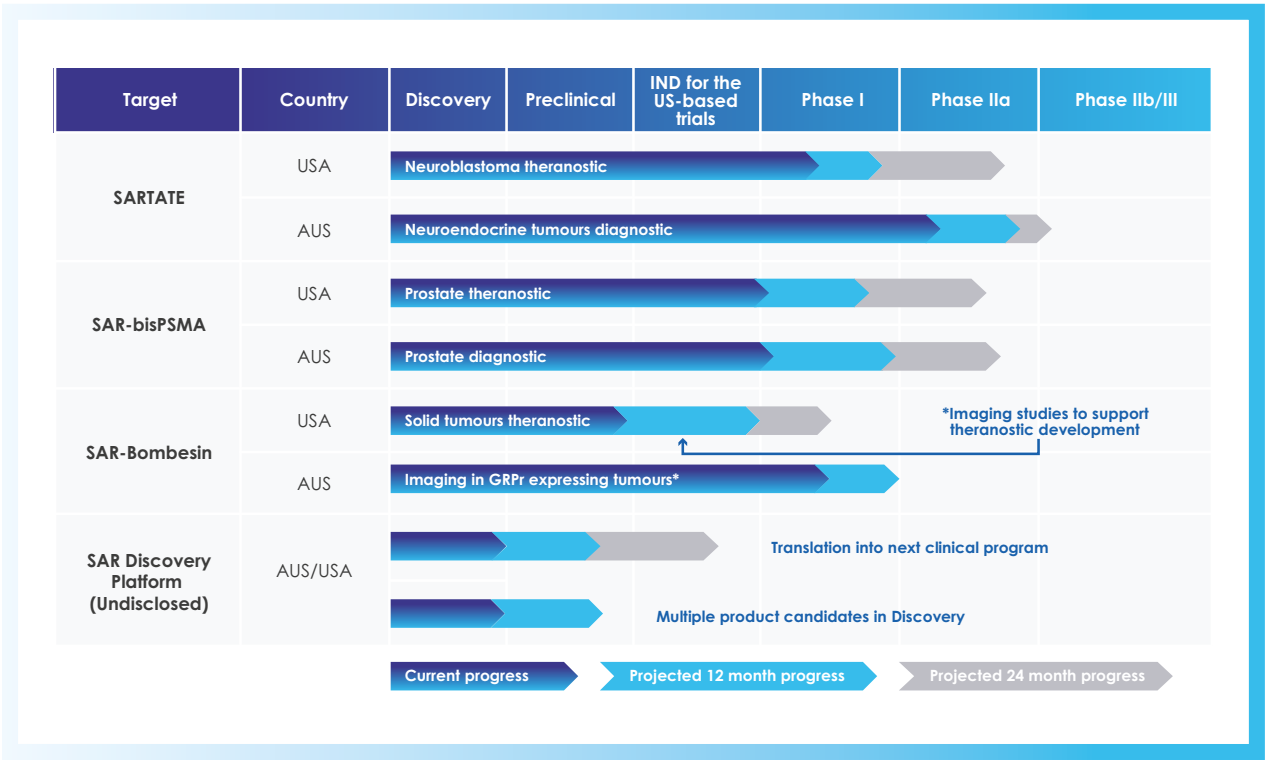
The prostate cancer market is a key focus for the Company. Clarity's SAR-bisPSMA products hold great promise of improving prostate cancer diagnosis and treatment and have the potential to provide multiple benefits in comparison to current products in the market. Clarity's ^{64}Cu SAR-bisPSMA diagnostic Phase I multicentre trial in Australia is currently open for recruitment. The theranostic $^{64/67}$Cu SAR-bisPSMA Phase I/IIa trial in the US is expected to commence in July 2021.

SAR-Bombesin is mid-way through a diagnostic clinical trial in breast cancer. SAR-Bombesin's clinical utility in prostate cancer has already been demonstrated with a small number of prostate cancer patients having SAR-Bombesin administered to assist with the diagnosis of their disease. Clarity will also explore the potential benefits of using the SAR-Bombesin product in other indications, such as brain cancer.

In addition to the development of SARTATE™, SAR-bisPSMA and SAR-Bombesin, Clarity has a number of other projects for therapeutic oncology indications in its Discovery Program, all of which are based on the SAR Technology platform and the utilisation of ^{64}Cu and ^{67}Cu.

Clarity is developing products for both rare and large indications of cancer, thereby positioning the products to take advantage of the high unmet needs that currently exist in respect of the medical treatment of these types of cancer. Clarity's focus in the development process is on high quality clinical sites and experienced investigators. The Company is targeting the lucrative US market for first product approvals.

Figure 21: Overview of Clarity's products and clinical trial status



3.4. Recent milestones

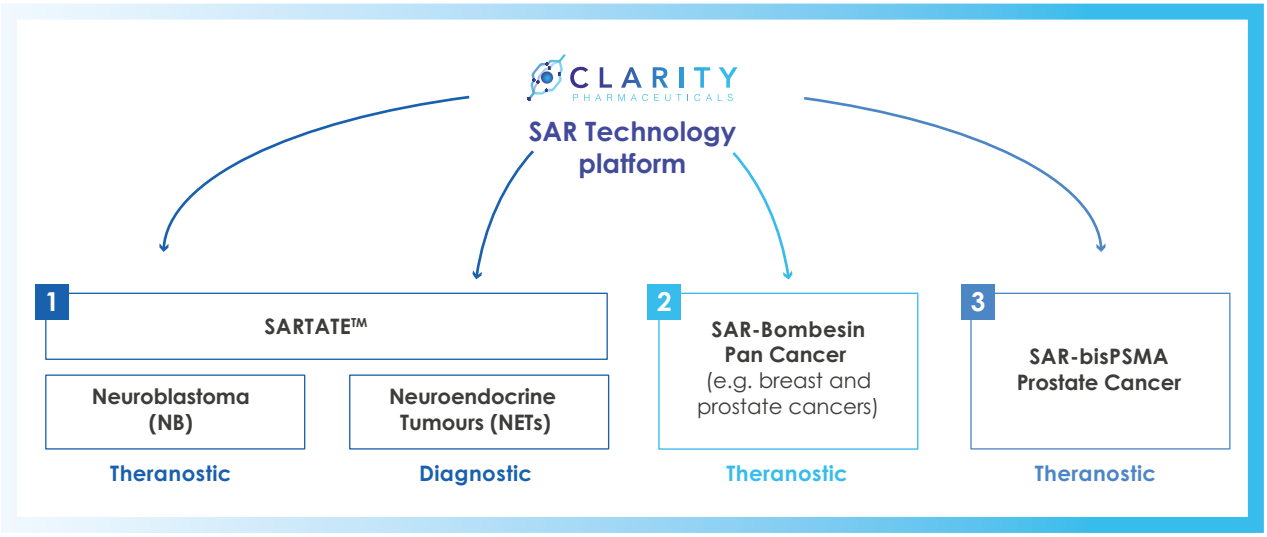
Clarity has reached significant milestones in its clinical processes since the beginning of 2020, with a number of important developments achieved in 2021.

Figure 22: Clarity's recent milestones in 2020 and 2021

2020	
Feb 11, 2020 –	NorthStar Medical Technologies Signs Letter of Intent to Supply Therapeutic Radioisotope copper-67
Mar 4, 2020 –	Commencement of capital raising of $25 million
Mar 13, 2020 –	Copper-67 Supply Agreement signed with Idaho State University's Idaho Accelerator Center
Apr 21, 2020 –	US FDA grants ^{67}Cu SARTATE Orphan Drug Designation for neuroblastoma
May 19, 2020 –	US FDA grants ^{64}Cu SARTATE Orphan Drug Designation for the clinical management of neuroblastoma
Jun 3, 2020 –	US FDA grants Rare Paediatric Disease Designation to ^{67}Cu SARTATE for the treatment of neuroblastoma
Jul 21, 2020 –	Clarity and ImaginAb to collaborate on new cancer targets
Jul 23, 2020 –	Clarity opens SARTATE™ neuroblastoma clinical trial
Jul 28, 2020 –	First patient treated with Clarity's copper-64 SAR-Bombesin in breast cancer clinical trial
Sep 9, 2020 –	US FDA Grants Rare Paediatric Disease Designation to ^{64}Cu SARTATE, a diagnostic for the clinical management of neuroblastoma
Nov 3, 2020 –	Patient treatments commence with Clarity's copper-64/copper-67 SARTATE in neuroblastoma clinical trial
2021	
Feb 2021 –	Assignment of certain patents from the University of Melbourne (previously licensed to Clarity)
Apr 2021 –	First patient treated in Clarity's copper-64 SARTATE Phase II trial in patients with neuroendocrine tumours (NETs)
May 2021 –	Clarity Received US FDA response on its Theranostic Investigational New Drug (IND) Application that the SAR-bisPSMA SECURE study may proceed
May 2021 –	SAR-bisPSMA patent granted in the US
May 2021 –	Shaemus Gleason Appointed Executive Vice President US Operations at Clarity Pharmaceuticals
May 2021 –	Ethics approval for ^{64}Cu SAR-bisPSMA trial in Australia
May 2021 –	Copper-67 supply agreement with NorthStar
June 2021 –	Neuroblastoma study in the US site expansion
July 2021 –	^{64}Cu SAR-bisPSMA trial (PROPELLER) opens for recruitment

3.5. Clarity's products

Figure 23: Clarity's SAR Technology platform, products, and cancer areas which Clarity's products target



3.5.1. SARTATE™

Clarity's lead product, SARTATE™, is a next-generation, highly targeted theranostic radiopharmaceutical which is being developed for diagnosing, staging and subsequently treating cancers that express somatostatin receptor 2 (SSTR2).

SARTATE™ combines the well characterised somatostatin analogue octreotate, which targets SSTR2-positive lesions, with Clarity's proprietary SAR Technology and the isotopes of copper. This approach, called Peptide Receptor Radionuclide Therapy (PRRT), is well established in NETs with the use of NETSPOT® (imaging) and LUTATHERA® (therapy). Both contain DOTA-octreotate (DOTATATE), a peptide with a bonded chelator, but use different radionuclides for imaging, gallium-68 (^{68}Ga), and therapy, lutetium-177 (^{177}Lu). ^{68}Ga DOTATATE and ^{177}Lu DOTATATE have been in many thousands of patients to date.

The human hormone somatostatin is released by neuroendocrine cells of the gastrointestinal (GI) tract and has an inhibitory effect on bowel motility, GI secretion, and absorption of nutrients. The physiological actions of somatostatin are mediated through 5 receptors (SSTR1 to 5) with research indicating that SSTR2 is also highly expressed at the cell surface of human cancers including, but not limited to, pancreatic[131], gastrointestinal[132,133] and pulmonary[134], NETs, meningiomas[135,136] and neuroblastomas[137,138].

131. Lamberts SW, Bakker WH, Reubi JC, Krenning EP. Somatostatin-receptor imaging in the localization of endocrine tumors. The New England journal of medicine. 1990;323(18):1246-1249.
132. Reubi JC, Hacki WH, Lamberts SW. Hormone-producing gastrointestinal tumors contain a high density of somatostatin receptors. The Journal of clinical endocrinology and metabolism. 1987;65(6):1127-1134.
133. Reubi JC, Laissue J, Waser B, Horisberger U, Schaer JC. Expression of Somatostatin Receptors in Normal, Inflamed, and Neoplastic Human Gastrointestinal Tissues. Annals of the New York Academy of Sciences. 1994;733:122-137.
134. Righi L, Volante M, Tavaglione V, et al. Somatostatin receptor tissue distribution in lung neuroendocrine tumours: a clinicopathologic and immunohistochemical study of 218 'clinically aggressive' cases. Annals of Oncology. 2010;21(3):548-555.
135. Dutour A, Kumar U, Panetta R, et al. Expression of somatostatin receptor subtypes in human brain tumors. International journal of cancer. 1998;76(5):620-627.
136. Henze M, Dimitrakopoulou-Strauss A, Milker-Zabel S, et al. Characterization of 68Ga-DOTA-d-Phe1-Tyr3-Octreotide Kinetics in Patients with Meningiomas. Journal of Nuclear Medicine. 2005;46(5):763-769.
137. Gains JE, Sebire NJ, Moroz V, et al. Immunohistochemical evaluation of molecular radiotherapy target expression in neuroblastoma tissue. European journal of nuclear medicine and molecular imaging. 2018;45(3):402-411.
138. Georgantzi K, Tsolakis AV, Stridsberg Met al. Differentiated expression of somatostatin receptor subtypes in experimental models and clinical neuroblastoma. Pediatric Blood and Cancer. 2011;56(4):584–589.

03 Company Overview continued

Clarity is initially developing SARTATE™ as a theranostic for the treatment of neuroblastoma, an aggressive childhood cancer, as well as a stand-alone diagnostic for NETs. The SSTR2 was shown to be expressed in 84% of neuroblastomas[139] and in 76% of primary NETs[140].

Future opportunities for this product include other SSTR2 positive diseases, including meningioma, embryonal tumours, such as medulloblastoma, and neuroendocrine neoplasms, like carcinoids and islet cell tumours.

Figure 24 provides an overview of Clarity's progress to date with clinical trials with SARTATE™.

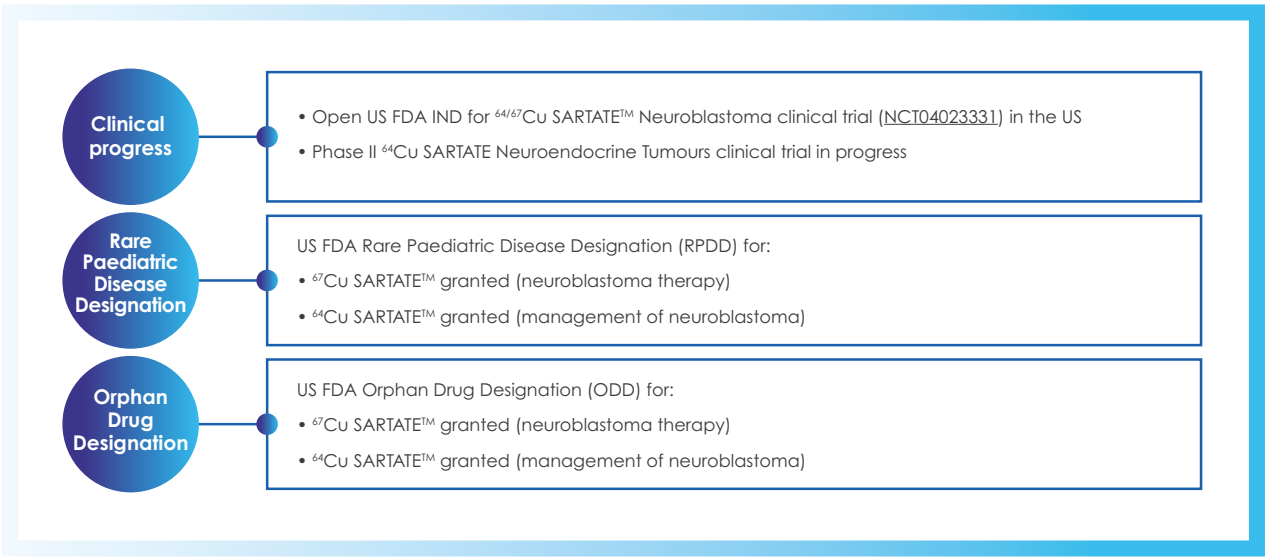
Figure 24: SARTATE™ clinical trial overview

Study name	Products	Indication	Phase	Number of patients	Location	Status	Reference
CL04	^{64}Cu SARTATE/ ^{67}Cu SARTATE	Neuroblastoma	I/IIa	24	US	**Recruiting**	NCT04023331
DISC	^{64}Cu SARTATE	NETs	II	63	AUS	**Recruiting**	NCT04438304
CL01	^{64}Cu SARTATE	NETs	I	10	AUS	Completed	NCT04440956
CL02	^{64}Cu SARTATE/ ^{67}Cu SARTATE	Meningioma	I/IIa	5	AUS	Completed	NCT03936426

Regulatory milestones

Clarity has reached several regulatory milestones and obtained several approvals from the FDA including the award of two RPDDs which may potentially allow the Company to access two PRVs as further discussed in Section 2.6.4, and two ODDs (although there can be no guarantee that these PRVs will be able to be accessed).

Figure 25: Regulatory Milestones



139. Albers, A. R., M. S. O'Dorisio, D. A. Balster, M. Caprara, P. Gosh, F. Chen, C. Hoeger, et al. 2000. "Somatostatin Receptor Gene Expression in Neuroblastoma." Regulatory Peptides 88 (1–3): 61–73.

140. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5067972/>.

3.5.1.1. SARTATE™ and neuroblastoma

3.5.1.1.1. Introduction

Neuroblastoma has been previously shown to be a SSTR2-expressing tumour and is therefore suited to diagnosis and therapy by radiopharmaceuticals based on somatostatin analogues. ^{68}Ga DOTATATE has been shown to successfully visualise lesions in neuroblastoma patients[141,142]. The current diagnostic standard of care, ^{123}I MIBG, is imaged using SPECT cameras which have lower resolution than PET and therefore provides a quality and specificity that can be improved upon by a PET agent such as ^{64}Cu SARTATE™ (see Section 2.4.4.1 for more information on the benefits of PET imaging).

^{177}Lu DOTATATE as a paired therapeutic to ^{68}Ga DOTATATE was used on a small number of neuroblastoma patients with some therapeutic effects[143,144]. These two independent studies have shown that treatment with a targeted radiopharmaceutical is safe, with minimal toxicity, and feasible in children with relapsed or primary refractory high-risk neuroblastoma. In a recent Phase II study in patients with relapsed or refractory neuroblastoma, participants received up to 4 cycles of ^{177}Lu DOTATATE[145]. Novartis/AAA is continuing the development and is currently recruiting for a Phase II trial in neuroblastoma in which the ^{177}Lu DOTATATE dose levels are increased (NCT04903899)[146]. This suggests that the development of a ^{64}Cu/^{67}Cu SARTATE™ theranostic may be a beneficial treatment option for this patient population with a high unmet need.

See Section 2.7.1 for further industry information on neuroblastoma.

3.5.1.1.2. Clinical development (theranostic)

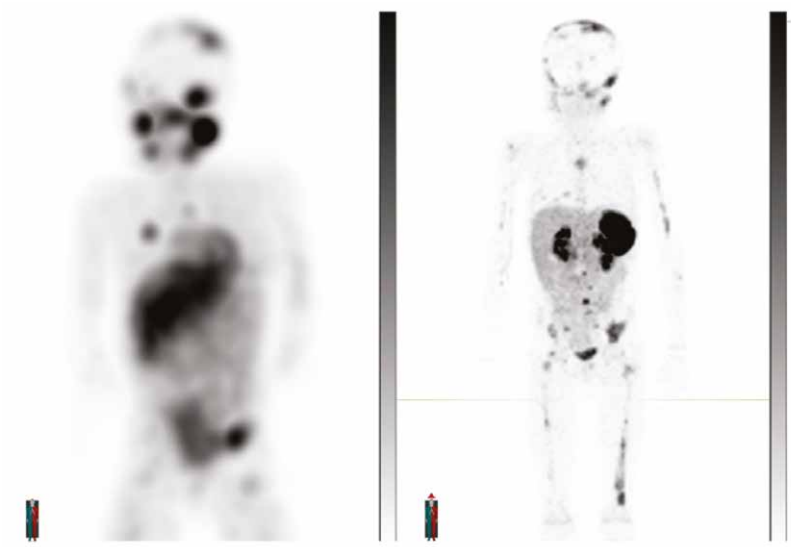
There is a high unmet need for neuroblastoma therapies with a higher efficacy and improved safety profiles and there is good supporting preclinical evidence to suggest that SARTATE™ may potentially be able to be used to successfully treat children with neuroblastoma.[147]

Clarity is conducting a ^{64}Cu/^{67}Cu SARTATE trial in neuroblastoma in the US. It is a multi-centre, dose-escalation, open label, non-randomised, theranostic clinical trial in paediatric patients with high-risk neuroblastoma (CL04)[148]. It is a Phase I/IIa trial with up to 34 patients. In this trial, not only the safety of both ^{64}Cu/^{67}Cu SARTATE is assessed, but also the effectiveness of ^{67}Cu SARTATE as a treatment for neuroblastoma. Patients who show uptake of ^{64}Cu SARTATE™ will continue in the trial and will receive treatment with ^{67}Cu SARTATE™.

Initial preliminary imaging data from the trial is shown in Figure 26 and Figure 27.

141. Gains JE, Bomanji JB, Fersht NL, et al. 177Lu-DOTATATE molecular radiotherapy for childhood neuroblastoma. Journal of nuclear medicine. 2011;52(7):1041-1047.
142. Kong G, Hofman MS, Murray WK, et al. Initial Experience With Gallium-68 DOTA-Octreotate PET/CT and Peptide Receptor Radionuclide Therapy for Pediatric Patients With Refractory Metastatic Neuroblastoma. Journal of pediatric hematology/oncology. 2016;38(2):87-96.
143. Gains JE, Bomanji JB, Fersht NL, et al. 177Lu-DOTATATE molecular radiotherapy for childhood neuroblastoma. Journal of nuclear medicine. 2011;52(7):1041-1047.
144. Kong G, Hofman MS, Murray WK, et al. Initial Experience With Gallium-68 DOTA-Octreotate PET/CT and Peptide Receptor Radionuclide Therapy for Pediatric Patients With Refractory Metastatic Neuroblastoma. Journal of pediatric hematology/oncology. 2016;38(2):87-96.
145. Gains JE, Moroz V, Aldridge MD, et al. A phase IIa trial of molecular radiotherapy with 177-lutetium DOTATATE in children with primary refractory or relapsed high-risk neuroblastoma. EJNMMI 2020;47(10):2348-2357.
146. US National Library of Medicine <ClinicalTrials.gov>. (Reference: NCT04903899).
147. Dearling JLJ, van Dam EM, Harris MJ, Packard AB. Detection and therapy of neuroblastoma minimal residual disease using [(64/67)Cu] Cu SARTATE in a preclinical model of hepatic metastases. EJNMMI Res. 2021, 11(20).
148. US National Library of Medicine <ClinicalTrials.gov>. (Reference: NCT04023331).

Figure 26: Clarity's diagnostic ^{64}Cu SARTATE™ compared to the current standard of care, ^{123}I MIBG *(in the same patient)*



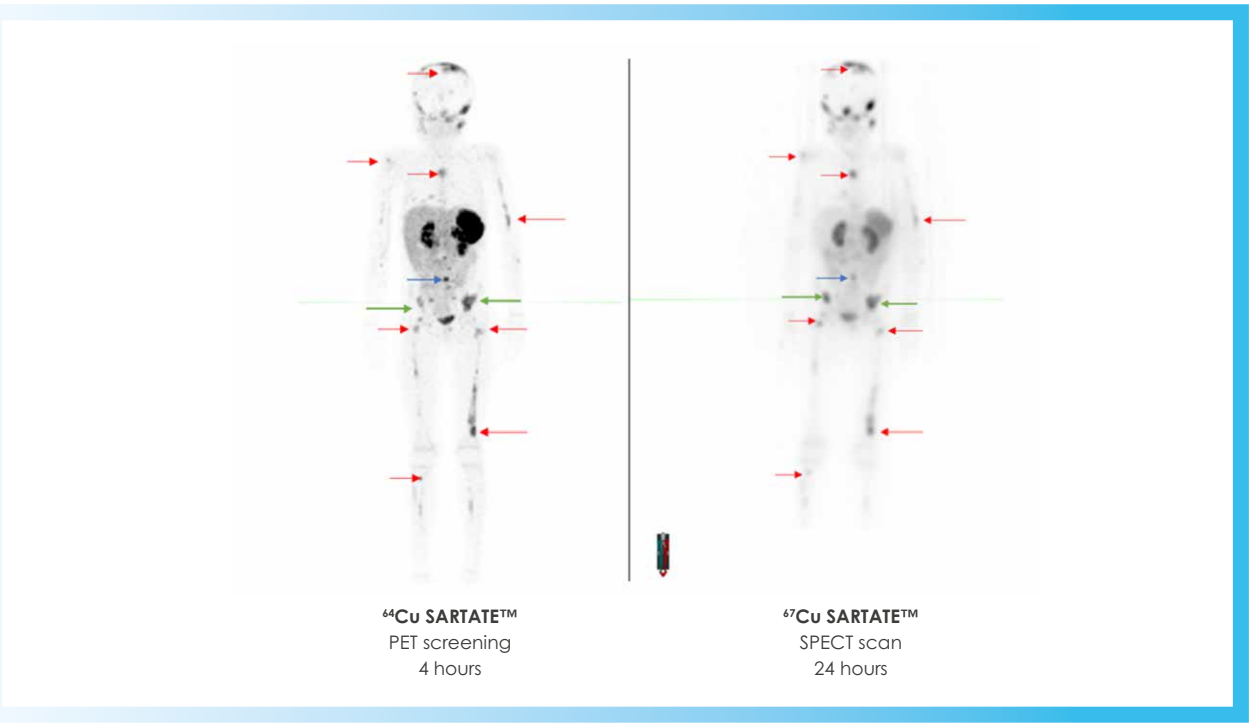
^{123}I MIBG
Current Standard of Care

^{64}Cu SARTATE™
PET screening

The initial preliminary data from this trial highlights two important points:

1. The current imaging modality for high-risk neuroblastoma patients, ^{123}I MIBG, is a poor resolution SPECT agent. ^{123}I MIBG is currently the main diagnostic tool for the treating physician to make clinical decisions on the status of the patient's disease and to determine the most appropriate therapy for the patient (e.g. radiation, chemotherapy, or other). The comparison of ^{123}I MIBG and ^{64}Cu SARTATE™ illustrated in Figure 26 suggests the SARTATE™ product may be able to visualise more areas of disease than ^{123}I MIBG.
2. ^{64}Cu SARTATE™ and ^{67}Cu SARTATE™ images in neuroblastoma patients on Figure 27 demonstrate uptake in the same areas of tumours for both the diagnostic (^{64}Cu SARTATE™ PET) and the therapeutic product (^{67}Cu SARTATE™ SPECT), illustrating that the product may have high precision.

Figure 27: Clarity's diagnostic ^{64}Cu SARTATE™ compared to therapeutic ^{67}Cu SARTATE™ *(in the same patient)*



3.5.1.2. SARTATE™ and neuroendocrine tumours (NETs)

Introduction

Clarity is developing SARTATE™ as a stand-alone diagnostic for neuroendocrine tumours (NETs). NET patients most commonly present at an advanced (metastatic) disease stage when a diagnosis is confirmed. Due to the rarity of NETs and nonspecific presentation of symptoms, a delay in diagnosis or misdiagnosis is common[149,150]. NET patients may be seen by multiple specialists and undergo extensive and repetitive testing, leading to varying and potentially conflicting treatment recommendations and contributing to delays in an accurate diagnosis[151].

SSTR expression has been extensively mapped in NETs[152,153,154] and forms the basis of somatostatin analogue therapy to improve symptoms caused by excessive secretion of hormones.[155] Somatostatin receptor imaging constitutes an integral part in NET visualisation and current practice. See Section 2.7.2 for further industry information on NETs.

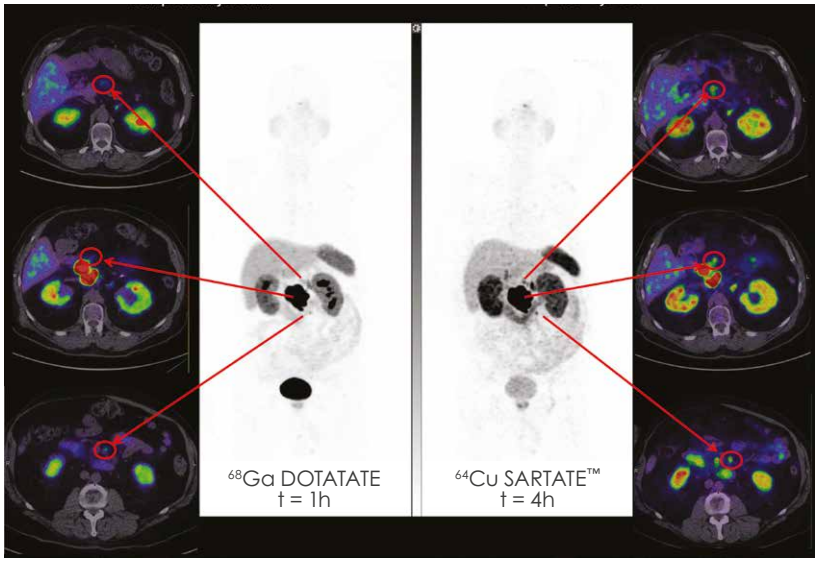
149. Raphael MJ, Chan DL, Law C, Singh S. Principles of diagnosis and management of neuroendocrine tumours. CMAJ. 2017;189(10):E398-e404.
150. Basuroy R, Bouvier C, Ramage JK, Sissons M, Srirajaskanthan R. Delays and routes to diagnosis of neuroendocrine tumours. BMC cancer. 2018;18(1):1122.
151. Singh S, Granberg D, Wolin E, et al. Patient-Reported Burden of a Neuroendocrine Tumor (NET) Diagnosis: Results From the First Global Survey of Patients With NETs. Journal of global oncology. 2017;3(1):43-53.
152. Korner M, Eltschinger V, Waser B, Schonbrunn A, Reubi JC. Value of immunohistochemistry for somatostatin receptor subtype sst2A in cancer tissues: lessons from the comparison of anti-sst2A antibodies with somatostatin receptor autoradiography. The American journal of surgical pathology. 2005;29(12):1642-1651.
153. Kulaksiz H, Eissele R, Rossler D, et al. Identification of somatostatin receptor subtypes 1, 2A, 3, and 5 in neuroendocrine tumours with subtype specific antibodies. Gut. 2002;50(1):52-60.
154. Papotti M, Bongiovanni M, Volante M, et al. Expression of somatostatin receptor types 1-5 in 81 cases of gastrointestinal and pancreatic endocrine tumors. A correlative immunohistochemical and reverse-transcriptase polymerase chain reaction analysis. Virchows Archiv : an international journal of pathology. 2002;440(5):461-475.
155. Oberg K. Future aspects of somatostatin-receptor-mediated therapy. Neuroendocrinology. 2004;80 Suppl 1:57-61.

Clinical development

Clarity has successfully completed a diagnostic imaging clinical trial evaluating ^{64}Cu SARTATE in patients with grade one or two NETs, which was led by Professor Rodney Hicks at the Peter MacCallum Cancer Centre, Australia. Ten participants were enrolled in this study and PET/CT imaging scans were performed over 20 hours.

The product was shown to be safe and able to identify SSTR2 positive tumours. It was found to be comparable to ^{68}Ga DOTATATE (NETSPOT®), when imaged at one hour, while comparable or improved lesion detection over ^{68}Ga DOTATATE was observed at 4 hours[156,157]. Figure 28 depicts the ^{68}Ga DOTATATE and ^{64}Cu SARTATE™ images of the same patient. On the far left and right, cross-sectional areas of the body are shown as combined PET/CT images, while the middle panels are the PET only images. Some of the tumours are circled in red. In this example, all tumours seen with ^{68}Ga DOTATATE were also seen with ^{64}Cu SARTATE™, but the ^{64}Cu SARTATE™ tumours had higher tumour contrast (i.e. were brighter and easier to identify).

Figure 28: Comparison of Clarity's ^{64}Cu SARTATE™ diagnostic product to ^{68}Ga DOTATATE

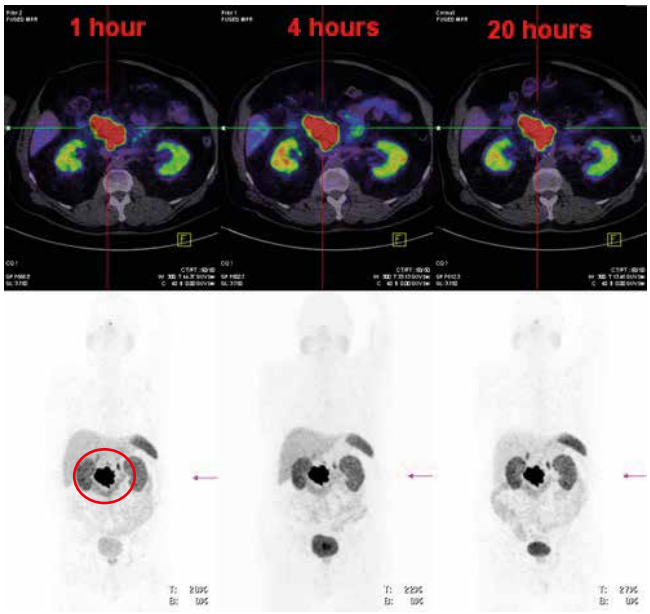


156. Hicks RJ, et al. ^{64}Cu SARTATE PET imaging of patients with neuroendocrine tumours demonstrates high tumor uptake and retention, potentially allowing prospective dosimetry for peptide receptor radionuclide therapy. Journal of Nuclear Medicine. 2019;60(6):777-785.

157. US National Library of Medicine – <ClinicalTrials.gov>. (Reference: NCT 04440956).

Figure 29 depicts ^{64}Cu SARTATE™ PET/CT images of the same patient with three imaging time points at 1, 4, and 20 hours post injection. The bottom panel in black and white are the PET images with the large NET in the centre of the body (circled in red) identified at 1 hour and retention of the product in the tumour over 20 hours. There is limited retention in the rest of the body. The top panel in colour is a cross-section of the body shown as combined PET/CT images where the colour is relative to the intensity of the concentration of the product, red being high and yellow being low. The tumour is the large red lesion in the centre of the body while the green semi-circles depict the kidneys.

Figure 29: Clarity's ^{64}Cu SARTATE™ diagnostic in the same patient imaged at 1, 4 and 20 hours post injection. The red lesion in the centre of the body is a large tumour while the green semi-circles depict the kidneys



Building on the promising data from the Phase I trial, Clarity is conducting a Phase II trial, a Diagnostic Imaging Study of Copper-64 SARTATE™ (DISCO) using PET on patients with known or suspected NETs.

The DISCO trial[158] is assessing the performance of ^{64}Cu SARTATE™ imaging agent in participants with known or suspected gastroenteropancreatic NETs as a potential new way to help diagnose and manage NETs. It is a Phase II study in 63 patients across three sites in Australia that compares the diagnostic performance of ^{64}Cu SARTATE™ at four and 20 hours to the current standard of care, ^{68}Ga DOTATATE, at one hour. ^{64}Cu SARTATE™ used for the trial is manufactured centrally in Australia and supplied from a central radiopharmacy to each clinical site, taking advantage of the longer half-life of ^{64}Cu and further validating the centralised radiopharmacy model, which distinguishes Clarity from other companies with theranostic products in development.

158. US National Library of Medicine – <ClinicalTrials.gov>. (Reference: NCT04438304).

3.5.2. SAR-Bombesin

3.5.2.1. Introduction

SAR-Bombesin is a highly targeted pan-cancer theranostic radiopharmaceutical being developed for identifying and selecting patients for subsequent treatment of their cancers that express gastrin releasing peptide receptor (GRPr).

A gastrin-releasing peptide (GRP) regulates numerous functions of the gastrointestinal and central nervous systems, including release of gastrointestinal hormones and smooth muscle cell contraction. The effects of GRP are mediated through the GRPr. GRPr was reported to be expressed in many cancers including those from the breast[159], prostate[160,161], uterus[162], ovaries[163], colon[164], gastrointestinal stromal tumours[165], lung (small and non-small cell)[166] and in gliomas[167]. This data suggests that GRPr could be a clinically relevant molecular target for the visualisation and therapy in a wide range of tumours.

Clarity is initially developing SAR-Bombesin as a theranostic for breast cancer and prostate cancer. GRPr was shown to be expressed in 83% of estrogen receptor (ER) positive breast cancers[168] and in 75-100% of prostate cancers.[169,170,171,172]

Future opportunities for this product include imaging and treatment of other GRPr positive cancers, such as ovarian cancer, colon cancer, and glioblastoma.

3.5.2.2. Clinical development

^{64}Cu/^{67}Cu SAR-Bombesin is under investigation as a theranostic pairing to treat breast and prostate cancer patients with tumours that express GRPr.

Imaging clinical development

Clarity is currently supporting an investigator-led imaging trial called C-BOBCAT, with principal investigator Prof. Louise Emmett and sponsored by St Vincent's Hospital Sydney, Australia. C-BOBCAT is a first in human pilot trial assessment of the diagnostic value of ^{64}Cu SAR-Bombesin PET/CT imaging for staging of hormone positive breast cancer patients with metastatic disease in comparison with standard of care imaging (CT, bone scan and ^{18}F FDG PET/CT). In addition, at this institution, ^{64}Cu SAR-Bombesin has been imaged in metastatic prostate cancer patients under a Special Access Scheme[173].

Figure 30 below is an example of Clarity's ^{64}Cu SAR-Bombesin product in a metastatic breast cancer patient and a metastatic prostate cancer patient. In both these patients, multiple tumours were seen with ^{64}Cu SAR-Bombesin PET imaging, some are highlighted with a blue circle.

159. Morgat C, MacGrogan G, Brouste V, et al. Expression of Gastrin-Releasing Peptide Receptor in Breast Cancer and Its Association with Pathologic, Biologic, and Clinical Parameters: A Study of 1,432 Primary Tumors. Journal of nuclear medicine. 2017;58(9):1401-1407.
160. Markwalder R, Reubi JC. Gastrin-releasing peptide receptors in the human prostate: relation to neoplastic transformation. Cancer research. 1999;59(5):1152-1159.
161. Fleischmann A, Waser B, Reubi JC. High expression of gastrin-releasing peptide receptors in the vascular bed of urinary tract cancers: promising candidates for vascular targeting applications. Endocrine-related cancer. 2009;16(2):623-633.
162. Fleischmann A, Waser B, Gebbers JO, Reubi JC. Gastrin-releasing peptide receptors in normal and neoplastic human uterus: involvement of multiple tissue compartments. The Journal of clinical endocrinology and metabolism. 2005;90(8):4722-4729.
163. Fleischmann A, Waser B, Reubi JC. High expression of gastrin-releasing peptide receptors in the vascular bed of urinary tract cancers: promising candidates for vascular targeting applications. *Endocrine-related cancer*. 2009;16(2):623-633.
164. Fleischmann A, Waser B, Reubi JC. High expression of gastrin-releasing peptide receptors in the vascular bed of urinary tract cancers: promising candidates for vascular targeting applications. *Endocrine-related cancer*. 2009;16(2):623-633.
165. Reubi JC, Korner M, Waser B, Mazzucchelli L, Guillou L. High expression of peptide receptors as a novel target in gastrointestinal stromal tumours. *European journal of nuclear medicine and molecular imaging*. 2004;31(6):803-810.
166. Mattei J, Achcar RD, Cano CH, et al. Gastrin-releasing peptide receptor expression in lung cancer. *Archives of pathology & laboratory medicine*. 2014;138(1):98-104.
167. Flores DG, Meurer L, Uberti AF, et al. Gastrin-releasing peptide receptor content in human glioma and normal brain. *Brain research bulletin*. 2010;82(1-2):95-98.
168. Morgat C, MacGrogan G, Brouste V, et al. Expression of Gastrin-Releasing Peptide Receptor in Breast Cancer and Its Association with Pathologic, Biologic, and Clinical Parameters: A Study of 1,432 Primary Tumors. Journal of nuclear medicine. 2017;58(9):1401-1407.
169. Markwalder R, Reubi JC. Gastrin-releasing peptide receptors in the human prostate: relation to neoplastic transformation. Cancer research. 1999;59(5):1152-1159.
170. Fleischmann A, Waser B, Reubi JC. High expression of gastrin-releasing peptide receptors in the vascular bed of urinary tract cancers: promising candidates for vascular targeting applications. Endocrine-related cancer. 2009;16(2):623-633.
171. Körner M, Waser B, Rehmann R, et al. Early over-expression of GRP receptors in prostatic carcinogenesis. Prostate 2014;74(2):217-224.
172. Reubi JC, Wenger S, Schmuckli-Maurer J, Schaer JC, Gugger M. Bombesin receptor subtypes in human cancers: detection with the universal radioligand (125)I-[D-TYR(6), beta-ALA(11), PHE(13), NLE(14)] bombesin(6-14). Clin Cancer Res. 2002;8(4):1139-1146.
173. Special Access Scheme | Therapeutic Goods Administration (TGA) <https://www.tga.gov.au/form/special-access-scheme>.

Figure 30: Copper-64 SAR-Bombesin in metastatic breast and metastatic prostate cancers

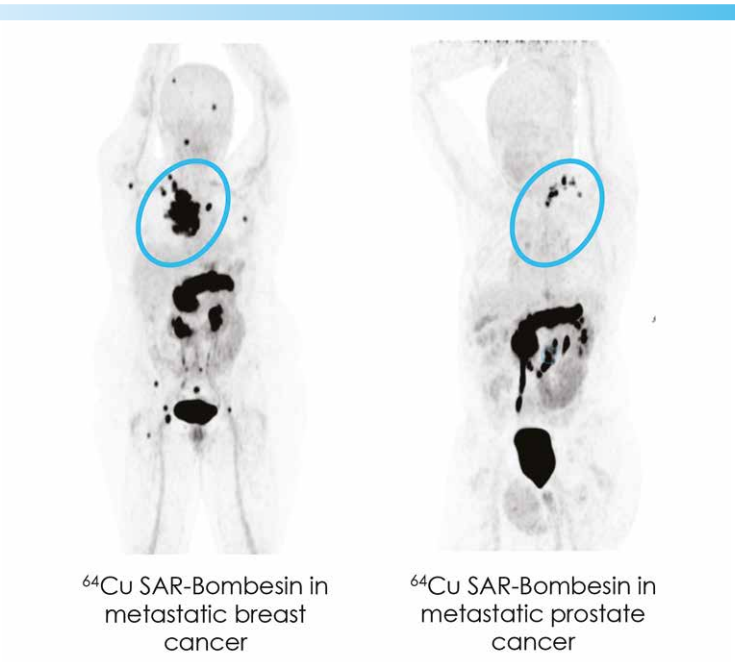
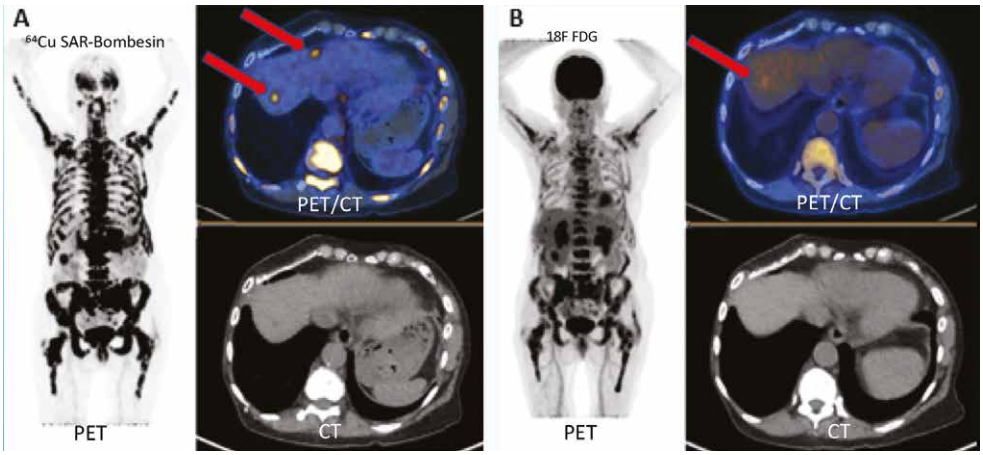


Figure 31 below shows initial results from C-BOBCAT suggesting that ^{64}Cu SAR-Bombesin (A) may offer some advantages over current imaging modalities, in this case, ^{18}F FDG (B). In this patient with breast cancer that has spread to the bones, ^{64}Cu SAR-Bombesin is seen in the bones, including tumours in the skull. ^{18}F FDG, however, is not able to show these tumours in the skull due to the normal uptake of ^{18}F FDG in the brain. Importantly, in this patient, some tumours in the liver (red arrow) are seen with ^{64}Cu SAR-Bombesin but not ^{18}F FDG. Overall, in this patient, ^{64}Cu SAR-Bombesin imaging detected a higher tumour volume with an overall higher uptake compared to ^{18}F FDG.

Figure 31: C-BOBCAT: One hour post ^{64}Cu SAR-Bombesin administration in a breast cancer patient



Preliminary data from the C-BOBCAT trial shows that ^{64}Cu SAR-Bombesin is highly avid with a high tumour volume compared to ^{18}F FDG in some patients. No adverse events have been reported as at the Prospectus Date. Whilst further investigation is warranted, preliminary results indicate ^{64}Cu SAR-Bombesin may have a role in imaging patients with hormone positive breast cancer, as shown in Figure 32[174] below, and as the product is retained in the tumour over time and cleared from the rest of the body, the theranostic pairing with ^{67}Cu SAR-Bombesin holds promise as a therapy to be determined in future clinical trials.

Figure 32: ^{64}Cu SAR-Bombesin in hormone positive metastatic breast cancer

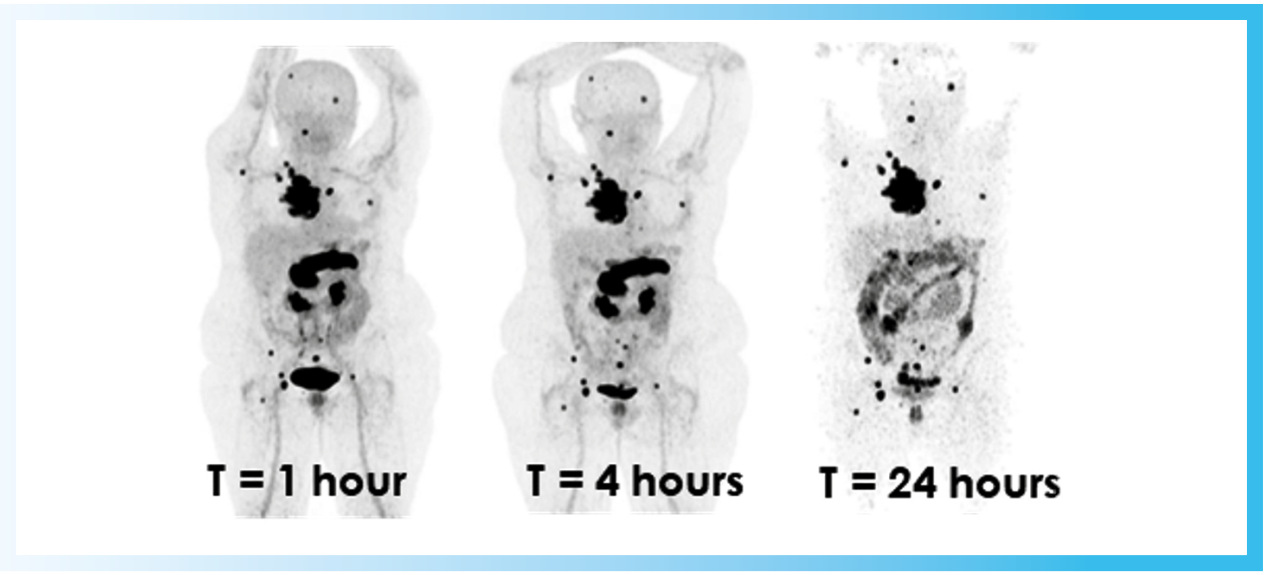
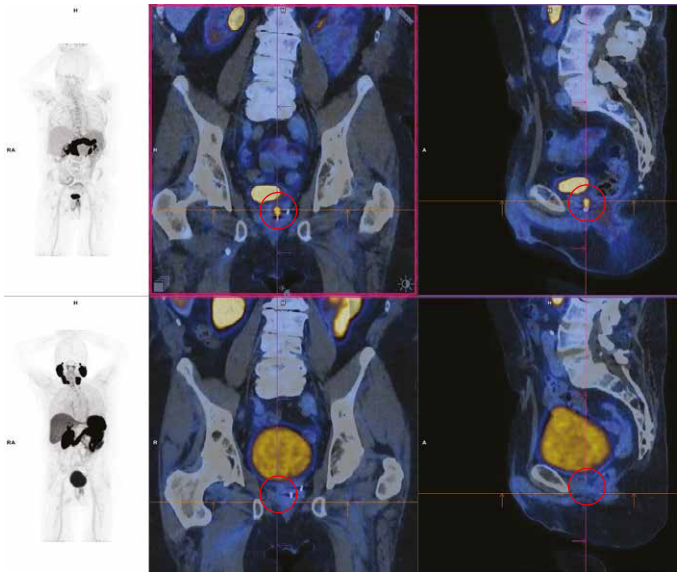


Figure 33 below depicts ^{64}Cu SAR-Bombesin (top) and ^{68}Ga PSMA (bottom) PET/CT images of the same patient with clinical signs of prostate cancer (a rising PSA score of 0.16). The left image (black and white) is a PET image while the coloured images are cross sectional PET/CT images. The top panel illustrates a suspected tumour circled in red identified with ^{64}Cu SAR-Bombesin while the bottom panel, with the same region encircled in red, does not show a suspected tumour using ^{68}Ga PSMA. Identifying additional tumour burden can change the treatment paradigm for patients and potentially change treatment outcomes as a result. If further investigations confirm the data acquired in this case study, it could suggest potential benefits of using ^{64}Cu SAR-Bombesin over ^{68}Ga PSMA for imaging patients with prostate cancer that has limited expression of PSMA. Further investigations are required to confirm that the suspected tumour is indeed a prostate cancer tumour. Subsequent clinical studies will need to be conducted to substantiate this result in other patients.

174. <https://cattendee.abstractsonline.com/meeting/10365/Presentation/1104>.

Figure 33: ^{64}Cu SAR-Bombesin (top) and ^{68}Ga PSMA (bottom) PET/CT images of the same patient with clinical signs of prostate cancer. A suspected tumour is identified as a yellow "hotspot" on the ^{64}Cu SAR-Bombesin image (red circles) but not on the ^{68}Ga PSMA image.

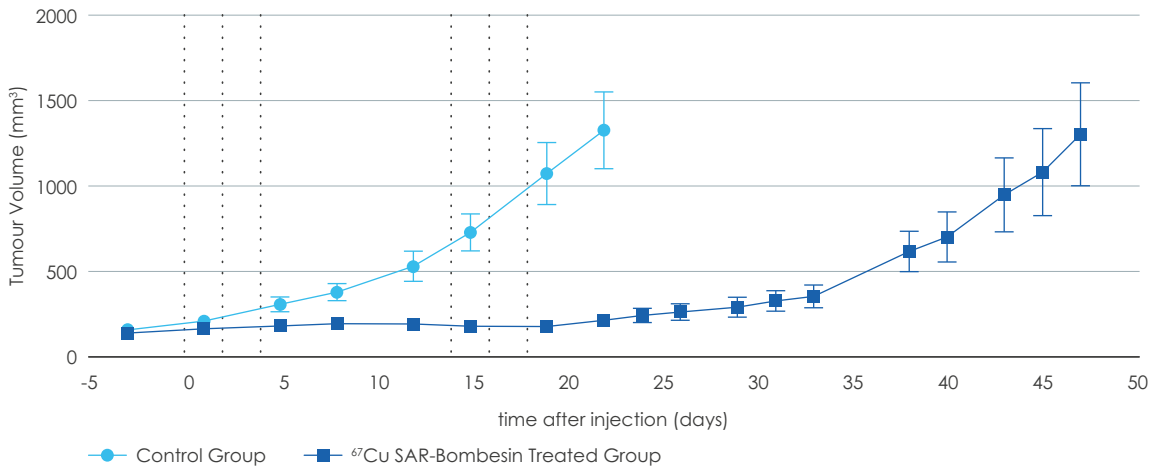


Theranostic clinical development

Data from the C-BOBCAT trial and the images obtained from patients using the Special Access Scheme will support future theranostic studies in GRPr expressing tumours, including prostate cancer.

Therapeutic ^{67}Cu SAR-Bombesin pre-clinical efficacy studies have been completed. ^{67}Cu SAR-Bombesin has demonstrated an anti-tumour effect in preclinical models of prostate cancer (see Figure 34 below). When compared to the control group (light blue), treatment with ^{67}Cu SAR-Bombesin (dark blue; administered six times over three weeks – vertical dotted lines) slowed down tumour growth and extended the lives of the mice significantly.

Figure 34: Efficacy of ^{67}Cu SAR-Bombesin in a mouse model of prostate cancer



See Sections 2.7.3 and 2.7.4 for further industry information on breast cancer and prostate cancer.

3.5.3. SAR-bisPSMA

3.5.3.1. Introduction

SAR-bisPSMA is a next-generation, highly targeted theranostic radiopharmaceutical, being developed for diagnosing, staging and subsequently treating cancers that express Prostate Specific Membrane Antigen (PSMA).

PSMA is a protein expressed in all types of prostate cancer and is an excellent diagnostic and therapeutic target. The expression of PSMA increases with tumour aggressiveness, metastatic disease, and recurrence[175].

In contrast to other PSMA-targeting products, SAR-bisPSMA connects two PSMA binding motifs linked to Clarity's SAR chelator technology instead of one, allowing the identical molecule to be used for diagnostic (via ^{64}Cu) and therapeutic applications (via ^{67}Cu), as displayed in Figure 36. The PSMA binding motif, conjugated to other chelators, has been in many thousands of patients to date.

Clarity is investigating SAR-bisPSMA both as a stand-alone diagnostic product in patients with confirmed prostate cancer, as well as a theranostic product in metastatic castrate resistant prostate cancer.

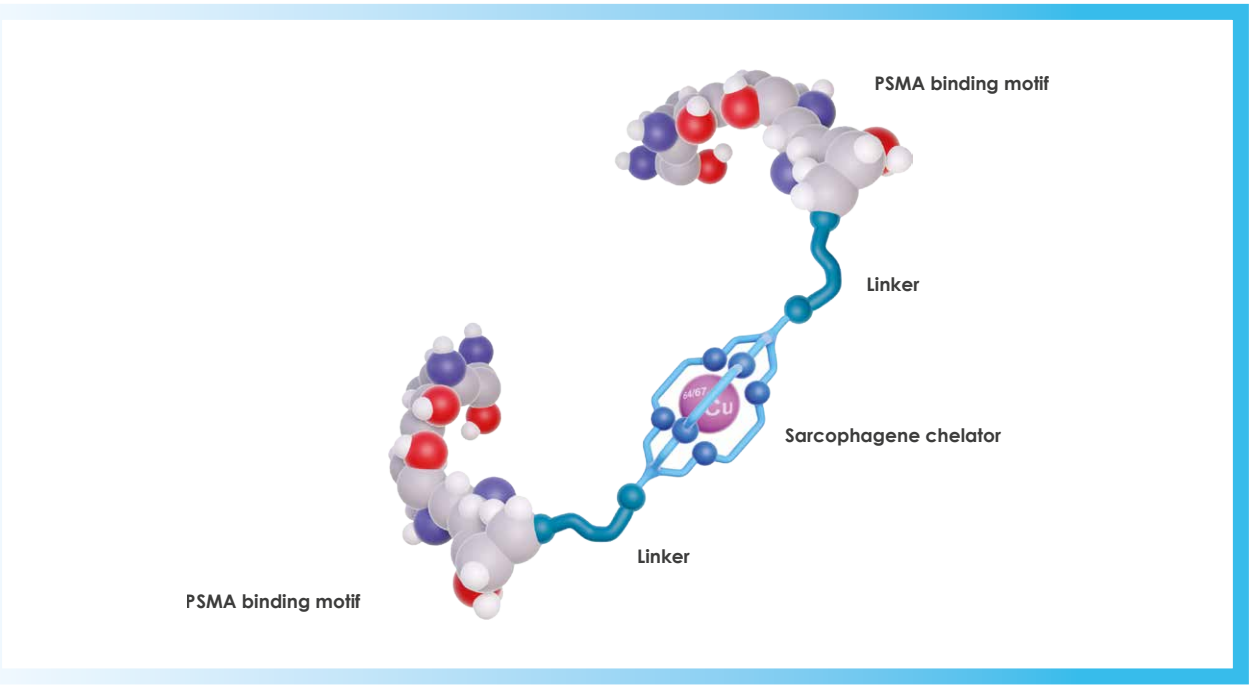
Future opportunities for this product include diagnosis and treatment of other PSMA positive cancers, such as renal cell carcinoma.

175. Silver DA, Pellicer I, Fair WR, et al, Prostate-specific membrane antigen expression in normal and malignant human tissues. Clin Can Res 1997;3(1):81-85; Kratochwil c, Afshar-Oromieh A, Kopka K, et al. Current status of prostate-specific membrane antigen targeting in nuclear medicine: clinical translation of chelator containing prostate-specific membrane antigen ligands into diagnostics and therapy for prostate cancer. Sem Nuc Med 2016;46(5):405-418; Santoni M, Scarpelli M, Mazzucchelli R, et al. Targeting prostate-specific membrane antigen for personalized therapies in prostate cancer: morphologic and molecular backgrounds and future promises. J Biol Reg Hom Ag 2014;28(4):555-563.

Figure 35: SAR-bisPSMA clinical trial overview

Study name	Products	Indication	Phase	Number of patients	Location	Status	Reference
PROPELLER	^{64}Cu SAR-bisPSMA	Prostate diagnostic	I	30	AUS	Open for recruitment	NCT04839367
SECURE	^{64}Cu SAR-bisPSMA/ ^{67}Cu SAR-bisPSMA	Prostate therapy	I/IIa	34-44	US	Commencing July 2021	NCT04868604

Figure 36: Graphic of Clarity's SAR-bisPSMA product



See Section 2.7.4 for further industry information on prostate cancer.

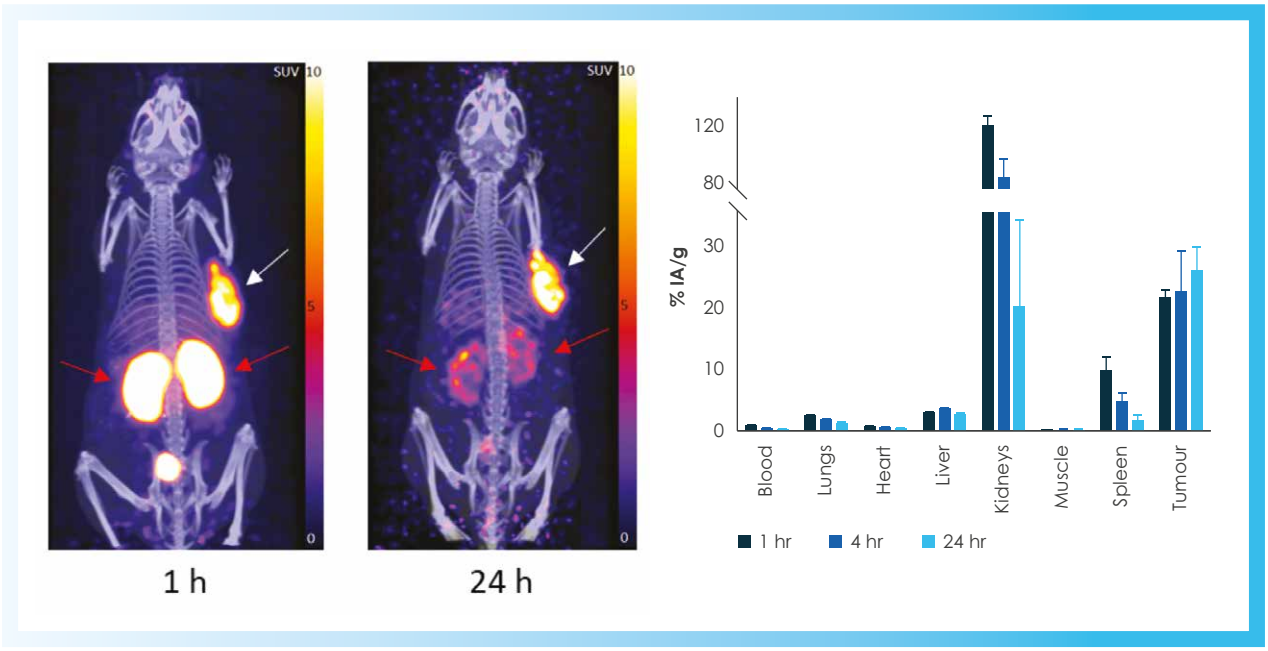
3.5.3.2. Clinical and preclinical development

Diagnostic preclinical and clinical development

To date, no clinical data on ^{64}Cu SAR-bisPSMA has been generated; however, there is strong preclinical data to suggest that SAR-bisPSMA has the potential to become best in class PSMA agent. Preclinical biodistribution and PET/CT imaging studies in a mouse model of prostate cancer indicate that ^{64}Cu SAR-bisPSMA displays high uptake and retention of ^{64}Cu SAR-bisPSMA in tumours with rapid clearance from non-target organs[176]. Uptake of ^{64}Cu SAR-bisPSMA in the tumour (white arrow) and clearance from the kidney (red arrows) and other organs are depicted in Figure 37.

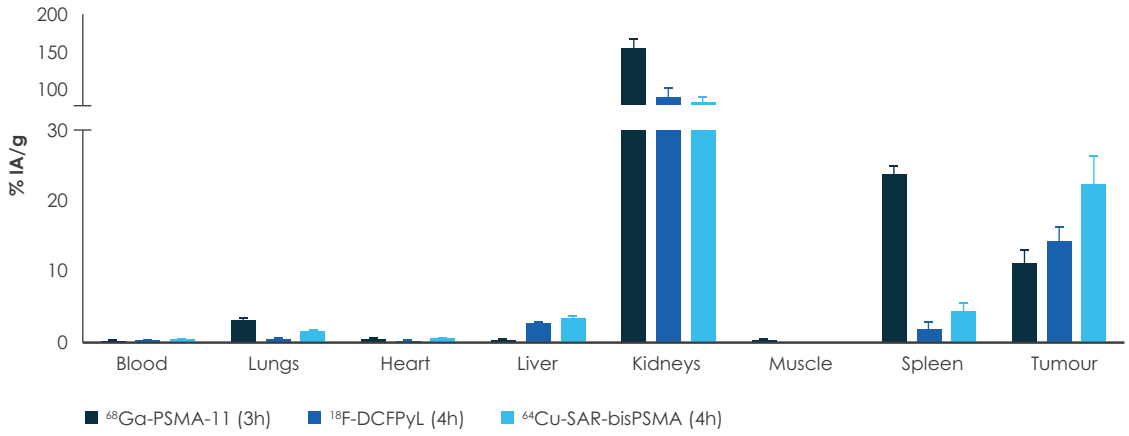
176. A Bivalent Inhibitor of Prostate Specific Membrane Antigen Radiolabeled with Copper-64 with High Tumour Uptake and Retention. Angew Chem 2019 (a study led by P Donnelly).

Figure 37: High uptake and retention of ^{64}Cu SAR-bisPSMA in the tumour in a mouse model of prostate cancer[177]



In this preclinical prostate cancer model, ^{64}Cu SAR-bisPSMA had more tumour uptake than competitor products ^{68}Ga PSMA-11 and ^{18}F DCFPyL (Figure 38, unpublished data).

Figure 38: Comparison of uptake of PSMA-targeting agents in a mouse model of prostate cancer



177. A Bivalent Inhibitor of Prostate Specific Membrane Antigen Radiolabeled with Copper-64 with High Tumour Uptake and Retention. Angew Chem 2019 (a study led by P Donnelly).

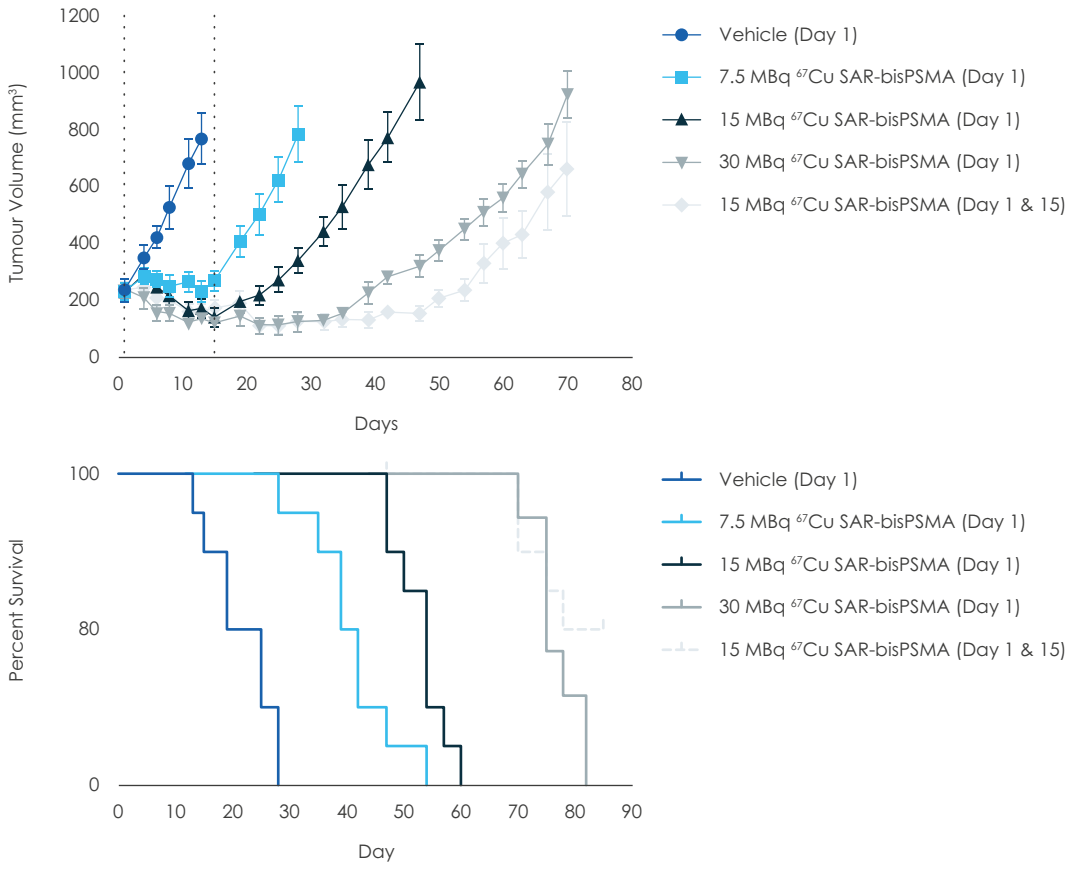
Clarity's ^{64}Cu SAR-bisPSMA diagnostic imaging trial in patients with confirmed prostate cancer in Australia is currently open for recruitment.

The trial is a Positron Emission Tomography (PET) Imaging of Participants With Confirmed Prostate Cancer Using ^{64}Cu SAR-bisPSMA (PROPELLER)[178]. It is a Phase I multi-centre, blinded review, dose ranging, non-randomised study in 30 patients across Australia. The aim of the PROPELLER study is to determine the safety and tolerability of ^{64}Cu SAR-bisPSMA in participants with untreated, confirmed prostate cancer and planned for radical prostatectomy, as well as compare ^{64}Cu SAR-bisPSMA to ^{68}Ga PSMA-11, the standard of care for prostate cancer imaging in Australia.

Theranostic preclinical and clinical development

Therapeutic ^{67}Cu SAR-bisPSMA pre-clinical efficacy studies demonstrate dose response with increasing activity of the product as depicted in Figure 39 below[179]. In this mouse model of prostate cancer, tumour growth was retarded at all dose levels, with a clear dose-dependent delay in eventual tumour regression. In addition, each dose level significantly increased survival compared to the dose level below.

Figure 39: Significant anti-tumour effect and increased survival

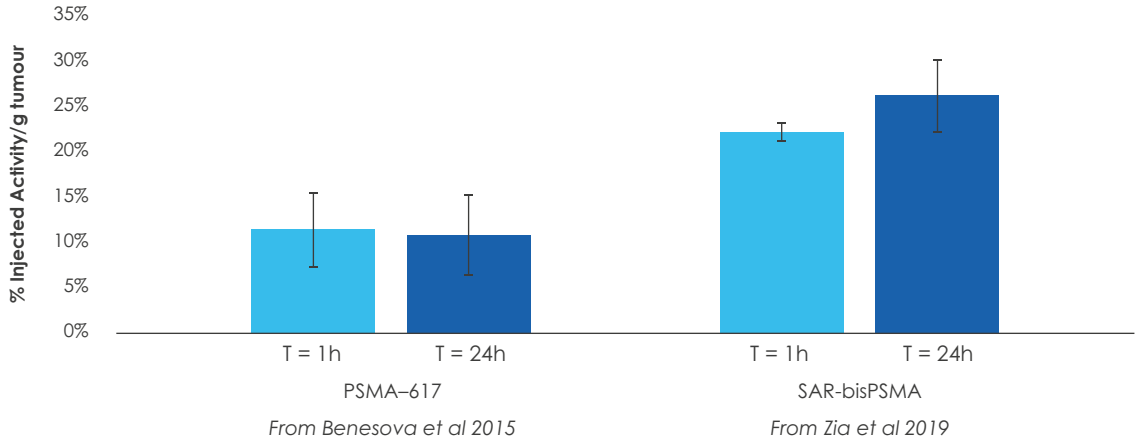


178. US National Library of Medicine – ClinicalTrials.gov (Reference: NCT04839367).

179. McInnes LE, Cullinane C., Roselt PD., Therapeutic Efficacy of a Bivalent Inhibitor of Prostate Specific Membrane Antigen Labeled with ^{67}Cu.

As outlined in Figure 40, ^{64}Cu SAR-bisPSMA has demonstrated tumour uptake in the LNCAP prostate cancer preclinical model to be 22%ID/g at one hour and 26%ID/g at 24 hours post injection (p.i.)[180]. In comparison using published data by others, ^{177}Lu PSMA-617 demonstrated 11%ID/g at one hour and 10%ID/g at 24 hours p.i. in their LNCAP prostate cancer preclinical model.[181]

Figure 40: Published data comparing % injected activity in tumour in the LNCAP preclinical model for SAR-bisPSMA and PSMA-617



Clarity will commence a theranostic $^{64/67}$Cu SAR-bisPSMA Phase I/IIa clinical trial in the US in July 2021.

The SECuRE trial (Systemic Cu theranostics in prostate cancer) is a Phase I/IIa study for identification and treatment of PSMA-expressing metastatic castrate resistant prostate cancer (mCRPC)[182]. SECuRE is a theranostic multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 patients. The trial employs diagnostic PET imaging with ^{64}Cu SAR-bisPSMA for selection of patients suitable for therapy cycles with ^{67}Cu SAR-bisPSMA.

3.6. Discovery program and research & development

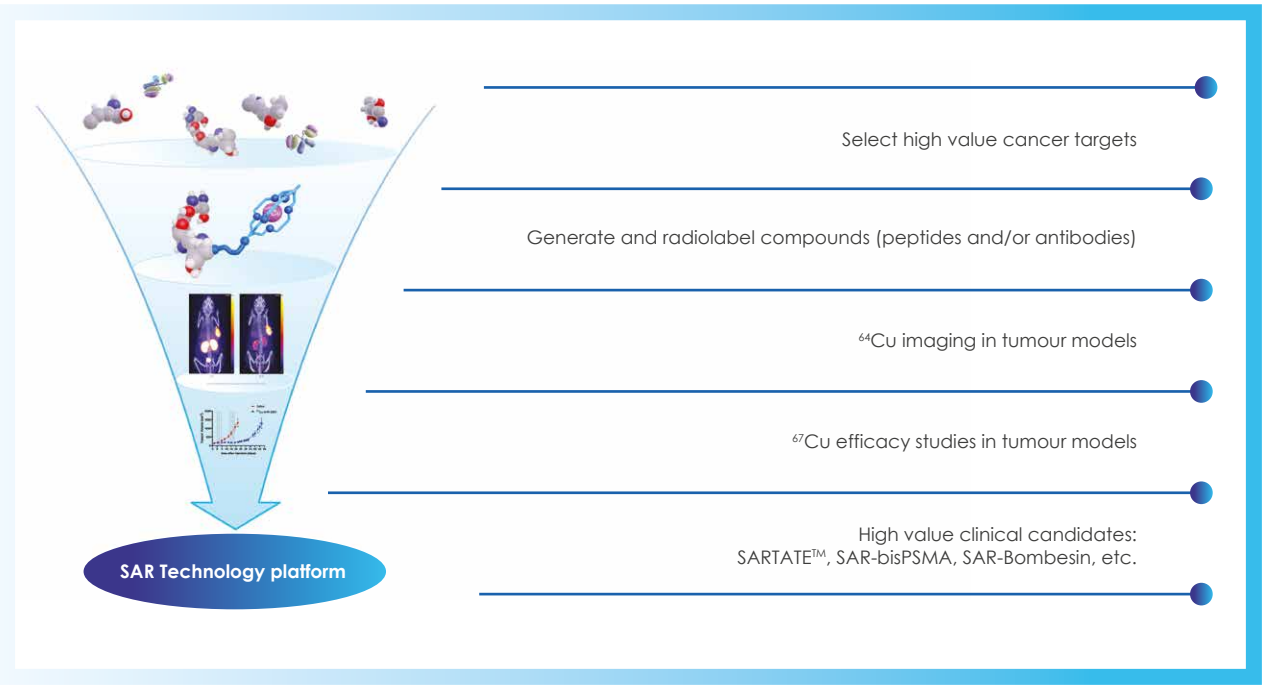
3.6.1. Discovery Program Overview

Clarity's SAR Technology platform can be used in conjunction with any number of cancer targeting molecules to create new radiopharmaceutical products, which are developed in Clarity's discovery program (**Discovery Program**).

Figure 41 provides a high-level overview of the Discovery Program process.

180. A Bivalent Inhibitor of Prostate Specific Membrane Antigen Radiolabeled with Copper-64 with High Tumour Uptake and attention. Angew Chem 2019 (a study led by P Donnelly).
181. Benesova, M et al. Preclinical Evaluation of a Tailor-Made DOTA-Conjugated PSMA Inhibitor with Optimized Linker Moiety for Imaging and Endoradiotherapy of Prostate Cancer. J Nucl Med. 2015;56(6):914-920.
182. US National Library of Medicine – <ClinicalTrials.gov>. (Reference: NCT04868604).

Figure 41: Clarity's Discovery Program



Clarity has a number of research and development projects in its Discovery Program, including:

i. New pipeline products; and

ii. Second generation technology.

The majority of the Discovery work is done in collaboration with Clarity's academic partners. The funding of the Discovery research is partially supported by grants and the Australian R&D Tax Incentive.

3.6.1.1. New pipeline products

Clarity's SAR Technology is applicable to a range of radiopharmaceuticals via biological targeting agents, such as octreotate for SARTATE™, bombesin for SAR-Bombesin and the PSMA inhibitor for SAR-bisPSMA. Similar to these products, Clarity can develop and test new biological targeting agents to validated cancer targets that bind to tumours and otherwise clear the body while aiming to minimise side effects to other (healthy) organs. The Company has had a long-standing collaboration with Professor Paul Donnelly of The University of Melbourne and successfully developed its three lead products together, for which Clarity owns the IP. In collaboration with researchers at the University of Queensland and funded by the ARC Training Centre for Innovation in Biomedical Imaging Technology (CIBIT) Grant, Clarity co-funds a PhD student to investigate new potential products for blood-based cancers. Clarity has a collaboration with ImaginAb Inc. (California in the US) to investigate the combination of ImaginAb's antibody platform with the SAR Technology platform to develop copper based theranostics. The work is concentrated on an undisclosed target to address an unmet clinical need. Clarity has the potential to roll out a range of products through its Discovery Program and will continue to do so in order for the Company to capitalise on its platform as appropriate.

3.6.1.2. Second generation technology

Clarity develops second generation technology with the goal of improving new products to be superior in the market. These improvements include investigating targeting molecules as well as other technologies to alter targeting of tumours and how long products stay in the body.

3.7. Manufacturing and supply strategy

3.7.1. Introduction

The manufacturing and supply chain are intrinsically critical for the supply of radiopharmaceuticals. The shelf life of the product determines how long it remains useable after being manufactured and is a function of the radioisotopes used in the radiopharmaceutical product. The longer the radioactive half-life, the longer the shelf life of the product can be.

Additional challenges arise from the production of the radioisotopes themselves, since they must be produced according to industry and quality standards, in a volume that can meet increased demand. It is imperative to avoid supply shortages and failures to deliver the products to physicians as it could damage the reputation of the radiopharmaceutical.

The supply of, and manufacturing process utilised in the production of, copper radioisotopes give Clarity an advantage in the commercialisation phase of its theranostic products. This advantage primarily relates to the fact that the production of ^{64}Cu occurs on existing cyclotrons (the infrastructure for which is well established worldwide). The 12.7 hour half-life of ^{64}Cu permits central manufacturing and regional distribution whereas competing isotopes used for diagnostic imaging, like ^{68}Ga, are short lived and therefore present logistical constraints for distribution.

The production of ^{67}Cu employs electron accelerators. By contrast, the production of the isotopes utilised by the Company's competitors, specifically ^{177}Lu, is reliant on a small number of nuclear reactors globally.

Establishment of robust and cost-efficient manufacturing for both Active Pharmaceutical Ingredients (API) and final drug products is critical for late-stage clinical trials and successful commercialisation of Clarity's products. Clarity works with outsourced commercial development manufacturing organisations (CDMOs) which can produce the quality and volume of products required for the Company's clinical trials. As clinical trials advance, the manufacturing and quality control requirements increase for all components of Clarity's products, as do the required volumes. Clarity will continue to build its network of manufacturers as requirements increase to meet its demand.

Clarity has built a manufacturing and supply chain which provides US domestic supply for its key radionuclides without the need for nuclear reactors. This may offer significant logistical advantages over therapeutic isotopes produced on nuclear reactors, with the major reactors currently being outside of the US, as it would not be affected by reactor outages which have caused shortages of radiopharmaceuticals.

Supply logistics of both ^{64}Cu and ^{67}Cu, as well as final radiopharmaceutical products, is another critical aspect. A robust supply chain is required to allow Clarity to have product available on demand for overnight shipping to end-users. In the US, there are well-established centralised radiopharmacy groups that routinely ship short half-life products across the country. Overnight logistics are adequate for all of Clarity's clinical products due to the favourable half-life of the copper isotopes.

The manufacturing and supply chain of Clarity's products can be broken down into four critical components that have their own specific production and supply requirements:

1. Copper-64;
2. Copper-67;
3. Non-radioactive components; and
4. Finished drug products.

3.7.2. Copper-64 (^{64}Cu)

3.7.2.1. Copper-64 production and supply

^{64}Cu can be produced in industrial levels suitable for commercial production on standard biomedical cyclotrons that are equipped with solid targetry. ^{64}Cu is produced by bombardment of Nickel-64 (^{64}Ni) plated discs. The production method is well established and multiple groups in the US and Australia produce ^{64}Cu on a weekly basis.

Overnight transport logistics from the isotope manufacturers to the central radiopharmacy are adequate for ^{64}Cu due to its 12.7 hour half-life. Importantly, imaging of ^{64}Cu labelled products can be performed at one hour after administration or up to 48 hours. It therefore fits well into current workflows at imaging sites and creates flexibility in the workflow at an imaging centre and maintains the option to re-image the same patient at later

time points. Other longer-lived diagnostic isotopes such as ^{89}Zr based imaging agents cannot be imaged on the day of administration, which as a result requires the patients to make at least two visits to hospital.[183]

Table 17: ^{64}Cu production facilities in Australia and the US

Region	Comments
Australia	• SAHMRI-MITRU • Austin Health • Sir Charles Gairdner Hospital • University of Queensland *Other cyclotron facilities have the capability to produce ^{64}Cu and could be utilised as demand increases.
United States	• Washington University in St Louis (WASHU) • University of Wisconsin-Madison • University of Alabama at Birmingham • MD Anderson • Curium Pharmaceuticals

Note: Clarity does not work with all production facilities listed.

3.7.2.2. Copper-64 supply strategy

There is an established network of producers in the US that serves both Clarity's shorter term needs as well as its longer term commercial strategies for ^{64}Cu. There is also an excess of cyclotron capacity in the US which can be repurposed to produce ^{64}Cu if the demand for this radioisotope increases.

The challenge of ^{64}Cu production is one of demand rather than supply. Until recently, there has been little demand for ^{64}Cu due to the lack of suitable chelator technologies that would prevent the leakage of ^{64}Cu from radiopharmaceutical products into the patient's body. Clarity's SAR Technology offers a chelator that has been demonstrated to securely hold copper (see Section 3.2.3.1 for more details), opening opportunities for the development of copper-based radiopharmaceuticals. As a result, Clarity has established supply agreements with ^{64}Cu suppliers for current clinical trials, which should increase their production volumes for future demand. The current agreements are with both the South Australian Health and Medical Research Institute Limited and Washington University. Further details of these agreements are set out in Sections 10.11.4, 10.11.5 and 10.11.6.

The production and distribution of ^{64}Cu based products is considerably facilitated by the longer half-life of ^{64}Cu, which enables overnight shipping for next day patient administration, and by the increasing availability of cyclotrons suitable for ^{64}Cu production.

3.7.3. Copper-67 (^{67}Cu)

3.7.3.1. Copper-67 production and supply

As Clarity is the leading company in the development of ^{67}Cu-based radiopharmaceuticals, the global supply is mainly dictated by the demands of Clarity's clinical program. Clarity has expanded its future supply arrangements with the signing of a Master Supply Agreement with NorthStar Medical Radioisotopes, LLC who will supply the isotope exclusively to Clarity (see Section 10.11.3 for further details).

183. Carrasquillo JA, Fine BM, Pandit-Taskar N, Larson SM, Fleming SE, Fox JJ, Cheal SM, O'Donoghue JA, Ruan S, Ragupathi G, Lyashchenko SK, Humm JL, Scher HI, Gönen M, Williams SP, Danila DC, Morris MJ. Imaging Patients with Metastatic Castration-Resistant Prostate Cancer Using ^{89}Zr-DFO-MSTP2109A Anti-STEAP1 Antibody. J Nucl Med. 2019 Nov;60(11):1517-1523. doi: 10.2967/jnumed.118.222844. Epub 2019 May 3. PMID: 31053681; PMCID: PMC6836860.

The main production method for ^{67}Cu is by irradiation of ^{68}Zn targets using electron accelerators. There are a number of potential advantages associated with electron accelerator production, including:

- very high specific activity;
- very high purity ^{67}Cu;
- modular scalability;
- lower cost compared to other isotope production methods, such as nuclear reactors;
- lower regulatory burden to operate than a nuclear reactor;
- proven technology; and
- potential high volume production with HE Rhodotrons.

^{67}Cu production development on electron accelerators has the potential to supply significant volumes of high purity and high specific activity of ^{67}Cu without the significant expense of constructing new high-flux nuclear reactors for the production of other isotopes, such as Lu-177.

Overnight transport logistics from the isotope manufacturers to the central radiopharmacy are adequate for ^{67}Cu due to its 2.6 day half-life.

3.7.3.2. Copper-67 supply strategy

NorthStar Medical Radioisotopes

In May 2021, Clarity entered into a Master Supply Agreement (**Supply Agreement**) for the commercial supply of ^{67}Cu with NorthStar Medical Radioisotopes, LLC (**NorthStar**), a global innovator in the development, production and commercialisation of radiopharmaceuticals used for therapeutic applications and medical imaging. Under the agreement, NorthStar will supply ^{67}Cu exclusively to Clarity. Further details of the Supply Agreement are set out in Section 10.11.3.

As Clarity progresses its Targeted Copper Theranostics (**TCT**) programs and further validates the SAR Technology platform, it creates the demand for ^{67}Cu, which has previously been limited due to the lack of an effective copper chelating technology. By signing this Supply Agreement with NorthStar, Clarity has sought to ensure that the supply of ^{67}Cu meets its demand as the company expands its clinical trials in large patient populations in the US and advances towards commercialisation of its products.

NorthStar has taken delivery of two IBA Rhodotron TT300 HEs into a custom-built accelerator facility in the US. These are expected to be fully commissioned by 2023. NorthStar has a further six IBA Rhodotron TT300 HE on order. The Rhodotron TT300HE's have ~125 kW power at 40 MeV and have the potential to become the preferred large-scale manufacturing method for ^{67}Cu as well as other radionuclides including molybdenum-99 (^{99}Mo or Mo-99) for technetium-99m (^{99m}Tc or Tc-99m) generators. The cost for a Rhodotron is around EUR6 million per instrument[184], which is a relatively low investment to establish production of a therapeutic radionuclide without reliance on a nuclear reactor.

Idaho Accelerator Center (IAC)

The Idaho Accelerator Center (**IAC**), a research facility operated by Idaho State University in the US, has pioneered the use of electron accelerators to produce ultra-high purity ^{67}Cu by irradiation of ^{68}Zn targets, via the ^{68}Zn (γ,p) ^{67}Cu reaction. IAC has several patents around the production and purification of ^{67}Cu. Clarity has worked with the IAC for a number of years around the upscale of ^{67}Cu production and supply of the radioisotope to Clarity's clinical trials. Clarity and IAC have a long-term supply agreement in place. Further details of the agreement with Idaho State University are set out in Section 10.11.2.

The IAC currently operates electron accelerators at 40MeV for the production of high specific activity ^{67}Cu, which has been used for Clarity's clinical studies in both the US and Australia.

Other groups producing ^{67}Cu

A number of other groups in North America are producing ^{67}Cu, including the US Department of Energy (**DOE**) and Canadian Isotope Innovations Centre (**CIIC**).

184. <https://www.globenewswire.com/news-release/2019/03/29/1788112/0/en/IBA-SELLS-FIRST-TWO-RHODOTRON-ACCELERATORS-TO-NORTHSTAR-MEDICAL-RADIOISOTOPES.html>.

3.7.4. Non-radioactive components

The targeting molecules and chelators that can be radiolabelled with ^{64}Cu and ^{67}Cu are non-radioactive. They can be manufactured to cGMP quality in significant volumes and have long shelf lives, with stability testing extending over several years. They are manufactured, tested and released by conventional CDMOs according to Clarity's specifications. The long shelf life makes these products available as a stock item at central radiopharmacy facilities.

3.7.5. Finished drug products

In both the US and Australia, Clarity manufactures its final drug product at central radiopharmacies as ready-to-use radiopharmaceuticals which are shipped to the treatment centres using overnight logistics.

In the US there are a number of central radiopharmacies that have supplied Phase III trials in the past and have proven expertise in the commercial supply of approved products. These companies have mature supply chains that can work with the shelf life of Clarity's Target Copper Theranostic products.

3.8. Intellectual property

Clarity has an extensive patent portfolio generated from a patent strategy designed to cover its SAR Technology platform and its radiopharmaceutical products as well as a 'Discovery Program' focused on developing new products and new intellectual property for a range of indications of cancer (see further information on the 'Discovery Program' in Section 3.6). Clarity works closely with experienced patent attorneys at the patent firm DCC and their overseas associates to protect its IP in accordance with the patent strategy. DCC has prepared an independent intellectual property report, which is contained in Section 9.

Clarity's current patent portfolio covers a broad range of countries and major markets, including United States, Australia, Europe, Japan, China, Canada, Singapore, Malaysia, South Korea, Russia, Mexico and India.

Originating from pioneering work at the Australian National University, The University of Melbourne and Australian Nuclear Science and Technology Organisation, Clarity has expanded its patent base, protecting its proprietary SAR Technology platform, existing products, Discovery Program pipeline, manufacturing and processes (see Figure 42 below).

Figure 42: Overview of Clarity's patent strategy

Clarity's patent strategy is based on supporting granted patents in major markets and extending existing patents where possible with divisional applications and patent continuations to capture all the inventions in the patents that support Clarity's products. The strategy goes further by extending the IP footprint with new patent applications filed in new inventions as they arise.

The Platform Protection is covered by granted patents and new patent applications over a broad family of novel SAR (sarcophagine) cages (chelators) and linkers. The multiple patent families enforce both offensive and defensive strategies that support the chelators used in lead products.

The Product Protection is covered by granted and new patent applications that include composition of matter patents on the lead compounds.

The Pipeline Protection is covered by existing and/or new patent applications that protect the chelators, linker chemistry, targeting moiety or the whole compound that is being developed and uses thereof.

Once a lead compound is established, Manufacturing and Process Protection is covered by new applications, encompassing areas that may include formulation, radiolabelling, stability and/or synthesis methods.

Clarity's patent approach to consolidate and support its intellectual property position is outlined in Figure 43.

Figure 43: Clarity's patent approach to consolidate and support its IP position

	Extending IP Footprint	Consolidating Existing IP Position
Platform Protection	• Granted and new chelator patents used in further developing lead and back-up products • Broad range of countries and major markets	• Chelator patents covering broad range of sarcophagine chelators • Broad range of countries and major markets
Pipeline Protection	• Granted and new chelator patents used in future discovery products • New patents filed on novel treatment regimes for radiopharmaceutical and imaging applications	• Additional chelator patents covering a further range of sarcophagine chelators • Broad range of countries and major markets
Product Protection	• Maintenance of pending applications for potential continuation or divisional filings (on existing important patents) • New patents filed on lead and back-up compounds	• Composition of matter patents on variants derived from initial lead compounds • Broad range of countries and major markets
Manufacturing and process protection	• Manufacturing and formulation patents • New patents filed on manufacturing processes	• Novel formulation patents to aid in delivery and storage stability • Broad range of countries and major markets

3.8.1. Regulatory protections

^{64}Cu SARTATE and ^{67}Cu SARTATE have both been granted FDA Orphan Drug Designation for the treatment and clinical management of neuroblastoma respectively. ODD provides further protection of the product in addition to patent protection and qualifies the sponsor of the drug for various development incentives (see Section 2.6.3 for more detail). Importantly, the FDA Orphan Drug Act grants a seven year market exclusivity, which attaches upon approval of a drug product with ODD if the statutory requirements are met, and applies specifically to that designated orphan use of the drug.

04

Financial Information

04 Financial Information

4.1. Introduction

The financial information for Clarity contained in this Section 4: includes:

- summary historical consolidated statement of profit or loss and other comprehensive income for the year ended 30 June 2019 (**FY2019**), year ended 30 June 2020 (**FY2020**) and 6 months ended 31 December 2020 (**1H2021**) with the 6 months ended 31 December 2019 comparative information (**1H2020**);
- summary historical consolidated statement of cash flows for FY2019, FY2020 and 1H2021 with 1H2020 comparative information; and
- historical consolidated and pro forma consolidated statements of financial position as at 31 December 2020 and the associated details of the pro forma adjustments,

(together, the **Historical Financial Information**).

The Historical Financial Information should be read together with the other information contained in this Prospectus, including:

- management's discussion and analysis set out in this Section 4;
- the risk factors described in Section 5 (including the impact of COVID-19 described in Section 5.2.16);
- the description of the use of the proceeds of the Offer described in Section 7;
- the Investigating Accountant's Report set out in Section 8; and
- the indicative capital structure of the Clarity Group described in Section 10.6.

Investors should note that past performance is not an indication of future performance.

4.2. Basis of preparation and presentation of the Historical Financial Information

The Directors of Clarity are responsible for the preparation and presentation of the Historical Financial Information.

The Historical Financial Information has been prepared in accordance with the recognition and measurement principles of Australian Accounting Standards adopted by the Australian Accounting Standards Board, which are consistent with International Financial Reporting Standards (**IFRS**) issued by the International Accounting Standards Board, and Clarity's accounting policies. Clarity's significant accounting policies are described in Appendix A of this Prospectus. The accounting policies of Clarity have been consistently applied throughout the periods presented.

All amounts disclosed in Section 4 and Appendix A are presented in Australian dollars and, unless otherwise noted, are rounded to the nearest thousand. Some numerical figures included in this Prospectus have been subject to rounding adjustments. Any differences between totals and sums of components in figures or tables contained in this Prospectus are due to rounding.

The Historical Financial Information (other than the pro forma adjustments to the historical statement of financial position as at 31 December 2020 and the results of those adjustments) has been derived from the audited General Purpose Financial Report of Clarity for FY2019, FY2020 and reviewed financial statements for 1H2021. The financial statements of Clarity were audited and reviewed by Grant Thornton Audit Pty Ltd in accordance with Australian Auditing Standards. The audit opinions issued to the Directors for FY2019 and FY2020 were unmodified but included an emphasis of matter regarding the existence of a material uncertainty which may cast significant doubt on the Clarity Group's ability to continue as a going concern. The review conclusion issued to the Directors for 1H2021 was also unmodified but included an emphasis of matter regarding the existence of a material uncertainty which may cast significant doubt on the Clarity Group's ability to continue as a going concern which is contingent upon the capital raising (as described in this Prospectus) and grant funding to support research and development activities.

The Historical Financial Information is presented in an abbreviated form and does not contain all of the disclosures, statements or comparative information required by Australian Accounting Standards applicable to financial reports prepared in accordance with the Corporations Act.

The Historical Financial Information has been reviewed in accordance with the Australian Standard on Assurance Engagements ASAE 3450 Assurance Engagements involving Fundraising and/or Prospective Financial Information by Grant Thornton Corporate Finance Pty Ltd as set out in the Investigating Accountant's Report. Investors should note the scope and limitations of the Investigating Accountant's Report.

The Historical Financial Information has been prepared for the purpose of the Offer.

4.3. Non IFRS/non GAAP financial measures

Clarity uses certain measures to manage and report on its business that are not recognised under IFRS. These measures are collectively referred to as "non IFRS/non GAAP financial measures". These non IFRS/non GAAP financial measures do not have a prescribed definition under IFRS and therefore may not be directly comparable to similarly titled measures presented by other entities.

These should not be construed as an indication of, or an alternative to, corresponding financial measures determined in accordance with IFRS. Although Clarity believes these non IFRS financial measures provide useful information to users in measuring the financial performance and condition of the business, investors are cautioned not to place undue reliance on any non IFRS financial measures included in this Prospectus.

In particular, the following non IFRS/non GAAP financial data is included:

- EBITDA which means earnings before interest, taxation, depreciation & amortisation, and is expressed before and after research and development expenses as well as share-based payments; and
- EBIT which means earnings before interest and taxation.

Potential investors should also refer to the description of the key financial terms set out in Section 4.5.

4.4. Changes in accounting standards and accounting policies

AASB 16 Leases

AASB 16 Leases replaces IAS 117 Leases. AASB 16 became mandatorily effective on 1 January 2019 and applied to the Clarity Group from 1 July 2019. The new standard introduces a single lessee accounting model that no longer requires leases to be classified as operating or financing. Other major changes include: the recognition of a right-to-use asset and liability, depreciation of right-to-use assets in line with AASB 116 Property Plant and Equipment, variable lease payments that depend on an index or rate are included in the initial measurement of lease liability; option for lessee not to separate non-lease components and account for all components as a lease; and additional disclosure requirements.

The impact of this new standard has been considered by Clarity and it has been determined that there is no material impact of the financial information as the Clarity Group's occupancy lease is held under a month by month lease agreement.

4.5. Historical statement of profit and loss and other comprehensive income

The table below presents the summary audited and reviewed historical statement of profit and loss and other comprehensive income for FY2019, FY2020, 1H2020 and 1H2021.

	Audited	Audited	Reviewed	Reviewed
$'000	Year ended 30 June 2019	Year ended 30 June 2020	Six months ended 31 December 2020	Six months ended 31 December 2019
Other income	2,643	2,839	1,382	1,210
Operating expenses	(1,757)	(4,598)	(2,642)	(2,108)
Research & development expenses	(4,107)	(4,037)	(2,441)	(1,885)
Share based payments	(522)	(1,194)	(1,171)	(565)
EBITDA	**(3,743)**	**(6,990)**	**(4,873)**	**(3,346)**
Depreciation	(22)	(17)	(7)	(9)
EBIT	**(3,765)**	**(7,007)**	**(4,880)**	**(3,355)**
Net interest income	81	53	25	59
Net Loss Before Tax	**(3,684)**	**(6,954)**	**(4,855)**	**(3,296)**
Income tax	–	–	–	–
Net Loss After Tax	**(3,684)**	**(6,954)**	**(4,855)**	**(3,296)**
Foreign exchange translation	9	1	(3)	1
Total comprehensive loss	**(3,676)**	**(6,953)**	**(4,858)**	**(3,295)**

Description of key financial terms

Set out below is a description of the key financial terms used in the presentation of the Historical Financial Information:

1. **Other income:** Other income relates to grants and research and development tax incentives received;
2. **Operating expenses:** Operating expenses relate to all indirect expenditure that is not attributable to research and development activities. These expenses include legal fees, corporate advisory costs, indirect employee costs, administration costs, travel costs, occupancy costs and patent costs (including costs of application for patents as well as patent protection);
3. **Research & development expenses:** Research and development expenses represent costs for employees, contractors, materials and other expenditure associated with the Clarity Group's research & development programs;
4. **Share based payments:** Share based payments represent the non-cash expense attributed to vested options and the expenses to date for options that have not yet vested (as the expense is spread over the vesting period). The options have been issued to key management personnel, employees and non-employees of the Clarity Group as well as advisers;
5. **Depreciation:** refers to the depreciation of office equipment and computers;
6. **Net interest income:** net interest income relates to interest income from cash at bank and term deposits held; and
7. **FX differences:** FX differences relate to the movements in the foreign exchange translation reserve, which arises as a result of the Belgium subsidiary functional currency on consolidation.

4.6. General factors affecting the historical operating results of clarity

Below is a discussion of the main factors which affected the Clarity Group's operations and relative financial performance in FY2019, FY2020 and 1H2021, which the Clarity Group expects may continue to affect it in the future. The discussion of these general factors is intended to provide a summary only and does not detail all factors that affected the Clarity Group's historical operating and financial performance, nor everything which may affect the Clarity Group's operations and financial performance in the future. Please also refer to Section 5 of this Prospectus which refers to some of the risk factors associated with an investment in the Company.

Management discussion and analysis of the Historical statement of profit and loss and other comprehensive income

Other income relates to grant income received predominately from the Department of Industry and Innovation, Science and Research in FY2019 and the State of Wallonia in Belgium in FY2020. The following R&D tax incentive refunds on eligible expenditure were recognised and subsequently received in cash, $1.3 million in FY2019; $2.5 million in FY2020; and $1.3 million in 1H2021.

Operating expenses include overhead costs that are not directly attributable to R&D. Indirect employee costs increased between FY2019 and 1H2021 as a result of bonus payments made to senior management and key employees for achieving key milestones as part of the Company's short term incentive plans.

R&D expenses include clinical trial costs, applicable R&D employment costs, contractors for outsourced research projects and contract manufacture for use in preclinical and clinical research. These have increased between FY2019 and 1H2021 as Clarity has progressed its product pipeline and increased its R&D activities thereby requiring further employees, research contractors and increased manufacturing activities in preparation for its expanded clinical program.

Movements in the share based payments expenses are a result of the valuation of outstanding options in accordance with the Black Scholes Model.

Depreciation relates to the depreciation expense incurred on laboratory equipment and computer equipment.

Net interest income relates to interest received on term deposits held as well as cash at bank.

4.7. Historical and pro forma statement of financial position

4.7.1. Statement of financial position

The table below sets out the reviewed historical statement of financial position as at 31 December 2020, the pro forma adjustments that have been made to the reviewed statement of financial position (further described in Section 4.7.2) and the pro forma statement of financial position as at 31 December 2020.

The pro forma statement of financial position is provided for illustrative purposes only and is not represented as being necessarily indicative of Clarity's view of its future financial position.

As at 31 December 2020	Ref	Reviewed $'000	Pro forma adjustments $'000	Pro forma $'000
Assets				
Cash and cash equivalents	4.7.3	10,986	89,093	100,079
Financial assets		11,500	–	11,500
Other receivables		3,950	(2,310)	1,639
Prepayments		149	–	149
Total current assets		**26,585**	**86,783**	**113,368**
Plant & equipment		96	–	96
Other financial assets		11	–	11
Total non current assets		**107**	**–**	**107**
Total assets		**26,692**	**86,783**	**113,475**
Liabilities				
Trade and other payables		1,527	–	1,527
Deferred income		81	–	81
Provisions		319	–	319
Total current liabilities		**1,927**	**–**	**1,927**
Provisions		90	–	90
Total non current liabilities		**90**	**–**	**90**
Total liabilities		**2,017**	**–**	**2,017**
Net assets		**24,675**	**86,783**	**111,458**
Share capital	4.7.4	44,772	87,499	132,271
Share option reserve	4.7.4	3,549	–	3,549
Accumulated losses	4.7.4	(23,661)	(716)	(24,377)
Foreign currency translation reserve	4.7.4	15	–	15
Total equity		**24,675**	**86,783**	**111,458**

4.7.2. Description of pro forma adjustments

The following transactions and events had not occurred prior to 31 December 2020, but have taken place or will take place on or before the date on which Shares are allotted under the Offer. The pro forma financial information in this Section 4.7.2 assumes that they occurred on or before 31 December 2020:

The following subsequent event transactions have occurred:

1. exercise of 93,333 share options and receipt of $225,000 for exercise of share options;
2. receipt of R&D tax incentive provided at 30 June 2020 amounting to $2.4 million; and
3. share split of the existing shares at a ratio of 20 to 1 which is a non cash transaction.

In addition, the following pro forma transactions and events will take place pursuant to this Prospectus:

4. the Offer of 65.7 million Shares at $1.40 each raising gross proceeds of $92 million; and

5. expenses associated with the Offer (including advisory, legal, accounting and administrative fees as well as printing, travelling and other expenses) amounting to cash costs of $5.57 million (including GST recoverable of $0.13 million) and a total amount of $4.73 million being capitalised to share capital and $0.73 million being expensed to accumulated losses.

A deferred tax asset has not been recognised in relation to the capitalised Offer costs due to the uncertainty surrounding the flow of economic benefits that will occur in future periods.

4.7.3. Calculation of the pro forma cash position

The table below sets out the reviewed cash and cash equivalents of Clarity as at 31 December 2020, the pro forma adjustments that have been made to the reviewed cash and cash equivalents (further described in Section 4.7.2) and the Clarity Group's pro forma cash and cash equivalents as at 31 December 2020. The numbers in the 'Pro forma adjustment' column correspond to the numbering of the pro forma transactions set out in 4.7.2 above.

Clarity expects that it will have sufficient cash to fund its operational requirements and business objectives following the Offer.

	Pro forma adjustment	Pro forma
Reviewed cash and cash equivalents at 31 December 2020		10,986
Pro forma transactions:		
Cash received from exercise of Share Options	4.7.2.1	225
R&D tax incentive received	4.7.2.2	2,437
Proceeds from the Offer	4.7.2.4	92,000
Offer costs remaining to be paid	4.7.2.5	(5,569)
Pro forma cash and cash equivalents		**100,079**

In addition to Cash and Cash Equivalents, Clarity had $11.5 million of Financial Assets in the form of term deposits at 31 December 2020. At the Prospectus Date the cash and cash equivalents (including the Term Deposits) amount to $17.63 million.

4.7.4. Calculation of the pro forma capital structure

The pro forma capital structure shown below is based on the following adjustments:

	Pro forma adjustment	Shares No.	Share capital $'000	Accumulated losses $'000	Share based payment reserve $'000	FCTR $'000	Net assets $'000
As at 31 December 2020		9,427,580	44,772	(23,661)	3,549	15	24,675
Subsequent events							
Share Options exercised		93,333	225	–	–	–	225
Share split (20:1)	4.7.2.3	180,897,347	–	–	–	–	–
Pre offer capital structure		**190,418,260**	**44,997**	**(23,661)**	**3,549**	**15**	**24,900**
Offer	4.7.2.4	65,714,286	92,000	–	–	–	92,000
Offer costs	4.7.2.5	–	(4,726)	(716)	–	–	(5,442)
Pro forma capital structure		**256,132,546**	**132,271**	**(24,377)**	**3,549**	**15**	**111,458**

4.8. Historical statement of cash flows

The table below presents the summary audited and reviewed historical statement of cash flows for FY2019, FY2020, 1H2020 and 1H2021.

	Audited	Audited	Reviewed	Reviewed
$'000s	Year ended 30 June 2019	Year ended 30 June 2020	6 months ended 31 December 2020	6 months ended 31 December 2019
Operating cash flow				
Other income	–	50	50	–
Net interest received	51	75	27	57
R&D incentive received	743	1,355	–	–
Grant income received	1,158	527	–	263
Payments to suppliers and employees	(5,659)	(8,836)	(4,079)	(4,028)
Net operating cash flows	**(3,707)**	**(6,830)**	**(4,002)**	**(3,708)**
Investing activities				
Payment for PP&E	(16)	(14)	(3)	(11)
Net investing cash flows	**(16)**	**(14)**	**(3)**	**(11)**
Financing activities				
Proceeds from issue of share capital	10,000	4,097	20,896	–
Cash held pending share placement	–	8	–	–
Transfer from/(to) financial assets	(4,523)	3,514	(10,500)	4,514
Exercise of share options	450	600	–	300
Net financing cash flows	**(5,927)**	**8,219**	**9,729**	**4,814**
Net change in cash and cash equivalents held	2,205	1,374	5,266	1,096
Effect of exchange rate changes on cash and cash equivalents	9	1	(3)	1
Cash and cash equivalents at the beginning of the financial year	**1,678**	**3,891**	**5,266**	**3,890**
Cash and cash equivalents at the end of the financial year	**3,891**	**5,266**	**10,986**	**4,987**

Management discussion and analysis of the Historical Cash Flows

Clarity is in the early stages of its business life cycle while it continues to perform research and development activities and has historically obtained income from government grants and R&D tax incentives. Operating cash outflows have increased to meet the increased costs associated with expanding its activities in order to further advance the product pipeline into clinical trials. There has been an increase in the investment in working capital, which is in line with the increase in the amount of expenses being incurred.

Investing cash flows relate to the purchases of laboratory equipment and computer equipment to support the progression of research activities.

Clarity has largely been financed by capital raisings through the issue of share capital, with $10.0 million raised in FY2019, $4.1 million in FY2020 and a further $20.9 million in 1H2021. The funds raised were invested in term deposits with some cash retained to meet working capital requirements.

4.9. Commitment & contingencies

As at 31 December 2020, the Company had intellectual property licences with The University of Melbourne, Australian Nuclear Science and Technology Organisation (**ANSTO**) and The Baker Heart and Diabetes Institute, representing contingent liabilities totalling $5.9 million. These contingent liabilities are dependent upon the high-risk nature of the clinical research being successful, as well as future decisions regarding the clinical focus of the Company, and are therefore not recognised in the statement of financial position. At the Prospectus Date these contingent liabilities amount to $11.2 million to The University of Melbourne and ANSTO. Licenses to The Baker Heart and Diabetes Institute were terminated after 31 December 2020. The increase from December is due to expansion and development of the intellectual property portfolio during the period. A summary of the licence agreements with The University of Melbourne and ANSTO are set out in Section 10.11.

4.10. Dividend policy

The Company has never paid a dividend and the Directors have no current intention of declaring or paying any dividends in the foreseeable future. The Directors will review this policy as appropriate and the declaration and amount of any dividends will be determined by, and at the sole discretion of, the Board. In making a decision regarding dividends, the Board will take into account the Company's earnings for the relevant period, future capital requirements and other relevant factors such as the outlook for the Company. No assurance can be given by the Company or its Directors about the payment of any dividend or distribution, or the level of franking on any such dividend at any point in the future.

05
Key Risks

05 Key Risks

5.1. Introduction

This Section 5 identifies key risks associated with an investment in the Company, but it should not be viewed as an exhaustive list of the only risk factors to which the Company and its Shareholders are exposed. The occurrence of, or consequences associated with, some of the risks detailed in this Section 5 are partially or completely outside of the control of the Company, the Directors and the Company's senior management team. It is important to also note that there can be no guarantee that the Company will achieve its stated objectives or that any forward-looking statements or forecasts will eventuate. Past performance may also not be a reliable indicator of future performance.

There are specific risks that relate directly to the Company. In addition, there are other general risk factors, individually or in combination, which could have a material adverse impact on the Company's assets and liabilities, financial position and performance, profits, losses and prospects, and the market price for the Shares. You should note that the risks described in this Section 5 are not the only risks faced by the Company. Additional risks (including risks of which the Company and the Directors are currently unaware) also have the potential to have a material adverse effect on the Company's business, financial position, operating and financial performance and the value of Shares.

The selection and order of the key risks set out below has been based on an assessment of the probability of a risk occurring, together with the potential impact of the risk on the Company if it did occur, as determined by the Directors as at the Prospectus Date. The importance or relevance of the key risks to the Company may change and other risks may emerge in the future.

An investment in the Shares offered under this Prospectus should be considered speculative. Before deciding whether to invest in the Company, you should read this Prospectus carefully in its entirety and satisfy yourself that you have a sufficient understanding of the actual and potential risks associated with such an investment. You should consider whether an investment in the Company is suitable for you having regard to your personal circumstances, investment objectives, financial circumstances, taxation position and particular needs. The Board strongly recommends that potential investors consider the key risk factors described below, together with the other information contained in this Prospectus, and consult their professional advisers (including stockbroker, lawyer, tax adviser, financial adviser or other independent financial adviser) before deciding whether to apply for Shares pursuant to this Prospectus.

5.2. Specific risks to the Clarity Group

5.2.1. Speculative nature of investment

As at the Prospectus Date, the Company does not generate revenue and does not have a product that is capable of generating revenue without completing further clinical trials and obtaining regulatory approvals. The Shares to be issued pursuant to this Prospectus carry no guarantee of profitability, dividend payments, returns of capital or an increase in the Share price. As a result, an investment in the Company should be considered speculative, and potential investors should consult their professional advisers before deciding whether to apply for Shares under this Prospectus.

The Company will need to successfully develop and commercialise products in order to generate revenue and to become, and then remain, profitable. In particular, the Company will need to successfully complete clinical trials for the Company's products and obtain all relevant regulatory approvals from regulatory bodies in the United States, together with other relevant jurisdictions such as Europe, for those product candidates and for the manufacturing, marketing and sale of the Company's products in those jurisdictions. As at the Prospectus Date, the Company is only at the preliminary stage of these activities and there is no guarantee that the Company will succeed in these activities. Should the Company be successful in these activities, there is still a risk that the Company may never generate enough revenue to achieve profitability or declare any dividends.

5.2.2. Success of clinical trials is not guaranteed

As mentioned above at Section 5.2.1, the Company's ability to generate revenue and become, and remain, profitable will largely depend on whether the Company's clinical trials are successful and whether the Company is able to demonstrate, through these clinical trials, that the Company's products are suitable for commercialisation.

The Company seeks to minimise its clinical trial risk by using targeted diagnostic products as part of its clinical trial process to select patients who are likely to respond to treatment with its therapeutic products. However, the success of the Company's clinical trials and the development of the Company's products, and therefore the Company's ability to generate revenue, is not guaranteed. The development of radiopharmaceutical products is typically comprised of three different phases of drug development, with each individual phase carrying a risk of failure. In particular, the Company's products are at risk of failing safety and efficacy steps throughout each individual development phase. In addition, the commencement and completion of clinical trials may be delayed due to various factors, such as unanticipated safety issues, issues relating to the correct dosage of the Company's product, lack of effectiveness during clinical trials, delays in patient recruitment, the inability to effectively monitor patients during or after treatment, the failure of medical investigators to follow clinical protocols, reliance on clinical research organisations and the termination of license agreements that are required in order to complete the clinical trials. If the Company's clinical trials fail or experience material delays, it is likely that Shareholder returns will be materially adversely affected.

5.2.3. The Company may not obtain the required regulatory approvals

The Company will need to obtain ongoing approvals from the FDA in the US, the TGA in Australia and the EMA in Europe in order to run its studies and clinical trials in those jurisdictions. The Company will also need new approvals from these regulators in order to further develop its products and, at a later stage, to distribute and market its products in each of the United States, Australia and Europe respectively. In addition, the Company will require approvals from equivalent regulatory authorities in other countries should the Company wish to conduct clinical trials or commercialise its products in those jurisdictions.

The Company has two open Investigational New Drugs (**INDs**) applications that received clearance to proceed to clinical trials from the FDA and has received approvals from the FDA for two Orphan Drug Designations (**ODD**) and two Rare Paediatric Disease Designations (**RPDD**). There is no guarantee that the Company will continue to receive the regulatory approvals that are necessary for the Company to run studies and clinical trials or to commercialise its products (including the INDs, OODs and RPDDs referred to above) in any jurisdiction. Whether the Company successfully obtains these regulatory approvals is, ultimately, outside of the Company's control and dependent on the decisions of the regulatory bodies in each relevant jurisdiction. If the Company does not receive the regulatory approvals that are required, the Company will not be able to commercialise its products or generate revenue in the relevant jurisdictions, which may have a material adverse impact on Shareholder returns.

In addition, the Company may experience delays in the application process for its regulatory approvals. The regulatory bodies in each jurisdiction have extensive discretion in their approval processes, and may request additional information from the Company, or further testing and trials, prior to considering the Company's regulatory application or granting the Company regulatory approval. If the Company experiences any delays in obtaining the necessary regulatory approvals, this may in turn delay the Company's ability to commercialise its products and generate revenue. This risk has the potential to materially and adversely impact the Company's planned future revenue, margins and profitability and reduce the value of an investment in the Shares.

5.2.4. Competitive industry

Clarity is operating in the pharmaceutical industry with a focus on the global oncology and radiopharmaceutical markets, which are competitive and subject to rapid and significant technological change. The Board considers that the Company has, as at the Prospectus Date, a competitive advantage in these markets for its products due to the versatility of the SAR Technology platform that enables the Company to focus on developing new products and IP for new indications of cancer through its Discovery Program that is focused on developing new products and intellectual property for various indications of cancer. However, these circumstances may change over time as there is always a risk of new entrants to the market, and the risk that an existing radiopharmaceutical company or another company within the oncology market may disrupt the Company's business operations and anticipated market share. The Company cannot predict the timing and scale of new competitors that may emerge.

In particular, the rise of the oncology and radiopharmaceutical industries may lead to a number of large corporations acquiring significant market share, either through expanding their product development or acquiring smaller companies that are in the development phase. As a result, many of the Company's current and potential competitors may obtain access to greater capital resources, research and development facilities, regulatory and operational experience, manufacturing and marketing experience and production facilities. There is a risk that the Company's competitors will succeed in developing alternative products that are safer, more effective or commercially superior to those being developed by the Company. If the Company is unable to compete effectively or expand its business, the Company's products could be rendered obsolete or otherwise uncompetitive, which may materially and adversely impact the Company's planned future revenue, margins and profitability and reduce the value of an investment in the Shares.

5.2.5. Clarity requires effective protection and maintenance of its intellectual property

The Company currently has title to a number of key patents and patent applications in respect of the technology that form the basis of a number of its product candidates. The success of the Company is therefore partly dependent on the Company's ability to continue to obtain and maintain commercially beneficial patents and to protect the intellectual property that it owns. The risks that the Company faces with respect to the patents and patent applications that it owns, and any future patents/patent applications that may be acquired or licensed, include but are not limited to the following:

- patent applications that are lodged by the Company may not result in granted patents;
- the Company may experience delays in obtaining the grant of patents;
- any request by the Company to obtain an extension to the term of a patent may not be granted or, if it is granted, the patent may be granted on the condition that revisions to the patent are imposed;
- the patents that are granted to the Company may not necessarily protect the Company's commercial activities;
- the patents that the Company owns or licences may be challenged at any time;
- other entities may independently develop similar, duplicate or alternative technologies to those of the Company;
- other entities may design workarounds to the Company's technology;
- other entities may own intellectual property that is relevant to the Company's technology or activities; and
- the value of the Company's intellectual property rights may diminish if a patent is not granted with respect to any patent application. Additionally, any information that is contained in the patent application will be publicly available information and as such will not be subject to any confidentiality restrictions.

The degree of protection that the Company may have with respect to its intellectual property rights is uncertain and subject to the risks detailed above as well as other potential unanticipated risks. In addition, the Company's intellectual property rights may be subject to change as laws and regulations relating to the scope and validity of patents continues to evolve.

If the Company is required to engage in legal proceedings with respect to its intellectual property – either to defend legal actions or claims against its intellectual property, or to assert an intellectual property right – the Company may incur extensive costs and may further experience delays in the development or commercialisation of its product candidates. Additionally, if a third party is successful in making a claim against the Company, the Company may be liable to pay damages or be required to refrain from using certain patents or other intellectual property.

There is also a risk that third parties may already be in possession of intellectual property that is relevant to the Company's business, which may prevent the Company from being able to successfully reach its goals and objectives. For example, the Company may be developing a product that is in the process of being registered by another third party. Alternatively, the Company may seek to license or acquire (i) intellectual property from a third party, (ii) design workarounds to third party intellectual property rights, or (iii) challenge a third-party with respect to their intellectual property rights either through the courts or at an administrative stage if required. There is no guarantee that the Company will be able to obtain, or use, intellectual property that it acquires through any of these means.

In addition, the Company cannot guarantee that its employees, third parties or consultants will not breach confidentiality, or infringe or otherwise exploit the Company's intellectual property, which could cause the Company to suffer a material loss.

These risks may materially and adversely impact the Company's planned future revenue, margins and profitability and reduce the value of an investment in the Shares. Full details of the Company's patent and trademark portfolio are detailed in Section 9 of this Prospectus.

5.2.6. Reliance on key suppliers

As detailed in this Prospectus, the Company does not have its own facilities from which to manufacture its products (including the materials required for its products) and it therefore relies on third parties for the supply of the critical materials that are necessary for the manufacture of its product candidates. These third parties include suppliers of radioisotopes, consumable and vial suppliers, suppliers of certain precursor elements of radiopharmaceuticals and sterility subcontractors. If these third parties are no longer able to provide such materials or services to the Company, the Company may be required to seek alternative suppliers which may cause delays to its clinical trial programs.

5.2.6.1. Supply of ^{64}Cu

Copper-64 (^{64}Cu) is a critical material necessary for the manufacture of the Company's product candidates. The Company's existing supply of ^{64}Cu is sufficient for the Company's current clinical trials program and the Company is expanding its network of ^{64}Cu suppliers to produce industrial levels of ^{64}Cu for its diagnostic products for commercial supply (refer to Section 5.2.7 below). However, if the Company does not receive a sufficient supply of ^{64}Cu on an ongoing basis, this could have an adverse impact on its ability to commercialise its products and therefore its ability to earn revenue.

The Company will continue to be reliant upon third parties for the supply of ^{64}Cu. Reliance on external supply of isotopes is common in the radiopharmaceutical market.

The Company has service agreements in place with South Australian Health and Medical Research Limited (**SAHMRI**) for ^{64}Cu SARTATE™ clinical supply and ^{64}Cu SAR-Bombesin clinical supply and a service agreement in place to validate the production of ^{64}Cu SAR-bisPSMA. The Company also currently has product supply agreements in place with Washington University in St Louis (US) for ^{64}Cu SARTATE™ production and ^{64}Cu SAR-bisPSMA production (**Product Supply Agreements**), which are part of an overall drug product manufacturing of finished goods supply arrangement.

Although the Company has these arrangements in place, the Product Supply Agreements provide the counterparty with broad termination rights, including that either party may terminate the Product Supply Agreements on 60 days' notice to the other party.

Broad termination rights may present a material risk to the Company in circumstances where it relies on a limited number of third parties to supply ^{64}Cu. Moreover, the facilities of the third party suppliers could suffer damages, or a force majeure event, or the suppliers may otherwise be unable to supply ^{64}Cu as required. In these circumstances, and if the Company is unable to locate or establish reliable alternative suppliers, it may be unable to develop its product candidates or commercialise its products. Any of these events could be costly for the Company and may have a material adverse effect on the Company's business, financial condition and results of operations.

However, as the Company progresses its Targeted Copper Theranostic (**TCT**) programs and further validates the SAR Technology platform, this may create an increased demand for ^{64}Cu which may encourage additional suppliers of ^{64}Cu to enter the market. The Company will continue to seek to enter into new contracts to reduce its reliance on single companies for the provision of products and/or services to the Company to limit this risk, including for the supply of ^{64}Cu.

5.2.6.2. Supply of ^{67}Cu

Copper-67 (^{67}Cu) is also a critical material necessary for the manufacture of the Company's product candidates. The Company is reliant upon third parties for the supply of ^{67}Cu. The existing supply of ^{67}Cu is sufficient for the Company's current clinical trials program and the Company has entered into supply agreements to produce industrial levels of ^{67}Cu for its therapeutic pipeline and commercialisation (see below and Section 5.2.7). However, if the Company does not receive a sufficient supply of ^{67}Cu on an ongoing basis, this could have an adverse impact on its ability to commercialise its products and therefore its ability to earn revenue from its therapeutic radiopharmaceutical products.

The Company currently has the following supply agreements in place for the supply of ^{67}Cu:

- Product Supply Agreement with Idaho State University (**ISU**); and
- Master Supply Agreement with NorthStar Medical Radioisotopes, LLC (**NorthStar**).

Although the Company has these arrangements in place, the relevant agreements provide the respective counterparties with broad termination rights, including:

- in the case of the Product Supply Agreement, ISU may terminate it without cause by providing six months written notice and ISU may also terminate the agreement if it loses regulatory approval to produce ^{67}Cu, if the legislature of the State of Idaho fails, neglects or refuses to grant sufficient funds as may be required for ISU to continue to perform the Product Supply Agreement, or if the executive branch of the State of Idaho mandates any cuts or holdbacks in spending; and
- in the case of the Master Supply Agreement, NorthStar may terminate the agreement for various reasons, including if it is unable to produce ^{67}Cu to the specifications under the Master Supply Agreement, or is unable to obtain relevant approvals to manufacture and sell ^{67}Cu after commercially reasonable efforts. In this regard, NorthStar has not yet reached production of ^{67}Cu and is currently developing its process in order to manufacture the product. NorthStar is expected to reach production of ^{67}Cu during 2023, if not earlier.

Broad termination rights present a material risk to the Company in circumstances where it relies on a limited number of third parties to supply ^{67}Cu. Moreover, the facilities of the third party suppliers could suffer damages, or a force majeure event, or the suppliers may otherwise be unable to supply ^{67}Cu as required. In these circumstances, and if the Company is unable to locate or establish reliable alternative suppliers, it may be unable to develop its product candidates or commercialise its products. Any of these events could be costly for the Company and may have a material adverse effect on the Company's business, financial condition and results of operations.

However, as the Company progresses its TCT programs and further validates the SAR Technology platform, this may create an increased demand for ^{67}Cu which may encourage additional suppliers of ^{67}Cu to enter the market. The Company will continue to seek to enter into new contracts to reduce its reliance on single companies for the provision of products and/or services to the Company in order to limit this risk, including for the supply of ^{67}Cu.

5.2.7. Reliance on contract development and manufacturing organisations and logistics partners

The Company relies on third parties to produce and manufacture its product candidates. Manufacturing radiopharmaceutical product candidates is a complex process, and contract development and manufacturing organisations (**CDMO's**) are typically in high demand. The Company's product candidates need to be produced at a high quality and on a consistent basis in accordance with a specific manufacturing process. Both the manufacture and delivery processes for the Company's product candidates, including the use of radioactive materials, must be completed in compliance with regulations applicable to local and international markets. As the Company relies on the CDMO's and logistics partners to manufacture and deliver its product candidates, the Company does not have control over issues that may arise during these processes, including potential difficulties with raw materials, equipment malfunctions and failures by personnel within the CDMO's or logistics partners to follow the appropriate protocols and procedures. For example, if certain materials required in the manufacturing process are stored incorrectly and suffer contamination or insufficient refrigeration, this could materially impact operations and delay the Company's clinical trials and product development.

Minor deviations in any part of the manufacturing process including sourcing materials, filing, labelling, packaging, storage, delivery and quality control testing may result in failures or manufacturing shut-downs, delays in product batch releases, product recalls, spoilage or regulatory action. If the CDMO's or logistics partners that the Company uses engage in or suffer such deviations, this may result in the need for the Company to revise its manufacturing process, change suppliers or alter its delivery processes, which could potentially result in increased costs and loss of efficiencies for the Company due to an unexpected allocation of resources and time. If such issues remain unresolved, there is a risk that the Company's clinical trials may be delayed, which could result in adverse consequences for the Company and Shareholders, including causing significant delays to the Company's development program.

As radiopharmaceutical products have a short half-life (being typically less than a week) due to radioactive decay, it is critical that the Company has effective manufacturing and delivery processes in order to achieve commercial success. These logistical preparations are costly and time-consuming to establish, and any failure in these processes could negatively impact the Company's operations.

In addition, although the Company uses CDMO's to produce and manufacture its product candidates, the Company has not yet manufactured any of its products on a commercial scale. If the Company's products are commercialised and the Company is unable to manufacture its products in sufficient quantities or at an appropriate cost level, either through its CDMO's or another manufacturer, the Company may not be able to meet demand for its products which may adversely impact the commercial sales of its products and therefore the Company's financial position.

5.2.8. Risk of failing to keep up with advances in radiopharmaceuticals

The Company is in the process of developing a number of innovative diagnostic imaging and therapeutic products that seek to improve the efficacy, safety, ease of use and cost-effectiveness of treatment for patients and the oncology market more broadly. In order for the Company to succeed in this pursuit, both in the short and long term, the Company will need to continuously adapt to changes and advances in the radiopharmaceutical market. In particular, it will be necessary for the Company to adapt to new technologies and anticipate and satisfy customer and patient needs. If the Company is unable to continuously innovate and develop new products or product candidates, adapt to changing technologies or anticipate changes in patient and customer needs, the Company's products may become obsolete which could have a material adverse effect on the Company's business and financial position.

5.2.9. Lack of acceptance of radiopharmaceuticals by the medical community

The success of the Company is largely dependent on whether the medical community accepts and embraces the use of radiopharmaceutical products and treatments. If there are any adverse results in the clinical trials of the Company's product candidates or in the clinical trials of the Company's competitors that are developing similar products, or any negative publicity with respect to the safety or efficacy of radiopharmaceutical products and treatments, this could result in the Company's products not being accepted or used by the medical community or the general public. This may have a material adverse effect on the Company's business and financial position.

5.2.10. Development program may be delayed

There may be delays in achieving critical milestones set out by the Company. These include completing clinical trials, obtaining regulatory or reimbursement approvals, establishing commercial manufacturing and commencing product launch and sales. If the Company experiences any material delays, this may have a material adverse effect on the Company's business and financial position.

5.2.11. Risk associated with the use of radiopharmaceuticals

The Company deals with radiopharmaceutical products that use radioactive materials, which generate medical and other regulated wastes. There are a number of risks associated with the use, possession and disposal of these materials and waste products, including physical injury and accidental environmental contamination. The storage, design and manufacturing processes for these radioactive materials may not entirely eliminate the risk of employees of the Company and others being exposed to radiation and radioactive materials. There is a risk that, at times, the Company may need to alter its storage and manufacturing processes in order to remain in compliance with radio-protection laws in the jurisdictions in which the Company operates. The Company is unable to completely eliminate all risk of accidental contamination or injury from these materials and waste products. Consequently, the Company is at risk of being held liable for any damages or losses that are suffered as a result of an accidental contamination or the injury to an employee or other person, and these damages could fall outside, or exceed the limits of, the Company's current insurance coverage. If this was to occur it may adversely impact the Company's financial position, business operations and reputation.

5.2.12. The pricing of the Company's products may be subject to external factors

In Australia and also in various overseas jurisdictions, the price of medicinal products and technologies is often regulated or influenced by government authorities, health insurers and other healthcare providers. In particular, these bodies often determine whether a customer or patient will receive a reimbursement or subsidy for the cost of their medicine or medical treatment.

Accordingly, if the Company is successfully able to sell its products to the market, the pricing of the Company's products will be influenced by these external factors, including the cost of healthcare and the level of reimbursement or subsidy available to customers or patients that use the Company's products.

As the pricing of the Company's products will be subject to these external factors, there is no guarantee that the Company will achieve its targeted price for the sale of its products. If the level of reimbursement available to customers or patients is less than anticipated, this may also negatively impact the profitability of the Company's products and therefore the Company's financial position.

5.2.13. Anticipated future expenses may be incorrect

In determining the use of funds under the Offer, the Company has considered the expenses that it anticipates it will incur. A number of these anticipated expenses relate to the engagement of third party suppliers, manufacturers and other service providers with whom the Company has not yet entered into contractual arrangements. As the Company is not yet party to any contractual agreement with those third parties, there is a risk that the Company may not be able to source the required supplies, manufacturing and services at the cost that it anticipates incurring. As a result, there is a risk that the anticipated future expenses of the Company may be incorrect and more than anticipated, and the Company will be required to adjust its use of funds raised under the Offer accordingly. This may have a material adverse effect on the Company's business and financial position.

5.2.14. Reliance on key personnel

The Company is heavily reliant on the capabilities of its key management personnel who have extensive experience in, and knowledge of, the Company's technology, its business and the market in which it operates. In particular, the loss of one or more of each of the executive directors, being Alan Taylor and Colin Biggin, or any other key executives or management, and any delay in sourcing their replacement, may adversely impact the ability of the Company to implement and expand its business and achieve its growth strategies. There is no guarantee that the Company will be able to retain its key management personnel or, in the event that their employment is terminated, be able to replace them in a timely manner with qualified individuals who have the necessary skills and expertise. This could have a material adverse impact on the Company's business, operating or financial performance.

In addition to the Company's key management personnel, the Company is also reliant on attracting and retaining qualified scientific and technical personnel who are experts in the radiopharmaceutical field. If the Company fails to attract or retain these key employees or contractors, the Company's business, including its research and development programs, could be adversely affected, which may in turn impact the Company's future product success and financial prospects. Additionally, as there is significant demand in the oncology and radiopharmaceutical market for expert qualified scientific and technical personnel, there is a likelihood that the Company's labour costs will increase in order to continue to attract and retain these personnel.

5.2.15. Product liability

Due to the innovative nature of the Company's products, the Company is exposed to the risk of product liability claims arising from defective products or products that are no longer viable, even where the Company has received prior regulatory approval. If the Company is subject to any product liability claims, this could result in the removal of regulatory approvals that the Company may have obtained. In addition, the Company may also incur unanticipated costs as a result of product liability claims, which may exceed or not be covered by the Company's insurance coverage.

5.2.16. COVID-19

Events related to COVID-19 have resulted in significant market volatility. There is continued uncertainty as to the ongoing and future response of governments and authorities globally, and a further Australian economic downturn is possible. As a result, the full impact of COVID-19 on consumer behaviour, original equipment manufacturers, suppliers, employees and the Company are not fully known. Given this, the impact of COVID-19 could potentially be materially adverse to the Company's current operational, and potential future financial, performance. It is possible that disruptions related to COVID-19 may impact the ability of the Company's suppliers and CDMOs to maintain timely product supply for the Company's clinical trials. It is also possible that clinical sites for the Company's trials will experience COVID-19 related disruptions, which could impact their ability to recruit and treat patients in line with forecasts.

Further, any government or industry measures in response to COVID-19 may materially adversely affect the Company's operations and are likely to be beyond the Company's control.

5.2.17. COVID-19 – State and Federal Government restrictions

Due to COVID-19, the Governments in various jurisdictions in which the Company has activities have imposed public health measures which have, and may continue to, disrupt the operations of the Company. Although the Company was able to run a clinical trial in New York during the COVID-19 pandemic, there is a risk that if these public health measures persist there will be a material impact on Clarity's operations in the US and Australia. This may include the ability for clinical trial sites to recruit and treat patients in a timely manner and suppliers and manufacturers to deliver product on schedule.

5.2.18. Supply Chain

Factors outside the control of the Company, for example COVID-19, may have a material adverse impact on the Company's supply chain. Restrictions on the manufacturing of ^{64}Cu and ^{67}Cu may restrict the ability of the Company to conduct clinical trials and other operations that are key to its business model such as research. This may materially impact the ability of the Company to meet its proposed development timetable and adversely impact the price of the Shares.

5.2.19. Information technology and Cybersecurity

The Company's business requires information technology systems in order to support and perform key functions and achieve business objectives. The information technology systems that are used by the Company are vulnerable to interruption or damage from:

- loss of power;
- failure of computer systems;
- telecommunications or data network failures;
- improper operation of the information technology systems by employees or others;
- loss of data;
- computer viruses;
- cyber threats (including but not limited to malware, ransomware, phishing and Distributed denial of service (DdoS) attacks); and
- natural disasters, terrorist attacks or other events outside of the control of the Company.

The Company retains a specialist information technology (**IT**) managed services firm to maintain processes and controls over its IT environment. Notwithstanding the remedial measures in place, any interruption or damage to the Company's IT systems could directly or indirectly impact the Company's ability to conduct its business and may result in the Company incurring unforeseen costs in order to take corrective measures, obtain or rebuild lost data or respond to regulatory inquiries or actions that may stem from a data breach.

5.2.20. Loss or misuse of personal information

The Company utilises confidential and other sensitive information that is stored within its information technology systems and networks. The Company has in place a range of security measures over these systems and networks. The Company places reliance on the security of those IT systems to ensure that this proprietary and confidential data is stored, processed and transmitted securely across systems and networks. The Company is at risk of these IT systems being exposed to security and privacy incidents, breaches, acts of theft or vandalism, misplaced or lost data, programming errors, human errors and other general cybersecurity risks.

A security breach or incident that involves the loss, exploitation or otherwise unauthorised disclosure or use of any confidential or sensitive information, whether by the Company or a third party, could have a materially negative effect on the Company's reputation, financial condition, cash flows, or results of operations. If any of these events occur, it may result in interruptions, delays, a corruption or loss of data, potential liability and regulatory action, potential liability under security and privacy laws or a discontinuance of the availability of IT systems. All could have a significant negative effect on the Company's financial performance, business operations and reputation.

5.2.21. Foreign operations

The Company has a subsidiary that is incorporated in Belgium and another subsidiary that is incorporated in the US. The Company may also conduct some activities in other overseas jurisdictions from time to time. As a result, the Company is exposed to various laws and regulations that it must consider and comply with in the relevant jurisdictions. If the Company does not always receive foreign legal advice in the jurisdictions within which it operates, the Company may be exposed to risks with respect to its asset ownership, labour practices, contract enforcement, changes in the relevant legal and regulatory structures and other issues that could arise in foreign jurisdictions in which the Company operates in (for example, government and regulatory authority practices).

5.3. General risks

5.3.1. Liquidity risk and escrow arrangements

As a result of the compulsory escrow requirements contained in Chapter 9 of the ASX Listing Rules and the voluntary escrow arrangements that have been entered into by certain Existing Shareholders with the Company, it is expected, subject to ASX confirmation, that approximately 155,355,708 of the Shares on issue as at Completion[185] (representing approximately 60.65% of the Shares on issue as at Completion) will be subject to escrow restrictions from Listing including 76,680,986 Shares (representing approximately 29.94% of the Shares on issue as at Completion) for a period of 24 months. The remaining 78,674,722 Shares (representing approximately 30.72% of the Shares on issue as at Completion) are expected to be released from escrow during the course of the initial six month period from Listing. Further details on these escrow restrictions are set out in Section 10.4. Following release from escrow, Shares held by these Shareholders (referred to as Escrowed Shareholders) will be freely tradeable on the ASX. A significant sale by an Escrowed Shareholder of its Shares following their release from escrow (or a perception that such sale has occurred or might occur) could also adversely affect the price of Shares.

There also can be no guarantee that an active market in the Shares will develop or continue, or that the market price of the Shares will increase. If a market does not develop or is not sustained, it may be difficult for investors to sell their Shares. Furthermore, the market price for Shares may fall or be made more volatile because of a relatively low volume of trading. When trading volume is low, significant price movements can be caused by trading a relatively small number of Shares (including for example a sale of Shares recently released from escrow). If illiquidity arises, there is a risk that Shareholders will be unable to realise their investment in the Company when they wish to do so.

5.3.2. Risk of Shareholder dilution

In the future, the Company may elect to conduct fundraisings through the issue of Shares, including for the purposes of raising proceeds for further research, clinical trials and/or acquisitions that the Company may decide to make. While the Company will be subject to the constraints of the ASX Listing Rules regarding the amount of capital it can issue within a 12 month period without obtaining Shareholder approval, Shareholders may be diluted as a result of such issues of Shares and may also experience a loss in value of their Shares.

The Company also currently has 51,088,812 Options on issue as at the Prospectus Date, representing approximately 26.83% of the undiluted share capital of the Company as at the Prospectus Date and will represent approximately 19.95% of the undiluted share capital of the Company as at Completion. If all of these Options are exercised, then Shareholders interests may be significantly diluted. The Company may also in the future issue additional Options to eligible participants either under the Equity Incentive Plan or otherwise to third parties such as consultants, advisers or strategic partners. If additional Options are issued and they are subsequently exercised by the relevant option holders, Shareholders' interests may be significantly diluted and they may also experience a loss in value of their Shares.

5.3.3. Risk of non-exercise of Options

The Company will have 51,088,812 Options on issue as at Completion (assuming no Options are exercised prior to Completion). As all of the Options on issue are exercisable at the sole discretion of the option holder once they become exercisable, there is no guarantee that any Options will ever be exercised. In addition, the Company Options and Adviser Options allow them to be exercised pursuant to a cashless exercise mechanism as detailed in Section 6.4.2.6, which means that no funds are received by the Company where this mechanism is utilised by an option holder.

185. Assumes 256,132,546 Shares on issue as at Completion and no Options have been exercised.

In relation to the China Grand Options, while there is no cashless exercise mechanism that may be utilised by China Grand, the China Grand Options will only vest and be capable of exercise by China Grand if the relevant vesting condition is satisfied (i.e. the Company has been admitted to the Official List and its Shares have been admitted to quotation on the ASX and the Company has also entered into a licence agreement with China Grand in respect of the territory of Greater China) prior to the China Grand Options Expiry Date set out in Section 10.7.4. As a result, there is no guarantee that the China Grand Options will vest before the China Grand Options Expiry Date and, even if they do vest, there is no obligation on China Grand to exercise any of the China Grand Options. Accordingly, the Company may never receive any funds from the China Grand Options.

If no or only limited funds are received by the Company from the exercise of any Options, this would impact the Company's potential future cash reserves. The Board, however, believes that the Company's current cash reserves plus the net proceeds of the Offer will be sufficient to fund the Company's stated business objectives.

5.3.4. The Company may need to raise future additional capital

As at the Prospectus Date, the Directors of the Company are of the view that the Company's current cash reserves plus the net proceeds from the Offer will be sufficient to fund the Company's stated business objectives. However, there can be no guarantee that this will be the case, particularly if the Company incurs or experiences unforeseen costs or delays. The Company may therefore need to raise additional capital in the future through debt or equity financing or other methods such as co-development arrangements or strategic alliances. If the Company does not succeed in eventually generating adequate revenue in order to fund its operations, or is unable to obtain or raise capital from other sources on commercially acceptable terms, the Company's financial position and its business may be materially adversely affected.

5.3.5. Price of Shares

The price at which the Shares may be quoted on the ASX may regularly increase or decrease due to a number of factors. These factors may cause the Shares to trade at prices below the Offer Price. There can be no guarantee that the price of the Shares will increase, or not decrease, following the commencement of their quotation on ASX. Some of the factors which may affect the price of the Shares include:

- the results of clinical trials conducted by the Company;
- the position taken by regulators in relation to the Company's applications for approval of its technology;
- fluctuations in the domestic and international market for listed stocks;
- general economic conditions, including interest rates, inflation rates, exchange rates and commodity and oil prices;
- changes to government fiscal, monetary or regulatory policies, legislation or regulation;
- inclusion in or removal from market indices;
- pandemic risk (including, for example, COVID-19);
- the nature of the markets in which the Company operates; or
- general operational and business risks.

5.3.6. Economic and government risks

The future viability of the Company is also dependent on a number of other factors affecting the performance of all industries and not just the radiopharmaceutical and oncology markets, including, but not limited to, the following:

- general economic conditions in jurisdictions in which the Company operates;
- changes in government policies and taxation and other laws in jurisdictions in which the Company operates;
- the strength of the equity and share markets in Australia and throughout the world, and, in particular, investor sentiment towards the radiopharmaceutical and oncology markets;
- movement in, or outlook on, interest rates and inflation rates in jurisdictions in which the Company operates; and
- natural disasters, social upheaval or war in jurisdictions in which the Company operates.

5.3.7. Climate change risk

Transitioning to a lower-carbon economy may entail extensive policy, legal, technology and market changes to address mitigation and adaption requirements related to climate change. Depending on the nature, speed and focus of these changes, transition risks may pose varying levels of financial and reputational risk to companies generally and may have a material adverse impact on the Company and its Shares. While the Company's production methods are not energy neutral, the ability to manufacture ^{64}Cu and ^{67}Cu without the need for a nuclear reactor is more favourable than other therapeutic radioisotopes.

Physical risks resulting from climate change can be event driven (acute) or longer term shifts (chronic) in climate patterns. Physical risks may have financial implications for companies generally, such as direct damage to assets and indirect impacts such as supply chain disruption.

5.3.8. Litigation risk

The Company may, from time to time, be involved in legal proceedings or disputes with a variety of parties, including, but not limited to, employees, former employees, government agencies or regulators, end-consumers, customers, competitors, vendors or suppliers arising in the ordinary course of business or otherwise. Defence and settlement costs can be substantial, even with respect to claims that have no merit. Due to the inherent uncertainty of the litigation process, there can be no assurance that the resolution of any particular legal proceeding will not have a material adverse effect on the Clarity Group's business, reputation, financial condition and operations.

5.3.9. Insurance risk

The Board is of the view that the Company holds levels of insurance that are appropriate for its current needs and the risks that are relevant to the Company. However, it is likely that the Company is not fully insured against all of the potential risks that could arise in connection with the Company's business. The gaps in the Company's insurance cover are due to a number of factors, including the likelihood of the risk eventuating, the costs of the insurance premiums and the availability of the appropriate insurance cover. If losses or liabilities are incurred that fall outside of the scope of the Company's insurance cover, the Company may suffer material financial loss and the value of the Company's assets may be at risk.

5.3.10. Exchange rate risk

The Australian value of foreign currency denominated costs will be affected by changes in currency exchange rates. The Company may engage in various transactions in foreign currencies (including, but not limited to, the supply of radioisotopes and clinical trial services) and is therefore potentially exposed to exchange rate fluctuations which may have an adverse effect on the costs incurred by the Company and consequently the Company's overall financial position.

5.3.11. Changes to laws and regulations

The Company is subject to, and must comply with, a variety of laws and regulations in Australia in the ordinary course of its business. These laws and regulations include those that relate to conducting clinical trial programmes, product safety, consumer protection, employment, taxation, GST, stamp duty and customs and tariffs. The Company is also subject to various laws of the US, including in relation to the conduct of its clinical trial programmes in that jurisdiction.

Changes to laws and regulations in these areas may materially adversely affect the Company, including by increasing the Company's costs either directly (such as an increase in the amount of tax the Company may need to pay), or indirectly (such as increased costs associated with complying with legal requirements). Any such adverse effect may impact the Company's future operating and/or financial performance.

5.3.12. Taxation

The acquisition and disposal of Shares will have tax consequences, which will differ depending on the individual financial affairs of each investor. All potential investors in the Company are urged to obtain independent legal, financial and taxation advice about the consequences of acquiring Shares from a taxation point of view and generally. To the maximum extent permitted by law, the Company, its officers and each of their respective advisers accept no liability and responsibility with respect to the taxation consequences of applying for Shares under this Prospectus. Please refer to Section 10.16 Australian Taxation Considerations for further comments in relation to the tax implications of the Offer. The information in Section 10.16 is not intended to be a substitute for investors obtaining independent tax advice in relation to their personal circumstances.

Further, changes in tax law, or changes in the way taxation laws are interpreted, may impact the tax liabilities of the Company or the tax treatment of an investor's investment. In particular, both the level and basis of taxation may change. In addition, from time to time, the ATO may review the tax treatment of transactions entered into by the Company. Any actual or alleged failure to comply with, or a change in the application or interpretation of, tax rules that apply to the Company in respect of such transactions could increase its tax liabilities or expose it to legal, regulatory or other actions.

5.3.13. Accounting standards

Australian Accounting Standards are set by the AASB and are outside the control of the Company, its Directors and its senior management team. The AASB may, from time to time, introduce new or refined Australian Accounting Standards in future periods, which may affect future measurement and recognition of key statements of income and balance sheet items, including sales and receivables.

There is also the risk that interpretations of existing Australian Accounting Standards, including those relating to the measurement and recognition of key statements of income and balance sheet items, including sales and receivables, may differ. Changes to the Australian Accounting Standards, issued by the AASB, or changes to the commonly held views on the application of those standards could materially adversely affect the financial performance and position reported in the Company's consolidated financial statements.

5.3.14. Force majeure events may occur

Events may occur within or outside the Australian markets that negatively impact the Company's financial performance, operations and/or the price of the Shares. These events include, but are not limited to, acts of terrorism, an outbreak of international hostilities, fires, floods, storms, hail, earthquakes, labour strikes, civil wars, natural disasters, outbreaks of disease or natural or man-made events or occurrences that may have a material adverse effect on the Company's suppliers, the demand for products and/or the ability to conduct business.

The Company has only a limited ability to insure against some of these risks.

5.3.15. Epidemics and pandemics

In addition to the force majeure events mentioned in Section 5.3.14, the rapid spread of infectious disease to a large number of people within a short period of time may occur within or outside the countries in which the Company operates. In particular, a pandemic similar in nature to the 2002-03 outbreak of Severe Acute Respiratory Syndrome (SARS), the 2009 swine flu outbreak or COVID-19 outbreak may adversely affect general economic sentiment, the global economy, stock markets and other financial markets. COVID-19 is currently of significant concern to the worldwide community and has clouded the near and medium term outlook for the global economy. Financial markets have also been volatile as market participants and governments worldwide continue to assess the risks associated with COVID-19 and global supply chains are being severely impacted across the major industries.

Measures introduced to limit the transmission of COVID-19 may have a negative impact on the global economy and economic growth. As a result of the global outbreak, monetary policy has been eased to provide additional support to employment and economic activity. Given the evolving situation, it is difficult to predict the nature and extent of the risk to, and the impact on, the Company. The impact of COVID-19 on consumer sentiment, demand for the Company's products, the Company's ability to conduct research and clinical trials as well as general market confidence could material adversely affect the Company's operations and/or financial performance.

5.3.16. Expected future events may not occur

Certain statements in this Prospectus constitute forward-looking statements, opinions and estimates. Such forward-looking statements, opinions and estimates rely on various contingencies and assumptions and involve known and unknown risks, uncertainties and other factors which may cause actual results, performance and achievements to be materially different from any future results, events, performance or achievements expressed or implied in such forward-looking statements, opinions and estimates. The actual performance of the Company or the radiopharmaceuticals market or the oncology market may not be as expected and this may have a material adverse impact on the value of the Shares.

Given these uncertainties, prospective investors should not place undue reliance on any forward-looking statement. In addition, under no circumstances should forward-looking statements be regarded as a representation or warranty by the Company or any other person referred to in this Prospectus that a particular outcome or future event is guaranteed.

5.3.17. No guarantee in respect of investment

The above list of risk factors should not be viewed as an exhaustive list of the risks faced by the Company or investors in the Company. The above risk factors, as well as other risk factors not specifically referred to above or not yet contemplated by the Company, may affect the financial performance of the Company and the value of the Shares offered under this Prospectus.

Accordingly, given the above risks and the fact that the Company is a clinical stage company and is not currently generating revenue, an investment in the Company should be regarded as speculative and neither the Company nor any of its Directors or any other party associated with the preparation of this Prospectus guarantees that any specific objectives of the Company will be achieved or that any particular value of the Company or of the Shares, including those offered under this Prospectus, will be achieved. Furthermore, there is no guarantee that the Shares will remain continuously quoted on the ASX, which could impact the ability of prospective Shareholders (as well as Existing Shareholders) to sell their Shares.

Investors should consult their professional advisers (including stockbroker, lawyer, tax adviser, financial adviser or other independent financial adviser) before deciding whether to apply for Shares pursuant to this Prospectus.

06

Key People, Interests and Benefits

06 Key People, Interests and Benefits

6.1. Board of Directors

6.1.1. Experience, expertise and qualifications

Clarity's Board has extensive capital markets, radiopharmaceutical and broader life sciences experience. The Board members have significant expertise in capital raisings and mergers and acquisitions, global corporate experience, as well as in-depth knowledge of nuclear medicine, clinical development and the bringing of radiopharmaceutical products to market.

Director	Expertise, experience and qualifications
 **Dr Alan Taylor, PhD** *Executive Chairperson*	Dr Taylor joined the Board in November 2013 as Executive Chairperson. Dr Taylor has been instrumental in the growth of the Company and has been heavily involved in all areas of the Company's business. Dr Taylor has approximately 15 years of investment banking experience focused predominantly on the life sciences sector, and has significant expertise in capital raisings, mergers and acquisitions, and general corporate advisory. Prior to joining Clarity, Dr Taylor was an Executive Director of Inteq Limited, a boutique Australian investment bank. After receiving the University Medal for his undergraduate degree in Applied Science at the University of Sydney, Dr Taylor completed his PhD in Medicine at the Garvan Institute of Medical Research. Dr Taylor has also completed a Graduate Diploma in Applied Finance at the Securities Institute of Australia.
 **Dr Colin Biggin, PhD** *Managing Director and CEO*	Dr Biggin joined the Board in October 2019 as Managing Director and CEO after playing an instrumental role in enhancing and designing the Company's product development and clinical programmes since he first joined the Company in January 2017. Dr Biggin has over 15 years of radiopharmaceutical development and commercialisation experience. Dr Biggin previously served with Algeta ASA during the development and commercialisation of its product Xofigo® (radium-223 dichloride) for metastatic prostate cancer, which was approved by the FDA in 2013. Prior to joining the Company, Dr Biggin also consulted to a range of biotech and large pharmaceutical companies developing radiopharmaceuticals. Dr Biggin holds a Bachelor of Science (Honours) and a PhD from the University of Glasgow.
 **Ms Rosanne Robinson** *Non-Executive Director*	Ms Robinson joined the Board in October 2010 as a Non-Executive Director. Ms Robinson brings extensive experience in the nuclear field and a range of commercial expertise to the Company and has over 25 years of experience in both governance and management roles in public and private companies and government. Ms Robinson is the General Manager of Business Development at Australian Nuclear Science and Technology Organisation. Ms Robinson's in-depth knowledge of the nuclear medicine industry provides the Company with a clear vision across the dynamics of, and most recent changes in, the sector. Ms Robinson holds a Bachelor of Business (Accounting), a Graduate Diploma of Accounting (CA) and is a Graduate of the Australian Institute of Company Directors.

06 Key People, Interests and Benefits continued

Director	Expertise, experience and qualifications
 **Dr Christopher Roberts, PhD** *Non-Executive Director*	Dr Roberts joined the Board in March 2016 as a Non-Executive Director. Dr Roberts has over 40 years of experience in the medical innovation space and has served on the boards of a number of ASX-listed companies during his career. Dr Roberts was previously the CEO of ASX-listed company Cochlear Limited and Chairman of ASX-listed company Sirtex Medical Ltd. Dr Roberts was also Executive Vice-President and a director of the dual-listed (ASX and NYSE) company ResMed Inc., a global sleep disorder treatment company. Dr Roberts is Chairman of the ASX-listed company Oncosil Ltd. Dr Roberts holds a Bachelor of Engineering (Honours) in Chemical Engineering from the University of New South Wales, an MBA from Macquarie University and a PhD from the University of New South Wales. He has also been awarded Honorary Doctor of Science degrees from Macquarie University and the University of New South Wales.
 **Dr Thomas Ramdahl, PhD** *Non-Executive Director*	Dr Ramdahl joined the Board in March 2019 as a Non-Executive Director. Dr Ramdahl is a pharmaceutical executive with over 20 years of clinical and development experience. In 2001, he became President and the first CEO of Algeta ASA. When Dr Ramdahl joined Algeta, he was one of six employees and he played an instrumental role in its success, serving in several senior positions within the company through to and post the acquisition of Algeta by Bayer AG in 2014 for US$2.9 billion. Dr Ramdahl has authored more than 40 publications and is a co-inventor of several patents. Dr Ramdahl currently serves as Chairman of Precirix (Belgium) and AppSens AS (Norway). Dr Ramdahl gained his PhD in Environmental Chemistry from the University of Oslo and holds a Master of Science in Organic Chemistry from the Norwegian Institute of Technology.
 **Dr Charles Gillies O'Bryan-Tear, MBBS FRCP** *Non-Executive Director*	Dr O'Bryan-Tear joined the Board in April 2019 as a Non-Executive Director. Dr O'Bryan-Tear has over 30 years of experience in the pharmaceutical industry in clinical development, medical management and commercial roles. He has held senior leadership roles in large and small pharmaceutical and biotech companies in the US and Europe and has been involved in multiple product approvals. He was previously the Chief Medical Officer of Algeta ASA. Dr O'Bryan-Tear has been an adviser to several US and European biotech companies and is a member of the Scientific Advisory Boards of Audentes, Inc. (US) and Fusion Pharmaceuticals Inc. (Canada). Dr O'Bryan-Tear obtained his Doctor of Medicine degrees from the Universities of Cambridge and London and trained in internal medicine and oncology in the United Kingdom.

Director	Expertise, experience and qualifications
 **Mr Robert Thomas** *Proposed Non-Executive Director (conditional upon Listing)*	It is proposed that Mr Thomas will join the Board upon Listing as a Non-Executive Director. Mr Thomas has a strong background in financial services and capital markets and has considerable expertise in mergers & acquisitions and capital markets including advising on the IPOs of the Commonwealth Bank of Australia and Qantas. Mr Thomas is the former CEO of County NatWest Securities and the former CEO (and then Chairman) of Citi Corporate and Investment Bank Australasia. Mr Thomas has also held the position of Chairman at Australian Wealth Management Ltd (ultimately IOOF Ltd), TAL (Australia's largest life insurance company) and the previously ASX-listed company HeartWare® International Inc. Mr Thomas is the Chairman of AusBio Ltd, Grahger Retail Securities Pty Ltd and ASX-listed Starpharma Holdings Limited, and is a non-executive director of Biotron Limited and O'Connell Street Associates. He is a past non-executive director of Reva Medical Inc. and Virgin Australia. Mr Thomas holds a Bachelor of Economics from Monash University and a Diploma of Business (Accounting) from Swinburne. He is a Fellow of the Securities Institute of Australia, Fellow of the Australian Institute of Company Directors and a Fellow of the Royal Society of New South Wales. He is also Co-Chair of the State Library of New South Wales Foundation.

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

6.1.2. Director disclosures

No Director nor the Proposed Director has been the subject of any disciplinary action, criminal conviction, personal bankruptcy or disqualification in Australia or elsewhere in the last ten years that is relevant to the role to be undertaken by the Directors and the Proposed Director and to the question of whether to invest in the Company.

No Director nor the Proposed Director has been an officer of a company that has entered into any form of external administration as a result of insolvency during the time that they were an officer or within a 12 month period after they ceased to be an officer.

Each Director and the Proposed Director has confirmed to the Company that he or she anticipates being available to perform his or her duties as a Non-Executive or Executive Director, as the case may be, without constraint from other commitments.

6.2. Senior management

The Company's senior management team has a diverse and in-depth level of expertise spanning corporate finance, management, operations, commercialisation and industry.

Name	Experience, expertise and qualifications
 **Dr Alan Taylor, PhD** *Executive Chairperson*	Refer to Section 6.1.1 above.
 **Dr Colin Biggin, PhD** *Managing Director and CEO*	Refer to Section 6.1.1 above.
 **Dr Matthew Harris, PhD, MBA** *Chief Scientific Officer*	Dr Harris is the founder, former CEO (2010-2019) and currently Chief Scientific Officer of the Company. Dr Harris has approximately 20 years of combined experience in cancer research, nuclear medicine and business and has a PhD in cancer research from the Australian National University. Dr Harris brings expertise in biotechnology, radiopharmaceuticals, academic research and investment to the Company and focuses on developing the technology behind the Company's products. Dr Harris has an MBA from the Australian Graduate School of Management. He has held leading managerial positions and director roles in several early stage Australian life science companies.

Name	Experience, expertise and qualifications
 **Ms Michelle Parker** *Director of Clinical Operations*	Ms Parker joined the Company in June 2018 and is the Company's Director of Clinical Operations. Ms Parker has over 20 years of experience spanning across nuclear medicine/PET and pharmaceutical industries both in Australia and internationally. Prior to joining the Company, Ms Parker held the position of Head of International Clinical Research Operations at Novartis Australia, a global pharmaceutical company, leading a multi-disciplinary, high performing team of over 35 associates responsible for end-to-end clinical trial execution. Ms Parker holds a Bachelor of Applied Science in Medical Radiation Technology (Nuclear Medicine) from the University of Sydney.
 **Dr Jennifer Rosenthal, PhD** *Director of Quality and Regulatory Affairs*	Dr Rosenthal joined the Company in October 2019 and is the Company's Director of Quality and Regulatory Affairs. Dr Rosenthal has over 20 years of management experience in the biotechnology industry, serving in senior director and executive level roles with an oncology focus. She has successfully developed strategy, and managed teams and projects in the areas of regulatory affairs (agencies include US Food and Drug Administration, European Medicines Agency and Australian Therapeutic Goods Administration), clinical trials, quality assurance and intellectual property. Prior to joining the Company, Dr Rosenthal managed the global regulatory team at the previously ASX-listed company Viralytics Limited, which was acquired by Merck & Co for $502 million in 2018. Prior to Viralytics, Dr Rosenthal spent 10 years at Alchemia Limited, and, prior to that, at Florigene and Davies Collison Cave Patent and Trademark Attorneys. Dr Rosenthal holds a Doctorate in genetics and molecular biology from Monash University.
 **Mr Robert Vickery** *Company Secretary and Chief Financial Officer*	Mr Vickery joined the Company in July 2019 and is the Company's Chief Financial Officer and Company Secretary. Mr Vickery is a finance executive with over 30 years of experience and has had extensive involvement in life sciences and early stage businesses. Prior to joining the Company, Mr Vickery led the finance function at the previously ASX-listed company, Viralytics Limited, and was a key member of the due diligence target team during the trade sale negotiations and due diligence process with the purchaser of the company (Merck & Co), liaising with legal and investment banking teams, as well as leading the finance, IT and HR integration efforts post acquisition. Mr Vickery holds a Bachelor of Commerce from the University of New South Wales and is an Associate of the Institute of Chartered Accountants and the Governance Institute of Australia.

06 Key People, Interests and Benefits continued

Name	Experience, expertise and qualifications
 **Mr Shaemus Gleason** *Executive Vice President US Operations*	Mr Gleason joined the Company in May 2021 and is the Company's Executive Vice President of US Operations. Mr Gleason has over 13 years of experience spanning across all facets of targeted radionuclide therapies and diagnostic radiopharmaceuticals. Prior to joining the Company, Mr Gleason was a member of the oncology strategy business unit at Bayer/Algeta where he was responsible for the technical operations in their phase I targeted alpha therapy development globally. Prior to this, he held a leadership role on the US commercial organisation supporting a marketed product Xofigo® (radium-223 dichloride) for metastatic prostate cancer.
 **Dr Mike Ironside, PhD** *Director of Operations*	Dr Ironside joined the Company in June 2020 and is the Company's Director of Operations. Dr Ironside has over 25 years of experience in senior roles in the global pharmaceutical industry, including key positions in Europe, US and Asia at contract development and manufacturing organisations (CDMOs) including Hovione FarmaCiencia SA and Albany Molecular Research Inc. (AMRI), as well as in the pharmaceutical and biotech sector at GlaxoSmithKline plc, Anacor Pharmaceuticals, Inc. and Biosignal, Inc. During his career, Dr Ironside has contributed to the development of more than a dozen approved drugs including Alosetron, Viracept, Vyvanse, Tavaborole and Zejula. Dr Ironside attained his PhD in Organic Chemistry from the University of Dundee and has undertaken a postdoctoral fellowship at the University of Sydney.

6.3. Scientific advisory board

The Company's scientific advisory board is comprised of global thought leaders with extensive capabilities, expertise and experience in developing radiopharmaceutical products.

Name	Experience, expertise and qualifications
 **Prof Oliver Sartor**	Professor Sartor is a medical oncologist and an internationally recognised expert in prostate cancer. He is the Laborde Professor for Cancer Research, Medical Director of the Tulane Cancer Center, and Assistant Dean for Oncology at Tulane University School of Medicine in New Orleans, Louisiana. Professor Sartor is a past member of the Board of Scientific Counselors (Clinical Sciences and Epidemiology) at the National Cancer Institute and previously served as Chairman of the Prostate Cancer Integration Panel for the US Department of Defense. Professor Sartor has chaired five Data Monitoring Committees for Phase III trials that lead to FDA approval. He is medical oncology chair of the Genitourinary committee of NRG Oncology. Professor Sartor received his Doctor of Medicine from Tulane University with honours in 1982. After his internship at the University of Pennsylvania, he trained in Internal Medicine at Tulane Medical School. After completing his fellowship at the National Cancer Institute in Bethesda, Maryland in 1989, he served until 1993 as a Senior Investigator at the National Cancer Institute with a focus on novel therapeutics for advanced prostate cancer patients.
 **Prof Richard Wahl**	Professor Wahl is the Elizabeth Mallinckrodt Professor, Chairman of the Department of Radiology and Director of the Mallinckrodt Institute of Radiology at Washington University School of Medicine in St Louis. Professor Wahl is recognised as a world leader in the field of targeted radiopharmaceuticals for diagnosing and treating cancer. With an emphasis on PET and multi-modality imaging, such as PET-CT, his work enables precision diagnosis of a broad array of human cancers and other serious diseases. Professor Wahl is one of the inventors of radio-immunotherapy of lymphoma, which is a combination of radiotherapy and immunotherapy that facilitates targeted treatments. He has also been an inventor of a number of FDA approved medical devices, such as radionuclide guided biopsy. Professor Wahl holds 18 radiology patents and has published more than 450 peer-reviewed scientific papers and several books. He has served as a chairman of the American Board of Nuclear Medicine (ABNM), president of the Institute for Clinical PET (ICP) program, refresher course chair for Radiological Society of North America and on multiple NIH study sections. He was elected as a member of the US National Academy of Medicine in 2015. Most recently, Professor Wahl was elected 2021-22 president of the Society of Nuclear Medicine and Molecular Imaging (SNMMI).

06 Key People, Interests and Benefits continued

Name	Experience, expertise and qualifications
 **Prof Jason Lewis**	Professor Lewis is the Emily Tow Jackson Chair in Oncology and serves as Vice Chair for Research in the Department of Radiology at Memorial Sloan Kettering Cancer Center (MSK), Chief of MSK's Radiochemistry & Imaging Sciences Service, and Director of MSK's Radiochemistry and Molecular Imaging Probe Core Facility. He is head of a laboratory in the Sloan Kettering Institute's Molecular Pharmacology Program and a Professor at the Gerstner Sloan Kettering Graduate School of Biomedical Sciences and at Weill Cornell Medical College. He is an Adjunct Professor in the Department of Biomedical Imaging and Image Guided Therapy, The Medical University of Vienna, Austria. Professor Lewis holds a PhD from The University of Kent (UK) and has published over 300 papers, books, book chapters, and reviews in the field of cancer imaging. He has served as the President of the World Molecular Imaging Society and was named a Fellow (FWMIS) in 2015. He has received the SNMMI Michael J. Welch award, the Paul C. Aebersold Award for Outstanding Achievement in Basic Science Applied to Nuclear Medicine, the Distinguished Investigator Award from the Academy of Radiology Research and the ACS Bioconjugate Chemistry Lectureship Award. He has been named a Fellow of the Society of Nuclear Medicine and Molecular Imaging (FSNMMI), a Fellow of the Royal Society of Chemistry (FRSC) and a Fellow of the American Association for the Advancement of Science (FAAAS). In 2019 Dr. Lewis was awarded an NCI Outstanding Investigator Award (R35) to support his work in radiochemistry and molecular imaging.
 **Prof Andreas Kjaer**	Professor Kjaer is a professor at the University of Copenhagen and a chief physician at the Department of Clinical Physiology, Nuclear Medicine & PET at Rigshospitalet, the National University Hospital of Denmark. Professor Kjaer is a former president of the Scandinavian Society of Clinical Physiology and Nuclear Medicine (SSCPNM) and served on the Scientific Committee of the Danish Cancer Society and the European Association of Nuclear Medicine (EANM) Oncology Committee. He is currently a member of the scientific advisory board of the European Neuroendocrine Tumor Society (ENETS) and a member of the Industrial Research Committee of the Innovation Fund Denmark. Professor Kjaer is founding Editor-in-Chief of Diagnostics (Basel), head of the Cluster for Molecular Imaging, and director of the Postgraduate School for Medical and Molecular Imaging at the Faculty of Health Sciences, University of Copenhagen. He is an elected member of the Danish Academy of Technical Sciences and a Knight of the Order of Dannebrog, a Danish Royal Order of Chivalry. Professor Kjaer has published more than 500 peer-reviewed articles and received numerous prestigious scientific awards over the years.
 **Prof Paul Donnelly**	Professor Donnelly is the Clarity Group leader of the Donnelly Research Group, The University of Melbourne, based in the state-of-art laboratories of the Bio21 Institute of Molecular Science and Biotechnology. Professor Donnelly's expertise is in the application of synthetic inorganic/organic chemistry in biology and materials science, with a particular focus on the application of coordination chemistry to metal based drugs and the study of metal ions in biological systems. Professor Donnelly has an impressive publication record and is the inventor of a number of novel and patented radiopharmaceutical technologies.

Name	Experience, expertise and qualifications
 **Prof Dale Bailey, PhD FIPEM FACPSEM MRCP (Lond.) CSci (UK)**	Professor Bailey is Principal Physicist in the Department of Nuclear Medicine, Royal North Shore Hospital, Sydney, and Professor in Medical Imaging Sciences at the University of Sydney. Professor Bailey is the former Director of the Sydney Vital Northern Translational Cancer Research Centre at Royal North Shore Hospital and the Flagship Leader of its Neuroendocrine Tumour programme. Professor Bailey's principal interests are in quantitative in vivo imaging with radiolabelled tracers using SPECT & PET and the biology of radionuclide therapy. He is currently a chief investigator for a number of grants including a multicentre study on PET imaging in brain tumours, a redifferentiation project in thyroid cancer and a number of investigator-initiated trials on the use of functional imaging in neo-adjuvant chemotherapy, predicting sites of future relapse in brain cancer and the influence of somatostatin analogues in imaging of neuroendocrine tumours.

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 nor the Proposed Director;
- 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 the Company; or
- underwriter to the Offer or financial services licensee named in this 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 the Company;
- property acquired or proposed to be acquired by the Company in connection with its formation or promotion, or in connection with 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 the Company or the Offer or to any Director or the Proposed Director to induce them to become, or qualify as, a Director.

6.4.1. Interests of advisers

The Company has engaged the following professional advisers in connection with the Offer and preparation of this Prospectus:

- Jefferies (Australia) Pty Ltd and Bell Potter Securities Limited have acted as Joint Lead Managers to the Offer. The Company has agreed to pay the Joint Lead Managers the fees described in Section 10.11.1 for these services;
- KPMG Law has acted as Australian legal adviser to the Company in relation to the Offer. The Company has paid, or agreed to pay, approximately $250,000 (excluding disbursements and GST) for these services up until the Prospectus Date. Further amounts may be paid to KPMG Law in accordance with its normal time-based charges. During the 24 months preceding lodgement of this Prospectus with ASIC, KPMG Law has been paid approximately $270,000 (excluding disbursements and GST) for the provision of other legal services to the Company;

- Grant Thornton Corporate Finance Pty Ltd has acted as the Investigating Accountant in connection with the Offer and has prepared the Investigating Accountant's Report. The Company has paid, or agreed to pay, approximately $45,000 (excluding disbursements and GST) for these services up until the Prospectus Date. Further amounts may be paid to Grant Thornton Corporate Finance Pty Ltd in accordance with its normal time-based charges. During the 24 months preceding lodgement of this Prospectus with ASIC, Grant Thornton Corporate Finance Pty Ltd has been paid approximately $115,000 (excluding disbursements and GST) for the provision of other financial and accounting services to the Company;
- Davies Collison Cave has acted as Patent Attorney to the Company in relation to the Offer. The Company has paid, or agreed to pay, approximately $20,000 (excluding disbursements and GST) for these services up until the Prospectus Date. Further amounts may be paid to Davies Collison Cave in accordance with its normal time-based charges. During the 24 months preceding lodgement of this Prospectus with ASIC, Davies Collison Cave has been paid approximately $377,000 (excluding disbursements and GST) for the provision of other patent attorney services to the Company; and
- KPMG has acted as the Australian taxation adviser to the Company in relation to the Offer. The Company has paid, or agreed to pay, approximately $30,000 (excluding disbursements and GST) for these services up until the Prospectus Date. Further amounts may be paid to KPMG for other work in accordance with its normal time-based charges. During the 24 months preceding lodgement of this Prospectus with ASIC, KPMG has been paid approximately $59,000 (excluding disbursements and GST) for the provision of other taxation services to the Company.

These amounts, and other expenses of the Offer, will be paid by the Company 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.

The Joint Lead Managers are also entitled to the fees set out in Section 10.7.4 in the event that any of the China Grand Options are validly exercised by China Grand.

6.4.2. Directors' interests and remuneration

6.4.2.1. Non-Executive Director remuneration

Non-executive director fees

Under ASX Listing Rule 10.17, the Company must not increase the total aggregate capped amount of fees payable to the Non-Executive Directors of the Company for their services in any financial year, without the approval of Shareholders in a general meeting.

This capped amount has been fixed by the Company at $500,000 per annum (including any superannuation payments) (**Director Fee Pool**) of which an amount of $240,900 is currently utilised as at the Prospectus Date. Any change to the Director Fee Pool will need to be approved by Shareholders and the Directors may seek the approval of Shareholders in this regard from time to time, as appropriate. The Director Fee Pool excludes, among other things, amounts payable to any Executive Director under any executive services agreement with the Clarity Group or any special remuneration which the Board may agree to pay to the Directors for special exertions or additional services performed by a Director for or at the request of the Company.

Under the Constitution that will come into effect on Completion, the Directors may divide all or some of the Director Fee Pool among themselves in any proportions and in any manner as they may determine from time to time. If the Directors do not, or are unable to, make a determination as to the apportionment of the Director Fee Pool, the amount determined to be paid must be divided among them equally.

The Company has entered into an appointment letter with each of its Non-Executive Directors. The following annual base fees are payable to the Non-Executive Directors and the Proposed Director with effect from Listing:

Table 18: Non-executive remuneration from Listing:

Non-Executive Director	Fees ($)
Ms Robinson	60,225
Dr Roberts	60,225
Dr Ramdahl	60,225
Dr O'Byran-Tear	60,225
Mr Thomas (Proposed Director)	60,225
Total	**301,125**

Equity entitlement

All existing issues of Options that have been made to Non-Executive Directors prior to the adoption of the Equity Incentive Plan are detailed in Section 6.4.2.6.

Each Non-Executive Director will be entitled to participate in the Equity Incentive Plan as described in Section 6.5.2 with effect from Listing.

6.4.2.2. Executive Director remuneration

Refer to Section 6.4.2.8 for a summary of the remuneration and benefits payable by the Company to its Executive Directors, Dr Taylor (Executive Chairperson) and Dr Biggin (Managing Director and CEO).

6.4.2.3. Payments in connection with Listing

No Director is entitled to receive any additional payments in connection with the Listing other than the vesting of certain Options that were issued prior to the Prospectus Date as further detailed in Section 6.4.2.6.

6.4.2.4. Deed of access, insurance and indemnity

The Company has entered into a deed of access, insurance and indemnity with each Director and the Proposed Director. Each deed contains the Director's right of access to certain books and records of the Company.

Pursuant to the Constitution that will come into effect on Completion (and subject to particular exclusions set out in the Constitution), the Company must indemnify each Director and secretary and each former Director and secretary against any liabilities that arise from their position as an officer of the Company to the extent permitted by law.

Under the deed of access, insurance and indemnity, the Company agrees to indemnify, to the extent permitted by law, each Director against any liability (other than excluded liabilities) to a third party or to the Company which arises as a result of or in connection with anything done, or omitted to be done, by the Director in good faith while a director of the Company and also the Director's reasonable legal costs incurred in relation to any claim by a third party in relation to such matters.

Pursuant to the Constitution that will come into effect on Completion, the Company may arrange and maintain directors' and officers' insurance for its Directors to the extent permitted by law. Under the deed of access, insurance and indemnity and to the extent permitted by law, the Company agrees to use reasonable endeavours to keep each Director insured, both while a current Director and for a period of seven years from the date that the Director ceases to be a Director, against liability and legal expenses in connection with any matter or thing done in good faith as a Director (other than excluded liabilities).

6.4.2.5. Directors' interests in Shares

The Directors and the Proposed Director are not required by the Constitution to hold any Shares in order to be a director of the Company. The Directors' and the Proposed Director's interests in Shares as at the Prospectus Date and as at Completion are set out in Table 19 below.

Table 19: Directors' interests in Shares

	Interests in Shares held at the Prospectus Date		Interests in Shares held at Completion	
Director	**Shares**	**% of ordinary Shares[186]**	**Shares[187]**	**% of ordinary Shares[188]**
Dr Taylor[i]	14,066,660	7.39%	14,066,660	5.49%
Dr Biggin	419,100	0.22%	419,100	0.16%
Dr Roberts[ii]	17,911,280	9.41%	17,911,280	6.99%
Mr Thomas	930,000	0.49%	930,000	0.36%

(i) Dr Taylor holds all of his interests in Shares through the Taylor Family Trust and persons connected to the Taylor Family Trust.

(ii) Dr Roberts holds all of his Shares through the Robwill Trust (Dr Roberts is a director and shareholder of the trustee and a beneficiary of the family trust).

The Directors and the Proposed Director are entitled to apply for Shares under the Offer. The above table does not take into account any Shares the Directors and the Proposed Director (and their associated entities) may acquire under the Offer or that they may acquire as a result of exercising any of their respective Options (as applicable). Final shareholdings held directly or indirectly by the Directors and the Proposed Director (and their associated entities) will be notified to ASX following Listing.

186. Based on 190,418,260 Shares being on issue at the Prospectus Date and no Options have been exercised.

187. Assumes no Director or the Proposed Director applies for additional Shares under the Offer.

188. Based on 256,132,546 Shares being on issue at Completion and no Options have been exercised.

6.4.2.6. Directors' interests in Options

The Directors' interests in Options as at the Prospectus Date and as at Completion are set out in Table 20 below. The table below assumes that no Options have been exercised.

Table 20 Directors' interests in Options

Name	Number of Options	Exercise Price	Grant Date	Number Vested	Expiry date	Remaining Vesting Conditions
Dr Taylor	600,000	$0.605	1 July 2019	600,000	5 August 2024	N/a
	1,200,000	$0.825	22 June 2021	0	18 December 2024	25% of which will vest on Listing, 25% on 13 April 2022, 25% on 13 April 2023 and 25% on 13 April 2024
	1,000,000	$0.94	1 July 2020	1,000,000	1 July 2025	N/a
Dr Biggin	200,000	$0.22	17 January 2017	200,000	16 January 2022	N/a
	200,000	$0.22	1 July 2017	200,000	30 June 2022	N/a
	400,000	$0.22	16 February 2018	400,000	14 February 2023	N/a
	1,000,000	$0.22	1 July 2018	1,000,000	30 June 2023	N/a
	600,000	$0.605	1 July 2019	400,000	1 July 2024	Remaining 200,000 options will vest on 1 July 2022
	1,000,000	$0.605	1 October 2019	1,000,000	1 October 2024	N/a
	1,200,000	$0.825	22 June 2021	0	18 December 2024	25% of which will vest on Listing, 25% on 13 April 2022, 25% on 13 April 2023 and 25% on 13 April 2024
	1,000,000	$0.94	1 July 2020	1,000,000	1 July 2025	N/a
Ms Robinson	200,000	$0.825	22 June 2021	0	18 December 2024	25% of which will vest on Listing, 25% on 13 May 2022, 25% on 13 May 2023 and 25% on 13 May 2024
Dr Roberts	200,000	$0.825	22 June 2021	0	18 December 2024	25% of which will vest on Listing, 25% on 13 May 2022, 25% on 13 May 2023 and 25% on 13 May 2024
Dr Ramdahl	400,000	$0.605	21 March 2019	0	21 March 2024	100% will vest on 21 March 2022
	200,000	$0.825	22 June 2021	0	18 December 2024	25% of which will vest on Listing, 25% on 13 May 2022, 25% on 13 May 2023 and 25% on 13 May 2024
Dr O'Bryan Tear	300,000	$0.605	21 March 2019	0	21 March 2024	100% will vest on 21 March 2022
	200,000	$0.825	22 June 2021	0	18 December 2024	25% of which will vest on Listing, 25% on 13 May 2022, 25% on 13 May 2023 and 25% on 13 May 2024
	400,000	$0.94	2 March 2020	400,000	2 March 2025	N/a

The Proposed Director has not been granted any Options as at the Prospectus Date.

Directors may hold their interests in the Options shown above (as well as any Shares issued on exercise of the Options) directly or indirectly through associated companies or trusts.

The terms of the Options held by the Directors (being part of the Company Options as detailed in Section 10.7) generally provide that:

- the Options have varying vesting and expiry dates, however, the total that are exercisable at each exercise price, and the number of Options that have vested as at the Prospectus Date, are detailed in the table above;
- the Options were issued with time based vesting conditions (i.e. a certain percentage of the relevant Options vest on specified dates). The relevant Option holder must satisfy the relevant vesting condition for an Option before it can be exercised;
- in the event that a Director leaves the Company, any unvested Options are cancelled and are incapable of being exercised;
- the exercise price of the Options may be satisfied as follows:
  - payment of the relevant exercise price (which varies, as detailed above) multiplied by the number of Shares in respect of which the relevant Options are being exercised; or
  - cashless exercise, which entitles an Option holder to set-off the aggregate exercise price payable for the exercise of the Options against the number of Shares that the Option holder is entitled to receive upon exercising the Options. If the vested Options are exercised by cashless exercise:
    - » the Option holder will not be required to pay the aggregate exercise price for those Options; and
    - » the Company will only issue or transfer to the Option holder such number of Shares that have a value equal to the market value of the Shares that would have been issued to the Option holder if the Options had been exercised other than by way of cashless exercise, less the aggregate exercise price that would otherwise have been payable on the exercise of the Options (rounded down to the nearest whole number of Shares);
- the Options do not carry rights to participate in any dividends (or any other return of capital) of the Company;
- in the event of a reorganisation of the issued capital of the Company the following terms apply:
  - in a consolidation of capital, the number of Options held by the relevant Option holder will be consolidated in the same ratio and the exercise price will be amended in inverse proportion to the relevant ratio;
  - in a sub-division of capital, the number of Options held by the relevant Option holder will be sub-divided in the same ratio and the exercise price will be amended in inverse proportion to the relevant ratio; and
  - in a return of capital, the number of Options held by the relevant Option holder will remain the same, and the exercise price will be reduced by the same amount as the amount returned in relation to each Share;
- the Options may generally be assigned to an immediate family member without the consent of the Company, but otherwise the Options cannot be assigned without the prior written consent of the Company; and
- the Options will not be listed for quotation on the ASX or any other securities exchange.

All of the Options held by the Directors as at the Prospectus Date are expected to be subject to mandatory escrow as further detailed in Section 10.4.1.

After Listing, the Board may grant additional Options to the Executive Chairperson, CEO, CFO and other members of senior management of the Company who are invited by the Board to participate in the Equity Incentive Plan. Directors of the Company may also be granted Options under the Equity Incentive Plan. As at the Prospectus Date, the Company has not agreed to grant any Options to any person under the Equity Incentive Plan or any other option arrangement. After Listing, any grant of Options to Directors or their associates under the Equity Incentive Plan (or any other option arrangement) will require Shareholder approval in accordance with the ASX Listing Rules.

6.4.2.7. Other information about Directors' interests and benefits

Directors (including the Proposed Director) are entitled to be paid all reasonable travelling, accommodation and other expenses properly incurred by them in attending and returning from meetings of the Board or any committee of the Board or general meetings or otherwise in the execution of their duties as Directors. A Director who is called upon by the Board to perform extra services or to make a special exertion or to undertake executive or other work for the Company beyond the Director's ordinary duties may be paid additional fees for those services, exertions or work.

In addition, the Clarity Group may also provide any other remuneration or benefit to a Director (including the Proposed Director) or the Director's nominee that is approved separately by a resolution of Shareholders (where required), including any remuneration or benefit under any share, option or equity incentive plans approved separately by a resolution of Shareholders.

There are no retirement benefit schemes for Directors or the Proposed Director, other than statutory superannuation contributions. Chapter 2E of the Corporations Act prohibits a company from giving a financial benefit to a related party (including any director) without the prior approval of its shareholders by ordinary resolution unless a statutory exemption applies.

6.4.2.8. Executive remuneration

a) Dr Taylor (Executive Chairperson)

The Company has entered into an employment agreement with Dr Taylor to govern his employment with the Company in the position of Executive Chairperson. Details of Dr Taylor's annual remuneration arrangements are outlined below.

Term	Description
Employer	Clarity Pharmaceuticals Ltd.
Fixed annual remuneration	Dr Taylor is entitled to receive an annual fixed remuneration of $475,000 (including superannuation). Dr Taylor's superannuation contributions are capped at the Super Concessional Contributions Cap.
Incentives	Dr Taylor is entitled to a short term incentive (STI) of up to 40% of his base salary of $475,000 per annum, subject to achieving personal performance targets. Dr Taylor will also be entitled to participate in the Equity Incentive Plan as described in Section 6.5.2. Dr Taylor currently holds 2,800,000 Options under his name as further detailed in Section 6.4.2.6.
Notice period, termination and termination payments	Dr Taylor or the Company may terminate Dr Taylor's employment by giving six months' notice, except in the case of misconduct where the Company has the right to immediately terminate his employment.
Non-solicitation/ restrictions on future activities	Dr Taylor is prohibited from divulging the Company's confidential information unless authorised to do so. Following termination of his employment, Dr Taylor cannot approach and solicit work from the Company's clients or potential clients for a period of 12 months following termination.
Other information	Details of Dr Taylor's escrow arrangements are set out in Section 10.4.

b) Dr Biggin (Managing Director and CEO)

The Company has entered into an employment agreement with Dr Biggin to govern his employment with the Company in the position of Managing Director and CEO. Details of Dr Biggin's annual remuneration arrangements are outlined below.

Term	Description
Employer	Clarity Pharmaceuticals Ltd.
Fixed annual remuneration	Dr Biggin is entitled to receive an annual fixed remuneration of $340,000 (including superannuation). Dr Biggin's superannuation contributions are capped at the Super Concessional Contributions Cap.
Incentives	Dr Biggin is entitled to a STI of up to 40% of his base salary of $340,000 per annum, subject to achieving personal performance targets. Dr Biggin will also be entitled to participate in the Equity Incentive Plan as described in Section 6.5.2. Dr Biggin currently holds 5,600,000 Options in his own name as further detailed in Section 6.4.2.6.
Notice period, termination and termination payments	Dr Biggin or the Company may terminate Dr Biggin's employment by giving six months' notice, except in the case of misconduct where the Company has the right to immediately terminate his employment.
Non-solicitation/ restrictions on future activities	During the course of his employment Dr Biggin must not be engaged, employed or hold a business concern or interest in any other business operating in the pharmaceutical industry without the Company's prior written consent. Dr Biggin is not to undertake any other form of employment whilst employed by the Company without disclosing this to the Company and there being no conflict. Dr Biggin is prohibited from divulging the Company's confidential information unless authorised to do so. Following termination of his employment, Dr Biggin cannot approach and solicit work from the Company's clients or potential clients for a period of 12 months following termination.
Other information	Details of Dr Biggin's escrow arrangements are set out in Section 10.4.

c) Mr Vickery (Chief Financial Officer and Company Secretary)

The Company has entered into an employment agreement with Mr Vickery to govern his employment with the Company in the position of Chief Financial Officer and Company Secretary. Details of Mr Vickery's annual remuneration arrangements are outlined below.

Term	Description
Employer	Clarity Pharmaceuticals Ltd.
Fixed annual remuneration	Mr Vickery is entitled to receive an annual fixed remuneration of $205,000 (plus superannuation paid at 9.5%), which is to be paid pro rata for his part-time employment (which is currently four days a week).
Incentives	Mr Vickery holds 740,000 Options under his own name. Mr Vickery is entitled to participate in the Equity Incentive Plan as described in Section 6.5.2.
Notice period, termination and termination payments	Mr Vickery or the Company may terminate Mr Vickery's employment by giving three months' notice, except in the case of misconduct where the Company has the right to immediately terminate his employment.
Other	Mr Vickery is prohibited from divulging the Company's confidential information unless authorised to do so and express provisions protecting the Company's confidential information and intellectual property generally apply.

d) Other senior management

The Company's other members of senior management are employed by the Company under individual employment agreements. The key terms and conditions of their employment establish:

- total remuneration packages (including mandatory superannuation contributions);
- leave entitlements in accordance with applicable legislation;
- express provisions protecting the Company's confidential information and intellectual property; and
- variable notice and termination of employment provisions of up to three months or by the Company in the case of misconduct where the Company has the right to immediately terminate employment.

In addition, these other members of senior management are eligible to participate in the Equity Incentive Plan (refer to Section 6.5.2 below).

6.5. Employee incentive arrangements

The Company has established various incentive arrangements, described below, to assist in the attraction, motivation and retention of employees of the Clarity Group.

The arrangements have been designed to support a high performance culture and encourage superior business performance.

In summary, the Board has determined that initially the remuneration framework for senior management should comprise the following components:

- fixed remuneration – consisting of base salary and superannuation contributions;
- short-term incentives paid in cash/a mixture of cash and equity (for example, under the Equity Incentive Plan); and/or
- long-term incentives granted in equity (for example under the Equity Incentive Plan).

As outlined below, the payment of cash under the Company's short-term incentive arrangements and the vesting of equity under the long-term incentive arrangements will be subject to the achievement of the various metrics and hurdles set by the Board.

6.5.1. Short-term incentive arrangements

The Board may elect to adopt and approve certain short-term incentive arrangements for management and other select Clarity Group employees.

Under the short-term incentive arrangements, participants will have an opportunity to generally receive a cash incentive payment calculated as a percentage of their fixed annual remuneration, conditional on the achievement of financial and non-financial performance measures.

The performance measures against which each participant's short-term incentive will be assessed and their relative weightings will be:

- tailored to a participant's role;
- set by the Board each year; and
- measured in respect of the Company's financial year (or such other period as set by the Board).

The Board may set certain conditions that must be met prior to participants receiving any payment and, if met, a balanced scorecard will be used to determine the quantum of the payment.

6.5.2. Equity based remuneration

The Board views equity-based remuneration as a strategic form of remuneration for management.

The Board has adopted the Equity Incentive Plan to facilitate the grant of equity to management and employees after Listing in circumstances in which the Board determines a grant of equity is appropriate.

Under the Equity Incentive Plan, the key terms of which are outlined in the table below, Options, Performance Rights and Restricted Shares may be granted to eligible participants which includes Directors and employees.

The Board may consider the future use of equity-based remuneration to reward, motivate and retain management including the use of equity as a means of deferring short-term incentives.

Table 21: Summary of the terms of the Equity Incentive Plan

Term	Description
Eligibility	Directors, employees, contractors or consultants of the Clarity Group or any other person who the Board determines in its discretion to be eligible to participate in the Equity Incentive Plan and who is invited to participate in the Plan.
Types of securities	The Equity Incentive Plan provides flexibility for the Board to grant one or more of the following securities subject to the terms of the individual invitation at the relevant time: • Options – Options are an entitlement to receive a Share upon the satisfaction of specified conditions and payment of a specified exercise price; • Performance Rights – Performance Rights are an entitlement to receive a Share for nil consideration upon the satisfaction of specified conditions; and • Restricted Shares – Restricted Shares are Shares subject to specified disposal restrictions. The Options or Performance Rights with a cash equivalent payment may be settled by a cashless exercise facility.

Term	Description
Invitations to participate	The Board may invite an eligible person to participate in the Equity Incentive Plan and grant an eligible person Options, Performance Rights and/or Restricted Shares in its discretion. The Board has the discretion to set the terms and conditions on which it will grant Options, Performance Rights and Restricted Shares in the individual invitations.
Consideration payable for grant of Options, Performance Rights and/or Restricted Shares	No consideration is payable by a participant in respect of the grant of Options, Performance Rights or Restricted Shares under the Equity Incentive Plan, unless the Board determines otherwise.
Performance conditions	Securities granted under the Equity Incentive Plan will vest subject to the satisfaction of performance conditions determined by the Board from time to time and set out in the individual invitations. Generally, the performance conditions must be satisfied in order for the securities to vest or otherwise cease to be subject to restrictions.
Rights associated with Options and Performance Rights	Options and Performance Rights will not carry any voting rights or right to dividends. Shares issued or transferred to participants on conversion of a Performance Right or exercise of an Option (as applicable) will have the same rights and entitlements as other issued Shares, including voting and dividend rights.
Rights associated with Restricted Shares	Restricted Shares will have the same rights and entitlements as other issued Shares, including voting and dividend rights.
Vesting	Vesting of Options, Performance Rights and Restricted Shares under the Equity Incentive Plan is subject to any vesting or performance conditions determined by the Board and specified in the individual invitations.
Restrictions on dealing	Participants must not sell, transfer, encumber, hedge or otherwise deal with securities granted under the Equity Incentive Plan. Following vesting of the applicable security and issue or transfer of a Share (as applicable), the participant will be free to deal with the Shares delivered, subject to the requirements of the Company's Securities Trading Policy.
Bonus issues, pro-rata issues and capital reorganisations and reconstructions	The Equity Incentive Plan provides for adjustments to be made to the number of Shares which a participant would be entitled to receive on the vesting and/or exercise of Performance Rights and/or Options (as applicable) in the event of a bonus issue or pro-rata issue to holders of Shares or a reorganisation of capital, subject to the ASX Listing Rules and all applicable laws. If the capital of the Company is reconstructed, the number of securities held by each participant under the Equity Incentive Plan may, in the discretion of the Board, be adjusted such that the value of the securities held prior to any reorganisation is restored.

Term	Description
Cessation of employment	If a participant is considered a "good leaver", a pro-rata portion of any unvested securities granted under the Equity Incentive Plan will remain on foot and will be tested at the end of the relevant Performance Period against the applicable performance conditions. A "good leaver" includes a participant who ceases employment with the Clarity Group by reason of retirement, genuine redundancy, death, invalidity or any other reason as determined by the Board. Generally, any unvested securities granted under the Equity Incentive Plan will forfeit or lapse where the participant ceases employment with the Clarity Group for any reason other than as a "good leaver."
Clawback of equity	The Board has the discretion to clawback unvested securities from participants in certain circumstances, including in the case of fraud, gross misconduct or material misstatement of the Company's financial statements.
Change of control	The Board has the discretion to determine whether, and the extent to which, securities granted under the Equity Incentive Plan vest or cease to be subject to restrictions upon a change of control.
Source of Restricted Shares and Shares	The Board has the discretion to issue or procure the transfer of any Restricted Shares or Shares delivered under the Equity Incentive Plan, including on the vesting and/or exercise of Performance Rights and/or Options (as applicable).
Trustee	The Company may appoint a trustee to acquire and hold Restricted Shares and Shares on behalf of participants or for the transfer to future participants or otherwise for the purposes of the Equity Incentive Plan.
Amendments to Equity Incentive Plan	Subject to the ASX Listing Rules, the Board may, in its absolute discretion, amend the Equity Incentive Plan rules or waive or modify the application of the Plan rules, except in certain circumstances.

The maximum number of equity securities (as defined by the ASX Listing Rules) to be issued under the Equity Incentive Plan for the next three years is 12,806,627, which is approximately 5% of the current number of Shares proposed to be on issue at the time of Listing (on an undiluted basis). The maximum number of equity securities is not intended to be a prediction of the actual number of equity securities to be issued under the Equity Incentive Plan but is specified for the purposes of setting a ceiling on the number of equity securities that may be issued under and for the purposes of ASX Listing Rule 7.2, Exception 13(a). It is not envisaged that the maximum number of equity securities will be issued immediately.

6.6. Corporate governance

This Section explains how the Board oversees the management of the Company's business. The Board is responsible for the overall corporate governance of the Company, including providing leadership and strategic guidance for the Clarity Group and establishing and monitoring key performance goals. The Board monitors the operational and financial position and performance of the Company and oversees the implementation of the Company's strategic objectives, including approving operating budgets and significant expenditure.

The Board is committed to maximising performance, generating appropriate levels of shareholder value and financial return, and sustaining the growth and success of the Company. In conducting the Company's business with these objectives, the Board seeks to ensure that the Company is properly managed to protect and enhance Shareholder interests, and that the Company and its Directors, officers and personnel operate in an appropriate environment of corporate governance. The Board has created a framework for managing the Company, including adopting relevant internal controls, risk management processes and corporate governance policies and practices which it believes are appropriate for the Company's business and which are designed to promote the responsible management and conduct of the Company.

The ASX Corporate Governance Council has published its fourth edition of the Corporate Governance Principles and Recommendations (**ASX Recommendations**) for listed entities on ASX in order to promote investor confidence and to assist companies in meeting stakeholder expectations. The ASX Recommendations are not prescriptions, but guidelines. However, under the ASX Listing Rules, the Company as a company listed on the ASX will be required to provide a corporate governance statement in its annual report (or a URL of the page on its website where a corporate governance statement is located) disclosing the extent to which it has followed the ASX Recommendations in the reporting period. If the corporate governance statement is not provided in its annual report, the Company must also give the ASX a copy of its corporate governance statement at the same time as it gives its annual report to the ASX.

Where the Company does not follow an ASX 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 adopted instead of the recommendation during that period. The Company's compliance with and, where applicable, departures from the ASX Recommendations will be announced prior to Listing. The Company intends to comply with all of the ASX Recommendations from the time of Listing, with the exception of the following:

- ASX Recommendation 2.4 regarding the recommendation to have a majority of independent directors on the Board, which is discussed in Section 6.6.1.2;
- ASX Recommendation 2.5 regarding the recommendation for the Board to be chaired by an independent director, which is discussed in Section 6.6.1.2; and
- ASX Recommendations 2.1 and 8.1 regarding the recommendation that the Nomination and Remuneration Committee be comprised of a majority of independent directors, which is as discussed in Section 6.6.1.4.

Copies of the Company's key policies and practices and the charters for the Board and each of its committees will be made available on the Company's website (www.claritypharmaceuticals.com).

6.6.1. The Board

6.6.1.1. Composition of the Board

As at the Prospectus Date, the Board comprises four Non-Executive Directors (one of whom is currently considered independent), the Managing Director and CEO and the Executive Chairperson. Upon Listing, the Board will include the Proposed Director (Mr Thomas) who is also considered independent. The name and biographical details of the members of the Board (including the Proposed Director) are provided in Section 6.1.

6.6.1.2. Independence of Directors

Each Director must bring an independent view and judgement to the Board and must declare all actual or potential conflicts of interest on an ongoing basis. Any issue concerning a Director's ability to properly act as a Director must be discussed at a Board meeting as soon as practicable.

The Board considers an independent Director to be a Non-Executive Director who is not a member of the Company's management and 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 judgment to bear on issues before the Board and to act in the best interests of the Company and its shareholders 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 Charter sets out guidelines of materiality for the purposes of determining independence of Directors in accordance with the ASX Recommendations. In assessing independence, the Board will have regard to the requirements for independence which are set out in Principle 2 of the ASX Recommendations. The Board will review the independence of each Director in light of interests disclosed to the Board from time to time.

Outlined below is the position regarding the independence of each Board member:

- Ms Robinson is considered by the Board to be independent.
- The Proposed Director, Mr Thomas, is also considered by the Board to be independent.
- Dr Taylor (Executive Chairperson) and Dr Biggin (Managing Director and CEO) are currently considered by the Board not to be independent on the basis that they are employed by the Company in executive capacities.
- Dr O'Bryan-Tear is not currently considered by the Board to be independent on account of the combination of his role as Chair of the Company's Global Clinical Development Group, the provision of consulting services provided by Dr O'Bryan Tear pursuant to a Consultant Services Agreement (refer to Section 6.7) and the Options he holds in the Company (refer to Section 6.4.2.6).

- Dr Roberts is not currently considered by the Board to be independent on the basis that he is a substantial shareholder of the Company and will continue to be a significant shareholder post-Listing.
- Dr Ramdahl is not currently considered by the Board to be independent on the basis that he provided consulting services to the Company under a consulting services agreement within the past three years.

Accordingly, upon Listing, the Board will:

- not be chaired by an independent director, as recommended in ASX Recommendation 2.5; and
- not consist of a majority of independent directors as recommended in ASX Recommendation 2.4.

Despite this, the Board has considered the Company's immediate requirements as it transitions to an ASX-listed company and is satisfied that the composition of the Board reflects an appropriate range of corporate memory, independence, skills and experience for the Company upon Listing.

The Board has formally considered the independence of the non-executive directors Dr O'Bryan-Tear, Dr Roberts and Dr Ramdahl. It has concluded for each of these Directors that their relationship to the Company does not compromise their ability to bring an independent judgement to bear on matters before the Board. The Board believes that each of Dr O'Bryan-Tear, Dr Roberts and Dr Ramdahl bring objective and unbiased judgement to the Board's deliberations and make an invaluable contribution to the Company through their deep understanding of its business and the industry in which it operates.

The Board will regularly review the independence of each Director, the Proposed Director, and any subsequent Directors appointed, in light of interests disclosed to the Board and will disclose any change to ASX, as required by the ASX Listing Rules. The composition of the Board may change over time, depending on the skills and expertise required to manage the Company.

6.6.1.3. Board Charter

The Board has adopted a written charter to provide a framework for the effective operation of the Board, which sets out the roles and responsibilities of the Board, which include:

- providing leadership, defining the Company's purpose and setting the strategic objectives of the Company;
- approving and upholding the Company's code of conduct (and any statement of values and standards contained therein);
- appointing the Chairperson (and deputy Chairperson where considered appropriate);
- appointing and, when necessary, replacing the CEO;
- overseeing management's implementation of the Company's strategic objectives, instilling of the Company's values, and overseeing its performance generally;
- through the Chairperson, overseeing the role of the Company Secretary;
- approving operating budgets and major capital expenditure;
- overseeing the integrity of the Company's accounting and corporate reporting systems, including the external audit;
- overseeing the Company's process for making timely and balanced disclosure of all material information concerning the Company that a reasonable person would expect to have a material effect on the price or value of the Company's securities if they are publicly traded;
- ensuring that the Company has an appropriate risk management framework and setting the risk appetite within which the Board expects management to operate;
- whenever required, acting as a check and balance on management decision making;
- approving the Company's remuneration framework as appropriate; and
- monitoring the effectiveness of the Company's governance practices.

The Board will review the Company's Board Charter from time to time and make amendments as necessary. A copy of the Company's Board Charter will be made available on the Company's website (www.claritypharmaceuticals.com).

6.6.1.4. Board committees

The Board may from time to time establish appropriate committees to assist in the discharge of its responsibilities and consider matters of special importance. The Board has established an Audit and Risk Committee and a Nomination and Remuneration Committee that are suitable for an ASX listed entity and each of which will come into operation upon Listing.

a) Audit and Risk Committee

The role of the Audit and Risk Committee is to assist the Board in fulfilling its accounting, auditing and financial reporting responsibilities, including oversight of:

- the integrity of the Company's financial reporting systems, internal and external financial reporting and financial statements;
- the appointment, remuneration, independence and competence of the Company's external auditors;
- the performance of the external audit functions and review of their audits;
- the effectiveness of the Company's system of risk management and internal controls; and
- the Company's systems and procedures for compliance with applicable legal and regulatory requirements.

With effect from Listing, the Audit and Risk Committee is proposed to be comprised of Mr Thomas (Chair), Ms Robinson and Dr Roberts.

The Company will comply with the ASX Recommendations in relation to the composition and operation of the committee, which will be comprised of at least three Non-Executive Directors, a majority of whom are independent, and an independent chair.

b) Nomination and Remuneration Committee

The Role of the Nomination and Remuneration Committee is to assist and advise the Board on:

- Board succession planning generally;
- induction and continuing professional development programs for Directors;
- the development and implementation of a process for evaluating the performance of the Board, its committees and Directors;
- the process for recruiting a new Director, including evaluating the balance of skills, knowledge, experience, independence and diversity on the Board and, in the light of this evaluation, preparing a description of the role and capabilities required for a particular appointment;
- the appointment and re-election of Directors; and
- ensuring there are plans in place to manage the succession of the CEO and other senior executives of the Company,

to ensure that the Board is of a size and composition conducive to making appropriate decisions, with the benefit of a variety of perspectives and skills and in the best interests of the Company as a whole.

With effect from Listing, the Nomination and Remuneration Committee is proposed to be comprised of Ms Robinson (Chair), Dr Ramdahl, Mr Thomas and Dr O'Bryan-Tear.

The Company will only partially comply with the ASX Recommendations in relation to the composition and operation of the Nomination and Remuneration Committee (that is, that it be comprised of at least three members, a majority of whom are independent directors, and be chaired by an independent director), since while it will be comprised of four Non-Executive Directors (one of whom will be the independent chair), only two of the Non-Executive Directors are currently independent Directors.

6.6.1.5. Corporate governance policies

The Board has adopted the following corporate governance policies, each of which has been prepared having regard to the ASX Recommendations and all which are either in effect or will take effect from Listing. The Company's corporate governance policies will continue to be reviewed regularly and will continue to be developed and refined to meet the needs of the Company and best practice.

a) Whistleblower Policy

The Company has adopted a whistleblower policy to encourage officers, employees, suppliers, consultants, contractors and associates of the Company to raise any concerns and report instances of misconduct or an improper state of affairs or circumstances in relation to the Company, including an offence against, or contravention of, law, a serious breach of any internal policy or code of the Company, and illegal, dishonest, fraudulent or corrupt activity. The whistleblower policy sets out the Company's commitment to investigating all matters reported in an objective and fair manner as soon as possible after the matter has been reported. The Board will be informed of any material reports raised under the whistleblower policy.

b) Code of Conduct

The Board recognises the need to observe the highest standards of corporate practice and business conduct and puts an emphasis on the Company's values and standards which guide interactions with other entities. The Company's value and standards are innovation, thought leadership, collaboration, reliability and trust. The Board has adopted a code of conduct which sets out these values and standards to guide ethical behaviour and which serves as a guide to employees conducting business on the Company's behalf.

c) Trading Policy

The Company has adopted a trading policy, to take effect from Listing, which explains the type of conduct in relation to dealings in Shares that is prohibited under the Corporations Act and establishes procedures in relation to dealings in the Shares by designated persons.

The trading policy defines certain "prohibited periods" during which certain designated persons are generally not permitted to deal with securities, along with a procedure under which designated persons are required to submit a request and obtain written confirmation prior to dealing in securities outside the prohibited periods.

The trading policy further provides that designated persons must not deal in Shares on a short-term or speculative basis and prohibits designated persons from hedging. The trading policy also sets out a process for maintaining the confidentiality of relevant information.

d) Auditor Independence Policy

The Company has adopted an auditor independence policy, to take effect from Listing, to provide guidance on the provision of external audit services for the Company to ensure that the Company's auditor carries out the statutory audit function in a manner which is at all times demonstrably independent of the Company. The policy details services which the external auditor can be engaged to perform and places responsibility on the external audit firm to maintain a quality control system that provides assurance that its independence will not be impaired.

e) Disclosure and Communication Policy

Once listed on the ASX, the Company will need to comply with the continuous disclosure requirements of the ASX Listing Rules and the Corporations Act. The Company will be required to disclose to the ASX any information concerning the Company which is not generally available and which a reasonable person would expect to have a material effect on the price or value of the Shares were that information to be generally available. The Company is committed to complying with its disclosure obligations. Accordingly, this policy, which will take effect from Listing, sets out certain procedures and measures which are designed to ensure that the Company complies with its continuous disclosure obligations from Listing.

The Board's aim is to ensure that Shareholders are informed in a timely and readily accessible manner of all major developments affecting the state of affairs of the Company. Information will be communicated to Shareholders through the lodgement of information with the ASX as required by the Company's continuous disclosure obligations and publishing information on the Company's website (www.claritypharmaceuticals.com). The Company's website will contain information about the Company, including periodic releases, key policies, the terms of reference of Board committees and other information relevant to Shareholders. All announcements made to the market and any other relevant information will be posted on the Company's website following release to the ASX.

f) Diversity and Inclusion Policy

The workforce of the Company is made up of individuals with diverse skills, backgrounds, perspectives and experiences, and this diversity is recognised, valued and respected. The diversity and inclusion policy aims to align the Company's business operations with the positive outcomes that can be achieved through a diverse workforce that recognises and utilises the contribution of diverse skills and talents amongst its employees, contractors and consultants.

g) Privacy Policy

The Company has adopted a privacy policy in relation to personal information collected and held by the Company in operating its business. The privacy policy explains how and when personal information is collected, with whom personal information is shared and how personal information is stored and secured.

h) Anti-Bribery and Corruption Policy

The Company is committed to promoting and supporting a culture of corporate compliance and ethical behaviour. The Company is focused on detecting and eliminating misconduct and promoting and supporting a culture of honesty, integrity, compliance and sound corporate governance. Accordingly, the Board has adopted an anti-bribery and corruption policy which sets out the responsibilities of the Company, its employees and other personnel or representatives in observing and upholding the prohibition on bribery and related improper conduct and provides information and guidance on how to recognise and deal with instances of bribery and corruption.

6.7. Related party transactions

The Company has entered into the following related party transactions with the Directors and the Proposed Director on arms' length terms:

- letters of appointment with each of its Non-Executive Directors and the Proposed Director (refer to Section 6.4.2.1 for details);
- employment agreements with its Executive Directors (refer to Section 6.4.2.8 for details);
- deeds of indemnity, insurance and access with each of its Directors and the Proposed Director (refer to Section 6.4.2.4 for details); and
- a Consulting Services Agreement with O'Bryan-Tear Consulting Ltd, an entity controlled by Dr O'Bryan-Tear, pursuant to which Dr O'Bryan Tear provides consulting services to the Company for a consulting fee of US$30,000 per annum. The Consulting Services Agreement commenced on 1 August 2018 and is due to expire on 31 December 2021.

In addition, Ms Robinson is the General Manager of Business Development at ANSTO. ANSTO holds 3,599,920 Shares (representing 1.89% of the undiluted issued share capital of the Company as at the Prospectus Date[189]) and is a supplier of research services to the Company. Approximately $65,000 was paid to ANSTO by the Company in FY2020. ANSTO is not considered a related party of the Company as Ms Robinson does not hold a position of control over ANSTO.

189. Assumes 190,418,260 Shares being on issue at the Prospectus Date and that no Options have been exercised.

07

Details of the Offer

07 Details of the Offer

7.1. Description of the Offer

This Prospectus relates to an initial public offering of new Shares by the Company at an Offer Price of $1.40 per Share. A total of 65.7 million Shares will be available under the Offer. These Shares will be available for investors under the Broker Firm Offer, the Institutional Offer and the Priority Offer.

The Shares offered under this Prospectus will represent approximately 26% of the Shares on issue at Completion of the Offer (excluding any Shares which are the subject of the Options). The Offer is expected to raise gross proceeds of approximately $92 million from the issue of Shares by the Company.

The total number of Shares on issue at Completion will be approximately 256.1 million (excluding any Shares which are the subject of the Options) and all Shares will, once issued, rank equally with each other.

The Shares held by certain of the Existing Shareholders will be subject to escrow arrangements described in Section 10.4 of this Prospectus.

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 10.11.1.

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 following components:

- The **Retail Offer**, comprising:
  - The **Broker Firm Offer**, which is an offer to Australian resident retail clients of Brokers who have received a firm allocation of Shares from their Broker (see Section 7.3);
  - The **Priority Offer**, which is open to selected investors in Australia nominated by the Company (see Section 7.4); and
- The **Institutional Offer**, which consists of an offer to Institutional Investors in Australia and other Permitted Jurisdictions (see Section 7.7).

No general public offer of Shares will be made under the Offer. Members of the public wishing to apply for Shares under the Offer must do so through a Broker with a firm allocation of Shares under the Broker Firm Offer.

The allocation of Shares between the Broker Firm Offer, the Priority Offer, and the Institutional Offer will be determined by agreement between Clarity and the Joint Lead Managers, having regard to the allocation policies outlined in Sections 7.3.4, 7.4.4 and 7.7.2 of this Prospectus.

7.1.2. Purpose of the Offer

The purpose of the Offer is to:

- support the Company's growth strategy, as further detailed in this Prospectus, by advancing and funding the clinical development of its three lead products, $^{64/67}$Cu SARTATE™, $^{64/67}$Cu SAR-Bombesin and $^{64/67}$Cu SAR-bisPSMA, through their respective phases of clinical trials in Australia and the US;
- provide funding and financial flexibility for general corporate purposes;
- assist with future growth opportunities;
- broaden Clarity's shareholder base and provide a liquid market for Shares;
- provide Clarity with access to the public equity capital markets, in order to improve its financial flexibility to pursue further growth opportunities and take advantage of the associated benefit of creating an increased profile that arises from being listed on the ASX; and
- pay transaction costs associated with the Listing and this Prospectus.

7.1.3. Sources and uses of funds

The proceeds of the Offer received by the Company will be applied as described in Figure 44. The Offer is expected to raise gross proceeds of approximately $92 million.

Figure 44: Sources and uses of funds

Sources of funds	A$ million
Gross cash proceeds received by Clarity under the Offer from the issue of Shares	$92.0
Existing cash reserves as at the Prospectus Date	$17.6
Total sources	**$109.6**

Uses of funds	A$ million	% of Total Funds
Pre-Clinical	$2.7	2.46
Clinical[i]	$84.0	76.64
Regulatory	$5.7	5.20
Patents	$1.4	1.28
Corporate	$10.4	9.49
Costs associated with the Offer[ii]	$5.4	4.93
Total uses	**$109.6**	**100%**

(i) Includes funds currently allocated by the Company to the advancing and funding of the clinical development of its key three lead products namely, Cu SARTATE, Cu SAR-Bombesin and Cu SAR-bisPSMA, through their respective phases of clinical trials in Australia and the US as well as other potential clinical programmes as required.

(ii) Excluding GST.

The Board believes that on Completion the Company will have sufficient funds available from the cash proceeds of the Offer to fulfil the purpose of the Offer and meet the Company's stated business objectives as stated in this Prospectus.

The above table is a statement of current intentions as at the Prospectus Date based on the Company's present plans and business conditions. Investors should note that, as with any budget, the allocation of funds set out in the above table may change depending on a number of factors, including the outcome of sales success, operational and development activities, regulatory developments and market and general economic conditions and also having regard to the risks specified in Section 5 of this Prospectus. In light of this, the Board reserves the right to alter the way in which the funds are applied with respect to the Company's current stated business objectives and/or alter the Company's business objectives (as applicable). More generally, the Board may consider the use of additional equity or debt funding if appropriate to further accelerate growth or fund the Company's current stated business objectives, or otherwise a specific project, transaction or acquisition opportunity (including if the Company's stated business objectives change).

7.1.4. Shareholding structure of Clarity

The shareholdings of the Existing Shareholders on the Prospectus Date and immediately following Completion of the Offer (excluding any Shares applied for under the Offer and on an undiluted basis i.e. assuming no Options have been exercised) are set out in Figure 45 below.

Figure 45: Ownership structure – Shares

	Shareholding as at the Prospectus Date		Shareholding following Completion	
Shareholder	**Shares**	**%**	**Shares**	**%**
TM Ventures Pty Ltd[i]	18,788,460	9.9%	18,788,460	7.3%
Dr Roberts[ii]	17,911,280	9.4%	17,911,280	7.0%
Dr Taylor[iii]	14,066,660	7.4%	14,066,660	5.5%
Charles Morgan[iv]	12,330,220	6.5%	12,330,220	4.8%
GenesisCare Ventures Pty Ltd	10,362,700	5.4%	10,362,700	4.0%
Dr Biggin	419,100	0.2%	419,100	0.2%
Directors[v]	930,000	0.5%	930,000	0.4%
Other senior management	8,775,800	4.6%	8,775,800	3.4%
Other Existing Shareholders	106,834,040	56.1%	106,834,040	41.7%
Investors under the Offer	–	–	65,714,286	25.7%
Total	**190,418,260**	**100%**	**256,132,546**	**100%**

(i) Dr Harris, current Chief Scientific Officer of the Company and former CEO, is a director and shareholder of TM Ventures Pty Ltd. Dr Harris is also a director of Boorris Pty Ltd ATF Boorris Trust and a beneficiary under that trust (whose shareholding in the Company is noted in Section 10.8).

(ii) Dr Roberts holds all of his Shares through the Robwill Trust (Dr Roberts is a director and shareholder of the trustee and a beneficiary of the family trust).

(iii) Dr Taylor holds all of his interests in Shares through the Taylor Family Trust and persons connected to the Taylor Family Trust.

(iv) Mr Morgan is also a shareholder of TM Ventures Pty Ltd (see Section 10.8).

(v) Including the Proposed Director but excluding Dr Roberts, Dr Taylor and Dr Biggin.

The interests of Option holders as at the Prospectus Date and immediately following Completion of the Offer (assuming no Options have been exercised) are set out in Figure 46 below.

Figure 46: Ownership structure – Options

	Option holding as at the Prospectus Date		Option holding following Completion	
Option holder	**Options**	**%**	**Options**	**%**
Company Options	24,626,680	48.2%	24,626,680	48.2%
Adviser Options	918,220	1.8%	918,220	1.8%
China Grand Options	25,543,912	50.0%	25,543,912	50.0%
Investors under the Offer	–	–	–	–
Total	**51,088,812**	**100%**	**51,088,812**	**100%**

7.1.5. Control implications of the Offer

The Board does not expect that any Shareholder will control (as defined by section 50AA of the Corporations Act) the Company on Completion.

7.2. Terms and conditions of the Offer

Figure 47: Terms and conditions of the Offer

What is the type of security being offered?	Shares (being fully paid ordinary shares in the issued capital of the Company).
What are the rights and liabilities attached to the security being offered?	A description of the Shares, including the rights and liabilities attaching to them, is set out in Section 10.10.
What is the consideration payable for the Shares?	Successful Applicants under the Offer will pay the Offer Price, being $1.40 per Share.
What is the Offer period?	The Retail Offer will open at 8.30am (Sydney time) on Tuesday 3 August 2021 and will close at 5.00pm (Sydney time) on Tuesday 10 August 2021. The key dates, including details of the Offer Period, are set out on page 5 of this Prospectus. The timetable is indicative only and may change. Unless otherwise indicated, all times are stated in Sydney, Australia time. The Company, in consultation with the Joint Lead Managers, reserves 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 Offer Period relating to any component of the Offer, or 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 notifying any recipient of this Prospectus or any Applicants). 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. No Shares will be issued on the basis of this Prospectus later than the Expiry Date (being 13 months after the Prospectus Date).
What are the cash proceeds to be raised?	Approximately $92 million in gross proceeds is expected to be raised under the Offer if it proceeds.
Is the Offer underwritten?	The Joint Lead Managers have fully underwritten the Offer pursuant to the Underwriting Agreement. Details are provided in Section 10.11.1.
Who are the Joint Lead Managers?	The Joint Lead Managers are Jefferies (Australia) Pty Ltd and Bell Potter Securities Ltd.
What is the minimum and maximum application size under the Retail Offer?	The minimum application size for investors in the Retail Offer is $2,000 in multiples of $500 worth of Shares thereafter. There is no maximum value of Shares that may be applied for under the Retail Offer. Clarity and the Joint Lead Managers reserve the right to treat any Applications in the Broker Firm Offer, which are from persons who they believe may be Institutional Investors, as bids in the Institutional Offer or to reject or scale back Applications. Clarity, along with the Joint Lead Managers, also reserves the right to aggregate any Applications believed to be multiple Applications from the same person.

What is the allocation policy?	The allocation of Shares between the Institutional Offer and Retail Offer was determined by agreement between the Company and the Joint Lead Managers, having regard to the allocation policies outlined in Sections 7.3.4, 7.4.4 and 7.7.2. With respect to the Broker Firm Offer, it is a matter for the Brokers as to how they allocate Shares among their retail clients. The allocation of Shares under the Priority Offer is at the absolute discretion of the Company. Clarity, along with the Joint Lead Managers, has absolute discretion regarding the allocation of Shares to Applicants under the Offer and may reject an Application, or allocate fewer Shares than the number or equivalent dollar amount applied for, in its absolute discretion. Clarity, in conjunction with the Joint Lead Managers, also reserves the right to aggregate any Applications that it believes 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 or about Wednesday, 25 August 2021. Refunds (without interest) to Applicants who make an Application and are scaled back (or otherwise receive Shares having a lesser value than the amount of Application Monies they have paid) will be made as soon as possible after Completion of the Offer.
Will the Shares be quoted?	Clarity will apply within seven days of the Prospectus Date to the ASX for admission to the Official List and quotation of its Shares on ASX (which is expected to be under the ticker code "CU6"). Completion is conditional on the ASX approving the admission 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. Clarity will be required to comply with the ASX Listing Rules, subject to any waivers obtained by it from time to time. The ASX takes no responsibility for the contents of this Prospectus or the investment to which it relates. The fact that Clarity may be admitted by ASX to the Official List is not to be taken as an indication of the merits of Clarity, the Offer, or the Shares offered under this Offer.
When are the Shares expected to commence trading?	It is expected that trading of the Shares on the ASX will commence on or around Wednesday, 25 August 2021 on a normal settlement basis. It is the responsibility of each Applicant to confirm their holding before trading Shares. Applicants who sell Shares before they receive an initial holding statement do so at their own risk. Clarity and its Directors and officers along with the Share Registry and the Joint Lead Managers disclaim all liability, whether in negligence or otherwise, to persons who sell Shares before receiving their holding statement, whether on the basis of a confirmation of allocation provided by any of them or a Broker or from the Clarity Offer Information Line.
Are there any escrow arrangements?	Yes. Details are provided in Section 10.4.
Has any ASIC relief or ASX waiver been sought or obtained?	The Company has applied to the ASX for in-principle advice as to the suitability of the Company for Listing but has not applied for any specific ASIC relief or ASX waivers. Please see Section 10.12.1 for further details.

Are there any taxation considerations for Australian investors?	Yes. Details are provided in Section 10.16.
Can I apply during the Exposure Period?	The Corporations Act prohibits the Company from processing Applications under this Prospectus during the Exposure Period. The Exposure Period may be extended by ASIC by up to a further seven days, being an Exposure Period of up to a total of 14 days. The purpose of the Exposure Period is to enable the Prospectus to be examined by market participants prior to the raising of funds under the Offer. Applications received during the Exposure Period will not be processed until after the expiry of the Exposure Period. No preference will be conferred on Applications received during the Exposure Period.
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. See Section 10.11.1 for details of various fees payable by Clarity to the Joint Lead Managers and by the Joint Lead Managers to certain Brokers (on behalf of the Company).
What should I do with any enquiries?	All enquiries in relation to this Prospectus should be directed to the Clarity Offer Information Line on 1800 645 237 (within Australia) or +61 1800 645 237 (outside Australia) between 8.30am and 5.30pm (Sydney time), Monday to Friday (Business Days only) if you require assistance to complete the Application Form, require additional copies of this Prospectus or have any questions in relation to the Offer. 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 stockbroker, solicitor, accountant, financial adviser or other independent professional adviser before deciding whether to invest.

7.3. Broker Firm Offer

7.3.1. Who may apply in the Broker Firm Offer

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 and are not located in the United States. If you have received an invitation to participate from your Broker, you will be treated as eligible to become a Broker Firm Offer Applicant under the Broker Firm Offer. You should contact your Broker to determine whether you can receive an allocation of Shares under the Broker Firm Offer.

7.3.2. How to apply for Shares under the Broker Firm Offer

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 Application Monies to the Share Registry.

Applicants under the Broker Firm Offer should contact their Broker to request a Prospectus and Broker Firm Offer Application Form. 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 (Sydney time) on the Closing Date for the Retail Offer (5.00pm (Sydney time) on Tuesday 10 August 2021) or any earlier closing date as determined by your Broker.

By making an Application, you declare that you were given access to this Prospectus (or any supplementary or replacement prospectus), together with an Application Form. The Corporations Act prohibits any person from passing an Application Form to another person unless it is included in, or accompanied by, a hard copy of this Prospectus or the complete and unaltered electronic version of this Prospectus.

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 of Shares. 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 under the Broker Firm Offer is $2,000 worth of Shares and in multiples of $500 worth of Shares thereafter. There is no maximum value of Shares that may be applied for under the Broker Firm Offer. Clarity 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. Any amount applied for in excess of the amount allocated to you, will be refunded by your Broker in full (without interest). Clarity 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.

Clarity, 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 Broker Firm Offer opens at 8.30am (Sydney time) on Tuesday 3 August 2021 and will close at 5.00pm (Sydney time) on Tuesday 10 August 2021. Clarity 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 for Applications under the Broker Firm Offer

Applicants under the Broker Firm Offer must pay their Application Monies in accordance with instructions provided by the applicable 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, have been determined by agreement between the Joint Lead Managers and Clarity. Shares that have been allocated to Brokers for allocation to their Australian resident clients will be issued to the Applicants nominated by those Brokers (subject to the right of Clarity and 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 Clarity or the Joint Lead Managers) will be responsible for ensuring that retail clients who have received a firm allocation from them receive the relevant Shares. Applicants under the Broker Firm Offer should confirm their allocation through the Broker from whom they received their allocation. However, if you sell Shares before receiving a holding statement, you do so at your own risk, even if you obtained details of your holding from the Clarity Offer Information Line or confirmed your allocation through a Broker.

Clarity and its directors and officers, the Joint Lead Managers and the Share Registry disclaim all liability, whether in negligence or otherwise, if you sell Shares before receiving your holding statement, even if you obtained details of your holding from the Clarity Offer Information Line or confirmed your firm allocation of Shares through a Broker.

7.3.5. Acceptance of applications under the Broker Firm Offer

An Application under the Broker Firm Offer is an offer by you to the Company to apply for Shares in the dollar amount 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 may not be varied and is irrevocable.

An Application may be accepted in respect of the full amount, or any amount lower than that specified in the Application Form, without further notice to the Applicant. Acceptance of an Application will give rise to a binding contract on allocation of Shares to Successful Applicants conditional on Settlement and the quotation of Shares on the ASX on an unconditional basis.

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 whom the Company believes is ineligible to participate in the Broker Firm Offer, or to waive or correct any errors made by the Applicant in completing their Application.

The final allocation of Shares to Applicants in the Broker Firm Offer will be at the Company's absolute discretion and the Company may reject an Application or allocate fewer Shares than the number or equivalent dollar amount applied for.

7.3.6. Application monies

Application Monies received under the Broker Firm Offer will be held in a special purpose account on trust for Applicants until such 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 dollar amount of Shares than the amount applied for, will be mailed (or otherwise in the Company's discretion provided with) 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 the Company.

7.4. Priority Offer

7.4.1. Who may apply in the Priority Offer

The Priority Offer is open to investors who have received an invitation to participate in the Priority Offer from Clarity and who have a registered address in Australia and are not located in the United States. If you have been invited by Clarity 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 and you will receive a personalised invitation to apply for Shares in the Priority Offer.

7.4.2. How to apply for Shares under the Priority Offer

If you have received a personalised invitation to apply for Shares under the Priority Offer and you wish to apply for some or all of those Shares, you should follow the instructions on your personalised invitation.

By making an Application, you declare that you were given access to this Prospectus (or any supplementary or replacement prospectus), together with an Application Form. The Corporations Act prohibits any person from passing an Application Form to another person unless it is included in, or accompanied by, a hard copy of this Prospectus or the complete and unaltered electronic version of this Prospectus.

Applications under the Priority Offer must be for a minimum of $2,000 worth of Shares and in multiples of $500 worth of Shares thereafter. There is no maximum number or value of Shares that may be applied for under the Priority Offer.

Applications must be received by the Share Registry on or before the Closing Date for the Retail Offer (5.00pm (Sydney time) on Tuesday 10 August 2021).

7.4.3. Payment methods for Applications under the Priority Offer

Payment must be made in Australian dollars and via BPAY®, and must otherwise be made in accordance with the instructions provided on your personalised invitation. Application Monies must be received by the Share Registry by 5.00pm (Sydney time) on Tuesday 10 August 2021. It is your responsibility to ensure that your BPAY® payment is received by the Share Registry by no later than 5.00pm (Sydney time) on Tuesday 10 August 2021. You should be aware that your financial institution may implement earlier cut-off times with regard to electronic payment, and you should therefore take this into consideration when making payment.

7.4.4. Allocation policy under the Priority Offer

The aggregate number of Shares offered under the Priority Offer will not exceed $10.4 million worth of Shares in aggregate. The allocation of Shares to Applicants under the Priority Offer will be made at the absolute discretion of Clarity. Clarity may reject an Application, or allocate a lesser dollar amount of Shares than the amount applied for, in its absolute discretion.

7.5. Acceptance of applications under the Retail Offer

An Application under the Retail Offer (which incorporates the Broker Firm Offer and the Priority Offer) is an offer by you to Clarity to apply for Shares in the dollar amount specified on 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 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 by Clarity in respect of the full amount specified on the Application Form, or any amount lower than that, without further notice to the Applicant. Clarity reserves the right to decline any Application (in whole or in part) if they believe any provisions or procedures in this Prospectus, the Application Form or other laws or regulations may not have been complied with in relation to the Application, or for any other reason.

Clarity and the Joint Lead Managers reserve the right to reject any Application which is not correctly completed or which is submitted by a person whom they believe is ineligible to participate in the Retail Offer, or to waive or correct any errors made by an Applicant in completing their Application. In addition, Clarity and the Joint Lead Managers reserve the right to aggregate any Applications which they believe may be multiple Applications from the same person or reject or scale back any Applications (or aggregation of Applications) which they believe may be from an Institutional Investor, or are for more than $250,000 worth of Shares.

Successful Applicants in the Retail 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.

7.6. Application Monies

Application Monies received under the Retail Offer will be held in a special purpose account until Shares are issued to Successful Applicants. Applicants under the Retail Offer whose Applications are not accepted, or who are allocated a lesser dollar amount of Shares than the amount applied for, will receive 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 Clarity. You should ensure that sufficient funds are held in the relevant account(s) to cover the amount of your BPAY® payment or electronic funds transfer. If the amount of your BPAY® payment or electronic funds transfer is less than the amount specified on the Application Form, you may be taken to have applied for such lower dollar amount of Shares.

7.7. Institutional Offer

7.7.1. Invitations to bid

The Institutional Offer consisted of an invitation to bid for an allocation of Shares at the Offer Price to certain Institutional Investors in Australia and other Permitted Jurisdictions and, for Institutional Investors in the United States, under the US Offering Circular, which includes this Prospectus. The Joint Lead Managers separately advised Institutional Investors of the application procedures for the Institutional Offer.

7.7.2. Allocation policy under the Institutional Offer

The allocation of Shares among bidders in the Institutional Offer was determined by agreement between the Joint Lead Managers and Clarity. Clarity and the Joint Lead Managers had absolute discretion regarding the basis of allocation of Shares among Institutional Investors.

Participants in the Institutional Offer have been advised of their allocation of Shares, if any, by the Joint Lead Managers.

The allocation policy was influenced, but not constrained, by the following factors:

- the number of Shares bid for by particular applicants;
- the timeliness of the bid by particular applicants;
- the Company's desire for an informed and active trading market following Listing;
- the Company's desire to establish a wide spread of institutional Shareholders;
- the anticipated overall level of demand under the Broker Firm Offer, Priority Offer and the Institutional Offer;
- the likelihood that particular bidders will be long term Shareholders; and
- any other factors that the Company and the Joint Lead Managers considered appropriate, in the Company's sole discretion.

7.8. Restrictions on distributions

This Prospectus does not constitute an offer in any place outside Australia where, or to any person to whom, it would not be lawful to make such offer. No action has been taken to register or qualify the Shares or the Offer, or to otherwise permit a public offer of the Shares, in any jurisdiction outside Australia.

The distribution of this Prospectus outside Australia may be restricted by law and persons who come into possession of this Prospectus should observe any such restrictions, including those set out in this Section. Any failure to comply with such restrictions could constitute a violation of applicable securities laws. In particular, this Prospectus may only be distributed in the United States to Institutional Investors by registered US broker-dealers of the Joint Lead Managers and only if this Prospectus is accompanied by the US Offering Circular.

Each Applicant under the Retail Offer, as well as each person to whom the Institutional Offer is made under this Prospectus, will be taken to have represented, warranted and agreed as follows:

- it understands that the Shares have not been, and will not be, registered under the US Securities Act or the securities laws of any state or other jurisdiction of the United States and may not be offered or sold in the United States except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and any other applicable US securities laws;
- it is resident or domiciled in Australia or, if outside Australia, is an Institutional Investor;
- it is located in Australia at the time of the Application and is not acting for the account or benefit of any person in the United States or any other foreign person, excluding Applicants who are Institutional Investors; and
- it has not sent and will not send the Prospectus or any other material relating to the Offer to any person in the United States or elsewhere outside Australia.

Each Applicant under the Offer will be deemed to have:

- agreed 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;
- acknowledged having personally received a printed or electronic copy of the Prospectus (and any supplementary or replacement prospectus) including or accompanied by 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 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 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.

Canada (British Columbia, Ontario and Quebec provinces)

This Prospectus constitutes an offering of Shares only in the Provinces of British Columbia, Ontario and Quebec (**Provinces**), only to persons to whom Shares may be lawfully distributed in the Provinces, and only by persons permitted to sell such securities. This Prospectus is not a prospectus, an advertisement or a public offering of securities in the Provinces. This Prospectus may only be distributed in the Provinces to persons who are "accredited investors" within the meaning of National Instrument 45-106 – *Prospectus Exemptions*, of the Canadian Securities Administrators.

No securities commission or authority in the Provinces has reviewed or in any way passed upon this Prospectus, the merits of the Shares or the offering of the Shares and any representation to the contrary is an offence.

No prospectus has been, or will be, filed in the Provinces with respect to the offering of Shares or the resale of such securities. Any person in the Provinces lawfully participating in the offer will not receive the information, legal rights or protections that would be afforded had a prospectus been filed and receipted by the securities regulator in the applicable Province. Furthermore, any resale of the Shares in the Provinces must be made in accordance with applicable Canadian securities laws. While such resale restrictions generally do not apply to a first trade in a security of a foreign, non-Canadian reporting issuer that is made through an exchange or market outside Canada, Canadian purchasers should seek legal advice prior to any resale of the Shares.

The Company as well as its directors and officers may be located outside Canada and, as a result, it may not be possible for purchasers to effect service of process within Canada upon the Company or its directors or officers. All or a substantial portion of the assets of the Company and such persons may be located outside Canada and, as a result, it may not be possible to satisfy a judgment against the Company or such persons in Canada or to enforce a judgment obtained in Canadian courts against the Company or such persons outside Canada.

Any financial information contained in this Prospectus has been prepared in accordance with Australian Accounting Standards and also comply with International Financial Reporting Standards and interpretations issued by the International Accounting Standards Board. Unless stated otherwise, all dollar amounts contained in this Prospectus are in Australian dollars.

Statutory rights of action for damages and rescission. Securities legislation in certain Provinces may provide a purchaser with remedies for rescission or damages if an offering memorandum contains a misrepresentation, provided the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's Province. A purchaser may refer to any applicable provision of the securities legislation of the purchaser's Province for particulars of these rights or consult with a legal adviser.

Certain Canadian income tax considerations. Prospective purchasers of the Shares should consult their own tax adviser with respect to any taxes payable in connection with the acquisition, holding or disposition of the Shares as there are Canadian tax implications for investors in the Provinces.

Language of documents in Canada. Upon receipt of this Prospectus, each investor in Canada hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the Shares (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

Cayman Islands

No offer or invitation to subscribe for Shares may be made to the public in the Cayman Islands or from within the Cayman Islands.

China

This Prospectus has not been approved by, nor registered with, any competent regulatory authority of the People's Republic of China (**PRC**) (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). Accordingly, the Shares may not be offered or sold, nor may any invitation, advertisement or solicitation for Shares be made from, within the PRC. This Prospectus does not constitute an offer of Shares within the PRC.

The Shares may not be offered or sold to legal or natural persons in the PRC other than to: (i) "qualified domestic institutional investors" as approved by a relevant PRC regulatory authority to invest in overseas capital markets; (ii) sovereign wealth funds or quasi-government investment funds that have the authorization to make overseas investments; or (iii) other types of qualified investors that have obtained all necessary PRC governmental approvals, registrations and/or filings (whether statutorily or otherwise).

European Union

This Prospectus has not been, and will not be, registered with or approved by any securities regulator in the European Union. Accordingly, this Prospectus may not be made available, nor may the Shares be offered for sale, in the European Union except in circumstances that do not require a prospectus under Article 1(4) of Regulation (EU) 2017/1129 of the European Parliament and the Council of the European Union (**Prospectus Regulation**).

In accordance with Article 1(4)(a) of the Prospectus Regulation, an offer of Shares in the European Union is limited to persons who are "qualified investors" (as defined in Article 2(e) of the Prospectus Regulation).

Hong Kong

WARNING: This Prospectus 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 (**SFO**). No action has been taken in Hong Kong to authorise or register this Prospectus or to permit the distribution of this Prospectus 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 Prospectus 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 Prospectus, you should obtain independent professional advice.

New Zealand

This Prospectus has not been registered, filed with or approved by any New Zealand regulatory authority under the *Financial Markets Conduct Act 2013* (**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.

Norway

This Prospectus has not been approved by, or registered with, any Norwegian securities regulator under the Norwegian Securities Trading Act of 29 June 2007 no. 75. Accordingly, this Prospectus shall not be deemed to constitute an offer to the public in Norway within the meaning of the Norwegian Securities Trading Act. The Shares may not be offered or sold, directly or indirectly, in Norway except to "professional clients" (as defined in the Norwegian Securities Trading Act).

Singapore

This Prospectus 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 Prospectus 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 (**SFA**), or as otherwise pursuant to, and in accordance with the conditions of any other applicable provisions of the SFA.

This Prospectus 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 Prospectus immediately. You may not forward or circulate this Prospectus 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.

Switzerland

The Shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange or on any other stock exchange or regulated trading facility in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the Shares constitutes a prospectus or a similar notice, as such terms are understood under art. 35 of the Swiss Financial Services Act or the listing rules of any stock exchange or regulated trading facility in Switzerland.

No offering or marketing material relating to the Shares has been, nor will be, filed with or approved by any Swiss regulatory authority or authorised review body. In particular, this Prospectus will not be filed with, and the offer of Shares will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

Neither this Prospectus nor any other offering or marketing material relating to the Shares may be publicly distributed or otherwise made publicly available in Switzerland. The Shares will only be offered to investors who qualify as "professional clients" (as defined in the Swiss Financial Services Act). This Prospectus is personal to the recipient and not for general circulation in Switzerland.

United Arab Emirates

This Prospectus does not constitute a public offer of securities in the United Arab Emirates and the Shares may not be offered or sold, directly or indirectly, to the public in the UAE. Neither this Prospectus nor the Shares have been approved by the Securities and Commodities Authority (**SCA**) or any other authority in the UAE.

This Prospectus may be distributed in the UAE only to "qualified investors" (as defined in the SCA Board of Directors' Chairman Decision No. 37 RM of 2019, as amended) and may not be provided to any person other than the original recipient. No marketing of the Shares has been, or will be, made from within the UAE other than in compliance with the laws of the UAE and no subscription for any securities may be consummated within the UAE.

No offer or invitation to subscribe for Shares is valid, or permitted from any person, in the Abu Dhabi Global Market or the Dubai International Financial Centre.

United Kingdom

Neither this Prospectus 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 Prospectus or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This Prospectus 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 Prospectus 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 Prospectus 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 Prospectus relates is available only to relevant persons. Any person who is not a relevant person should not act or rely on this Prospectus.

United States

This Prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States. The Shares have not been, and will not be, registered under the US Securities Act of 1933 or the securities laws of any state or other jurisdiction of the United States. Accordingly, the Shares may not be offered or sold in the United States except in transactions exempt from, or not subject to, the registration requirements of the US Securities Act and applicable US state securities laws.

The Shares will only be offered and sold in the United States under the US Offering Circular to:

- "qualified institutional buyers" (as defined in Rule 144A under the US Securities Act); and
- dealers or other professional fiduciaries organized or incorporated in the United States that are acting for a discretionary or similar account (other than an estate or trust) held for the benefit or account of persons that are not US persons and for which they exercise investment discretion, within the meaning of Rule 902(k)(2)(i) of Regulation S under the US Securities Act.

7.9. Discretion regarding the Offer

Clarity 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).

Clarity and the Joint Lead Managers also reserve the right to close the Offer or any part of it early, extend the Offer or any part of it, accept late Applications either generally or in particular cases, reject any Application, or (subject to the terms of any guaranteed allocations referred to in this Prospectus) allocate a lesser number of Shares than that applied for.

7.10. ASX listing, registers and holding statements, and conditional and deferred settlement trading

7.10.1. Application to the ASX for listing of the Company and quotation of Shares

Clarity will apply to the ASX for admission to the Official List and quotation of its Shares on the ASX within seven days of the Prospectus Date (which is expected to be under the ticker code "CU6").

The ASX takes no responsibility for the contents of this Prospectus or the investment to which it relates. The fact that the ASX may admit Clarity to the Official List is not to be taken as an indication of the merits of Clarity, the Offer or the Shares offered under this Prospectus.

If permission is not granted for the official quotation of the Shares on the ASX within three months after the Prospectus Date (or any later date permitted by law), the Offer will be withdrawn and all Application Monies received by Clarity will be refunded (without interest) as soon as practicable in accordance with the requirements of the Corporations Act.

From the date of Listing, Clarity will be required to comply with the ASX Listing Rules, subject to any waivers obtained by Clarity from time to time.

7.10.2. CHESS and issuer sponsored holdings

The Company will apply to participate in the ASX's Clearing House Electronic Subregister System (**CHESS**) and will comply with the ASX Listing Rules and the ASX Settlement Operating Rules. CHESS is an electronic transfer and settlement system for transactions in securities quoted on the ASX under which transfers are effected in an electronic form.

When the Shares become approved financial products (as defined in the ASX Settlement Operating Rules), holdings will be registered in one of two subregisters, being an electronic CHESS subregister or an issuer sponsored subregister. 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 subregister. All other Shares will be registered on the issuer sponsored subregister.

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 for CHESS holders or, where applicable, the Securityholder Reference Number 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 subregister or through the Share Registry in the case of a holding on the issuer sponsored subregister.

The Company and the Share Registry may charge a fee for these additional issuer sponsored statements.

7.10.3. Trading and selling Shares on-market

It is expected that trading of the Shares on ASX will commence on a normal settlement basis on Wednesday, 25 August 2021. It is very important to note, however, that the timetable for Listing and trading of the Shares on ASX is indicative only and may change without notice.

If the Offer is withdrawn before Shares have commenced trading, all contracts for the sale of Shares on ASX will be cancelled and any Application Monies received will be refunded (without interest) as soon as possible.

It is the responsibility of each person who trades in Shares to confirm their holding before trading in Shares. If Shares are sold before receiving a holding statement, Successful Applicants do so at their own risk. The Company, the Share Registry and the Joint Lead Managers disclaim all liability, whether in negligence or otherwise, if a Shareholder sells Shares before receiving a holding statement, even if the Shareholder obtained details of their holding from the Clarity Offer Information Line or confirmed their firm allocation through a Broker.

7.11. Underwriting arrangements

The Company and the Joint Lead Managers have entered into an underwriting agreement dated 16 July 2021 pursuant to which the Joint Lead Managers have agreed, subject to certain conditions and termination events, to act as joint lead managers and bookrunners for, and to manage, the Offer, and to underwrite subscriptions for the Institutional Offer and Retail Offer.

A summary of the terms of the Underwriting Agreement, including the termination provisions, is provided in Section 10.11.1.

7.12. Summary of rights and liabilities attaching to Shares and other material provisions of the constitution

The rights and liabilities attaching to ownership of Shares are:

- detailed in the Constitution that will come into effect on Completion, which may be inspected during normal business hours at the registered office of the Company; and
- regulated (as applicable) by the Corporations Act, the ASX Listing Rules, the ASX Settlement Operating Rules and all other applicable laws and regulations.

A summary of the significant rights, liabilities and obligations attaching to the Shares and a description of other material provisions of the Constitution that will come into effect on Completion is set out in section 10.10 of this Prospectus.

7.13. Questions or further information

If you have any queries in relation to this Prospectus, including how to complete the Application Form or how to obtain additional copies, then you can:

- call the Clarity Offer Information Line on 1800 645 237 (within Australia) or 1800 645 237 (outside Australia) between 8.30am and 5.30pm (Sydney time), Monday to Friday (Business Days only); or
- visit www.claritypharmaceuticals.com to download an electronic copy of the Prospectus.

If you are unclear in relation to any matter or are uncertain as to whether the Company is a suitable investment for you, you should seek professional guidance from your stockbroker, solicitor, accountant, financial adviser or other independent professional adviser before deciding whether to invest.

08

Investigating Accountant's Report

08 Investigating Accountant's Report

Grant Thornton
An instinct for growth™

Board of Directors
Clarity Pharmaceuticals Ltd
National Innovation Centre
Australian Innovation Park
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Eveleigh NSW 2015

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Sydney NSW 2000
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Queen Victoria Building NSW 1230

T +61 2 8297 2400

16 July 2021

Dear Directors

INVESTIGATING ACCOUNTANT INDEPENDENT LIMITED ASSURANCE REPORT AND FINANCIAL SERVICES GUIDE

Introduction

This report has been prepared at the request of the directors of Clarity Pharmaceuticals Ltd and its controlled entities ("Clarity" or the "Group") for inclusion in the prospectus (the "Prospectus") to be issued by the Group on or about 16 July 2021 in respect of the initial public offering of fully paid ordinary shares in the Group (the "Offer") and admission to the Australian Securities Exchange.

Grant Thornton Corporate Finance Pty Ltd ("Grant Thornton Corporate Finance") holds an Australian Financial Services Licence (AFS Licence Number 247140). This report is both an Independent Limited Assurance Report, the scope of which is set out below, and a Financial Services Guide, as attached at **Appendix A**.

Expressions defined in the Prospectus have the same meaning in this report, unless otherwise specified.

Scope

You have requested Grant Thornton Corporate Finance to perform a limited assurance engagement in relation to the historical and pro forma historical financial information included in Section 4 of the Prospectus.

Historical Financial Information

The historical and pro forma historical financial information of the Group, as set out in the Prospectus comprises:

- The historical consolidated statement of profit or loss and other comprehensive income for the year ended 30 June 2019 ("FY2019"), the year ended 30 June 2020 ("FY2020") and the six months ended 31 December 2020 (1HY2021) with the six months ended 31 December 2019 comparative information ("1HY2020").

- The historical consolidated statement of cash flows for FY2019, FY2020 and 1HY2021 with 1HY2020 comparative information.

- The historical consolidated statement of financial position as at 31 December 2020;

Pro Forma Financial Information

- The pro forma consolidated statement of financial position as at 31 December 2020, which assumes completion of the transactions outlined in Section 4.7 of the Prospectus as though they had occurred at that date.

(collectively referred to as the "Historical Financial Information")

The Historical Financial Information is presented in an abbreviated form insofar as it does not include all of the presentation and disclosures required by Australian Accounting Standards and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in Australia in accordance with the Corporations Act 2001 (Cth).

The Historical Financial Information has been prepared for inclusion in the Prospectus and has been derived from the audited consolidated financial statements of the Group for FY2019 and FY2020 and reviewed financial statements for 1HY2021. The financial statements for FY2019, FY2020 and 1HY2021 were audited and reviewed by Grant Thornton Audit Pty Ltd in accordance with Australian Auditing Standards. The audit opinions issued to the Directors for FY2019 and FY2020 and review conclusion for 1HY2021 were unmodified but contained an emphasis of matter regarding the existence of a material uncertainty which may cast significant doubt on the Group's ability to continue as a going concern which is subject to future capital raisings and/ or obtaining grant funding.

As stated in Section 4.2 of the Prospectus the basis of preparation is the recognition and measurement principles contained in International Financial Reporting Standards ("IFRS") and the Group's adopted accounting policies set out in Appendix A of the Prospectus.

Directors' Responsibility

The Directors are responsible for:

- the preparation and presentation of the Historical Financial Information including the selection and determination of the pro forma adjustments made to the historical financial information and the basis of preparation of the Historical Financial Information; and
- the information contained within the Prospectus.

This responsibility also includes compliance with applicable laws and regulations and for such internal controls as the Directors determine necessary to enable the preparation of the Historical Financial Information that are free from material misstatement, whether due to fraud or error.

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Our Responsibility

Our responsibility is to express a limited assurance conclusion on the Historical Financial Information based on the procedures performed and evidence we have obtained. We have conducted our engagement in accordance with the Standard on Assurance Engagements ASAE 3450: "*Assurance Engagements involving Corporate Fundraisings and/ or Prospective Financial Information*".

A limited assurance engagement consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and review procedures. A limited assurance engagement is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain reasonable assurance that we would become aware of all significant matters that might be identified in a reasonable assurance engagement. Accordingly, we do not express an audit opinion.

Our engagement did not involve updating or reissuing any previously issued audit or review reports on any financial information used as a source of the Historical Financial Information.

We have performed the following procedures as we, in our professional judgement, considered reasonable in the circumstances:

- consideration of work papers, accounting records and other documents, including those dealing with the extraction of Historical Financial Information from the audited and reviewed consolidated financial statements of the Group covering the years ended 30 June 2019 and 30 June 2020 and six months ended 31 December 2020 including the six months ended 31 December 2019 comparative information;
- consideration of the appropriateness of the pro forma adjustments described in Section 4.7 of the Prospectus;
- enquiry of the Directors, management and others in relation to the Historical Financial Information;
- analytical procedures applied to the Historical Financial Information; and
- a review of the consistency of the application of the stated basis of preparation and adopted accounting policies as described in the Prospectus used in the preparation of the Historical Financial Information.

Our limited assurance engagement has not been carried out in accordance with auditing or other standards and practices generally accepted in any jurisdiction outside of Australia and accordingly should not be relied upon as if it had been carried out in accordance with those standards and practices.

We have assumed, and relied on representations from certain members of management of the Group, that all material information concerning the Historical Financial Information and historical operations of the Group has been disclosed to us and that the information provided to us for the purposes of our work is true, complete and accurate in all respects. We have no reason to believe that those representations are false.

Conclusion

Historical Financial Information

Based on our limited assurance engagement, which is not an audit, nothing has come to our attention which causes us to believe that:

The Historical Financial Information as set out in the Prospectus and comprising:

- the historical consolidated statement of consolidated profit or loss and other comprehensive income for FY2019, FY2020 and 1HY2021 with 1HY2020 comparative information;
- the historical consolidated statement of cash flows for FY2019, FY2020 and 1HY2021 with 1HY2020 comparative information;
- the historical consolidated statement of financial position as at 31 December 2020;
- the pro forma consolidated statement of financial position as at 31 December 2020; or
- the pro forma transactions set out in Section 4.7 of the Prospectus;

are not presented fairly, in all material aspects, in accordance with the stated basis of preparation described in Section 4.2 of the Prospectus.

Restriction on Use

Without modifying our conclusion, we draw your attention to Section 4.2 of the Prospectus which describes the purpose of the Historical Financial Information, being for inclusion in the Prospectus. As a result, this Independent Limited Assurance Report may not be suitable for use for another purpose.

Consent

Grant Thornton Corporate Finance Pty Limited has consented to the inclusion of this Independent Limited Assurance Report in the Prospectus in the form and context in which it is included.

Liability

The liability of Grant Thornton Corporate Finance Pty Limited is limited to the inclusion of this report in the Prospectus. Grant Thornton Corporate Finance makes no representation regarding, and has no liability for, any other statements or other material in, or omissions from the Prospectus.

Independence or Disclosure of Interest

Grant Thornton Corporate Finance does not have any pecuniary interests that could reasonably be regarded as being capable of affecting its ability to give an unbiased conclusion in this matter. Grant Thornton Corporate Finance will receive a professional fee for the preparation of this Independent Limited Assurance Report.

Yours sincerely

GRANT THORNTON CORPORATE FINANCE PTY LTD

Neil Cooke

Partner

#5390681v3

Grant Thornton Corporate Finance Pty Ltd
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383 Kent Street
Sydney NSW 2000
Locked Bag Q800
Queen Victoria Building NSW 1230

T +61 2 8297 2400

Appendix A (Financial Services Guide)

This Financial Services Guide is dated 16 July 2021.

1 About us

Grant Thornton Corporate Finance Pty Ltd (ABN 59 003 265 987 and Australian Financial Services Licence no 247140) ("Grant Thornton Corporate Finance") has been engaged by Clarity Pharmaceuticals Ltd and its controlled entities ("Clarity" or the "Group") to provide general financial product advice in the form of an Independent Limited Assurance Report (the "Report") in relation to the offer of fully paid ordinary shares in the Group (the "Offer"). This report is included in the prospectus dated on or about 16 July 2021 (the "Prospectus"). You have not engaged us directly but have been provided with a copy of the Report as a retail client because of your connection to the matters set out in the Report.

2 This Financial Services Guide

This Financial Services Guide (FSG) is designed to assist retail clients in their use of any general financial product advice contained in the report. This FSG contains information about Grant Thornton Corporate Finance generally, the financial services we are licensed to provide, the remuneration we may receive in connection with the preparation of the report, and how complaints against us will be dealt with.

3 Financial services we are licensed to provide

Our Australian financial services licence allows us to provide a broad range of services, including providing financial product advice in relation to various financial products such as securities and superannuation products and deal in a financial product by applying for, acquiring, varying or disposing of a financial product on behalf of another person in respect of securities and superannuation products.

4 General financial product advice

The report contains only general financial product advice. It was prepared without taking into account your personal objectives, financial situation or needs. You should consider your own objectives, financial situation and needs when assessing the suitability of the Report to your situation. You may wish to obtain personal financial product advice from the holder of an Australian Financial Services Licence to assist you in this assessment.

Grant Thornton Corporate Finance does not accept instructions from retail clients. Grant Thornton Corporate Finance provides no financial services directly to retail clients and receives no remuneration from retail clients for financial services. Grant Thornton Corporate Finance does not provide any personal financial product advice directly to retail investors nor does it provide market-related advice directly to retail investors.

5 Fees, commissions and other benefits we may receive

Grant Thornton Corporate Finance charges fees to produce reports, including the report. These fees are negotiated and agreed with the entity which engages Grant Thornton Corporate Finance to provide a report. Fees are charged on an hourly basis or as a fixed amount depending on the terms of the agreement with the person who engages us. In the preparation of this report, Grant Thornton Corporate Finance will receive from the Company a fee of $45,000 (plus GST), which is based on commercial rates plus reimbursement of out-of-pocket expenses.

Partners, Directors, employees or associates of Grant Thornton Corporate Finance, or its related bodies corporate, may receive dividends, salary or wages from Grant Thornton Australia Ltd. None of those persons or entities receive non-monetary benefits in respect of, or that is attributable to, the provision of the services described in this FSG.

6 Referrals

Grant Thornton Corporate Finance - including its Partners, Directors, employees, associates and related bodies corporate - does not pay commissions or provide any other benefits to any person for referring customers to us in connection with the reports that we are licenced to provide.

7 Associations with issuers of financial products

Grant Thornton Corporate Finance and its Partners, Directors, employees or associates and related bodies corporate may from time to time have associations or relationships with the issuers of financial products. For example, Grant Thornton Australia Ltd may be the auditor of, or provide financial services to the issuer of a financial product and Grant Thornton Corporate Finance may provide financial services to the issuer of a financial product in the ordinary course of its business.

In the context of the report, Grant Thornton Corporate Finance considers that there are no such associations or relationships which influence in any way the services described in this FSG.

8 Independence

Grant Thornton Corporate Finance is required to be independent of Clarity in order to provide this report. The following information in relation to the independence of Grant Thornton Corporate Finance is stated below.

"Grant Thornton Corporate Finance and its related entities do not have at the date of this report, and have not had within the previous two years, any shareholding in or other relationship with Clarity (and associated entities) that could reasonably be regarded as capable of affecting its ability to provide an unbiased opinion in relation to the Offer.

Grant Thornton Corporate Finance has no involvement with, or interest in the outcome of the Offer, other than the preparation of this report.

Grant Thornton Corporate Finance will receive a fee based on commercial rates for the preparation of this report. This fee is not contingent on the outcome of the Offer.

Grant Thornton Corporate Finance's out of pocket expenses in relation to the preparation of the report will be reimbursed. Grant Thornton Corporate Finance will receive no other benefit for the preparation of this report.

9 Complaints

Grant Thornton Corporate Finance has an internal complaint handling mechanism and is a member of the Australian Financial Complaints Authority (AFCA) (membership no. 11800). All complaints must be in writing and addressed to the Head of Corporate Finance at Grant Thornton Corporate Finance. We will endeavour to resolve all complaints within 30 days of receiving the complaint. If the complaint has not been satisfactorily dealt with, the complaint can be referred to AFCA who can be contacted at:

Australian Financial Complaints Authority

GPO Box 3
Melbourne, VIC 3001
Telephone: 1800 931 678

Email: info@afca.org.au

Grant Thornton Corporate Finance is only responsible for the report and FSG. Grant Thornton Corporate Finance will not respond in any way that might involve any provision of financial product advice to any retail investor.

10 Compensation arrangements

Grant Thornton Corporate Finance has professional indemnity insurance cover under its professional indemnity insurance policy. This policy meets the compensation arrangement requirements of section 912B of the Corporations Act, 2001.

11 Contact Details

Grant Thornton Corporate Finance can be contacted by sending a letter to the following address:

Head of Corporate Finance
Grant Thornton Corporate Finance Pty Ltd
Level 17, 383 Kent Street
Sydney, NSW, 2000

09

Intellectual Property Report

09 Intellectual Property Report

DAVIES COLLISON CAVE

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Via Email Only
mharris@claritypharmaceuticals.com

DCC Ref: 35276395

14 July 2021

Attention: Matthew Harris

Contact: Gavin Recchia
GRecchia@dcc.com

The Board of Directors
Clarity Pharmaceuticals Ltd ("**Clarity**")
National Innovation Centre
4 Cornwallis Street
Eveleigh NSW 2015

The Members (and their representatives) of the Due Diligence Committee established in connection with the proposed initial public offering and associated listing on the Australian Securities Exchange ("**DDC"**)
c/- Clarity Pharmaceuticals Ltd
National Innovation Centre
4 Cornwallis Street
Eveleigh NSW 2015

Dear Directors of Clarity and Members (and their affiliates) of the DDC,

Re: Clarity Pharmaceuticals Ltd - IP Report

Please find ***attached*** an Intellectual Property ("**IP**") Report on behalf of Clarity Pharmaceuticals Ltd ("**Clarity**").

This report has been prepared by Davies Collison Cave Pty Ltd ("**DCC**") for inclusion in a prospectus to be issued by Clarity in connection with its initial public offering and associated listing on the Australian Securities Exchange. DCC provides permission for the report to be used in the prospectus.

Yours sincerely,
DAVIES COLLISON CAVE PTY LTD

DR GAVIN RECCHIA
Principal
grecchia@dcc.com
Encl.

DR MATHEW LUCAS
Principal
mlucas@dcc.com

Intellectual Property Report – Clarity Pharmaceuticals Ltd
Prepared by Davies Collison Cave Pty Ltd

About Davies Collison Cave Pty Ltd (DCC)

DCC is one of Australia's leading intellectual property firms. It specialises in providing advice relating to protecting and enforcing intellectual property rights. DCC has over 200 professionals and staff working for the firm and can trace its history back more than 130 years, making it one of Australia's longest established IP firms.

The services provided by DCC cover aspects of IP including patents, registered designs, trade marks, copyright and plant breeders' rights, and is provided by attorneys possessing a diverse range of technical skills in areas including chemistry and materials, clean energy, engineering, physics and electronics, information technology, life sciences, pharmaceuticals, medical devices, nanotechnology and plant innovation.

Intellectual Property Overview

Intellectual property is a collective term used to refer to a number of different rights including patents, registered designs, trade marks, copyright and trade secrets. DCC is currently engaged to manage patent and trade mark related matters on behalf of Clarity, both of which are addressed in this report.

Patents

A patent is a legally enforceable and exclusive right to commercially exploit an invention for a defined period of time in a particular territory.

In Australia, where the invention is a product, exploitation includes making, hiring, selling or otherwise disposing of the product, or offering to make, sell, hire or otherwise dispose of the product, using or importing the product, or keeping the product for the purpose of doing any of those things. For a method or process, exploitation includes using the method or process or exploiting a product resulting from performing the method or process. Other countries have their own laws regarding the rights afforded by a granted patent, and advice should be sought on a country by country basis if further information is required.

A patent is granted for inventions that meet defined criteria. The laws of different countries generally have different criteria, and hence make their own assessment as to the patentability of an invention. In general, the requirements include that the claimed invention is novel, involves an inventive step and meets subject matter eligibility requirements.

Patent Application Process

In order to obtain patent protection, it is ultimately necessary for an application to be filed with a Patent Office in each country where protection is to be sought. However, international conventions exist that enable a patent application to be initially filed in a single country, with subsequent applications being filed individually in each country within a defined time limit.

For example, the Paris Convention provides a mechanism that allows patent applications to be filed to cover additional countries within 12 months of the date of lodging a first patent application. Thus, one or more provisional patent applications can be filed in a single country, and then subsequent applications can be filed covering other countries within 12 months of the earliest provisional patent application, using a process known as claiming priority.

The subsequent applications can be separate applications in each country of interest. Alternatively, a single International Patent Cooperation Treaty ("**PCT**") application can be filed covering a number of contracting states. The PCT application does not ultimately get granted as a patent, but rather allows the filing of national patent applications in individual countries to be deferred up to a set date, typically 30 months from the filing date of the first patent application, such as the first provisional patent application.

Once filed, the PCT application undergoes an assessment process, in which a designated patent office performs a search and issues an International Search Report and associated International Search Opinion, providing a preliminary view on whether the patent application meets novelty, inventive step and industrial applicability requirements. Responses to the International Search Opinion can be optionally filed during a subsequent examination process, before an International Preliminary Report on Patentability issues, providing an opinion of patentability.

It should be noted however that the outcome of this process is not binding and subsequent assessment is typically performed by patent offices in each country, after individual national patent applications have been filed. In this regard, each country will typically perform an independent search, and then assess whether the patent application meets the patentability requirements, additionally taking into account their own local law.

Whilst most countries require a local patent application to be filed, in some cases regional patent applications can be filed covering a group of individual countries. For example, a European patent application can be filed, which can allow subsequent patents to be granted in over 35 countries.

Assuming any objections are overcome, a patent can then be granted on the application allowing this to be subsequently enforced to prevent third parties exploiting the invention.

Trade Marks

Trade marks are names, words, logos, aspects of packaging, shapes, scents or combinations of these which distinguish goods or services dealt with or provided by one person from those of another. Like patents, registration of a trade mark in Australia is effected under Commonwealth legislation (*Trade Marks Act 1995*), but the registration is not subject to a maximum period. A trade mark registration continues indefinitely, subject to the requirement that the mark is renewed periodically and it is not successfully challenged by a third party.

A primary requirement for registration is that a trade mark must be capable of distinguishing the applicant's goods or services. Trade marks which are directly descriptive of the goods and services or which contain commonly used words such as "Super" or commonly used logos such as grapes for wine, may be difficult to register. However, if it can be shown that the trade mark has been used to such an extent that it does distinguish the goods or services of the applicant, registration may be obtained.

There is no statutory obligation to register a trade mark and mere use of an unregistered trade mark will in itself start to establish enforceable rights in the geographical area in which a reputation has been established. A major benefit of registration is that ownership of a mark is normally Country-wide and it is possible to prevent unauthorised use of the trade mark without having to first establish that a reputation exists. Registration therefore facilitates protection of rights cost-effectively. The prevention of unauthorised use of an unregistered trade mark is usually more difficult, expensive and less certain.

Trade Mark Application Process

To register a trade mark, the trade mark owner must apply to register the trade mark with the Trade Marks Office in each country where protection is to be sought, or with the European Union Trademarks Office in relation to a European Union trade mark (EUTM). This can either be achieved directly or, in many cases, through the Madrid Protocol International Registration System ("**Madrid System**"). This is a system that enables an application to be filed in one member country and which can designate several other countries. However even under the Madrid System the applications are still examined separately and independently by each country's national Trade Marks Office.

Once a trade mark application has been filed in any country it will be examined to ensure that it complies with the trade mark law of that country. Once it has been accepted for registration it will be advertised for opposition purposes and then proceed through to registration in that country, unless opposed.

Trade mark registrations are renewable and can effectively exist in perpetuity, so long as they are renewed as required.

Clarity Patent Portfolio

Details of the patents and patent applications in the name of, or we have been informed are licensed to, Clarity ("**the Patent Portfolio**") are provided in the Patent Schedule below. The Patent Portfolio includes 14 families of related patents and applications. DCC is managing patent families 1 to 3 and 5 and 14. Patent family 4 is managed by another IP firm.

The information has been prepared based on our records and on information supplied by Clarity and overseas IP firms and Patent Offices in relevant jurisdictions (and by the managing IP firm in the case of family 4). DCC cannot take responsibility for missing or erroneous data that is provided by others.

Family 1 – Formulations for radiotherapy and diagnostic imaging

This patent family derives from Australian provisional patent application, AU 2016904515, filed on 4 November 2016. PCT application PCT/AU2017/051205, claiming priority from the provisional application, was filed on 2 November 2017.

The abstract of the PCT application states that the invention relates to formulations of radiolabelled compounds that are of use in radiotherapy and diagnostic imaging.

Family 2 – Formulations and kits for radiotherapy and diagnostic imaging

This patent family derives from Australian provisional patent applications, AU 2018901195 and AU 2018901196, both filed on 11 April 2018. PCT application PCT/AU2019/050324, claiming priority from both provisional applications, was filed on 11 April 2019.

The abstract of the PCT application states that the invention relates to formulations and kits of compounds that are of use in radiotherapy and diagnostic imaging.

Family 3 – Nitrogen-containing macrocyclic conjugates as radiopharmaceuticals

This patent family derives from an Australian provisional patent application, AU 2008906239, filed on 2 December 2008. PCT application PCT/AU2009/001572, claiming priority from this provisional application, was filed on 2 December 2009.

The abstract of the PCT application states that the invention relates to compounds that are useful as metal ligands and which either contain a molecular recognition moiety or can be bound to a molecular recognition moiety and methods of making these compounds. The abstract also states that the invention relates to methods of diagnosis and therapy utilising compounds containing the molecular recognition moiety coordinated with a suitable metallic radionuclide.

Family 4 - Process for the preparation of asymmetrical bis(thiosemicarbazones)

This patent family derives from an Australian provisional patent application, AU 2008906411, filed 12 December 2008. PCT application PCT/AU2009/001612, claiming priority from this provisional application, was filed on 11 December 2009.

The abstract of the PCT application states that the invention relates to a method for making asymmetrical bis(thiosemicarbazones) and compounds useful as synthetic intermediates in the method. The abstract also states that the invention relates to bis(thiosemicarbazones) accessible by use of the method, and to methods of treatment and imaging using such bis(thiosemicarbazones).

Family 5 – Cage amine ligands for metallo-radiopharmaceuticals

This patent family derives from a US provisional patent application, US 61/567262, filed on 6 December 2011. PCT application PCT/AU2012/001484, claiming priority from this provisional application, was filed on 6 December 2012.

The abstract of the PCT application states that the invention relates to compounds useful as metal ligands and which can be bound to a biological entity such as a molecular recognition moiety. The invention also relates to methods of making such compounds. The abstract also states that the invention relates to methods of diagnosis and therapy utilising the radiolabelled compounds of the invention, since the compounds coordinated with a suitable metallic radionuclide bind to a biological entity and are therefore useful as radiopharmaceuticals in radiotherapy and diagnostic imaging.

Family 6 – Functionalisation of cage amine ligands for metallo-radiopharmaceuticals

This patent family derives from a US provisional patent application, US 61/567255, filed on 6 December 2011. PCT application PCT/AU2012/001483, claiming priority from this provisional application, was filed on 6 December 2012.

The abstract of the PCT application states that the invention relates to compounds useful as metal ligands and contain a moiety capable of binding to a biological entity. The invention also relates to methods of making such compounds. The abstract also states that such compounds are of interest as they can be bound to a biological entity and coordinated with a suitable metallic radionuclide, and are therefore useful as radiopharmaceuticals in radiotherapy and diagnostic imaging.

Family 7 – Radiopharmaceuticals, radioimaging agents and uses thereof

This patent family derives from Australian provisional patent application, AU 2017902151, filed on 6 June 2017. PCT application PCT/AU2018/050555, claiming priority from the provisional application, was filed on 5 June 2018.

The abstract of the PCT application states that the invention relates to compounds that are useful as radiopharmaceuticals and radioimaging agents which bear a radionuclide-chelating agent. The abstract also states that the invention also relates to methods of diagnosis, prognosis and therapy utilising the non-coordinated and radiolabelled compounds of the invention.

Family 8 – Targeting compounds and methods for their production

This patent family derives from Australian provisional patent application, AU 2018901197, filed on 11 April 2018. PCT application PCT/AU2019/050322 claiming priority from the provisional application, was filed on 11 April 2019.

The abstract of the PCT application states that the invention relates to targeting compounds and methods for their production.

Family 9 – Formulations of PSMA imaging agents

This patent family derives from Australian provisional application, AU 2019901765, filed on 24 May 2019. PCT application PCT/AU2020/050509 claiming priority from the provisional application, was filed on 22 May 2020.

The abstract of the PCT application states that the invention relates to formulations of radiolabelled compounds that are of use in radiotherapy and diagnostic imaging related to prostate specific membrane antigen (PSMA).

Family 10 – Cryptate compounds

This patent family derives from an Australian provisional patent application, AU 2011902708, filed on 7 July 2011. PCT application PCT/AU2012/000817, claiming priority from this provisional application, was filed on 6 July 2012.

The abstract of the PCT application states that the invention relates to methods for coupling a first compound of formula (I) with a second compound containing a carbonyl group. The invention also relates to compounds formed by the coupling of formula (I) with a carbonyl compound and uses of the compounds.

Family 11 – Radiolabelled targeting ligands

This patent family derives from Australian provisional patent applications, AU 2019904218, filed on 8 November 2019. PCT application PCT/AU2020/051209, claiming priority from both this provisional application, was filed on 6 November 2020.

The abstract of the PCT application states that the invention relates to compounds that are useful as radioimaging agents and radiopharmaceuticals. The compounds of the invention may be coordinated with a radionuclide and may be useful in diagnostic imaging and radiotherapy. The invention also relates to methods of prognosis and therapy utilising the non-coordinated and radiolabelled compounds of the invention.

Family 12 – Radiopharmaceuticals, uses thereof, and methods for the production thereof

This provisional application was filed on 14 August 2020. In order to claim priority from this provisional application, a complete application(s) is due to be filed by 14 August 2021.

Family 13 – Radiopharmaceuticals, methods for their production, and uses in diagnosis and imaging diseases

This provisional application was filed on 14 August 2020. In order to claim priority from this provisional application, a complete application(s) is due to be filed by 14 August 2021.

Family 14 – Cancer targeting compounds and methods for their production

This provisional application was filed on 29 September 2020. In order to claim priority from this provisional application, a complete application(s) is due to be filed by 29 September 2021.

Clarity Trade Mark Portfolio

Details of the trade marks and trade mark applications in the name of Clarity ("**the Trade Mark Portfolio**"), and for which DCC is responsible, are provided in the Trade Mark Schedule below.

CLARITY PHARMACEUTICALS PTY LTD
PATENT PORTFOLIO SCHEDULE
JULY 2021

FAMILY 1 – Formulations for radiotherapy and diagnostic imaging

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia	2017354941	2017354941	4 Nov 2016	2 Nov 2017	Patent granted
Brazil	112019009172.6		4 Nov 2016	2 Nov 2017	Application pending
Canada	3042737		4 Nov 2016	2 Nov 2017	Application pending
China	201780081459.0		4 Nov 2016	2 Nov 2017	Application pending
Europe	17867174.9		4 Nov 2016	2 Nov 2017	Application pending
Japan	2019-544941		4 Nov 2016	2 Nov 2017	Application pending
Korea	10-2019-7015869		4 Nov 2016	2 Nov 2017	Application pending
Russia	2019116385		4 Nov 2016	2 Nov 2017	Application pending
USA	17/164,338		4 Nov 2016	2 Nov 2017	Application pending

FAMILY 2 – Formulations and kits for radiotherapy and diagnostic imaging

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia	2019251769		11 Apr 2018	11 Apr 2019	Application pending
China	201980024880.7		11 Apr 2018	11 Apr 2019	Application pending
Europe	19784634.8		11 Apr 2018	11 Apr 2019	Application pending
USA	17/042,772		11 Apr 2018	11 Apr 2019	Application pending

FAMILY 3 - Nitrogen-containing macrocyclic conjugates as radiopharmaceuticals

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia[1]	2009322081	2009322081	02 Dec 2008	02 Dec 2009	Patent granted
Canada[1]	2745495	2745495	02 Dec 2008	02 Dec 2009	Patent granted
China[1]	200980156413.6	ZL200980156413.6	02 Dec 2008	02 Dec 2009	Patent granted
Europe	09829884.7	2370447	02 Dec 2008	02 Dec 2009	Patent granted
Austria		2370447	02 Dec 2008	02 Dec 2009	Validated
Belgium		2370447	02 Dec 2008	02 Dec 2009	Validated
France		2370447	02 Dec 2008	02 Dec 2009	Validated
Germany		2370447	02 Dec 2008	02 Dec 2009	Validated
Netherlands		2370447	02 Dec 2008	02 Dec 2009	Validated
Sweden		2370447	02 Dec 2008	02 Dec 2009	Validated
Switzerland		2370447	02 Dec 2008	02 Dec 2009	Validated
UK		2370447	02 Dec 2008	02 Dec 2009	Validated
Europe	16172324.2 (divisional of 09829884.7)	3098225	02 Dec 2008	02 Dec 2009	Patent granted
Austria		3098225	02 Dec 2008	02 Dec 2009	Validated
Belgium		3098225	02 Dec 2008	02 Dec 2009	Validated
Denmark		3098225	02 Dec 2008	02 Dec 2009	Validated
Finland		3098225	02 Dec 2008	02 Dec 2009	Validated
France		3098225	02 Dec 2008	02 Dec 2009	Validated
Germany		3098225	02 Dec 2008	02 Dec 2009	Validated
Italy		3098225	02 Dec 2008	02 Dec 2009	Validated
Netherlands		3098225	02 Dec 2008	02 Dec 2009	Validated
Norway		3098225	02 Dec 2008	02 Dec 2009	Validated

Spain		3098225	02 Dec 2008	02 Dec 2009	Validated
Sweden		3098225	02 Dec 2008	02 Dec 2009	Validated
Switzerland		3098225	02 Dec 2008	02 Dec 2009	Validated
UK		3098225	02 Dec 2008	02 Dec 2009	Validated
Japan	2015-022109	5981580	02 Dec 2008	02 Dec 2009	Patent granted
USA[1]	13/132,194	9,701,694	02 Dec 2008	02 Dec 2009	Patent granted
USA[1]	15/612,009 (continuation of US 13/132,194)	10,544,164	02 Dec 2008	02 Dec 2009	Patent granted
USA[1]	15/612,185 (continuation of US 13/132,194)	10,301,326	02 Dec 2008	02 Dec 2009	Patent granted
USA[1]	16/378,716 (divisional of US 15/612,185)	10,870,664	02 Dec 2008	02 Dec 2009	Patent granted
USA[1]	16/712,485 (continuation of US 15/612,009)		02 Dec 2008	02 Dec 2009	Application allowed

[1] Assignment from University of Melbourne recorded/registered at the relevant patent office

FAMILY 4 – Process for the preparation of asymmetrical bis(thiosemicarbazones)

Owner: The University of Melbourne

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia	2009326867	2009326867	12 Dec 2008	11 Dec 2009	Patent granted
Canada	2746070	2746070	12 Dec 2008	11 Dec 2009	Patent granted
China	200980156755.8	ZL 200980156755.8	12 Dec 2008	11 Dec 2009	Patent granted
Europe	09831324.0	2379493	12 Dec 2008	11 Dec 2009	Patent granted
France		2379493	12 Dec 2008	11 Dec 2009	Validated
Germany		2379493	12 Dec 2008	11 Dec 2009	Validated
UK		2379493	12 Dec 2008	11 Dec 2009	Validated
India	4843/CHENP/2011	293406	12 Dec 2008	11 Dec 2009	Patent granted
Japan	2011-539850	5711142	12 Dec 2008	11 Dec 2009	Patent granted

FAMILY 5 - Cage amine ligands for metallo-radiopharmaceuticals

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia[1]	2012350147	2012350147	6 Dec 2011	6 Dec 2012	Patent granted
Europe	12856044.8		6 Dec 2011	6 Dec 2012	Application pending
Japan	2014-545038	6047581	6 Dec 2011	6 Dec 2012	Patent granted
USA[1]	14/363,219	9,457,107	6 Dec 2011	6 Dec 2012	Patent granted
USA[1]	15/240,836 (divisional of 14/363,219)	9,861,714	6 Dec 2011	6 Dec 2012	Patent granted

[1] Assignment from University of Melbourne recorded/registered at the relevant patent office

FAMILY 6 - Functionalisation of cage amine ligands for metallo-radiopharmaceuticals

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia[1]	2012350146	2012350146	6 Dec 2011	6 Dec 2012	Patent granted
Europe	12856248.5	2788354	6 Dec 2011	6 Dec 2012	Patent granted
Austria		2788354	6 Dec 2011	6 Dec 2012	Validated
Belgium		2788354	6 Dec 2011	6 Dec 2012	Validated
Denmark		2788354	6 Dec 2011	6 Dec 2012	Validated
Finland		2788354	6 Dec 2011	6 Dec 2012	Validated
France		2788354	6 Dec 2011	6 Dec 2012	Validated
Germany		2788354	6 Dec 2011	6 Dec 2012	Validated
Ireland		2788354	6 Dec 2011	6 Dec 2012	Validated
Italy		2788354	6 Dec 2011	6 Dec 2012	Validated
Netherlands		2788354	6 Dec 2011	6 Dec 2012	Validated
Norway		2788354	6 Dec 2011	6 Dec 2012	Validated
Portugal		2788354	6 Dec 2011	6 Dec 2012	Validated
Spain		2788354	6 Dec 2011	6 Dec 2012	Validated
Sweden		2788354	6 Dec 2011	6 Dec 2012	Validated
Switzerland		2788354	6 Dec 2011	6 Dec 2012	Validated
UK		2788354	6 Dec 2011	6 Dec 2012	Validated
Japan	2014-545037	6051227	6 Dec 2011	6 Dec 2012	Patent granted
USA[1]	14/363,242	9,364,570	6 Dec 2011	6 Dec 2012	Patent granted

[1] Assignment from University of Melbourne recorded/registered at the relevant patent office

FAMILY 7 – Radiopharmaceuticals, radioimaging agents and uses thereof

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia[1]	2018280338		6 Jun 2017	5 Jun 2018	Application allowed
Brazil	112019025881.7		6 Jun 2017	5 Jun 2018	Application pending
Canada	3066525		6 Jun 2017	5 Jun 2018	Application pending
China	201880037177.5		6 Jun 2017	5 Jun 2018	Application pending
Europe	18813763.2		6 Jun 2017	5 Jun 2018	Application pending
India	201917049617		6 Jun 2017	5 Jun 2018	Application pending
Japan	2019-565549		6 Jun 2017	5 Jun 2018	Application pending
South Korea	10-2019-7035829		6 Jun 2017	5 Jun 2018	Application pending
Mexico	MX/a/2019/014758		6 Jun 2017	5 Jun 2018	Application pending
Malaysia	PI2019007250		6 Jun 2017	5 Jun 2018	Application pending
Russia[1]	2019144070		6 Jun 2017	5 Jun 2018	Application pending
Singapore[1]	11201910602V		6 Jun 2017	5 Jun 2018	Application pending
USA[1]	16/619,073	10,975,089	6 Jun 2017	5 Jun 2018	Patent granted
USA[1]	17/198,131 (continuation of 16/619,073)		6 Jun 2017	5 Jun 2018	Application pending

[1] Assignment from University of Melbourne recorded/registered at the relevant patent office

FAMILY 8 – Targeting compounds and methods for their production

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia[1]	2019251767		11 Apr 2018	11 Apr 2019	Application pending
China	201980024850.6		11 Apr 2018	11 Apr 2019	Application pending
Europe	19785497.9		11 Apr 2018	11 Apr 2019	Application pending
USA[1]	17/046,053		11 Apr 2018	11 Apr 2019	Application pending

[1] Assignment from University of Melbourne recorded/registered at the relevant patent office

FAMILY 9 – Formulations of PSMA imaging agents

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
PCT	PCT/AU2020/050509		24 May 2019	22 May 2020	Filed

FAMILY 10 - Cryptate compounds

Owner: Australian Nuclear Science & Technology Organisation & The Australian National University

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Europe	12807763.3	2729467	7 Jul 2011	6 Jul 2012	Patent granted
Austria		2729467	7 Jul 2011	6 Jul 2012	Validated
Belgium		2729467	7 Jul 2011	6 Jul 2012	Validated
France		2729467	7 Jul 2011	6 Jul 2012	Validated
Germany		2729467	7 Jul 2011	6 Jul 2012	Validated
Netherlands		2729467	7 Jul 2011	6 Jul 2012	Validated
Sweden		2729467	7 Jul 2011	6 Jul 2012	Validated
Switzerland		2729467	7 Jul 2011	6 Jul 2012	Validated
UK		2729467	7 Jul 2011	6 Jul 2012	Validated
Japan	2014-517341	6207504	7 Jul 2011	6 Jul 2012	Patent granted
Japan	2017-102471 (divisional of 2014-517341)	6789881	7 Jul 2011	6 Jul 2012	Patent granted
USA	14/129,855	10,717,741	7 Jul 2011	6 Jul 2012	Patent granted
USA	16/900,335 (continuation of 14/129,855)		7 Jul 2011	6 Jul 2012	Application pending
USA	16/900,451 (divisional of 14/129,855)		7 Jul 2011	6 Jul 2012	Application pending

FAMILY 11 – Radiolabelled targeting ligands

Owner: The University of Queensland and Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
PCT	PCT/AU2020/051209		8 Nov 2019	6 Nov 2020	Filed

FAMILY 12 - Radiopharmaceuticals, uses thereof, and methods for the production thereof

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia (provisional)	2020902889		14 Aug 2020		Filed

FAMILY 13 - Radiopharmaceuticals, methods for their production, and uses in diagnosis and imaging diseases

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia (provisional)	2020902901		14 Aug 2020		Filed

FAMILY 14 - Cancer targeting compounds and methods for their production

Owner: Clarity Pharmaceuticals Ltd

Jurisdiction	Application No.	Patent No.	Earliest Priority Date	Effective Filing Date	Status
Australia (provisional)	2020903514		29 Sep 2020		Filed

CLARITY PHARMACEUTICALS LTD
TRADE MARK PORTFOLIO SCHEDULE
JULY 2021

Country	Trade Mark	Official No.	Application Date	Renewal Date	Goods/Services	Status
Australia	PlateView	1697982	3 Jun 2015	3 Jun 2025	05: Pharmaceuticals and other preparations for medical and veterinary purposes	Registered
Australia	SarTate	1570316	23 Jul 2013	23 Jul 2023	05: Pharmaceuticals and other preparations for medical and veterinary purposes	Registered

Limitations and Reliance

Patent and Trade Mark Office Information
The above schedules have been prepared based on information supplied by patent and trade mark offices in relevant jurisdictions, either through official communications or through publication on official databases. We cannot take responsibility for missing or erroneous data that is provided by the patent and trade mark offices and as such DCC is not responsible for the accuracy of the information provided.

Scope of Patents
DCC can provide no assurance that any of the patent applications listed in the Patent Schedule will result in the grant of a patent, or that the scope of protection provided by any patent that is granted will be identical to the scope of the claims in an application as originally filed.

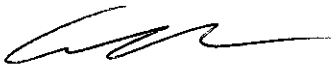
Validity of Patents
It is important to understand that granting of a patent is not a guarantee of validity and patents can be held subsequently unenforceable, for example during court proceedings or third party oppositions in some jurisdictions. DCC can provide no assurance as to the validity of the patent applications or any patent granted based thereon.

Commercial Activities
DCC can provide no assurance that any patents or patents granted on the patent applications listed in the Patent Schedule, even if valid, will cover the commercial activities of Clarity, or that exploitation of the inventions described and claimed in the patent applications listed in the Schedule, or any patents granted thereon, will not infringe any rights held by third parties. Similarly, DCC can provide no assurance that the trade marks listed in the Trade Mark Schedule will be applicable to the commercial activities of Clarity.

It is important to understand that granting of a patent provides a monopoly right to prevent exploitation of the invention by third parties, but provides no guarantee that the invention can be commercialised without infringing other third party rights. DCC can therefore provide no assurances as to Clarity's freedom to operate in respect to their commercial activities.

Patent Searches
Searches may be conducted in respect of patents or patent applications to ascertain their validity or to identify other third party patent rights. No search can provide completely comprehensive results and it is not possible to guarantee the accuracy of any such results, conducted by any parties, due to a range of limitations. DCC cannot therefore provide assurances as to the accuracy of any searches that may have been performed.

DAVIES COLLISON CAVE PTY LTD



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DR MATHEW LUCAS
Principal
mlucas@dcc.com

10 Additional Information

10 Additional Information

10.1. Registration

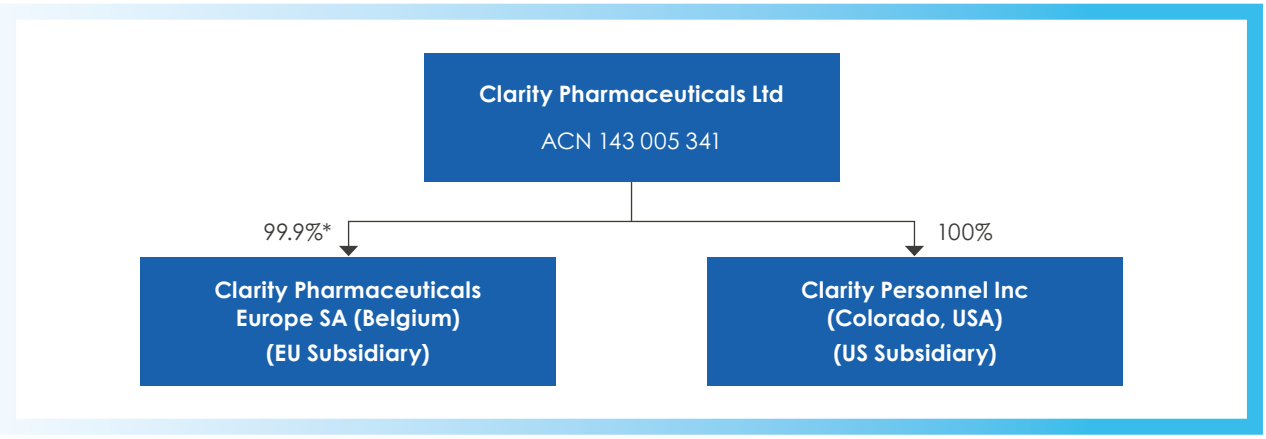
The Company was incorporated in New South Wales on 8 April 2010 as an Australian proprietary company limited by shares. It was converted to a public company limited by shares on 3 February 2017. The Company is the ultimate holding company of the Clarity Group.

10.2. Company tax status and financial year

The Company is and will be subject to tax at the Australian corporate tax rate on its taxable income. The Company's financial year for taxation purposes ends on 30 June. The Company is a standalone taxpayer and is not a member of an income tax consolidated group.

10.3. Corporate structure

The following diagram sets out the corporate structure of the Clarity Group as at the Prospectus Date:



* Dr Matthew Harris, Chief Scientific Officer of the Company, holds the remaining 0.1% of share capital in Clarity Pharmaceuticals Europe SA due to local legal requirements.

The EU Subsidiary was established to conduct some of the Clarity Group's early stage research and development activities. It is expected that the EU Subsidiary will be wound up in due course.

The US Subsidiary was only recently established in March 2021 and will be utilised to build out the Company's US team.

10.4. Escrow Arrangements

10.4.1. Mandatory Escrow

There are a number of Shares and Options that certain Existing Shareholders and Option holders of the Company will be mandatorily restricted from dealing in and/or disposing of (**Escrowed Securities**) as a result of the requirements of the ASX Listing Rules. These mandatory restrictions are expected to be imposed by the ASX based on the category of the security holder and date of issue of the relevant securities.

These mandatory restrictions are put into effect by a restriction deed (**Restriction Deed**) entered into by the Company with the relevant security holder or by a restriction notice (**Restriction Notice**) issued by the Company to the relevant security holder. Under the terms of the Restriction Deed or Restriction Notice, the relevant Shareholder or Option holder will be restricted, except as permitted by the ASX Listing Rules or ASX, from dealing with Escrowed Securities in a number of ways, including but not limited to:

- selling, assigning, transferring or otherwise disposing of the legal, beneficial or economic interest in the Escrowed Securities or agreeing or offering to do any of those things;

- creating or agreeing to create any security interest in the Escrowed Securities; or
- doing or omitting to do any act that would have the effect of transferring effective ownership or control of the Escrowed Securities.

ASX has not yet confirmed the final mandatory escrow position applicable to the Company's Shareholders and Option holders. Accordingly, the numbers below only set out the anticipated position. The number of Shares and Options that are subject to mandatory escrow is determined by ASX at its discretion in accordance with the ASX Listing Rules and underlying policy. The below numbers represent a good faith estimate of the Shares and Options that are expected to be made subject to mandatory escrow by ASX. The Company will announce to the ASX full details (including quantity and duration) of the Shares and Options that will be subject to mandatory escrow prior to the Shares commencing trading on ASX.

At the Completion of the Offer, it is expected, subject to ASX confirmation as detailed above, that a total of 89,559,154 Shares (representing approximately 34.97% of the Shares on issue at Completion[190]) will be mandatorily escrowed for varying periods with 76,680,986 of those Shares being escrowed for a period of 24 months from Listing (as further detailed below) representing approximately 29.94% of the Shares on issue at Completion[191]. It is also expected that 14,218,220 Options will be mandatorily escrowed (representing approximately 27.83% of all Options on issue at Completion[192]) for a period of 24 months from Listing. The remaining 12,878,168 Shares that are expected to be mandatorily escrowed will be released from escrow during the course of the initial six month period from Listing.

A summary of the expected mandatory escrow position is set out below:

Escrowed Shareholders	Indicative Number of Shares	Restriction Ends	As a % of total Shares on issue as at Completion
Mandatory Escrow			
Existing Shareholders who are related parties or promoters			
Board of Directors and their related parties	31,043,412	24 months from Listing	12.12%
Other related parties or promoters	44,170,914	24 months from Listing	17.25%
Existing Shareholders who are a professional adviser or consultant			
Various service providers and consultants	1,466,660	24 months from Listing	0.57%
Existing Shareholders who are not related parties or promoters			
Other Shareholders	6,265,585	29 September 2021	2.45%
Other Shareholders	6,612,583	15 December 2021	2.58%
Total Mandatory Escrowed Shares	**89,559,154 Shares**		**34.97**

Escrowed Option Holders	Indicative Number of Options	Restriction Ends	% of total Options on issue as at Completion
Mandatory Escrow			
Existing Option holders who are related parties or promoters			
Board of Directors and their related parties	10,300,000	24 months from Listing	20.16%
Other related party/promoter	300,000	24 months from Listing	0.59%
Existing Option holders who are a professional adviser or consultant			
Professional adviser	918,220	24 months from Listing	1.80%
Other Option holders	2,700,000	24 months from Listing	5.28%
Total Mandatory Escrowed Options	**14,218,220 Options**		**27.83%**

190. Assumes 256,132,546 Shares on issue as at Completion and no Options have been exercised.
191. Assumes 256,132,546 Shares on issue as at Completion and no Options have been exercised.
192. Assumes 51,088,812 Options on issue as at Completion and no Options have been exercised.

10.4.2. Voluntary Escrow

In addition to the mandatory escrow arrangements that will apply to certain of the Shares and Options (as detailed in Section 10.4.1 of this Prospectus) certain Existing Shareholders of the Company have also agreed to voluntarily escrow their Shares, and have entered into voluntary escrow deeds under which they have agreed to be restricted from dealing in a specified number of Shares held by them for a period of six months from Listing. A total of 65,796,554 Shares will be voluntarily escrowed under these arrangements (representing approximately 25.69% of the Shares on issue at Completion[193]). No Options will be voluntarily escrowed.

The following Existing Shareholders have agreed to be subject to voluntary escrow arrangements with respect to the following number of Shares with effect from Completion:

Escrowed Shareholders	Number of Shares	Restriction Ends	As a % of total Shares on issue as at Completion
Voluntary Escrow			
Board of Directors and their related parties	2,720,676	6 months from Listing	1.06%
Other related party/promoter	1,109,716	6 months from Listing	0.43%
Other Shareholders (not related parties or promoters)	61,966,162	6 months from Listing	24.19%
Total Voluntary Escrowed Shares	**65,796,554 Shares**		**25.69%**

10.4.3. Further restrictions on dealing

If during the relevant period of escrow (for either mandatory or voluntary escrow) (**Escrow Period**) the Company is subject to a takeover bid or enters into a merger by way of scheme of arrangement, the Shareholders and Option holders that are subject to escrow (**Escrowed Security Holders**) may deal in their Shares or Options that are escrowed (**Relevant Escrowed Securities**) to the extent that the dealing is:

- to accept a bona fide takeover bid in respect of all or a proportion of the Shares, provided the holders of at least half of the Shares that are not subject to escrow (or otherwise restricted securities), and to which the offers under the bid relate, have accepted an offer under the takeover bid; or
- in connection with the transfer or cancellation of the Relevant Escrowed Securities as part of a merger by way of a scheme of arrangement under Part 5.1 of the Corporations Act,

provided, in each case, that if for any reason any or all Relevant Escrowed Securities (that are subject to mandatory escrow) are not transferred or cancelled in accordance with such a takeover bid or scheme of arrangement (including because the takeover bid does not become unconditional), then the Relevant Escrowed Securities (that are subject to mandatory escrow) that are not acquired will remain subject to the relevant Restriction Deed or Restriction Notice.

10.4.4. Free float

The Company's 'free float' (being the percentage of Shares not subject to mandatory or voluntary escrow at the time of Listing) is expected to be approximately 39.35% of the Shares on issue at Completion (subject to ASX's decision on the mandatory escrow arrangements referred to above).

193. Assumes 256,132,546 Shares on issue as at Completion and no Options have been exercised.

10.5. Current capital structure

The issued capital of the Company at the Prospectus Date is set out below:

Share Capital	Securities
Shares	190,418,260
Options	51,088,812
Total diluted share capital	**241,507,072**

A breakdown of the Company's ownership structure and interests of Option holders on the Prospectus Date is set out in Section 7.1.4.

10.6. Capital structure following the Offer

The anticipated issued capital structure of the Company on Listing is set out in Section 7.1.4 and also summarised below:

Share Capital	Securities
Shares	256,132,546
Options	51,088,812
Total diluted share capital	**307,221,358**

A breakdown of the Company's anticipated ownership structure and interests of Option holders following Completion of the Offer is set out in Section 7.1.4.

10.7. Options currently on issue

10.7.1. Overview

The Company has issued various Options with different terms and exercise prices since its incorporation. None of these Options have been issued under the Equity Incentive Plan which will only take effect from Listing.

The Options have been issued to:

- Directors, employees and consultants of the Clarity Group under various employee option plans operated by the Company since its incorporation. There are currently 24,626,680 Options held by Directors, employees and consultants of the Clarity Group (**Company Options**). Details of the terms on which the Company Options have been issued are set out below. Details of all Company Options currently held by the Directors and the Proposed Director are set out in Section 6.4.2.6;
- a professional adviser to the Company (who is not a related party of the Clarity Group). There are currently 918,220 Options held by the professional adviser (**Adviser Options**). Details of the terms of the Adviser Options are set out below; and
- a strategic partner to the Company (who is not a related party of the Clarity Group). There are currently 25,543,912 Options held by China Grand (**China Grand Options**). Details of the terms of the China Grand Options are set out below.

A summary of the Options on issue as at the Prospectus Date is set out below:

Number of Options on Issue	Number of Vested Options	Exercise Price ($)	Latest Expiry date	Type of Options
7,266,680	6,933,360	0.22	1 July 2023	Company Options
4,700,000	3,900,000	0.605	1 December 2024	Company Options
7,100,000	0	0.825	18 December 2024	Company Options
5,560,000	3,893,320	0.9375	10 May 2026	Company Options
918,220	918,220	1.125	15 December 2023	Adviser Options
25,543,912	0	1.75	The six month anniversary of the date of the Company's Listing (further detail below)	China Grand Options

10.7.2. Company Options

The terms of the Company Options are varied as they have been issued under different option arrangements, but they generally provide that:

- the Company Options have varying vesting and expiry dates, however, the total that are exercisable at each exercise price, and the number of Company Options that have vested as at the Prospectus Date, are detailed in the table above;
- the Company Options were issued with time based vesting conditions (i.e. a certain percentage of the relevant Company Options vest on specified dates). The relevant Company Option holder must satisfy the relevant vesting condition for a Company Option before it can be exercised;
- in the event that the Company Option holder leaves the Company, any unvested Company Options are cancelled and are incapable of being exercised;
- the exercise price of the Company Options may be satisfied as follows:
  - payment of the relevant exercise price (which varies, as detailed above) multiplied by the number of Shares in respect of which the relevant Company Options are exercised; or
  - cashless exercise in the manner set out in Section 6.4.2.6;
- the Company Options do not carry rights to participate in any dividends (or any other return of capital) of the Company;
- in the event of a reorganisation of the issued capital of the Company the following terms apply:
  - in a consolidation of capital, the number of Company Options held by the Company Option holder will be consolidated in the same ratio and the exercise price will be amended in inverse proportion to the relevant ratio;
  - in a sub-division of capital, the number of Company Options held by the Company Option holder will be sub-divided in the same ratio and the exercise price will be amended in inverse proportion to the relevant ratio; and
  - in a return of capital, the number of Company Options held by the Company Option holder will remain the same, and the exercise price will be reduced by the same amount as the amount returned in relation to each Share;
- the Company Options may generally be assigned to an immediate family member without the consent of the Company, but otherwise the Company Options cannot be assigned without the prior written consent of the Company; and
- the Company Options will not be listed for quotation on the ASX or any other securities exchange.

All Company Options held by Directors as at the Prospectus Date are expected to be subject to mandatory escrow as further detailed in Section 10.4.1.

10.7.3. Adviser Options

The terms of the Adviser Options include:

- the Adviser Options were granted to Blue Ocean Equities Pty Limited on 15 December 2020 and expire on 15 December 2023;
- all of the Adviser Options have vested and are capable of being exercised;
- the exercise price of the Adviser Options may be satisfied as follows:
  - payment of the relevant exercise price (being $1.125) multiplied by the number of Shares in respect of which the Adviser Options are exercised; or
  - cashless exercise in the manner set out in Section 6.4.2.6;
- in the event of a reorganisation of the issued capital of the Company the following terms apply:
  - in a consolidation of capital, the number of Adviser Options held by the Adviser Option holder will be consolidated in the same ratio and the exercise price will be amended in inverse proportion to the relevant ratio;
  - in a sub-division of capital, the number of Adviser Options held by the Adviser Option holder will be sub-divided in the same ratio and the exercise price will be amended in inverse proportion to the relevant ratio; and
  - in a return of capital, the number of Adviser Options held by the Adviser Option holder will remain the same, and the exercise price will be reduced by the same amount as the amount returned in relation to each Share;
- the Adviser Options cannot be assigned without the prior written consent of the Company;
- the Adviser Options will not be listed for quotation on the ASX or any other securities exchange;
- the Adviser Options do not carry rights to participate in any dividends (or any other return of capital) of the Company; and
- all of the Adviser Options are expected to be subject to mandatory escrow as further detailed in Section 10.4.1.

10.7.4. China Grand Options

The Company and China Grand have agreed to enter into discussions, on an exclusive basis, regarding a proposal for the Company to grant China Grand a licence of the right to develop, manufacture and commercialise one or more of the Company's products in the Greater China territory (being Mainland China, Hong Kong (SAR), Macau (SAR) and Taiwan) on terms to be agreed. As at the Prospectus Date, a licence agreement has not been entered into by the parties and there can be no guarantee that an agreement will be entered into. In connection with these discussions, the Company and China Grand entered into an option deed on 1 July 2021 pursuant to which the Company granted the China Grand Options to China Grand.

The material terms of the China Grand Options (in summary) as set out in the option deed include:

- the China Grand Options will expire on the earlier of: (i) 5.00pm (Sydney time) on the date that is the six month anniversary of the date of the Company's admission to the Official List; (ii) 5.00pm (Sydney time) on 1 March 2022, if the Company is not admitted to the Official List by that date; (iii) 5.00pm (Sydney time) on the fifth business day after the occurrence of a 'Change of Control Event' (as defined in the option deed) or a date determined by the Board where it expects a 'Change of Control Event' to occur; and (iv) either the Company or China Grand suffering an 'Insolvency Event' (as defined in the option deed), unless otherwise determined by the Board (**China Grand Options Expiry Date**);
- as a result of a share split that was approved by Shareholders prior to the Prospectus Date, a total of 25,543,912 Options have been issued to China Grand which are exercisable into 25,543,912 Shares (but they are only exercisable if the vesting condition set out below has been satisfied). If all of the China Grand Options were to be validly exercised, the Shares issued to China Grand would equate to approximately 8.31% of the Company's issued share capital on a fully diluted basis immediately after Completion (i.e. assuming all Options on issue at Completion including the China Grand Options were exercised);

- the China Grand Options will only vest upon both of the following conditions being satisfied on or before the China Grand Options Expiry Date (the vesting condition): (i) the Company is admitted to the Official List and its Shares are quoted on ASX; and (ii) the Company and China Grand validly execute a binding licence agreement on terms that are acceptable to both parties. If the China Grand Options do not vest or are not exercised (if they have vested) on or prior to the China Grand Options Expiry Date, then they will immediately lapse and not be capable of exercise;
- each vested China Grand Option may only be exercised by China Grand making payment of the relevant exercise price to the Company (which is $1.75 per China Grand Option);
- China Grand is permitted to exercise the China Grand Options that have vested in whole or in part provided that (i) the first number of vested China Grand Options exercised by China Grand must be equal to at least 50% of the total number of China Grand Options that have vested; and (ii) any subsequent exercise of the China Grand Options that have vested must be in at least multiples of 1,000,000 unless all of the remaining unexercised vested China Grand Options are being exercised under the relevant exercise notice;
- in the event of a reorganisation of the issued capital (including consolidation, subdivision, reduction or return), the China Grand Options will be adjusted to the extent necessary to comply with the Corporations Act and the ASX Listing Rules applying to a reorganisation of capital at the time of the reorganisation;
- if, at any time after the issue of the China Grand Options, there is a pro rata issue of Shares to all holders of Shares for which no consideration is payable, then the number of China Grand Options will be increased by the same proportion as if the China Grand Options were Shares;
- the China Grand Options cannot be assigned or transferred without the prior written consent of the Company;
- the China Grand Options do not carry rights to participate in any dividends (or any other return of capital) of the Company; and
- depending on the date on which the China Grand Options are exercised, Corporations Act or ASX resale restrictions may apply to the sale or transfer of any of the Shares that are issued on exercise of the China Grand Options. In the event that there are no Corporations Act or ASX restrictions that apply, then any Shares issued to China Grand upon the exercise of vested China Grand Options are likely to be freely tradable (subject to the Company being able to issue a notice for the purposes of section 708A(5)(e) of the Corporations Act in respect of those Shares).

In consideration for services provided to the Company in connection with the grant of the China Grand Options, the Joint Lead Managers will be entitled to be paid a capital raising fee that is equal to 5% of the total gross proceeds received by Company as a result of China Grand validly exercising any vested China Grand Options. The total gross proceeds amount is the amount determined by multiplying the number of vested China Grand Options validly exercised by the exercise price of each of those vested China Grand Options.

10.8. Substantial Shareholders

The following Shareholders have a 'substantial holding' (as that term is defined in the Corporations Act) in the Company at the Prospectus Date:

SHAREHOLDER	Shares held	Direct Interest	Relevant Interest
TM Ventures Pty Ltd[i]	18,788,460	9.87%	13.97%
Cabbit Pty Ltd ATF Robwill Trust	17,911,280	9.41%	9.41%
A.C.N. 136 437 913 Pty Ltd ATF Taylor Family Trust[ii]	13,266,660	6.97%	7.39%
Charles Morgan[iii]	12,330,220	6.48%	16.34%
GenesisCare Ventures Pty Ltd	10,362,700	5.44%	5.44%
Boorris Pty Ltd ATF Boorris Trust[iv]	7,815,800	4.10%	13.97%

(i) TM Ventures Pty Ltd holds a direct interest in 18,788,460 Shares as at the Prospectus Date (representing 9.87% of the Shares on issue as at the Prospectus Date). In addition to this direct holding, TM Ventures Pty Ltd is taken to have a relevant interest in the Shares held by Boorris Pty Ltd ATF Boorris Trust, thereby taking its total relevant interest to 13.97% of the Shares on issue as at the Prospectus Date. Dr Harris, current Chief Scientific Officer of the Company and former CEO, is a director and shareholder of TM Ventures Pty Ltd.

(ii) A.C.N. 136 437 913 Pty Ltd ATF Taylor Family Trust holds a direct interest in 13,266,660 Shares as at the Prospectus Date (representing 6.97% of the Shares on issue as at the Prospectus Date). In addition to this direct holding, A.C.N. 136 437 913 Pty Ltd ATF Taylor Family Trust is taken to have a relevant interest in certain Shares held by a family member of Dr Alan Taylor, thereby taking its total relevant interest to 7.39% of the Shares on issue as at the Prospectus Date.

(iii) Charles Morgan holds a direct interest in 12,330,220 Shares as at the Prospectus Date (representing 6.48% of the Shares on issue as at the Prospectus Date). In addition to his direct holding, Mr Morgan is taken to have a relevant interest in the Shares held by TM Ventures Pty Ltd, thereby taking his total relevant interest to 16.34% of the Shares on issue as at the Prospectus Date. Mr Morgan is a shareholder of TM Ventures Pty Ltd.

(iv) Boorris Pty Ltd ATF Boorris Trust holds a direct interest in 7,815,800 Shares as at the Prospectus Date (representing 4.10% of the Shares on issue as at the Prospectus Date). In addition to this direct holding, Boorris Pty Ltd as trustee for the Boorris Trust is taken to have a relevant interest in the Shares held by TM Ventures Pty Ltd, thereby taking its total relevant interest to 13.97% of the Shares on issue as at the Prospectus Date. Boorris Pty Ltd ATF Boorris Trust also holds 300,000 Options as at the Prospectus Date. Dr Harris, current Chief Scientific Officer of the Company and former CEO, is a director and shareholder of TM Ventures Pty Ltd. Dr Harris is also a director of Boorris Pty Ltd ATF Boorris Trust and a beneficiary under that trust.

It is expected that the following Shareholders will have a 'substantial holding' (as that term is defined in the Corporations Act) in the Company following Completion[194]:

SHAREHOLDER	Shares held	Direct Interest	Relevant Interest
TM Ventures Pty Ltd[i]	18,788,460	7.34%	10.39%
Cabbit Pty Ltd ATF Robwill Trust	17,911,280	6.99%	6.99%
A.C.N. 136 437 913 Pty Ltd ATF Taylor Family Trust[ii]	13,266,660	5.18%	5.49%
Charles Morgan[iii]	12,330,220	4.81%	12.15%
Boorris Pty Ltd ATF Boorris Trust[iv]	7,815,800	3.05%	10.39%

(i) It is expected that TM Ventures Pty Ltd will hold a direct interest in 18,788,460 Shares at Completion (representing 7.34% of the Shares on issue at Completion). In addition to this direct holding, TM Ventures Pty Ltd will have a relevant interest in the Shares expected to be held by Boorris Pty Ltd ATF Boorris Trust at Completion, thereby taking its total relevant interest to 10.39% of the Shares on issue at Completion. Dr Harris, current Chief Scientific Officer of the Company and former CEO, is a director and shareholder of TM Ventures Pty Ltd.

(ii) It is expected that A.C.N. 136 437 913 Pty Ltd ATF Taylor Family Trust will hold a direct interest in 13,266,660 Shares at Completion (representing 5.18% of the Shares on issue at Completion). In addition to this direct holding, A.C.N. 136 437 913 Pty Ltd ATF Taylor Family Trust will have a relevant interest in certain Shares expected to be held by a family member of Dr Alan Taylor at Completion, thereby taking its total relevant interest to 5.49% of the Shares on issue at Completion.

(iii) It is expected that Charles Morgan will hold a direct interest in 12,330,220 Shares at Completion (representing 4.81% of the Shares on issue at Completion). In addition to his direct holding, Mr Morgan will have a relevant interest in the Shares expected to be held by TM Ventures Pty Ltd at Completion, thereby taking his total relevant interest to 12.15% of the Shares on issue at Completion. Mr Morgan is a shareholder of TM Ventures Pty Ltd.

(iv) It is expected that Boorris Pty Ltd ATF Boorris Trust will hold a direct interest in 7,815,800 Shares at Completion (representing 3.05% of the Shares on issue at Completion). In addition to this direct holding, Boorris Pty Ltd as trustee for the Boorris Trust will have a relevant interest in the Shares expected to be held by TM Ventures Pty Ltd at Completion, thereby taking its total relevant interest to 10.39% of the Shares on issue at Completion. Boorris Pty Ltd ATF Boorris Trust is also expected to hold 300,000 Options at Completion. Dr Harris, current Chief Scientific Officer of the Company and former CEO, is a director and shareholder of TM Ventures Pty Ltd. Dr Harris is also a director of Boorris Pty Ltd ATF Boorris Trust and a beneficiary under that trust.

10.9. Control implications of the Offer

As also detailed in Section 7.1.5, the Directors do not expect any Shareholder to "control" the Company on Completion (as defined in Section 50AA of the Corporations Act).

10.10. Rights and liabilities attaching to shares and other material provisions of the constitution

10.10.1. Introduction

The rights and liabilities attaching to the ownership of Shares are:

- detailed in the Constitution, which may be inspected during normal business hours at the registered office of the Company; and
- regulated (as applicable) by the Corporations Act, the ASX Listing Rules, the ASX Settlement Operating Rules and the general law.

194. This does not include Shares (if any) that the relevant shareholder may acquire as part of the Offer.

A summary of the significant rights, liabilities and obligations attaching to the Shares and a description of other material provisions of the Constitution is set out below. This summary relates to the Constitution that will come into effect on Completion and 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.

All Shares issued pursuant to this Prospectus will, from the time they are issued, rank equally with all existing Shares.

10.10.2. Voting at a general meeting

At a general meeting of the Company, every Shareholder present in person or by proxy, representative or attorney or who has cast a direct vote that is entitled to vote (including each holder of a preference share who has a right to vote) has one vote on a show of hands and, on a poll, one vote for each fully paid Share held by that Shareholder and a fraction of a vote for each partly paid Share, equivalent to the proportion which the amount paid (not credited) is of the total amounts paid and payable (excluding amounts credited) for that Share (or, where applicable, a fraction of a Share), ignoring any amounts paid in advance of a call.

A Shareholder is not entitled to vote at a general meeting of the Company in respect of a Share held by that Shareholder unless all calls and other sums payable by the Shareholder in respect of the Share have been paid. In addition, where a breach of the ASX Listing Rules relating to restricted securities continues or while a breach subsists of a restriction agreement entered into by the Company under the ASX Listing Rules or while a breach subsists of the Constitution in relation to Shares which are restricted securities, the restricted securities do not confer on the Shareholder any voting rights.

If a Share is held jointly, only one of the joint holders may vote (if entitled to vote in respect of that Share). If more than one of the joint holders tenders a vote, the vote of the holder whose name in respect of those Shares appears first in the register is to be treated as the only vote in relation to those Shares.

If the votes are equally divided on a show of hands or a poll, the chairperson of the meeting does not have a casting vote in addition to any votes to which the chairperson may be entitled as a Shareholder, proxy, attorney or representative. If the vote is tied, the resolution is not passed.

10.10.3. Meetings of members

Each Shareholder is entitled to receive written notice of general meetings of the Company and to receive all notices, accounts and other documents required to be sent to Shareholders under the Constitution, the Corporations Act and the ASX Listing Rules.

10.10.4. Dividends

Subject to the Corporations Act, the ASX Listing Rules and the rights of any person entitled to Shares with preferential, special or qualified rights to dividends, the Directors may determine to pay a dividend (including an interim dividend) and fix the amount, the time for payment and the method of payment. No dividends are expected to be paid in at least the near term following the Company's Listing.

10.10.5. Transfer of Shares

Subject to the Constitution, the Corporations Act, the ASX Listing Rules and the ASX Settlement Operating Rules, a Shareholder may transfer all or any Shares by completing:

- a written transfer document (duly stamped if necessary), in a common form, signed by or on behalf of the Shareholder and the transferee; or
- a form approved by the Directors and permitted by the Corporations Act signed by or on behalf of the Shareholder and the transferee.

The Board may refuse to register a transfer of Shares where it is permitted to do so under the Corporations Act, the ASX Listing Rules or the ASX Settlement Operating Rules. The Board must refuse to register a transfer of Shares when required by the Corporations Act, the ASX Listing Rules or the ASX Settlement Operating Rules.

10.10.6. Issue of further Shares

Subject to the Constitution, the Corporations Act and the ASX Listing Rules, the Directors may issue, allot, cancel or grant options for, or otherwise dispose of, Shares on such terms and conditions and to such persons as the Directors decide.

10.10.7. Winding up

If the Company is wound up, any assets available for distribution to Shareholders will, subject to the rights of the holders of Shares issued on special terms and conditions, the Constitution, the Corporations Act and the ASX Listing Rules, be distributed amongst the Shareholders to return capital paid up on their Shares and any surplus will be distributed in proportion to the amount paid up (not credited) on Shares held by them.

10.10.8. Sale of non-marketable parcels

Subject to the Constitution, 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 Shares.

10.10.9. Share buy-backs

The Company may, in accordance with the Corporations Act and the ASX Listing Rules, buy back its own shares on any terms and conditions as determined by the Directors.

10.10.10. Proportional takeover provisions

The Constitution contains provisions for Shareholder approval to be required in relation to any proportional takeover bid.

These provisions will cease to apply unless renewed by special resolution of the Shareholders in general meeting by the third anniversary of the date of the Constitution's adoption.

10.10.11. Variation of class rights

At present, the Company's only class of shares on issue is ordinary shares. Subject to the Corporations Act and the terms of issue of a class of shares, the rights attaching to any class of shares may be varied or cancelled:

- 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.

10.10.12. Dividend reinvestment plan

The Constitution allows the Directors, on any terms and at their discretion, to establish a dividend reinvestment plan (under which any Shareholder may elect that the dividends payable by the Company be reinvested by a subscription for securities in the Company).

10.10.13. Directors – appointment and removal

In accordance with the Constitution, the Company must have at least three Directors and not more than the number determined by the Directors from time to time, which until otherwise determined by the Directors is nine.

Directors are elected by resolution of the Shareholders of the Company. The Directors of the Company may also at any time appoint a person to be a Director, either to fill a casual vacancy or as an addition to the existing number of Directors provided that the total number of Directors must not at any time exceed the number of Directors fixed by or under the Constitution. Any Director (except the managing Director) appointed by the Directors of the Company after the Company is listed on the ASX must retire from office at, and will be eligible for re-election at, the next annual general meeting of the Company following the Director's appointment.

A Director must not hold office without re-election following the third annual general meeting after the Director's appointment or last re-election or for more than three years, whichever is the longest. However, this requirement

only applies with effect from the Company's Listing and, accordingly, in the case of a Director appointed prior to the Company's Listing, the Director must not hold office (without re-election) past the third annual general meeting following the Company's Listing or three years following the Company's Listing, whichever is longer.

At least one Director must stand for election or re-election at each annual general meeting. If no Director is standing for election or re-election or is required to retire at an annual general meeting, then the Director who has been longest in office since that Director's last election must retire from office at that annual general meeting.

10.10.14. Directors – voting

Questions arising at a meeting of the Board will be decided by a majority of votes cast by Directors present and entitled to vote at a meeting at which a quorum is present. At a meeting of Directors, the number of Directors whose presence is necessary to constitute a quorum is three unless another number is determined by the Directors. If an equal number of votes are cast for and against a resolution, the chairperson does not have a casting vote in addition to the chairperson's vote as a Director and the resolution is not passed.

10.10.15. Directors remuneration

See Section 6.4.2 of this Prospectus for a description of the remuneration arrangements for Directors.

10.10.16. Indemnity and insurance

The Company, to the extent permitted by law, indemnifies officers including the Directors and Secretary of the Company, against any liability incurred by that person as an officer, Director or Secretary of the Company, and legal costs incurred by that person in defending an action for a liability of that person. The Company, to the extent permitted by law, may make a payment (whether by way of advance, loan or otherwise) for any legal costs incurred by that person in defending an action for a liability of that person.

The Company has entered into deeds of access, insurance and indemnity with each Director and the Proposed Director. These are summarised in Section 6.4.2.4 of this Prospectus.

10.10.17. Variation of the Constitution

The Constitution can only be amended by special resolution passed by at least 75% of the votes cast by Shareholders (whether by direct vote or by being present (in person or by proxy) at the general meeting) entitled to vote on the resolution at a general meeting of the Company.

10.11. Material contracts

The Directors consider that the material contracts described below are those which an investor would reasonably regard as material and which investors and their professional advisers would reasonably expect to find described in this Prospectus for the purpose of making an informed assessment of an investment in the Company under the Offer.

This Section 10.11 contains a summary of the material contracts and their substantive terms which are not otherwise disclosed elsewhere in the Prospectus.

10.11.1. Underwriting Agreement

The Offer is fully underwritten by the Joint Lead Managers pursuant to an underwriting agreement dated 16 July 2021 (**Underwriting Agreement**) between the Company and the Joint Lead Managers. Under the Underwriting Agreement, the Joint Lead Managers have agreed to arrange, manage and underwrite the Offer on an exclusive basis. The material terms of the Underwriting Agreement are as follows:

- (**Fees, costs and expenses**) the Company must pay to the Joint Lead Managers in accordance with the Underwriting Agreement:
  - an underwriting fee equal to 4.0%; and
  - a management and selling fee equal to 1.0%,

  of the Offer proceeds.

The Company may, in its absolute and unfettered discretion, pay to the Joint Lead Managers an aggregate incentive fee of up to 1.0% of the Offer proceeds.

In addition to the fees described above, the Company must reimburse the Joint Lead Managers for certain agreed costs and expenses incurred by the Joint Lead Managers in relation to the Offer.

The Joint Lead Managers must pay, on behalf of the Company, any commissions and fees payable to any co-lead managers, co-managers and brokers appointed by the Joint Lead Managers in relation to the Offer.

- (**termination events not subject to materiality**) a Joint Lead Manager may, at any time after the date of the Underwriting Agreement until 4.00pm on the Settlement date (or at any other time as specified in the Underwriting Agreement), terminate the Underwriting Agreement without cost or liability by notice to the Company and the other Joint Lead Manager if any of the following events occur:
  - (**disclosures**) a statement in any of the Offer documents or public information is or becomes misleading or deceptive or is likely to mislead or deceive, or a matter required to be included is omitted from an Offer document;
  - (**new circumstances**) there occurs a new circumstance that arises after this Prospectus is lodged with ASIC that would have been required to be included in this Prospectus if it had arisen before lodgement;
  - (**supplementary Prospectus**) the Company issues or, in the reasonable opinion of the terminating Joint Lead Manager, is required under section 719 of the Corporations Act to lodge a supplementary Prospectus with ASIC; or lodges a supplementary Prospectus with ASIC in a form and substance that has not been approved by the Joint Lead Managers in circumstances required by the Underwriting Agreement;
  - (**market fall**) at any time the S&P/ASX 200 Index falls to a level that is 90% or less of the level as at the close of trading on the last trading day before the date of the close of the bookbuild conducted by the Joint Lead Managers;
  - (**mandatory escrow deed**) any mandatory escrow deed is withdrawn, varied, terminated, rescinded, altered, amended or breached or failed to be complied with except as required by any applicable law, ASX, a court or any governmental agency;
  - (**voluntary escrow deed**) any voluntary escrow deed is withdrawn, varied, terminated, rescinded, altered, amended or breached or failed to be complied with except as required by any applicable law, ASX, a court or any governmental agency or with the consent of the Joint Lead Managers;
  - (**future matters**) in the reasonable opinion of the terminating Joint Lead Manager, there are not, or there ceases to be, reasonable grounds for any statement or estimate in the Offer documents which relate to a future matter;
  - (**fraud**) the Company, a Clarity Group member, or any of their respective directors or officers engage, or have engaged since the date of the Underwriting Agreement, in any fraudulent conduct or activity whether or not in connection with the Offer;
  - (**listing and quotation**) approval is refused or not granted, or approval is granted subject to conditions other than customary conditions, to: the Company's admission to the Official List on or before the listing approval date agreed with the Joint Lead Managers; or the quotation of all of the Shares, including the Shares the subject of the Offer, on ASX or for the Shares, including the Shares the subject of the Offer, 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 conditions reasonably satisfactory to the Joint Lead Managers) or withheld;
  - (**ASIC**) any of the following notifications are made in respect of the Offer:

    (i) ASIC issues an order (including an interim order) under section 739 of the Corporations Act;

    (ii) ASIC holds a hearing under section 739(2) of the Corporations Act; or

    (iii) an application is made by ASIC for an order under Part 9.5 of the Corporations Act in relation to the Offer or an Offer document or ASIC commences any investigation or hearing under Part 3 of the ASIC Act in relation to the Offer or an Offer document,

    and any such order, application, investigation or hearing either: becomes public; or is not withdrawn within two business days after it is made or commenced or, where it is made or commenced less than two business days before the Settlement date, it has not been withdrawn before the Settlement date;

- (**notifications**) any person (other than the Joint Lead Managers) who has previously consented to the inclusion of its name in any Offer document withdraws that consent; or any person (other than the Joint Lead Managers) gives a notice under section 730 of the Corporations Act in relation to this Prospectus;
- (**certificate not provided**) the Company does not provide a closing certificate as and when required by the Underwriting Agreement;
- (**material contracts**) if any of the obligations of the relevant parties under any of the contracts that are material to the business of the Clarity Group or any of the material contracts are not capable of being performed in accordance with their terms (in the reasonable opinion of the terminating Joint Lead Manager) or if all or any part of any of such contracts:

  (i) is amended or varied without the prior written consent of the Joint Lead Managers;

  (ii) is terminated;

  (iii) is breached in a material respect;

  (iv) ceases to have effect, otherwise than in accordance with its terms; or

  (v) is or becomes void, voidable, illegal, invalid or unenforceable (other than by reason only of a party waiving any of its rights) or its performance is or becomes illegal;
- (**withdrawal**) the Company withdraws an Offer document or the Offer or indicates that it does not intend to proceed with the Offer or any part of the Offer;
- (**insolvency events**) any Clarity Group member becomes insolvent, or there is an act or omission which is likely to result in a Clarity Group member becoming insolvent;
- (**timetable**) an event specified in the timetable included in the Underwriting Agreement up to and including the Settlement date is delayed by more than two business days (other than a delay agreed to between the parties);
- (**unable to issue new Shares**) the Company is prevented from allotting and issuing (as applicable) the Shares the subject of the Offer within the time required by the timetable, the Offer documents, the ASX Listing Rules, by applicable laws, an order of a court of competent jurisdiction or a governmental authority;
- (**change to Company**) the Company: alters the issued capital of the Company or a Clarity Group member (other than pursuant to an employee share or option plan or other issue or option described in this Prospectus); or disposes or attempts to dispose of a substantial part of the business or property of the Company or a Clarity Group member, without the prior written consent of the Joint Lead Managers;
- (**regulatory approvals**) if a regulatory body withdraws or revokes; or amends in a material respect, any regulatory approvals required for the Company to perform its obligations under the Underwriting Agreement or to carry out the transactions contemplated by the Offer documents;
- (**force majeure**) 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 the Underwriting Agreement, or to market, promote or settle the Offer;
- (**change in Chairperson or management**) a change occurs in the Chairperson or Managing Director and Chief Executive Officer of the Company or either of them dies or becomes permanently incapacitated;
- (**regulatory enquiry or action**) any regulatory body commences any enquiry or public action against a Clarity Group member;
- (**constitution**) the Company varies any term of its constitution without the prior written consent of the Joint Lead Managers; and
- (**prosecution)** any of the following occur: a director or proposed director or member of senior management of the Company named in this Prospectus is charged with an indictable offence; any governmental agency commences any public action against the Company or any of its directors or senior managers in their capacity as a director or senior manager of the Company, or announces that it intends to take action; or any director or proposed director of the Company named in this Prospectus is disqualified from managing a corporation under Part 2D.6 of the Corporations Act;

- (**termination events subject to materiality**) a Joint Lead Manager may, at any time after the date of the Underwriting Agreement until 4.00pm on the Settlement date (or at any other time as specified in the Underwriting Agreement), terminate the Underwriting Agreement without cost or liability by notice to the Company and the other Joint Lead Manager if any of the following events occur and the Joint Lead Manager has reasonable grounds to believe that the event:
  - » has or is likely to have a materially adverse effect on: the success, settlement, outcome or marketing of the Offer or on the ability of the Joint Lead Manager to market or promote or settle the Offer or on the likely price at which the Shares the subject of the Offer will trade on ASX; or the willingness of investors to subscribe for the Shares the subject of the Offer; or
  - » will, or is likely to, give rise to a liability of the Joint Lead Manager under, or give rise to, or result in, a contravention by the Joint Lead Manager or its affiliates or the Joint Lead Manager or its affiliates being involved in a contravention of, any applicable law:
  - (**change in directors**) a change occurs in the directors of the Company (other than the Chairperson), or a director of the Company (other than the Chairperson) dies or becomes permanently incapacitated;
  - (**disclosures in the due diligence report and any other information**) the due diligence report or verification material or any other information supplied by or on behalf of the Company to the Joint Lead Managers is (or is likely to), or becomes (or becomes likely to be), misleading or deceptive, including by way of omission;
  - (**adverse change**) an event occurs which is, or is likely to give rise to: any adverse change in the assets, liabilities, financial position or performance, profits, losses or prospects of the Company and the Clarity Group (insofar as the position in relation to an entity in the Clarity Group affects the overall position of the Company), including any adverse change in the assets, liabilities, financial position or performance, profits, losses or prospects of the Company or the Clarity Group from those respectively disclosed in any Offer document or public information; or an adverse change in the nature of the business conducted by the Clarity Group as disclosed in this Prospectus;
  - (**change of law**) there is introduced, or there is a public announcement of a proposal to introduce, into the Parliament of Australia, New Zealand, Hong Kong, Singapore, the Peoples Republic of China, any member states of the European Union, the United Kingdom or the United States or any State or Territory of Australia a new law, or the Reserve Bank of Australia, or any Commonwealth or State authority in Australia, including ASIC, adopts or announces a proposal to adopt a new policy (other than a law or policy which has been announced before the date of the Underwriting Agreement);
  - (**breach of laws**) there is a contravention by the Company or any other Clarity Group member of the Corporations Act, the *Competition and Consumer Act 2010* (Cth), ASIC Act (or any regulations under those acts) or any other applicable law or regulation;
  - (**compliance with law**) any of the Offer documents or any aspect of the Offer does not comply with the Corporations Act or any other applicable law or regulation;
  - (**representations and warranties**) a representation, warranty, undertaking or obligation contained in the Underwriting Agreement on the part of the Company is breached, becomes not true or correct in any material respect or is not performed;
  - (**breach**) the Company defaults on one or more of its obligations under the Underwriting Agreement;
  - (**legal proceedings**) the commencement of legal proceedings against the Company, any other Clarity Group member or any director of the Company or any other Clarity Group member in that capacity;
  - (**information supplied**) any information supplied (including any information supplied prior to the date of the Underwriting Agreement) by or on behalf of a Clarity Group member to the Joint Lead Managers in respect of the Offer or the Clarity Group is, or is found to be, misleading or deceptive, or likely to mislead or deceive (including by omission);
  - (**hostilities**) hostilities not presently existing commence (whether war has been declared or not) or an escalation in existing hostilities occurs (whether war has been declared or not) involving any one or more of Australia, New Zealand, Singapore, the United Kingdom, Hong Kong, the People's Republic of China, Democratic Peoples' Republic of Korea, any member state of the European Union or the United States or a major terrorist act is perpetrated anywhere in the world or any diplomatic, military, commercial or political establishment of any of those countries or anywhere else in the world;
  - (**certificate incorrect**) a statement in any closing certificate is false, misleading, inaccurate, untrue or incorrect; and

- (**disruption in financial markets**) any of the following occurs: a general moratorium on commercial banking activities in Australia, New Zealand, Canada, the People's Republic of China, Japan, Singapore, Hong Kong, the United Kingdom, the United States, the United Arab Emirates, Switzerland, Norway or a Member State of the European Union is declared by the relevant central banking authority in those countries, or there is a disruption in commercial banking or security settlement or clearance services in any of those countries; any adverse effect on the financial markets in Australia, New Zealand, Canada, the People's Republic of China, Japan, Singapore, Hong Kong, the United Kingdom, the United States, the United Arab Emirates, Switzerland, Norway or a Member State of the European Union, or in foreign exchange rates or any development involving a prospective change or break up in political, financial or economic conditions in any of those countries; or trading in all securities quoted or listed on ASX, NASDAQ, New York Stock Exchange, London Stock Exchange, Hong Kong Stock Exchange or the Tokyo Stock Exchange is suspended or limited in a material respect for one day (or a substantial part of one day) on which that exchange is open for trading.

- (**representations, warranties and undertakings**) the Underwriting Agreement contains certain standard representations, warranties and undertakings by the Company to the Joint Lead Managers.

  The representations and warranties given by the Company relate to matters such as conduct of the Company, power and authorisations, information provided by the Company, financial information, information in this Prospectus, the conduct of the Offer, compliance with laws, the ASX Listing Rules and other legally binding requirements.

  The Company also provides representations and warranties in connection with matters including, but not limited to, its assets, material contracts, licences, insurance, intellectual property, dividends and distributions and eligibility for Listing.

  The Company's undertakings include, among other things, that it will not, during the period following the date of the Underwriting Agreement until 120 days after the Shares the subject of the Offer have been issued, issue (or agree to issue) any Shares or securities without the prior written consent of the Joint Lead Managers, subject to certain exceptions.

- (**indemnity**) subject to the maximum extent permitted by law and certain customary exclusions (including gross negligence, wilful misconduct, fraud or wilful default), the Company agrees to indemnify the Joint Lead Managers and certain affiliated parties from and against losses suffered as a result of or in connection with the Offer.

- (**governing law**) the Underwriting Agreement is governed by the laws of New South Wales (except for United States indemnities, which are governed by the laws of the State of New York).

10.11.2. Product Supply Agreement with Idaho State University

The Company entered into a product supply agreement with Idaho State University (**ISU**) on 6 March 2020 to produce and supply copper-67 (**^{67}Cu**) to the Company (**PSA**). ^{67}Cu is a critical material necessary for the manufacture of the Company's product candidates. The PSA is governed by the laws of the State of Idaho in the US. The material terms of the PSA are as follows:

- (**term and termination**) the PSA has an initial term that ends on 1 January 2025. The term automatically and continually renews for three-year terms unless a party provides written notice six months before the expiry of the initial or any additional three-year term. The PSA may be terminated:

  - by mutual agreement between the parties;
  - by either party without cause upon providing six months' written notice;
  - by either party where the other party has materially breached the PSA and failed to remedy the breach on 30 days' notice;
  - by the Company if ISU loses regulatory approval to produce ^{67}Cu; or
  - by ISU if the Company loses regulatory approval to market or run clinical trials where ^{67}Cu is manufactured, delivered or sold.

  Additionally, ISU retains a right to terminate the PSA if in its judgment the legislature of the State of Idaho fails, neglects or refuses to grant sufficient funds as may be required for ISU to continue the PSA or the executive branch of the State of Idaho mandates any cuts or holdbacks in spending.

- (**purchase amount**) the Company must purchase certain volumes of product from ISU based on quarterly demands per quarter.
- (**responsibility of Clarity**) Clarity is responsible for providing ISU with all necessary regulatory and project related information to enable ISU to produce and supply ^{67}Cu at the quality agreed to between the parties pursuant to the PSA.
- (**deliveries and inspection**) quantities of product actually shipped by ISU may vary by up to 100% compared to the Company's monthly purchase orders and in such circumstances ISU will still be deemed compliant with its obligations under the PSA, however the Company will only be invoiced and required to pay for the quantities of product that ISU actually ships. ISU must inform the Company within 48 hours if it is to be subject to governmental inspection and must provide the Company with copies of correspondence from such governmental authorities resulting from the inspection to the extent relevant to the Company's product.
- (**price and payment terms**) the per-unit price payable by the Company for all quantities of the product ordered is specified in the pricing schedule to the PSA and may be revised in writing by the parties. Pricing is tiered based on cumulative contract year volume. The Company must pay to ISU all taxes of any relevant taxing authority arising from the sale of the product, other than taxes based upon ISU's income, and any tax that may be assessed on the bulk product for shipment between production sites. ISU is exclusively entitled to claim any research and development tax credits.
- (**indemnity and liability**) the Company has agreed to indemnify, defend and hold harmless ISU and the State of Idaho and its officers, directors, agents, affiliates and their respective employees and representatives from and against all third-party claims resulting from the Company's negligence or wilful misconduct or the Company's breach of representations, warranties and covenants under the PSA. The Company, its officers, directors, agents, affiliates and their respective employees and representatives will be indemnified, defended and held harmless by ISU from all third-party claims resulting from ISU's negligence in the manufacture of ^{67}Cu. All claims arising out of and related to the PSA are capped according to the limits set out in the Idaho Tort Claims Act (Idaho Code § 6-901-929).
- (**insurance**) the Company must maintain either a commercial general liability insurance policy or a program of self-insurance that provides ISU substantially the same coverage and is both primary and non-contributory. The limit of the policy must be at least US$1,000,000 per occurrence for bodily injury, property damage and for personal injury liability, at least US$2,000,000 aggregate for products or completed operations, and at least US$2,000,000 for general aggregate.

10.11.3. Master Supply Agreement with NorthStar Medical Radioisotopes, LLC

The Company entered into a master supply agreement (**Supply Agreement**) with NorthStar Medical Radioisotopes, LLC (**NorthStar**) on 20 May 2021 under which NorthStar has agreed to manufacture and supply ^{67}Cu dichloride to the Company for its clinical radiotherapeutic development program, related development and validation studies and commercial use. The Supply Agreement is governed by the laws of the State of Wisconsin in the US. The material terms of the Supply Agreement are as follows:

- (**term and termination**) the initial term of the Supply Agreement expires at the end of the second year after the first commercial US patient dose shipments of the SAR-bisPSMA product are made and thereafter the agreement will be automatically renewed with successive one-year terms until either party provides at least 120 days' written notice, or the Supply Agreement is terminated:
  - (for cause) by either party if the other party has materially breached the Supply Agreement and failed to remedy the breach on 30 days' notice or if the other party becomes insolvent or the subject of any insolvency proceedings as debtor, makes an arrangement for the benefit of its creditors or initiates dissolution or liquidation proceedings;
  - (discontinuance of activities) by the Company, if it discontinues all clinical studies and commercial activities in relation to ^{67}Cu dichloride; or
  - (no supply) by NorthStar, if it is unable to produce ^{67}Cu dichloride to the specifications under the Supply Agreement or is unable to obtain relevant approvals to manufacture and sell ^{67}Cu dichloride after commercially reasonable efforts.

- (**payment terms**) the Company must pay NorthStar for all products sold to the Company under the Supply Agreement on a 30 day net basis from the shipment date. Product prices have been agreed in writing by the parties in the Supply Agreement. The Company is liable for any federal, state, local or other taxes, duties, customs, or assessments in connection with the purchase, transportation, use or possession of the products ordered.
- (**pricing**) pricing for the clinical development periods will be tiered based on the amount of the product delivered per month. Prices will be reviewed annually but will generally not be subject to an adjustment of more than five percent per year.
- (**indemnity and liability**) each party fully indemnifies, defends and holds the other party harmless from and against any and all claims and costs and expenses that may be incurred as a result of any actual or alleged breach of any representation, warranty or covenant made by the party in the Supply Agreement or any purchase order, the negligent acts or omissions or intentional misconduct of the party or its employees, agents or subcontractors, or any actual or alleged injury to or death of any person, or any actual or alleged damage to or loss of property arising out of goods in the possession or under the control of the other party.
- (**insurance**) NorthStar must maintain during and for three years after the end of the Supply Agreement (or five years if the policy is a claims-made based policy) commercial general liability insurance of not less than US$2,000,000 per occurrence and US$5,000,000 in the aggregate; products and completed operations liability insurance per occurrence and general aggregate annual limits of not less than US$2,000,000; professional services errors & omissions liability insurance with per claim and aggregate annual limits of not less than US$1,000,000; workers compensation insurance in compliance with applicable laws; and product recall insurance extended to cover loss by the Company, with per occurrence and general aggregate limits of not less than US$5,000,000.
- (**Quality Agreement**) under the Supply Agreement the parties have agreed to enter into a separate agreement at a time of mutual agreement which outlines the specific commitments by each party to assure the quality of the ^{67}Cu dichloride produced (**Quality Agreement**). Terms in the Quality Agreement will supersede quality related terms documented in the Supply Agreement. The Quality Agreement has not yet been negotiated or entered into.
- (**exclusivity**) NorthStar has agreed to not sell or distribute ^{67}Cu dichloride to a competitor of the Company (for pre-clinical and clinical development, or commercial sale). The exclusivity period ends: by mutual agreement; after termination or expiry of the Supply Agreement; if the Company does not purchase certain volumes of its annual ^{67}Cu needs from NorthStar; if the Company's product sales do not represent a proportion of the United States commercial volume of therapies using the ^{67}Cu dichloride; if one or more commercial scale manufacturers of ^{67}Cu dichloride are supplying suitable quality products and have the capacity to supply at a certain volume of the United States commercial volume of therapies using ^{67}Cu dichloride; or the last day of any calendar year (but no earlier than December 31, 2029), if the Company does not achieve a certain percentage of the target sales of ^{67}Cu dichloride.

10.11.4. Clinical Trial Supply Agreement with Washington University – ^{64}Cu SARTATE™

The Company entered into a clinical trial supply agreement (**CTS Agreement**) with Washington University (**WU**) on 24 October 2017 for WU to provide manufacturing, quality control, release, dispensing and distribution services with respect to ^{64}Cu SARTATE™ in clinical trials. The CTS Agreement is governed by the laws of the State of New York in the US. An amendment was entered into on 8 January 2019 which extended the term of the CTS Agreement and amended certain terms under the CTS Agreement. The material terms of the CTS Agreement (as amended) are as follows:

- (**term and termination**) the CTS Agreement will continue until 1 July 2022, unless terminated or extended by written agreement between the parties. Either party can terminate the CTS Agreement upon 60 days' written notice to the other party or if the other party has materially breached the CTS Agreement and not cured the breach within 30 days' written notice.
- (**payment and invoicing**) WU must be paid for the services properly performed in accordance with the terms of the CTS Agreement on a fixed price basis. WU will invoice the Company monthly in arrears for product manufactured and delivered to the Company in the amounts specified in the CTS Agreement, with a minimum order of one dose per month, starting from the date of the first order for the first patient recruited in the US.

- (**indemnification**) the Company agrees to indemnify, defend and hold harmless WU and its affiliates, and their respective officers, directors, employees and agents from and against any third party claims, damages, losses, liabilities, or expenses related to a claim or cause of action suffered or incurred as a result of: any clinical trials, ownership, testing, use, or application of the ^{64}Cu SARTATE™ meeting the specifications of the Company or Company-supported clinical trial sites; any negligent acts or intentional or reckless misconduct on the part of the Company; the Company's breach of the CTS Agreement; certain claims of infringement of the intellectual property rights of a third party; or any use or commercialisation of any deliverables under the CTS Agreement whether by or through the Company.
- (**insurance**) WU must maintain insurance to ship the ^{64}Cu SARTATE™ to a site or the Company with costs to be paid by the Company. For the term of the CTS Agreement and for five years thereafter, the Company must obtain and maintain comprehensive general liability and product liability insurance, naming WU as an additional insured in the following minimum annual limits: US$2,000,000 per occurrence and US$5,000,000 in the aggregate.

10.11.5. Clinical Trial Supply Agreement with Washington University – ^{67}Cu SAR-bisPSMA and ^{64}Cu SAR-bisPSMA

The Company entered into a second CTS Agreement (**Second CTS Agreement**) with WU on 17 June 2020 under which WU will supply ^{67}Cu SAR-bisPSMA and ^{64}Cu SAR-bisPSMA and provide associated production, quality control release, dispensing and distribution services to the Company. The Second CTS Agreement is governed by the laws of the State of New York in the US. An amendment to the Second CTS Agreement was agreed on 1 May 2021 which expanded the work requested for ^{67}Cu SAR-bisPSMA. The material terms of the Second CTS Agreement (as amended) are as follows:

- (**term and termination**) the Second CTS Agreement will continue until 1 May 2023. After expiry of this term, the Second CTS Agreement will automatically renew on a yearly basis unless either party provides written notice of its desire not to renew the CTS Agreement prior to the expiration of the current term. Either party can terminate the CTS Agreement upon 60 days' written notice to the other party or if the other party has materially breached the CTS Agreement and not cured the breach within 30 days' written notice.
- (**payment terms**) WU is to be paid for the services performed in accordance with the Second CTS Agreement on a fixed price basis. WU will invoice the Company monthly in arrears for product produced and delivered to the Company (in the amounts specified in the CTS Agreement).
- (**indemnification**) each party has agreed to indemnify, defend and hold harmless the other party and its affiliates, and their respective officers, directors, employees and agents from and against any third party claims, damages, losses, liabilities, or expenses related to a claim or cause of action suffered or incurred as a result of: any negligence or wilful misconduct; or any breach of representations, warranties or obligations, except to the extent that it is caused by negligence, wilful misconduct or breach of the party. The Company's indemnification of WU also extends to: any claim that the services or deliverables involves an infringement of the intellectual property rights of a third party; any use or commercialisation of deliverables; or any clinical trials, ownership, testing, use, or application of ^{67}Cu SAR-bisPSMA and ^{64}Cu SAR-bisPSMA meeting the specifications.
- (**regulatory approval**) the Company has agreed to obtain and maintain all regulatory approvals and necessary records required to conduct the clinical investigation of ^{67}Cu SAR-bisPSMA and ^{64}Cu SAR-bisPSMA. The Company represents and warrants to WU that the investigation will be conducted under a valid and existing FDA IND approval and that no notice or communication from FDA will affect the investigation.
- (**recall of products**) unless otherwise agreed, the Company is responsible for coordinating all activity associated with a recall of ^{67}Cu SAR-bisPSMA or ^{64}Cu SAR-bisPSMA. The Company is also responsible for all recall expenses incurred by both parties, except for expenses directly attributable to matters within the scope of WU's indemnity.
- (**insurance**) WU must maintain insurance to ship ^{67}Cu SAR-bisPSMA and ^{64}Cu SAR-bisPSMA. WU must also maintain the following insurance policies during the term of the agreement (plus the subsequent five years if the policy is a claims-made policy): commercial general liability insurance of not less than US$2,000,000 per occurrence and US$5,000,000 in the aggregate; products and completed operations liability insurance per occurrence and general aggregate annual limits of not less than US$2,000,000; professional services errors & omissions liability insurance with per claim and aggregate annual limits of not less than US$1,000,000; and workers compensation insurance in compliance with applicable laws. Throughout the term of the Second CTS Agreement and the subsequent five years, the Company must maintain comprehensive general liability and product liability insurance of not less than US$2,000,000 per occurrence and US$5,000,000 in the aggregate.

10.11.6. Services Agreement with South Australian Health and Medical Research Institute Limited

The Company has entered into a services agreement (**SAHMRI Agreement**) with South Australian Health and Medical Research Institute Limited (**SAHMRI**) pursuant to which SAHMRI has agreed to provide certain services to supply Cu-64 Investigational Medicinal Products (**IMPs**) for Company sponsored phase II trials and beyond in Australia. The SAHMRI Agreement is governed by the laws of South Australia. The material terms of the SAHMRI Agreement are as follows:

- (**term and termination**) the SAHMRI Agreement commenced on 1 May 2020 and remains in force until 30 April 2023, unless: terminated earlier with immediate effect upon written notification by either party if the other party is deemed in default or insolvent under the SAHMRI Agreement; or terminated by written agreement of the parties.
- (**fees**) the Company must pay to SAHMRI the fees for the services in accordance with the payment terms outlined in the SAHMRI Agreement and must pay the fees within 30 days of SAHMRI providing a tax invoice to the Company. SAHMRI may charge an annual interest rate of 5% for late payments by the Company. SAHMRI may suspend performance of the services or other obligations under the SAHMRI Agreement until all overdue payments are paid.
- (**warranty and liability**) each party makes a number of express warranties under the SAHMRI Agreement, including having the authority and ability to perform obligations under the agreement and not infringing the intellectual property rights of any third party or breaching any applicable law or regulation in performing its obligations under the agreement. SAHMRI excludes any implied warranty as to the standard of work and, the accuracy of, or fitness for a particular purpose of, the services. The Company assumes sole responsibility and risk in interpreting, using and exploiting the results of the services provided by SAHMRI (including reports). Neither party is liable to the other for any special, indirect, pure economic or consequential losses. SAHMRI's liability under the SAHMRI Agreement is limited to the aggregate fees paid by the Company to SAHMRI under the agreement and (in the case of goods) the repair or replacement of the goods or the supply of equivalent goods (or the payment of costs equivalent for each) and (in the case of services) supplying the services again or paying the cost of having the services supplied again.
- (**indemnity**) the Company indemnifies SAHMRI from and against any reasonably incurred costs, losses, damages, expenses (including legal expenses), liabilities or other outgoings of whatever kind suffered or incurred by SAHMRI arising out of or in respect of any negligence, wrongful act or omission or breach of the SAHMRI Agreement by the Company. The liability of the Company to indemnify SAHMRI will be reduced proportionately to the extent that the loss or liability indemnified was caused or contributed to by the negligence, wrongful act or omission or breach of the SAHMRI Agreement by SAHMRI.
- (**insurance**) each party must effect and maintain all necessary and appropriate insurance policies as separately agreed between them, or in default covering the risks associated with the conduct of the services and the performance of the relevant party's obligations under the SAHMRI Agreement.
- (**disputes**) the parties must negotiate in good faith and resolve any dispute between them arising from the SAHMRI Agreement. Disputes must be initially referred to the nominated representatives of each party for resolution or failing that be referred to a meeting of the CEO, managing director or equivalent of each party or failing that the parties will agree upon an appropriate mediator or failing that may commence court proceedings 20 business days after referral to a mediator.

The Company also has service agreements in place with SAHMRI for ^{64}Cu SAR-Bombesin clinical supply (see Section 3.5.2) and to validate the production of ^{64}Cu SAR-bisPSMA (see Section 3.5.3).

10.11.7. Core Facility Service Agreement with Memorial Sloan Kettering Cancer Center

The Company has entered into a core facility service agreement with Memorial Sloan Kettering Cancer Center (**MSKCC**) (**CFSA**) pursuant to which MSKCC has agreed to perform certain services, including development project setup, ^{67}Cu SARTATE™ trial runs and ^{67}Cu SARTATE™ validation runs. The CFSA is governed by the laws of the State of New York in the US. The material terms of the CFSA are as follows:

- (**term and termination**) the CFSA commenced on 6 March 2019 and remains in force until completion of the project, unless terminated earlier in accordance with the CFSA. Either party may renew the CFSA for an additional six month term by providing the other party with written notice of its intent to renew at least 30 days prior to the end of the then-current term. Either party can terminate the CFSA upon 30 days' written notice to the other party; or effective immediately, upon written notice to the other party:
  - if the other party materially breaches any provision of the CFSA and either such breach cannot be cured or, if such breach can be cured, it is not cured by the other party within ten days after receipt of written notice of such breach;
  - if the other party becomes insolvent, is generally unable to pay, or fails to pay, its debts as they become due, files for voluntary or involuntary bankruptcy or if any other relevant insolvency issue occurs over its property or business;
  - if the other party is found guilty or liable for billing fraud or abuse or related offenses with regard to services provided under the CFSA by any governmental agency or professional organization having jurisdiction;
  - if the other party, or an officer, director or employee of such party, is excluded, suspended or terminated from participation in any 'Federal Health Care Program' or convicted of a health care-related felony, or suffers a loss or suspension of a provider license or a loss of credentials for stated quality reasons; or
  - if the other party has violated any other material term of certain exclusions by the Office of Inspector General for the US Department of Health and Human Services under such party's responsibilities in the CFSA.
- (**fees and payment**) the Company must pay the total amount indicated in the budget to MSKCC in accordance with the payment schedule specified in the CFSA. The fees payable/paid to MSKCC are on a "net of tax" basis, and any taxes (e.g., withholding taxes or any indirect taxes) will be borne fully by the Company. Should the Company fail to pay MSKCC monies due and payable for more than 30 days following the invoice date, MSKCC will have the right to terminate the CFSA on 30 days' written notice, unless the Company pays MSKCC within the 30 day period all such payments due. The Company is responsible for all collection costs associated with non-payment. Payments made after the due date will accrue interest beginning the tenth day following the due date, calculated at an annual rate equal to the sum of (i) two percent (2%); plus (ii) the prime interest rate quoted by the Wall Street Journal on the date said payment is due.
- (**export control**) each party acknowledges that any information or materials provided by the other under the CFSA may be subject to US export laws and regulations. Because MSKCC is an academic research institution and has many faculty, staff, students, and visitors who are foreign persons, the Company must not disclose, and must use commercially reasonable efforts to prevent disclosure to MSKCC of, any information subject to export controls. The Company agrees to indemnify, defend and hold harmless MSKCC, its officers, agents and employees from all liability involving the violation of such export regulations, either directly or indirectly by the Company.
- (**indemnification**) the Company must defend, indemnify and hold MSKCC, the Project Director and any of MSKKC's employees, trustees, officers, affiliates and agents, harmless from any claim, suit, loss, cost, damage, liability or expense (**Loss**) arising out of the Company's (including the Company's employees, affiliates, contractors, licensees or agents) performance or actions under the CFSA, the Company's use of any information, data, or deliverables, MSKCC's use of Company resources, data, information, compounds, reagents, materials, or other property, used for the purposes provided by the Company, and claims by or relating to the Company's employees, affiliates, contractors, licensees or agents. The Company will not be liable to the extent a Loss results from the gross negligence or wilful misconduct on the part of MSKCC.
- (**insurance**) each party agrees to maintain reasonable coverage for liabilities under the CFSA either from commercial insurance or a reasonable self-insurance mechanism, verification of which must be provided to the other party upon request.

10.11.8. Master Services Agreement with Medpace, Inc.

The Company entered into a Master Services Agreement (**MSA**) with Medpace, Inc. (**Medpace**) on 1 October 2019 under which Medpace has agreed to provide services in relation to the design and execution of clinical development programs. The precise services to be performed by Medpace are to be mutually agreed upon by the parties set forth in individual task orders, which provide the scope of work, project milestones and completion dates and a budget. The MSA is governed by the laws of the State of Ohio in the US. The material terms of the MSA are as follows:

- (**term and termination**) a task order can be terminated by the Company without cause immediately upon giving Medpace notice of such termination. Medpace can only terminate a task order if:
  - the Company has defaulted on its obligations under the MSA or any task order and has not cured such default within 10 days after receipt of written notice if the default is a failure to pay Medpace any amount due under the MSA or within 30 days after receipt of written notice in the event of any other default under the MSA; or
  - the parties fail to reach an agreement for a proposed amendment to a task order.
- (**indemnity and liability**) subject to certain exclusions relating to, among other things, gross negligence, wilful misconduct, a breach of law or a material breach of the MSA or a task order, each party has agreed to indemnify, defend and hold harmless the other party from and against all damages, losses, liabilities, costs or expenses resulting or arising from claims in connection with the MSA or services provided. Neither party (to the extent permitted by law) will be liable to the other for any lost profits, punitive damages or indirect, incidental, special or consequential damages.
- (**no solicitation**) the Company must not directly or indirectly hire, recruit, solicit or entice any employees of Medpace for employment during the term of the MSA and the subsequent 12 months after termination of the MSA.
- (**project budget, payment schedule and terms**) the Company is required to reimburse Medpace for reasonable pass-through costs incurred by Medpace in the performance of services under each relevant task order.

10.11.9. Master Services Agreement with GenesisCare Clinical CRO Pty Ltd

The Company entered into an MSA with GenesisCare Clinical CRO Pty Ltd (**GenesisCare**) on 20 August 2020. GenesisCare is a Contract Research Organisation which provides scientific research services, including clinical research and scientific consulting to the Company. The MSA commenced on 5 May 2020. The services to be provided under the MSA are set out in work orders agreed between the parties. Upon agreement between the parties as to its terms, a work order is incorporated in and becomes part of the MSA. The MSA is governed by the laws of New South Wales, Australia. The material terms of the MSA are as follows:

- (**work order**) individual work orders set out the terms and conditions upon which GenesisCare agrees to provide certain research services to the Company to assist with a study on PET imaging of patients with known or suspected Gastroenteropancreatic Neuroendocrine Tumors and a study on PET imaging of patients confirmed with prostate cancer.
- (**term and termination**) either party may terminate the MSA immediately on giving written notice to the other party if that party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, or files or has filed against it a petition in bankruptcy, or has a receiver appointed for a substantial part of its assets. Otherwise, the MSA will expire on 5 May 2025 unless earlier terminated by either party if the other party materially breaches its obligations under the MSA and the breach is not remediable; or if the breach is capable of remedy, the other party fails to remedy the breach within 30 days after receipt of written notice.
- (**indemnity and liability**) the Company indemnifies GenesisCare against all costs, claims, losses, liabilities, damages, demands and expenses (including all legal costs, fees and expenses) arising out of any claim alleging that any of the test materials or other data provided to GenesisCare, for the purposes of providing the services, infringes any personal rights. The Company also indemnifies, in certain circumstances, GenesisCare and members of and advisers to The Human Research Ethics Committee against all costs, claims, losses, liabilities, damages, demands and expenses (including all legal costs, fees and expenses) arising directly or indirectly out of any claim alleging personal injury (including death) to an individual which arise out of or in connection with the performance of services.
- (**record retention**) if the Company is an 'Australian Sponsor' under a work order, the Company is obligated to retain all essential documents for at least 15 years after the expiry or termination of the MSA.

10.11.10. General Services Agreement with IQVIA RDS Pty Ltd

The Company entered into a General Services Agreement (**GSA**) with IQVIA RDS Pty Ltd (**IQVIA**), effective from 27 February 2020. The GSA provides the terms and conditions upon which IQVIA agrees to perform certain clinical services relating to a multi-centre, dose-escalation, open-label, non-randomized, phase I-IIA theranostic clinical trial (**Services**). The GSA is governed by the laws of Australia. The material terms of the GSA are as follows:

- (**term and termination**) the GSA will continue until the Services are completed or until the GSA is terminated: by either party for a material breach if such breach has not been substantially cured within 30 days' written notice; by the Company providing 60 days' written notice; by IQVIA, if it determines that the performance of the Services would constitute a potential or actual violation of regulatory, scientific or ethical standards of integrity, by giving written notice stating the effective date (which may be less than 30 days from the notice date) of such termination; or by either party, immediately upon provision of written notice if the other party becomes insolvent or files for bankruptcy.
- (**indemnity and liability**) each party indemnifies, defends and holds harmless the other party in relation to any damages or expenses (including attorney fees) that are incurred due to third-party claims or investigations relating to the services provided under the agreement, except to the extent such damages or expenses are caused by the negligence or wilful misconduct of the indemnified party. IQVIA's aggregate liability is capped at the amount of fees actually received by IQVIA from the Company under the GSA.
- (**insurance**) during the term of the GSA (and for four years after its expiration or earlier termination), the Company is required to maintain insurance coverage to cover its obligations under the GSA of at least US$5,000,000 for clinical trials and/or product liability and at least US$1,000,000 for general liability. These amounts will increase to US$10,000,000 and US$3,000,000 respectively if IQVIA is acting as a local representative in the country in which the Services are conducted. IQVIA is also required to maintain professional liability and general liability insurance under the GSA.

10.11.11. Master Services Agreement with InClin Pty Ltd

The Company entered into a MSA with InClin Pty Ltd (InClin) pursuant to which InClin has agreed to provide certain strategic planning, expert consultation, clinical trial, statistical programming and analysis, data processing, data management, regulatory, clerical, project management, medical writing and other research and development services to the Company pursuant to individual work orders. The MSA is governed by the laws of the State of California in the US. The material terms of the MSA are as follows:

- (**term and termination**) the MSA commenced on 5 November 2020 and remains in force until terminated. The Company may terminate the MSA or any work order with or without cause upon providing 30 days' written notice to InClin. InClin may terminate the MSA or any work order immediately upon written notice if it determines that continued performance would require InClin to potentially violate regulatory or scientific standards of integrity. Either party may terminate the MSA and all work orders in the event of the failure of the other party to cure a breach or threatened breach within 30 days of written notice.
- (**work order**) one work order has been issued under the MSA pursuant to which InClin is to provide project management, clinical monitoring, data management, biometrics, medical writing, medical monitoring and quality assurance support in relation to the study CLP05 entitled "A Phase I/IIa theranostic study of ^{64}Cu SAR-bisPSMA and ^{67}Cu SAR-bisPSMA for identification and treatment of PSMA-expressing metastatic castrate resistant prostate cancer".
- (**indemnity and liability**) the Company must indemnify, defend and hold harmless InClin, its employees, affiliates, directors, officers and agents from all damages, fines, penalties, losses, liabilities, costs or expenses, including reasonable attorneys' fees that are incurred in connection with claims relating to the development or commercialization of devices, the performance of services and infringement of third party intellectual property rights using the Company's confidential information under work orders except to the extent determined to have resulted from the negligence, gross negligence or intentional misconduct or contravention of law or material breach of the MSA by InClin, its employees, affiliates or agents. The Company is indemnified and is to be held harmless by InClin for any claim arising from InClin's negligence, gross negligence or wilful misconduct or breaches of InClin's obligations under the MSA.
- (**compensation**) the Company will pay fees and expenses for the performance of services provided in each work order, and in accordance with the payment terms set forth in each work order under monthly invoices. For any project spanning multiple calendar years, the budget will be subject to an annual cost adjustment of 1.5% (in relation to the labour costs for services performed in a calendar year that was not contemplated in the budget).

10.11.12. ANSTO Licence Agreement

The Company entered into a licence agreement with Australian Nuclear Science and Technology Organisation (**ANSTO**) on 29 September 2010 (**Licence Agreement**) pursuant to which ANSTO granted an exclusive, non-transferable and worldwide right to certain licenses to patents for cryptate compounds and methods for diagnosis and therapy (**Licensed Patents**). The Licence Agreement is governed by the laws of New South Wales, Australia. The material terms of the Licence Agreement are as follows:

- (**term**) the term of the Licence Agreement commenced on 29 September 2010. The term expires on the date of expiry, lapse or revocation of the last Licensed Patent in a particular territory, or the date the licenced know-how ceases to be confidential (whichever is later).
- (**termination of Licence Agreement**) ANSTO may terminate the Licence Agreement:
  - on 30 days' notice to the Company in writing if certain fees payable to ANSTO under the Licence Agreement are in arrears and unpaid for a period of 60 days after written notice from ANSTO that they have become due and payable, except that the Company will have three months to rectify a breach of non-payment of Licence Fee payments;
  - on 30 days' notice to the Company in writing if the Company commits or allows to be committed a breach of the Licence Agreement and does not within 90 days, or 60 days where the breach relates to a failure to pay money, of receiving a written notice from ANSTO rectify that breach; or
  - immediately by written notice to the Company if the Company will be dissolved, cease active business operations or be liquidated (unless assigned to a successor), or in the event the Company is determined insolvent by a court, or insolvency or reorganization proceedings have been commenced, or such proceedings have been brought against the Company and remained undismissed for a period of 60 days or the Company has made a general assignment for the benefit of creditors or a receiver has been appointed and not discharged within 60 days.
- (**termination by the Company**) the Company may terminate the Licence Agreement on 30 days written notice to ANSTO if ANSTO breaches the Licence Agreement and causes material damage to the Company after the Company has given written notice to ANSTO specifying the particulars of the breach and requiring that it be rectified and ANSTO has failed to rectify the breach within 90 days. Providing it is acting in good faith, the Company may also terminate the Licence Agreement by providing 90 days written notice (including setting out the reasons for termination and steps taken to avoid or overcome the relevant reason) to ANSTO for sound business or technical reasons.
- (**consideration**) in consideration for the Licensed Patents, the Company issued 100,000 ordinary shares to ANSTO in 2010 (which now represent 2,000,000 Shares as a result of a share split in respect of the Shares that was approved by Shareholders in July 2021).
- (**milestone fees, royalties and sub-licence fees**) the Company is obliged to meet milestones and pay milestone fees upon the filing of certain regulatory applications to conduct human clinical trials with certain clinical imaging products, upon the commencement of sales of certain clinical imaging products and upon the commencement of sales of certain therapeutic products. The Company must also pay ANSTO royalties based on sales of certain research products, clinical imaging products, therapeutic products and other products which incorporate elements of the Licenced Patents in combination with the ingredients of a third party (which range from 2% to 5% of net sales depending on the nature of the product that is sold) and sub-licence royalties (which are 25% of relevant licence revenue). Further information regarding contingent liabilities of the Company to ANSTO, which are referrable to these royalties, is contained in Section 4.9.

- (**indemnity**) ANSTO indemnifies the Company against all damages and costs from claims by third parties arising from any breach by ANSTO of the Licence Agreement or its warranties. The Company releases and indemnifies ANSTO from all claims, damages, costs, proceedings or any other remedies actual, contingent or otherwise, and demands (including those brought by third parties), arising directly or indirectly in connection with any breach by the Company of the Licence Agreement, any breach of the Company's warranties or obligations under the Licence Agreement, breach of statute, tort (including any negligent act or omission) or otherwise, the design, manufacture, marketing, supply or use of the products, any person's use of the products, the exploitation by the Company or any sub-licensee of the Company of products or any failure of the Company or any sub-licensee of the Company to comply with any law and from all damages, costs and expenses incurred in defending or settling any claim, proceeding or demand.
- (**liability**) to the extent permitted by law, ANSTO excludes all liability to the Company, whether direct or indirect, under or in connection with the Licence Agreement, however caused, under any theory of liability whether based in contract, tort (including negligence and breach of statutory duty) or otherwise in respect of the suitability of the licensed intellectual property rights for the exploitation of products, the quality or performance of products, or any claims by the Company or any third parties arising from the Company's research, development, manufacture, import, export, marketing, use, sale, or supply of products arising from the exploitation of any part of the licensed intellectual property rights, whether or not ANSTO has been advised of the possibility of such loss or damage. The Company's aggregate liability for all loss and damage suffered or incurred by ANSTO in connection with the Licence Agreement however caused, under any theory of liability, and whether or not the Company has been advised of the possibility of such loss or damage, will not exceed A$10,000,000. However, the Company's liability in relation to claims asserted by third parties against ANSTO, for accrued but unpaid payments under the Licence Agreement, and for infringement of the licensed intellectual property rights after termination of the Licence Agreement is not limited.
- (**insurance**) the Company must take out and maintain in force comprehensive general liability insurance, including advertising and product liability insurance for personal injury and property damage and product recall insurance, in relation to all products under the Licence Agreement on terms reasonably satisfactory to ANSTO.

10.11.13. Fee for Service Agreement with Radiopharmaceutical Imaging and Dosimetry, LLC

The Company entered into a fee for service agreement (**FSA**) with Radiopharmaceutical Imaging and Dosimetry, LLC (**RID**) on 25 June 2019 under which RID has agreed to undertake various work on the analyses of data sets provided by the Company. An addendum executed on 4 December 2019 sets out the specific scope of services, project milestones, target completion dates, budget and schedule of payments for imaging analysis and dosimetry services for a ^{64}Cu and ^{67}Cu clinical study. The FSA is governed by the law of the State of Maryland in the US. The material terms of the FSA are as follows:

- (**term and termination**) by amendment to the FSA made on 1 July 2021, the FSA will expire on 25 June 2024, unless earlier terminated with cause by the Company upon 30 days' written notice; or by RID for frustration upon 30 days' written notice if circumstances beyond their control preclude the performance of their services under the FSA.
- (**indemnity and warranty**) the Company must indemnify, defend and hold harmless RID, its affiliates, trustees, officers, agents, employees, students and any other person holding academic appointments in those institutions, from liability, loss, or damage suffered resulting from claims or judgements that arise from participation in the FSA to the extent that it is not a result of the gross negligence or intentional misconduct of RID. RID makes no warranties regarding the work including warranties as to the merchantability and fitness for a particular purpose and provides the work on the condition that RID will have no liability of any kind as a result of its performance of the work. The Company agrees to hold RID harmless from any claims it or third parties may have as a result of the Company's use of the work.
- (**payment**) the Company must pay RID for the services performed pursuant to a payment schedule in the FSA which stipulates the amount payable to RID upon specific triggers, deliverables or tasks.

10.11.14. Deed of Assignments with The University of Melbourne (UOM)

Overview

The Company entered into seven Deeds of Assignment (each a **Deed**, or together the **Deeds**) with The University of Melbourne (**UOM**) on 22 December 2020 in relation to the following patents and patent applications:

- patents and patent applications arising from PCT/AU2009/001572 entitled "Nitrogen-containing macrocyclic conjugates as radiopharmaceuticals" (**COSar Deed**);
- patents and patent applications arising from PCT/AU2012/001483 entitled "Functionalisation of cage amine ligands for metallo-radiopharmaceuticals";
- patents and patent applications arising from PCT/AU2012/001484 entitled "Cage amine ligands for metallo-radiopharmaceuticals";
- patents and patent applications arising from Australian Provisional Patent Application No. 2017902151 entitled "Radiopharmaceuticals, radio-imaging agents, and uses thereof" and Australian Provisional Patent Application No. 2019901765 entitled "Formulations of PSMA imaging agents". If royalties are payable under this Deed, which relate to the same product under the COSar Deed, then the obligation to pay royalties in respect of that product pursuant to this Deed prevails;
- patents and patent applications arising from PCT/AU2019/050322 entitled "Targeting compounds and methods for their production";
- patents and patent applications arising from Australian Provisional Patent Application No. 2020902889 entitled "Albumin targeting compounds"; and
- patents and patent applications arising from Australian Provisional Patent Application No. 2020902901 entitled "Radiopharmaceuticals, methods for the production thereof, and uses in diagnosis and imaging diseases".

The material terms of the Deeds are as follows:

- (**assignment**) the Deeds contain clauses that assign to the Company all rights, title and interest to the respective patents.
- (**licences**) the Deeds contain licences to the relevant know-how for the purposes of commercialising the products that relate to the patent.
- (**term**) the term of each Deed is defined to be the period of time from the respective effective date until the end of the last 6-month period in which the relevant product ceases to be covered by a patent or know-how.
- (**royalties**) the Company has agreed to pay certain milestone payments and royalties that are a percentage of net sales revenue of a product (which generally vary between 2.5% and 5% of the net sales revenue of certain qualifying products) and sub-licence royalties (which generally vary between 10% and 30% of sub-licence revenue, depending on the nature of the sub-licence). Further information regarding contingent liabilities of the Company to UOM, which are referrable to these royalties, is contained in Section 4.9.
- (**third party claims**) UOM is required to cooperate with the Company in defending third party claims against the Company that relate to an infringement of intellectual property rights vested in the third party and such cooperation will be at the Company's cost.
- (**grant of licence back to UOM**) the Company has granted UOM a limited licence to use the respective patents for its internal research and teaching including the right to sub-licence the patents to public research institutions for the purposes of collaborating on internal non-commercial research.
- (**publication**) the Company is deemed to provide consent to UOM publishing the Company's confidential information if, upon UOM providing the Company with copies of the proposed disclosure at least 30 days before the publication submission date, the Company does not object to the proposed disclosure within 20 days after delivery of the proposed disclosure.
- (**assignment back**) the patents assigned to the Company under the Deeds will automatically be assigned by the Company back to UOM in the event the Company becomes insolvent and, 24 months after a liquidator is appointed to liquidate the assets of the Company, the liquidator is unable to sell the technology to a purchaser who meets these reassignment conditions.

10.12. Regulatory relief

10.12.1. ASX waivers and confirmation

The Company has applied to ASX for in-principle advice on its suitability for admission to the Official List under Listing Rule 1.1 condition 1 and Listing Rule 1.19 ahead of lodging its application for admission to ASX. ASX has confirmed the following:

- *Based solely on the information provided to ASX and the facts at the date of ASX's review, ASX is not aware of any reasons that would cause the Company not to have a structure and operations suitable for a listed entity for the purposes of ASX Listing Rule 1.1 Condition 1 or that would cause ASX to exercise its discretion to refuse the admission of Clarity to the Official List of ASX under ASX Listing Rule 1.19.*
- *However, the above is not a guarantee that the Company will in fact be admitted to the Official List and the Company must still meet all the requirements for admission and quotation set out in Chapters 1 and 2 of the Listing Rules to ASX's satisfaction.*

The Company may, after further consultation with ASX, apply to ASX for customary waivers and confirmations with respect to the ASX Listing Rules in connection with its existing Options, but no waivers or confirmations have been obtained as at the Prospectus Date.

10.12.2. ASIC exemptions and relief

The Company has not applied to ASIC for any relief from, and modifications to, the Corporations Act, as at the Prospectus Date.

10.13. Ownership restrictions

The sale and purchase of Shares in Australia is regulated by a number of laws that restrict the level of ownership or control by any one person (either alone or in combination with others). This Section 10.13 contains a general description of these laws.

10.13.1. Corporations Act

The takeover provisions in Chapter 6 of the Corporations Act 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 the acquisition falls within a relevant exception contained in the Corporations Act. The Corporations Act also imposes notification requirements on persons having voting power of 5% or more in the Company either themselves or through an associate.

10.13.2. Foreign Acquisitions and Takeovers Act 1975 (Cth) and Federal Government Foreign Investment Policy

Generally, the *Foreign Acquisitions and Takeovers Act 1975* (**FATA**) applies to acquisitions of shares and voting power in a company of 20% or more by a single foreign person and its associates, or 40% or more by two or more unassociated foreign persons and their associates, where the acquisition meets a threshold value (which varies by investor type, asset type and industry). In addition, the FATA applies to acquisitions of a direct interest in an Australian company by foreign governments and their related entities irrespective of the acquisition value. FATA also applies to acquisitions of a direct interest in a national security business or in a company carrying on a national security business. Under the FATA, a "direct interest" means any investment of 10% or more of the shares (or other securities or equivalent economic interest or voting power) in an Australian company (or offshore entity with Australian assets), an interest of at least 5% in the entity or business if the person who acquires the interest has entered into a legal arrangement relating to the businesses of the person and the entity or business, or any interest where the acquirer obtains potential influence or control over the target investment. There are exemptions which can apply to certain acquisitions.

Where the FATA applies to the acquisition, the acquisition may not occur unless notice of it has been given to the Federal Treasurer and the Federal Treasurer has either notified that there is no objection to the proposed acquisition (with or without conditions) or a statutory period has expired without the Federal Treasurer objecting. An acquisition to which the FATA applies may be the subject of a divestment order by the Federal Treasurer unless the process of notification, and either a non-objection notification or expiry of a statutory period without objection, has occurred. Criminal offences and civil penalties can apply for failing to give notification of certain acquisitions, undertaking certain acquisitions without a no objection notification or contravening a condition in a no objection notification.

10.14. Foreign selling restrictions

See Section 7.8 of this Prospectus.

10.15. Litigation and claims

The Company may, from time to time, be party to litigation and other claims and disputes incidental to the conduct of its business, including employment disputes, contractual disputes, indemnity claims and occupational and personal claims. Such litigation, claims and disputes, including the costs of settling claims and operational impacts, could materially adversely affect the Company's business, operating and financial performance.

As far as the Directors are aware as at the Prospectus Date, there is no current, pending or threatened civil litigation, arbitration proceeding or administrative appeal, or criminal or Governmental prosecution of a material nature in which the Company is directly or indirectly concerned which is likely to have a material adverse impact on the business or financial position of the Company.

Further details regarding the litigation risks relevant to the Clarity Group are provided in Section 5.3.7.

10.16. Australian taxation considerations

The following tax comments are based on the tax law in Australia in force as at the Prospectus Date. Australian tax laws are complex. This summary is general in nature and is not intended to be an authoritative or complete statement of all potential tax implications for each investor. During the ownership of the Shares by investors, the taxation laws of Australia or their interpretation may change. The precise implications of ownership or disposal will depend upon each investor's specific circumstances. Investors should seek their own professional advice on the taxation implications of holding or disposing of the Shares, taking into account their specific circumstances.

The following information is a general summary of the Australian income tax and stamp duty implications for Australian resident individuals, complying superannuation entities, trusts, partnerships and corporate investors that hold their Shares on capital account. These comments do not apply to investors that hold Shares as trading stock on revenue account, investors who are exempt from Australian income tax or investors subject to the Taxation of Financial Arrangements regime in Division 230 of the *Income Tax Assessment Act 1997* (Cth) which have made elections for the fair value or Reliance on Financial Reports (**ROFR**) methodologies.

Taxation issues, such as (but not limited to) those covered by this Section, are only one of the matters an investor needs to consider when making a decision about a financial product. Investors should consider taking advice from someone who holds an Australian financial services licence before making such a decision.

10.16.1. Dividends paid on Shares

Dividends may be paid to Shareholders by the Company where the relevant legal and accounting requirements are met. The Company may attach 'franking credits' to such dividends. Franking credits broadly represent the extent to which a dividend is paid by the Company out of profits that have been subject to Australian tax. It is possible for a dividend to be fully franked, partly franked or unfranked.

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. No assurance in relation to the payment of dividends or franking credits attaching to dividends can be given by the Directors.

Australian resident individuals and complying superannuation entities

Dividends paid by the Company on a Share will constitute assessable income of an Australian tax resident investor. Australian tax resident investors who are individuals or complying superannuation entities should include the dividend in their assessable income (some superannuation funds may be exempt in relation to Shares to the extent they are held to support current pension liabilities) in the year the dividend is paid, together with any franking credit attached to that dividend. Such investors should be entitled to a tax offset equal to the franking credit attached to the dividend. The tax offset can be applied to reduce the tax payable on the investor's taxable income. Where the tax offset exceeds the tax payable on the investor's taxable income, such investors should be entitled to a tax refund.

To the extent that the dividend is unfranked, the investor should include the dividend in their assessable income with no tax offset.

Australian tax resident corporate investors

Corporate investors are also required to include both the dividend and associated franking credit in their assessable income. They are then allowed a tax offset up to the amount of the franking credit on the dividend. Where the tax offset exceeds the tax payable, the excess cannot give rise to a refund for a company but can be converted into carry forward tax losses.

An Australian resident corporate investor should be entitled to a credit in its own franking account to the extent of the franking credit on the distribution received. This will allow the corporate investor to pass on the benefit of the franking credits to its own investor(s) on the payment of dividends.

Excess franking credits received cannot give rise to a refund for a company but can be converted into carry forward tax losses.

Australian tax resident trusts and partnerships

Investors who are trustees (other than trustees of complying superannuation entities) or partnerships should include the franking credit in determining the net income of the trust or partnership. The relevant beneficiary or partner may be entitled to a tax offset equal to the beneficiary's or partner's share of the net income of the trust or partnership.

Qualified person

The benefit of franking credits can be denied where an investor is not a 'qualified person' in which case the investor will not need to include an amount for the franking credits in their assessable income and will not be entitled to a tax offset.

Broadly, to be a 'qualified person', two tests must be satisfied, namely the holding period rule and the related payment rule.

Under the holding period rule, an investor is required to hold Shares "at risk" for more than 45 days continuously over a specified period in order to qualify for franking benefits, including franking credits. This period is measured as the period commencing the day after the Shares were acquired and ending on the 45th day after the Shares become ex-dividend.

Shares are held 'at risk' to the extent no material 'positions' are adopted in relation to the Shares which have the effect of diminishing the economic exposure associated with holding the Shares (for example, certain derivatives or agreements to sell the Shares).

This holding period rule is subject to certain exceptions, including where the total franking offsets of an individual in a year of income do not exceed $5,000. Special rules apply to trusts and beneficiaries.

Under the related payment rule, a different testing period applies where the investor has made, or is under an obligation to make, a related payment in relation to the dividend. The related payment rule requires the investor to have held the Shares at risk for the continuous 45 day period as above but within the limited period commencing on the 45th day before, and ending on the 45th day after, the day the Shares become ex-dividend.

Investors should seek professional advice to determine if these requirements, as they apply to them, have been satisfied.

10.16.2. Disposal of Shares

Australian tax resident Shareholders who hold their Shares on capital account will be required to consider the impact of the Australian capital gains tax (**CGT**) provisions in respect of the disposal of their Shares.

Where the capital proceeds received on disposal of the Shares exceed the CGT cost base of those Shares, Australian tax resident Shareholders will be required to recognise a capital gain. The CGT cost base of the Shares should generally be equal to the issue price or acquisition price of the Shares plus, among other things, incidental costs associated with the acquisition and disposal of the Shares. In respect of the CGT cost base of the Shares, this amount may be reduced as a result of receiving non-assessable distributions from the Company, such as returns of capital.

Conversely, Australian tax resident Shareholders may recognise a capital loss on the disposal of Shares where the capital proceeds received on disposal are less than the reduced CGT cost base of the Shares.

All capital gains and losses recognised by an Australian tax resident Shareholder for an income year are added together. To the extent that a net gain exists, such Shareholders should be able to reduce the gain by any amount of unapplied net capital losses carried forward from previous income years (provided certain loss recoupment tests are satisfied). Any remaining net gain (after the application of any carried forward capital losses) will then be required to be included in the Australian tax resident Shareholder's assessable income (subject to the comments below in relation to the availability of the CGT discount concession) and will be taxable at the Shareholder's applicable rate of tax. Where a net capital loss is recognised, the loss will only be deductible against future capital gains. Capital losses are capable of being carried forward indefinitely, provided the relevant loss recoupment tests are satisfied.

Non-corporate Shareholders may be entitled to a concession which discounts the amount of capital gain that is assessed. Broadly, the concession is available where the Shares have been held for at least 12 months prior to disposal. The concession results in a 50% reduction in the assessable amount of a capital gain for an individual Shareholder or trust, and a one third reduction of a capital gain for an Australian tax resident complying superannuation entity Shareholder. The concession applies to any net capital gain (i.e. it applies after capital losses have been deducted against any gains). The concession is not available to corporate Shareholders.

In relation to trusts, the rules surrounding capital gains and the CGT discount are complex, but the benefit of the CGT discount may flow through to relevant beneficiaries, subject to certain requirements being satisfied. Shareholders which are trusts should seek specific advice as to the circumstances in which a beneficiary may be entitled to a CGT discount.

10.16.3. Tax file numbers and Australian Business Number

A Shareholder is not obliged to quote their tax file number (**TFN**), or where relevant, Australian Business Number (**ABN**), to the Company. However, if a TFN or ABN is not quoted and no exemption is applicable, income tax is required to be deducted by the Company at the highest marginal tax rate plus the Medicare levy from certain dividends paid.

No withholding requirement applies in respect of fully franked dividends paid by the Company on the Shares.

10.16.4. Stamp duty

The below provides high level guidance on the landholder duty implications for the acquisition of Shares. However, investors would need to seek their own advice to determine whether any duty would be payable on the acquisition of Shares under the Offer and any subsequent acquisitions/disposal of Shares.

Landholder duty

Stamp duty is an Australian State and Territory based tax. An entity will be a landholder if it holds, directly or indirectly through its subsidiaries, interests in land (i.e. freehold land, leaseholds and fixtures/assets fixed to land depending on the jurisdiction) which have an unencumbered market value that meets or exceeds the relevant statutory landholder duty threshold in the relevant State or Territory.

The landholder duty threshold in each State and Territory ranges from nil to $2 million and landholder duty is calculated at rates of up to 5.95% on the unencumbered market value of the landholder's interests in land (and goods in certain jurisdictions). From 1 July 2021 the general rate in Victoria increased from 5.5% to 6.5%. Higher rates apply to residential land if the acquirer of the interest is a foreign person.

The Company is not a landholder

No stamp duty should be payable by investors in respect of the Offer on the basis that the Company does not hold any material land or interests in land in any State or Territory of Australia (nor have entered into any agreements to acquire land in any State or Territory of Australia at the time at which Shares are issued under the Offer).

If the Company subsequently directly or indirectly acquires land in any State or Territory of Australia, no liability for stamp duty should arise provided no Shareholder (alone or with any associated persons or persons acquiring under one arrangement or in concert) will acquire or hold 90% or more of the interests in the Company.

10.16.5. Australian Goods and Services Tax

Under current Australian GST law, GST should not be payable in respect of the issue of Shares by the Company or the sale of Shares in the Company made to Australian investors. No GST will be payable on the payment of dividends by the Company.

However, Australian investors may incur GST on brokerage, or other professional advisory services acquired by them in their own right in relation to the Offer.

Australian investors should seek their own advice in relation to the GST implications associated with the Offer, including to determine whether they will be entitled to claim GST incurred on costs associated with the acquisition of Shares.

10.17. Consent to be named and statement of disclaimers of responsibility

Each of the below listed parties has given and has not, before the Prospectus Date, withdrawn its written consent to being named in the Prospectus and to the inclusion, in the form and context in which it is included, of any information described below as being included with its consent.

Chapter 6D of the Corporations Act imposes a liability regime on the Company (as the offeror of the Shares), the Directors of the Company, any underwriters, persons named in the Prospectus with their consent as having made a statement in the Prospectus and persons involved in a contravention in relation to the Prospectus, with regard to misleading or deceptive statements made in the Prospectus. Although the Company bears primary responsibility for the Prospectus, other parties involved in the preparation of the Prospectus can also be responsible for certain statements made in it.

Each of the parties referred to below, to the maximum extent permitted by law, expressly disclaims and takes no responsibility for any part of this Prospectus other than the reference to its name and any statement or report included in this Prospectus with the consent of that party as described below:

- Jefferies (Australia) Pty Limited and Bell Potter Securities Limited have each given, and have not withdrawn prior to the Prospectus Date, its written consent to be named in this Prospectus as Joint Lead Managers to the Offer in the form and context in which it is named;
- KPMG Law has given, and has not withdrawn prior to the Prospectus Date, its written consent to be named in this Prospectus as Australian legal adviser to the Company in relation to the Offer in the form and context in which it is named;
- Grant Thornton Corporate Finance Pty Ltd has given, and has not withdrawn prior to the Prospectus Date, its written consent to be named in this Prospectus as Investigating Accountant to the Company in relation to the Financial Information in the form and context in which it is named and has given and not withdrawn its consent to the inclusion in this Prospectus of its Investigating Accountant's Report in the form and context in which it is included;
- Grant Thornton Audit Pty Ltd has given, and has not withdrawn prior to the Prospectus Date, its written consent to be named in this Prospectus as auditor to the Company, in the form and context in which it is named and has given and not withdrawn its consent to be named as auditor in the form and context in which it is included;
- Davies Collison Cave has given, and has not withdrawn prior to the Prospectus Date, its written consent to be named in this Prospectus as Patent Attorney to the Company, in the form and context in which it is named and has given and not withdrawn its consent to the inclusion in this Prospectus of its Intellectual Property Report in the form and context in which it is included;

- KPMG has given, and has not withdrawn prior to the Prospectus Date, its written consent to be named in the Prospectus as Australian tax adviser to the Company in relation to the Offer in the form and context in which it is named;
- Link Market Services Limited has given, and has not withdrawn prior to the Prospectus Date, its written consent to be named in this Prospectus as the Share Registry in the form and context in which it is named; and
- Dr P Donnelly, Dr R Hicks and Dr L Emmett have each given, and have not withdrawn prior to the Prospectus Date, their written consent to the inclusion of statements attributable to them in the form and context in which they appear. Although these are statements used from books, journals or comparable publications, they are directly in relation to the work conducted on behalf of the Clarity Group.

No entity or person referred to above in this Section 10.17 has made any statement that is included in this Prospectus or any statement on which a statement made in this Prospectus is based, except as stated above. Each of the persons and entities referred to above in this Section 10.17 has not authorised or caused the issue of this Prospectus, does not make any offer of Shares and expressly disclaims and takes no responsibility for any statements in or omissions from this Prospectus except as stated above in this Section 10.17.

Third party publications

This Prospectus includes other statements from books, journals and comparable publications that are not specific to, and have no connection with, the Company. Except where indicated otherwise, the authors of these books, journals and comparable publications have not provided their consent for these statements to be included in this Prospectus, and the Company is relying upon ASIC Corporations (Consents to Statements) Instrument 2016/72 for the inclusion of these statements in this Prospectus without that consent having been obtained.

10.18. Expenses of the Offer

A summary of the Offer costs is set out below:

Offer Costs	A$ million
Joint Lead Manager fees	4.6
Legal fees	0.3
Independent accountant and patent advisor	0.1
ASX Listing fee	0.3
Other Costs	0.2
Total	**5.4**

The Company has paid, or will pay, all of the costs associated with the Offer. If the Offer proceeds, the total estimated cash expenses in connection with the Offer (including management, advisory, legal, accounting, tax, listing and administrative fees as well as printing, advertising and other expenses) are estimated to be approximately $5.4 million (excluding GST).

10.19. Working capital statement

The Board believes that the Company's current cash reserves plus the net proceeds of the Offer will be sufficient to fund the Company's stated business objectives.

The Board will consider the use of further equity funding or placements if appropriate to further accelerate growth or fund a specific project, transaction or expansion.

10.20. Subsequent events

There has not arisen, at the Prospectus Date, any item, transaction or event of a material or unusual nature not already disclosed in this Prospectus, which is likely, in the opinion of the Directors of the Company, to affect substantially:

- the operations of the Company;
- the results of those operations; or
- the state of affairs of the Company.

10.21. Prospectus available free of charge

During the Offer Period, a paper copy of this Prospectus will be available for Australian residents free of charge by contacting the Clarity Offer Information Line on 1800 645 237 (within Australia) or +61 1800 645 237 (outside Australia) between 8.30am and 5.30pm (Sydney time), Monday to Friday (Business Days only).

The Prospectus is also available in electronic form at the Offer website, https://events.miraqle.com/clarity-ipo.

The Offer constituted by this Prospectus in electronic form is available only to persons within Australia and is not available to persons in other jurisdictions. Persons who access the electronic version of this Prospectus must ensure that they download and read the entire Prospectus. If you are unsure about the completeness of this Prospectus received electronically, or a printed copy of it, you should contact the Company.

10.22. Continuous disclosure obligations

Following admission of the Company to the Official List, the Company will be a "disclosing entity" (as defined in Section 111AC of the Corporations Act) and, as a result, will be subject to regular reporting and disclosure obligations. Specifically, like all listed companies, the Company will be required to continuously disclose any information it has to the market which a reasonable person would expect to have a material effect on the price or the value of the Company's securities, unless an exception applies.

Price sensitive information will be publicly released on ASX before it is disclosed to Shareholders and market participants. Distribution of other information to Shareholders and market participants will also be managed through disclosure to ASX. In addition, the Company will post this information on its website after ASX confirms an announcement has been made, with the aim of making the information readily accessible to the widest audience.

10.23. Privacy

By filling out the Application Form to apply for Shares, you are providing personal information to the Company through its service provider, the Share Registry, which is contracted by the Company to manage Applications. The Company, and the Share Registry on its behalf, collects, holds and uses that personal information in order to process your Application, service your needs as a Shareholder, provide facilities and services that you request and carry out appropriate administration.

If you do not provide the information requested in the Application Form, the Company 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 in the Share register. In accordance with the requirements of the Corporations Act, information on the Share register may be accessible by members of the public. Your name and details must continue to be included in the Share register for a period of seven years after you cease to be a Shareholder.

The personal information may also be provided to the Company's agents and service providers on the basis that they deal with such information in accordance with the Company's privacy policy. The Company's 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. The types of agents and service providers that may be provided with your personal information and the circumstances in which your personal information may be shared are:

- the Share Registry for ongoing administration of the Share register;
- the Joint Lead Managers in order to assess your Application;
- brokers for the purpose of providing their services;
- printers and other companies for the purposes of preparation and distribution of statements and for handling mail;
- market research companies for the purpose of analysing the Company's shareholder base; and
- legal and accounting firms, auditors, contractors, consultants and other advisers for the purpose of administering, and advising on, the Shares and for associated actions.

Information contained in the Company's Share register is also used to facilitate corporate communications (including the Company's financial results, annual reports and other information that the Company may wish to communicate to Shareholders) and compliance by the Company with legal and regulatory requirements.

Under the *Privacy Act 1988* (Cth), Applicants may request access to their personal information held by or on behalf of the Company by contacting the Company's registered office or the Share Registry as set out in the Corporate Directory. You may be required to pay a reasonable charge to the Share Registry in order to access your personal information.

Applicants can obtain a copy of the Company's privacy policy by visiting the Company's website (www.claritypharmaceuticals.com). By submitting an Application, you agree that the Company and the Share Registry may communicate with you in electronic form or contact you by telephone in relation to the Offer.

10.24. Electronic prospectus

Pursuant to Regulatory Guide 107, ASIC has exempted compliance with certain provisions of the Corporations Act to allow distribution of an electronic prospectus on the basis of a paper prospectus lodged with ASIC and the issue of Shares in response to an electronic application form, subject to compliance with certain provisions. If you have received this Prospectus as an electronic Prospectus, please ensure that you have received the entire Prospectus accompanied by the Application Form. If you have not, please contact the Company and the Company will send you, free of charge, either a hard copy or a further electronic copy of this Prospectus or both.

The Company reserves the right not to accept an Application Form from a person if it has reason to believe that when that person was given access to the electronic Application Form, it was not provided together with the electronic Prospectus and any relevant supplementary or replacement prospectus or any of those documents were incomplete or altered. In such a case, the Application Monies received will be dealt with in accordance with section 722 of the Corporations Act.

The Offer constituted by this Prospectus is available electronically only to investors in Australia accessing or downloading or printing the electronic version of the Prospectus within Australia. The Offer constituted by this Prospectus in electronic format is not available to investors outside of Australia.

10.25. Investor considerations

Before deciding to participate in this Offer, you should consider whether the Shares to be issued are a suitable investment for you. There are general risks associated with any investment in the stock market. The value of Shares listed on ASX may rise or fall depending on a range of factors beyond the control of the Company.

The potential tax effects relating to the Offer will vary between investors. Investors are urged to consider the possible tax consequences of participating in the Offer by consulting a professional tax adviser.

10.26. Governing Law

This Prospectus 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 for Shares under this Prospectus and a bidder for Shares submits to the exclusive jurisdiction of the courts of New South Wales, Australia.

10.27. Statement of Directors

The Directors report that after due enquiries by them, in their opinion, since the date of the financial statements in the Investigating Accountant's Report in Section 8, there have not been any circumstances that have arisen or that have materially affected or will materially affect the assets and liabilities, financial position, profits or losses or prospects of the Company, other than as disclosed in this Prospectus.

This Prospectus is authorised by each Director and Proposed Director who consents to its lodgement with ASIC and its issue and has not withdrawn that consent.

Signed for the purposes of section 351 of the *Corporations Act 2001* (Cth)

Name: Dr Alan Taylor

Capacity: Executive Chairperson of Clarity Pharmaceuticals Ltd

Dated: 16 July 2021

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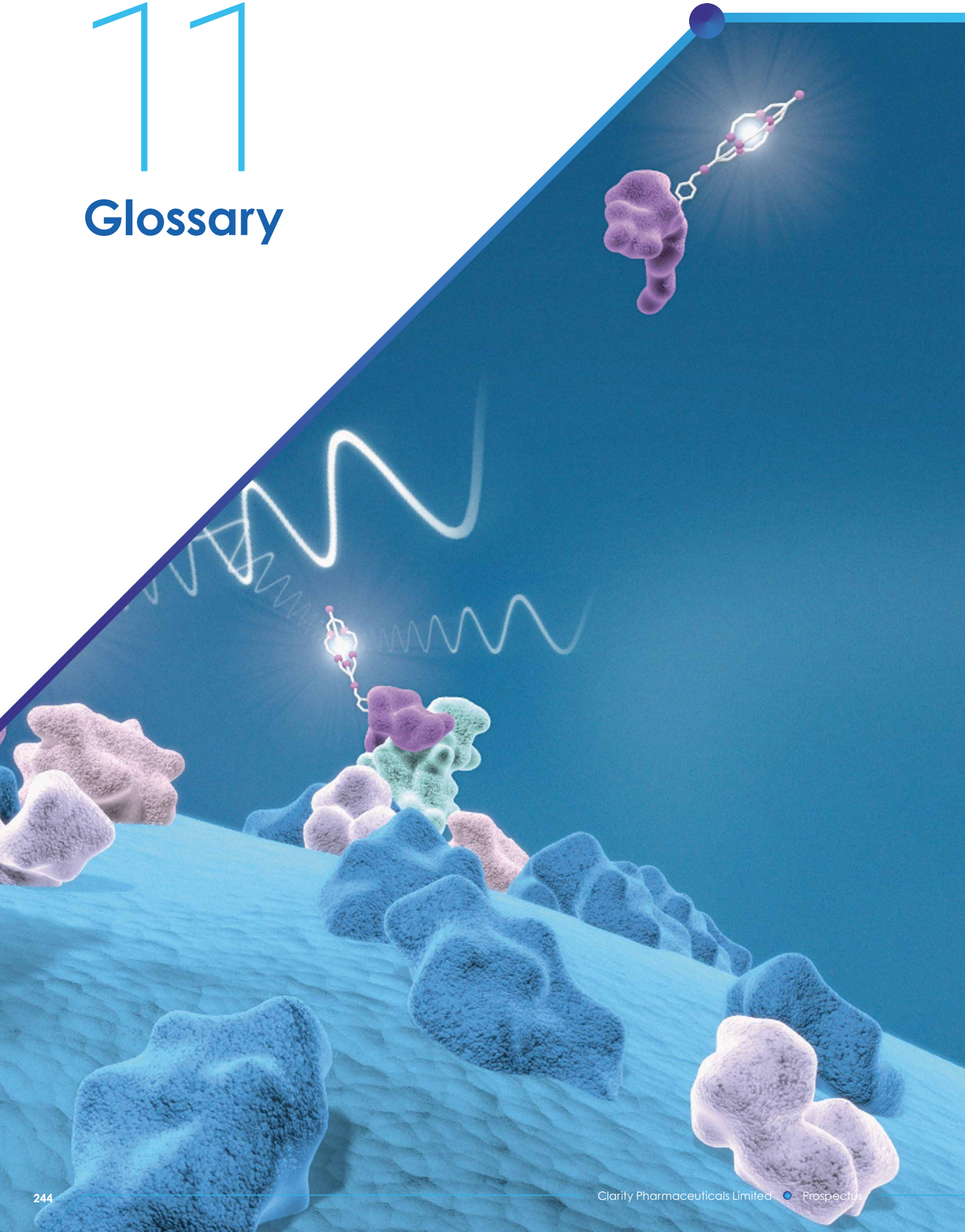
Glossary



11 Glossary

Term	Meaning
1H	First half of the relevant financial year
AAS and **AASB**	Australian Accounting Standards and Australian Accounting Standards Board
ABN	Australian Business Number
ACN	Australian Company Number
Adviser Options	The Options held by a professional adviser to the Clarity Group as described in Section 10.7.3
ANSTO	Australian Nuclear Science and Technology Organisation
Applicant	A person who submits an Application
Application	An application made to subscribe for Shares offered under this Prospectus
Application Form	The application form attached to or accompanying this Prospectus (including the electronic form provided by an online application facility)
Application Monies	The amount of money accompanying an Application Form submitted by an Applicant
ASIC	Australian Securities and Investments Commission
ASIC Act	*Australian Securities and Investments Commission Act 2001* (Cth)
ASX	ASX Limited (ABN 98 008 624 691) or, as the context requires, the financial market operated by it
ASX Listing Rules	The rules of the ASX that govern the admission, quotation and removal of securities from the Official List as amended, varied or waived from time to time
ASX Recommendations	The fourth edition of the Corporate Governance Principles and Recommendations
ASX Settlement Operating Rules	The settlement rules of the ASX as amended, varied or waived from time to time
ATO	Australian Taxation Office
AUD, A$** or **$	Australian dollar
Audit and Risk Committee	The committee described in Section 6.6.1.4a)
Australian Accounting Standards	Accounting Standards defined by the Corporations Act
Australian Government	Government of the Commonwealth of Australia
Bell Potter	Bell Potter Securities Limited (ACN 006 390 772)
Board	The board of directors of the Company
Broker	Any ASX participating organisation selected by the Joint Lead Managers and the Company to act as a broker to the Offer
Business Day	Has the meaning given in the ASX Listing Rules
CDMO	Commercial development manufacturing organisations

11 Glossary continued

Term	Meaning
CEO	Chief Executive Officer
cGMP	Current Good Manufacturing Practice
CGT	Capital gains tax
CHESS	Clearing House Electronic Subregister System, operated in accordance with the ASX Listing Rules and the ASX Settlement Operating Rules
China Grand	China Grand Pharmaceutical and Healthcare Holdings Limited (Registered Company Number 21251), a company registered in Hong Kong
China Grand Options	Options issued by the Company to China Grand pursuant to the option deed described in Section 10.7.4
Clarity Group	The Company and its subsidiaries
Clarity Offer Information Line	1800 645 237 (within Australia) and +61 1800 645 237 (outside Australia) between 8.30am and 5.30pm (Sydney time), Monday to Friday (Business Days only)
Closing Date	The date on which the Offer is expected to close, being Tuesday 10 August 2021 in respect of the Retail Offer. This date may be varied without prior notice
Code of Conduct	The corporate governance policy document described in Section 6.6.1.5b)
Company, we, us, our or **Clarity**	Clarity Pharmaceuticals Ltd (ABN 36 143 005 341)
Company Options	Options held by Directors, employees and consultants of the Clarity Group as described in Section 10.7.2
Company Secretary	Each company secretary of the Company from time to time
Completion	The completion of the Offer, being the date on which Shares are issued to Successful Applicants in accordance with the terms of the Offer
Constitution	The constitution of the Company as amended from time to time
Corporations Act	*Corporations Act 2001* (Cth)
COVID-19	The coronavirus disease
DCC	Davies Collison Cave, the Company's patent attorneys
Directors	Each of the directors of the Company from time to time
Disclosure and Communication Policy	The policy document described in Section 6.6.1.5e)
Discovery Program	The Company's discovery program that is focused on developing new products and new intellectual property for a range of indications of cancer
EBIT	Earnings before interest and tax
EBITDA	Earnings before interest, tax, depreciation and amortisation
EU	European Union
Existing Shareholders	Those persons holdings Shares immediately prior to Completion

Term	Meaning
Expiry Date	The date which is 13 months after the Prospectus Date
Exposure Period	The seven day period after the Prospectus Date, 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)
FDA	The United States Food and Drug Administration
FDA Orphan Drug Act	US Orphan Drug Act of 1983
Financial Information	Has the meaning given in Section 4
FY	Financial year to 30 June
Grant Thornton	Grant Thornton Corporate Finance Pty Ltd (ABN 59 003 265 987)
GST	Goods and Services Tax
HIN	Holder Identification Number for CHESS
IAC	Idaho Accelerator Center
IND	Investigational New Drug
Institutional Investors	Investors who are: • Persons in Australia who are a "wholesale client" for the purposes of section 761G of the Corporations Act and who are also either a "professional investor" or "sophisticated investor" under sections 708(11) and 708(8) of the Corporations Act; or • Institutional or professional investors in other Permitted Jurisdictions, to whom offers or invitations in respect of securities can be made without the need for a lodged or registered prospectus or other form of disclosure document or filing with, or approval by, any governmental agency (except Canada, where a notice reporting any sales of securities must be filed with the relevant provincial securities regulator), and in particular: (i) in **Canada (British Columbia, Ontario and Quebec provinces only)**, it (and any person for whom it is acting) is an "accredited investor" (as defined in National Instrument 45-106 – *Prospectus Exemptions*) and a "permitted client" (as defined in National Instrument 31-103 – Registration *Requirements, Exemptions and Ongoing Registrant Obligations*); (ii) in **Cayman Islands**, it (and any person for whom it is acting) acknowledges that any communications received in relation to the Offer occurred from outside the Cayman Islands; (iii) in **China**, it (and any person for whom it is acting) is (i) a "qualified domestic institutional investor" as approved by a relevant PRC regulatory authority to invest in overseas capital markets; (ii) a sovereign wealth fund or quasi-government investment fund that has the authorization to make overseas investments; or (iii) another type of qualified investor that has obtained all necessary PRC governmental approvals, registrations and/or filings (whether statutorily or otherwise);

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Term	Meaning
Institutional Investors continued	(iv) in **European Union (excluding Austria)**, it (and any person for whom it is acting) is a "qualified investor" (as defined in Article 2(e) of the Regulation (EU) 2017/1129 of the European Parliament and the Council of the European Union); (v) in **Hong Kong**, it (and any person for whom it is acting) is a "professional investor" as defined under the Securities and Futures Ordinance of Hong Kong, Chapter 571 of the Laws of Hong Kong; (vi) in **New Zealand**, it (and any person for whom it is acting) is a person who (i) is an investment business within the meaning of clause 37 of Schedule 1 of the Financial Markets Conduct Act 2013 (New Zealand) (**FMC Act**), (ii) meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act, (iii) is large within the meaning of clause 39 of Schedule 1 of the FMC Act, (iv) is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act or (v) is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act (and, if an eligible investor, have provided the necessary certification); (vii) in **Norway**, it (and any person for whom it is acting) is a "professional client" as defined in Norwegian Securities Trading Act of 29 June 2007 no. 75; (viii) in **Singapore**, it (and any person for whom it is acting) is an "institutional investor" or an "accredited investor" (as such terms are defined in the Securities and Futures Act of Singapore ("SFA")); (ix) in **Switzerland**, it (and any person for whom it is acting) is a "professional client" within the meaning of article 4(3) of the Swiss Financial Services Act ("FinSA") or have validly elected to be treated as a professional client pursuant to article 5(1) of the FinSA; (x) in **United Arab Emirates** (excluding financial zones), it (and any person for whom it is acting) is a "qualified investor" (as defined in the Securities and Commodities Authority Board of Directors' Chairman Decision No. 37 RM of 2019, as amended); (xi) in **United Kingdom**, it (and any person for whom it is acting) is (i) a "qualified investor" within the meaning of Article 2(e) of the UK Prospectus Regulation; and (ii) within the categories of persons referred to in Article 19(5) (investment professionals) or Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the UK Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended; and (xii) in **United States**, it (and any person for whom it is acting) is a QIB or an Eligible US Fund Managers.
Institutional Offer	The invitation to Institutional Investors under this Prospectus to acquire Shares, as described in Section 7.7
Investigating Accountant	Grant Thornton Corporate Finance Pty Ltd (ABN 59 003 265 987)
Investigating Accountant's Report	The report provided by Grant Thornton Corporate Finance Pty Ltd contained in Section 8
IP	Intellectual property
IPO	Initial public offering
Jefferies	Jefferies (Australia) Pty Ltd (ABN 76 623 059 898)
Joint Lead Managers	One or both of Jefferies and Bell Potter

Term	Meaning
KPMG	KPMG (ABN 51 194 660 183)
KPMG Law	KPMG Law (ABN 78 399 289 481)
Listing	The admission of the Company to the Official List of the ASX and quotation of the Shares on the ASX
MSA	Master services agreement
New Shareholders	Persons acquiring Shares under the Offer (excluding any Existing Shareholders who acquire Shares under the Offer)
Nomination and Remuneration Committee	The committee described in Section 6.6.1.4b)
ODD	Orphan Drug Designation
Offer	The offer under this Prospectus of new Shares for issue by the Company
Offer Period	The period commencing from the Opening Date and ending on the Closing Date
Offer Price	$1.40 per Share
Official List	The official list of the ASX
Opening Date	The opening date for receipt of Application Forms under this Prospectus being Tuesday 3 August 2021
Option	An option to be issued a Share in the Company and includes the Company Options, the Adviser Options and the China Grand Options
Permitted Jurisdictions	Australia, Canada (British Columbia, Ontario and Quebec provinces only), Cayman Islands, China, European Union (excluding Austria), Hong Kong, New Zealand, Norway, Singapore, Switzerland, United Arab Emirates (excluding financial zones), United Kingdom and the United States
PET	Positron emission tomography
Priority Offer	The component of the Offer under which investors who have received a personalised invitation are invited to apply for Shares, as described in Section 7.4.
Privacy Policy	The policy document described in Section 6.6.1.5
Proposed Director	Mr Robert Thomas
Prospectus	This document (including the electronic form of this Prospectus) and any supplementary or replacement prospectus in relation to this document
Prospectus Date	The date on which a copy of this Prospectus was lodged with ASIC, being 16 July 2021
PRV	Priority Review Voucher
QIB	"qualified institutional buyer" (as defined in Rule 144A under the US Securities Act)
R&D	Research and development
RPDD	Rare Paediatric Disease Designation

11 Glossary continued

Term	Meaning
SAHMRI	South Australian Health and Medical Research Limited
Settlement	The settlement in respect of the Shares the subject of the Offer occurring under the Underwriting Agreement and associated settlement support arrangements
Share	A fully paid ordinary share in the capital of the Company
Share Registry	Link Market Services Limited (ACN 083 214 537)
Shareholders	The holders of Shares
Successful Applicant	An Applicant who is issued Shares under the Offer
Sydney time	Australian Eastern Standard Time
TFN	Tax file number
TGA	The Australian Therapeutic Goods Administration
Underwriting Agreement	Has its meaning given in Section 10.11.1
UOM	The University of Melbourne
US or United States	United States of America, its territories and possessions
USD or **US$**	United States dollar
US Offering Circular	The offering circular that must accompany any distribution of the Prospectus in the United States to Institutional Investors
US Securities Act	US Securities Act of 1933, as amended

APPENDIX A:
Significant Accounting Policies

Appendix A: Significant Accounting Policies

The following is a summary of the significant accounting policies used in the preparation of the Historical Financial Information set out in this Prospectus.

a) Basis of consolidation

The Historical Financial Information consolidates those of the Parent Company and its subsidiaries. The parent controls a subsidiary if it is exposed, or has rights, to variable returns from its involvement with the subsidiary and can affect those returns through its power over the subsidiary. The only subsidiary has a reporting date of 31 December. All transactions and balances between Clarity Group companies are eliminated on consolidation as at 30 June, including unrealised gains and losses on transactions between Clarity Group companies. Where unrealised losses on intra-group asset sales are reversed on consolidation, the underlying asset is also tested for impairment from a Clarity Group perspective.

b) Functional currency translation

The Historical Financial Information is presented in Australian dollars ($), which is also the functional currency of the Parent Company. Foreign currency transactions are translated into the functional currency of the respective Clarity Group entity, using the exchange rates prevailing at the dates of the transactions (spot exchange rate). Foreign exchange gains and losses resulting from the settlement of such transactions and from the re-measurement of monetary items at year end exchange rates are recognised in profit or loss.

Non-monetary items are not translated at year-end and are measured at historical cost (translated using the exchange rates at the date of the transaction), except for non-monetary items measured at fair value which are translated using the exchange rates at the date when fair value was determined. In the Historical Financial Information, all assets, liabilities and transactions of Clarity Group entities with a functional currency other than the $ are translated into $ upon consolidation. The functional currency of the entities in the Clarity Group has remained unchanged during the reporting period. On consolidation, assets and liabilities have been translated into $ at the closing rate at the reporting date. Goodwill and fair value adjustments arising on the acquisition of a foreign entity have been treated as assets and liabilities of the foreign entity and translated into $ at the closing rate. Income and expenses have been translated into $ at the average rate over the reporting period. Exchange differences are charged and/or credited to other comprehensive income and recognised in the currency translation reserve in equity.

c) Other income

The following recognition criteria must be met before other income is recognised.

Grant Income – Grant Income is recognised when the expenditure related to the grant is recognised. Grant monies that have been received or are receivable but have not yet been expended at balance date are carried forward as unexpended grants.

Finance Income – Finance Income relates to interest from bank and term deposits and is recognised on an accruals basis.

Research & Development Incentive – Research & Development incentive is recognised as income when a reliable estimate can be made of the amounts receivable.

d) Income tax

The charge for current income tax expense is based on the profit for the period adjusted for any non-assessable or disallowed items. It is calculated using tax rates that have been enacted or are substantively enacted by the statement of financial position date.

Deferred tax is accounted for using the statement of financial position liability method in respect of temporary differences arising between the tax bases of the assets and liability and their carrying amounts in the financial statements. No deferred income tax will be recognised from the initial recognition of an asset or liability, excluding a business combination, where there is no effect on accounting or taxable profit or loss.

Deferred tax assets are recognised to the extent that it is probable that sufficient taxable amounts will be available against which deductible temporary differences or unused tax losses and tax offsets can be utilised.

e) Goods and services tax (GST)

Revenues, expenses and assets are recognised net of the amount of GST, except:

Where the amount of GST incurred is not recoverable from the Australian Tax Office (ATO). In these circumstances the GST is recognised as part of the cost of acquisition of the asset or as part of an item of the expense.

Receivables and payables in the Statement of Financial Position are shown inclusive of GST.

The net amount of GST recoverable from, or payable to, the ATO is included as part of receivables or payables in the Statement of Financial Position.

Cash flows are included in the Statement of Cash Flows on a gross basis and the GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the ATO are classified as operating cash flows.

Commitments and contingencies are disclosed net of the GST recoverable from, or payable to, the ATO.

f) Trade and other receivables

Trade receivables, which generally have a 30 day term, are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method, less an allowance for impairment.

The Clarity Group makes use of a simplified approach in accounting for trade and other receivables as well as contract assets and records the loss allowance as lifetime expected credit losses. These are the expected shortfalls in contractual cash flows, considering the potential for default at any point during the life of the financial instrument. In calculating, the Clarity Group uses its historical experience, external indicators and forward-looking information to calculate the expected credit losses using a provision matrix.

g) Cash and cash equivalents

Cash and cash equivalents include cash on hand and short-term deposits with banks or financial institutions, with an original maturity of three months or less. For the purpose of the Statement of Cash Flows, cash and cash equivalents consist of cash and cash equivalents as defined above, net of outstanding bank overdrafts.

h) Impairment of assets

At each reporting date, the Clarity Group reviews the carrying values of its tangible assets to determine whether there is any indication that those assets have been impaired. If such an indication exists, the recoverable amount of the asset, being the higher of the asset's fair value less costs to sell and value in use, is compared to the asset's carrying value. Where the asset does not generate cash flows that are independent from other assets, the Clarity Group estimates the recoverable amount of the cash generating unit to which it belongs. Any excess of the asset's carrying value over its recoverable amount is expensed to the Statement of Profit or Loss.

i) Plant and equipment

Plant and equipment are measured at cost less depreciation and impairment losses. Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Clarity Group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the statement of profit or loss and other comprehensive income during the financial period in which they are incurred.

j) Depreciation

The depreciable amount of all fixed assets is depreciated on a diminishing value basis over their useful lives to the Clarity Group commencing from the time the asset is held ready for use. The depreciation rates used for each class of depreciable assets are:

Class of Fixed Asset	Depreciation Rate
Plant and Equipment	30%

The assets residual values and useful lives are reviewed, and adjusted if appropriate, at each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount. Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These gains or losses are included in the statement of profit or loss and other comprehensive income. When revalued assets are sold, amounts included in the revaluation reserve relating to that asset are transferred to retained earnings.

k) Patent expenses

The Clarity Group has re-assessed the accounting treatment of patent expenses and determined that it is more appropriate to expense all patent costs as incurred. Previously patents obtained by the Clarity Group were stated at cost less accumulated amortisation and impairment losses. Capitalised costs principally related to the costs of legal counsel in obtaining the patent.

In the Clarity Group's judgement, expensing these costs is considered more prudent and appropriate for the current stage of product development.

This change in accounting for patent expenses impacts on the Clarity Group's financials as a net decrease to intangible assets and an increase in expenses recognised in the profit or loss. The Clarity Group has restated each of the affected financial statement line items for the prior periods.

l) Operating leases

Operating lease payments are charged to the Statement of Profit or Loss in the periods in which they are incurred, as this represents the pattern of benefits derived from the leased asset.

m) Financial instruments Recognition

Financial assets at amortised cost

Financial assets are measured at amortised cost if the assets meet the following conditions (and are not designated as FVTPL):

- they are held within a business model whose objective is to hold the financial assets and collect its contractual cash flows; or
- the contractual terms of the financial assets give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding.

After initial recognition, these are measured at amortised cost using the effective interest method. Discounting is omitted where the effect of discounting is immaterial. The Clarity Group's cash and cash equivalents, trade and most other receivables fall into this category of financial instruments as well as listed bonds that were previously classified as held-to-maturity under IAS 39.

Financial assets at fair value through profit or loss (FVTPL)

Financial assets that are held within a different business model other than 'hold to collect' or 'hold to collect and sell' are categorised at fair value through profit and loss. Further, irrespective of business model financial assets whose contractual cash flows are not solely payments of principal and interest are accounted for at FVTPL.

Fair value

Fair value is determined based on current bid prices for all quoted investments. Valuation techniques are applied to determine fair value for all unlisted securities, including recent arm's length transactions, references to similar instruments and option pricing models.

Impairment

IFRS 9's impairment requirements use more forward-looking information to recognise expected credit losses – the 'expected credit loss (ECL) model'. This replaced IAS 39's 'incurred loss model'. Instruments within the scope of the new requirements included loans and other debt-type financial assets measured at amortised cost and FVOCI, trade receivables, contract assets recognised and measured under IFRS 15 and loan commitments and some financial guarantee contracts (for the issuer) that are not measured at fair value through profit or loss.

n) Employee benefits

Provision is made for the Clarity Group's liability for employee benefits arising from services rendered by employees to the end of the reporting period. Employee benefits that are expected to be settled within one year have been measured at the amounts expected to be paid when the liability is settled.

Employee benefits payable later than one year have been measured at the present value of the estimated future cash outflows to be made for those benefits. In determining the liability, consideration is given to employee wage increases and the probability that the employee may satisfy vesting requirements. Those cash flows are discounted using market yields on national government bonds with terms to maturity that match the expected timing of cash flows.

The fair value of options granted are valued under AASB 2 (Share-based Payment) using the Black Scholes valuation method. This is a non-cash expense item.

o) Critical accounting estimates and judgements

The directors evaluate estimates and judgements incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both externally and within the Clarity Group.

Key estimate – Research and Development Tax Incentive – The Clarity Group assesses its Australian Federal Government Research and Development Tax Incentive receivable at each reporting date, by tracking its eligible research and development expenditure, applying the Research and Development Tax Incentive refundable tax offset rate and applying applicable clawback provisions to its related grant expenditure.

Key estimates – Share Based Payments – The Clarity Group measures cost of equity settled share-based payments at Future Value (FV) at grant date using the Black Scholes valuation methodology considering the terms & conditions upon which the instruments were granted. Inputs into the Black Scholes valuation model require a level of estimation and judgement. As the Clarity Group is not trading publicly, judgement is also required to determine the share price input for the Black Scholes valuation.

Key judgement – Recognition of deferred tax assets – The extent to which deferred tax assets can be recognised is based on an assessment of the probability that future taxable income will be available against which the deductible temporary differences and tax loss carry-forwards can be utilised. This includes an assessment of the amount and likelihood of the Clarity Group's ability to successfully claim the R&D Tax Incentive cash offset.

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CLARITY PHARMACEUTICALS

CLARITY PHARMACEUTICALS LTD
ABN 36 143 005 341

Broker Code

Adviser Code

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If you are in doubt as to how to deal with this Application Form, please contact your accountant, lawyer, stockbroker or other professional adviser. The Prospectus contains information relevant to a decision to invest in Shares and you should read the entire Prospectus carefully before applying for Shares. By Applying under the Broker Firm Offer, you make the acknowledgments, declarations, representations and warranties set out in the Prospectus. Defined terms in the Prospectus have the same meaning as in this Application Form. The Corporations Act 2001 (Cth) prohibits any person from passing on this Application Form (whether in paper or electronic form) unless it is attached to or accompanied by a complete an unaltered copy of the Prospectus (whether in paper or electronic form).

A Shares applied for

(minimum $2,000, thereafter in multiples of $500)

at Price per Share **A$1.40**

B Application Monies A$

PLEASE COMPLETE YOUR DETAILS BELOW (refer overleaf for correct forms of registrable names)

C

Applicant #1
Surname/Company Name

Title | First Name | Middle Name

Joint Applicant #2
Surname

Title | First Name | Middle Name

Designated account e.g. <Super Fund> (or Joint Applicant #3)

D

TFN/ABN/Exemption Code
First Applicant | Joint Applicant #2 | Joint Applicant #3

TFN/ABN type – if NOT an individual, please mark the appropriate box ☐ Company ☐ Partnership ☐ Trust ☐ Super Fund

PLEASE COMPLETE ADDRESS DETAILS

E

PO Box/RMB/Locked Bag/Care of (c/-)/Property name/Building name (if applicable)

Unit Number/Level | Street Number | Street Name

Suburb/City or Town | State | Postcode

Email address (only for purpose of electronic communication of shareholder information)

F

CHESS HIN
X

If you have a Broker Sponsored account and would like your securities to be allocated to this account, it is important that you enter your HIN at this step. Failure to do so will result in your securities being allocated to a new Issuer Sponsored account. You will not be able to change this until after the stock exchange listing takes place and you will need to request your broker to do this for you.

G

Telephone Number where you can be contacted during Business Hours ( )

Contact Name (PRINT)

Cheques or bank drafts should be drawn up according to the instructions given by your Broker.

H

Cheque or Bank Draft Number | BSB - | Account Number

Total Amount A$

LODGEMENT INSTRUCTIONS

You must return your application so it is received by your Broker by the deadline set out in their offer to you.

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Please complete all relevant white sections of the Application Form in BLOCK LETTERS, using black or blue ink. These instructions are cross-referenced to each section of the form.

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The Australian Securities and Investments Commission requires that a person who provides access to an electronic application form must provide access, by the same means and at the same time, to the relevant Prospectus. This Application Form is included in the Prospectus. By Lodging the Application Form, the Applicant agrees that this Application for Shares in Clarity Pharmaceuticals Ltd is upon and subject to the terms of the Prospectus and the Constitution of Clarity Pharmaceuticals Ltd, 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 in the Application Form are complete and accurate.

The Prospectus contains important information about investing in the Shares. You should read the Prospectus before applying for Shares.

A Insert the number of Shares you wish to apply for. The Application must be for a minimum of $2,000 worth of Shares and thereafter in multiples of $500. You may be issued all of the Shares applied for or a lesser number.

B Insert the relevant amount of Application Monies. To calculate your Application Monies, multiply the number of Shares applied for by the issue price. Amounts should be in Australian dollars. Please make sure the amount of your cheque or bank draft equals this amount.

C Write the full name you wish to appear on the register of Shares. This must be either your own name or the name of a company. Up to three joint Applicants may register. You should refer to the table below for the correct registrable title.

D Enter your Tax File Number (TFN) or exemption category. Business enterprises may alternatively quote their Australian Business Number (ABN). Where applicable, please enter the TFN or ABN for each joint Applicant. Collection of TFN(s) and ABN(s) is authorised by taxation laws. Quotation of TFN(s) and ABN(s) is not compulsory and will not affect your Application. However, if these are not provided, Clarity Pharmaceuticals Ltd will be required to deduct tax at the highest marginal rate of tax (including the Medicare Levy) from payments.

E Please enter your postal address for all correspondence. All communications to you from Clarity Pharmaceuticals Ltd and the Share Registry will be mailed to the person(s) and address as shown. For joint Applicants, only one address can be entered.

F If you are already a CHESS participant or sponsored by a CHESS participant, write your Holder Identification Number (HIN) here. If the name or address recorded on CHESS for this HIN is different to the details given on this form, your Shares will be issued to Clarity Pharmaceuticals Ltd's issuer sponsored subregister.

G Please enter your telephone number(s), area code and contact name in case we need to contact you in relation to your Application.

H Please complete the details of your cheque or bank draft in this section. The total amount of your cheque or bank draft should agree with the amount shown in section B.

If you receive a firm allocation of Shares from your Broker make your cheque payable to your Broker in accordance with their instructions.

CORRECT FORMS OF REGISTRABLE NAMES

Note that ONLY legal entities are allowed to hold Shares. Applications must be in the name(s) of natural persons or companies. At least one full given name and the surname is required for each natural person. The name of the beneficiary or any other non-registrable name may be included by way of an account designation if completed exactly as described in the examples of correct forms below.

Type of Investor	Correct Form of Registration	Incorrect Form of Registration
Individual Use given names in full, not initials	Mrs Katherine Clare Edwards	K C Edwards
Company Use Company's full title, not abbreviations	Liz Biz Pty Ltd	Liz Biz P/L or Liz Biz Co.
Joint Holdings Use full and complete names	Mr Peter Paul Tranche & Ms Mary Orlando Tranche	Peter Paul & Mary Tranche
Trusts Use the trustee(s) personal name(s)	Mrs Alessandra Herbert Smith <Alessandra Smith A/C>	Alessandra Smith Family Trust
Deceased Estates Use the executor(s) personal name(s)	Ms Sophia Garnet Post & Mr Alexander Traverse Post <Est Harold Post A/C>	Estate of late Harold Post or Harold Post Deceased
Minor (a person under the age of 18 years) Use the name of a responsible adult with an appropriate designation	Mrs Sally Hamilton <Henry Hamilton>	Master Henry Hamilton
Partnerships Use the partners' personal names	Mr Frederick Samuel Smith & Mr Samuel Lawrence Smith <Fred Smith & Son A/C>	Fred Smith & Son
Long Names	Mr Hugh Adrian John Smith-Jones	Mr Hugh A J Smith Jones
Clubs/Unincorporated Bodies/Business Names Use office bearer(s) personal name(s)	Mr Alistair Edward Lilley <Vintage Wine Club A/C>	Vintage Wine Club
Superannuation Funds Use the name of the trustee of the fund	XYZ Pty Ltd <Super Fund A/C>	XYZ Pty Ltd Superannuation Fund

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Corporate Directory

Company's Registered Office

Clarity Pharmaceuticals Ltd

C/- Company Matters Pty Limited
Level 12, 680 George Street
Sydney NSW 2000

Joint Lead Managers

Jefferies (Australia) Pty Ltd

Level 22
60 Martin Place
Sydney NSW 2000

Bell Potter Securities Ltd

Level 29
101 Collins Street
Melbourne VIC 3000

Australian Legal Adviser

KPMG Law

Level 38, Tower Three
International Towers Sydney
300 Barangaroo Avenue
Sydney NSW 2000

Investigating Accountant

Grant Thornton Corporate Finance Pty Ltd

Level 17, 383 Kent Street
Sydney NSW 2000

Australian Tax Adviser

KPMG

Level 38, Tower Three
International Towers Sydney
300 Barangaroo Avenue
Sydney NSW 2000

Independent Auditor

Grant Thornton Audit Pty Ltd

Level 17, 383 Kent Street
Sydney NSW 2000

Patent Attorney

Davies Collison Cave Pty Ltd

Level 14
255 Elizabeth Street
Sydney NSW 2000

Share Registry

Link Market Services Limited

Level 12
680 George Street
Sydney NSW 2000

Clarity Offer Information Line

1800 645 237 (within Australia)
+61 1800 645 237 (outside Australia)
Between 8.30am and 5.30pm (Sydney time),
Monday to Friday (Business Days only)

Offer Website

https://events.miraqle.com/clarity-ipo

Corporate Website

https://www.claritypharmaceuticals.com/


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