PITT STREET RESEARCH

Invion Ltd

Advancing its clinical programs

Share Price: A$0.005

ASX: IVX

Sector: Pharmaceuticals & Life Sciences

14 February 2024

Invion Ltd (ASX: IVX) is a life sciences company developing Photosoft™, a novel Photodynamic Therapy (PDT) for treating various types of cancer and other medical indications. PDT technology utilises a photosensitising compound, oxygen, and light to generate destructive reactive oxygen species (ROS), promoting an anti-cancer immune response. Invion's lead drug candidate from the Photosoft™ technology is the PDT photosensitiser – INV043, which works additively with blockbuster immune checkpoint inhibitors (ICI) drugs. It is non-toxic and supports translation into successful clinical trials.

Extension of technological distribution rights to South Korea provides significant boost to market opportunity

In September 2023, the existing perpetual license and distribution rights for cancer indications of Photosoft technology were expanded to include the territory of South Korea. This expansion represents a new and significant opportunity for Invion, considering the oncology drugs market in South Korea is projected to grow to US$7.4 billion by 2030. With this broadening of distribution rights, Invion is poised to advance further toward its goal of expanding into territories in the Asia Pacific region, enhancing shareholder value through the development of the Photosoft™ technology.

Making strong progress on multiple clinical trials

Currently, multiple clinical trials are planned for cancers and infectious diseases (specifically periodontal diseases). In the realm of cancer, there is a significant market opportunity for non-melanoma skin cancers (NMSC) and its Ph I/II trial is set to commence in a few months. Invion's exclusive territories provide access to markets with more than 3 billion people for oral microbial diseases. The company is on track to commence its Phase I clinical trial on NMSCs in the coming months. Additionally, Invion is conducting tests to demonstrate that the technology could also be effective against several other diseases, including the Zika virus, Dengue, bacteria and fungi.

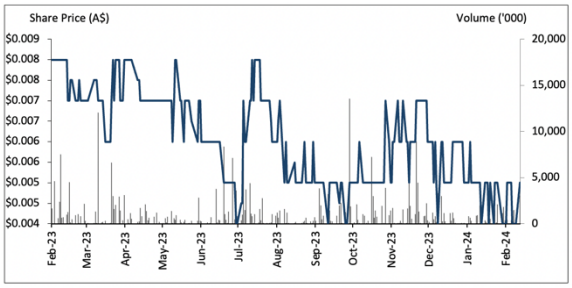
Valuation range of A$0.016-A$0.021 per share

We continue to value Invion at A$0.016-A$0.021 per share using a weighted DCF approach. Although Invion's valuation has retreated from the highs of 2021, along with the broader biotechnology sector, we believe that Invion has the potential to re-rate as the clinical development of INV043 de-risks its future prospects. Please see page 11 for key risks.

Market Cap. (A$ m)	32.1
# shares outstanding (m)	6,421.6
# shares fully diluted	6,728.3
Market Cap Ful. Dil. (A$ m)	33.6
Free Float	47.3%
52-week high/low (A$)	0.08 / 0.004
Avg. 12M daily volume (m)	1,317.4
Website	https://inviongroup.com/

Source: Company, Pitt Street Research

Share price (A$) and avg. daily volume (m, r.h.s.)



Source: Refinitiv, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A$)	0.016–0.021
WACC	15.6%
Assumed terminal growth rate	2.0%

Source: Pitt Street Research

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Re-introducing Invion

Invion (ASX: IVX) is a leading life sciences company spearheading the research and development of the Photosoft™ product portfolio—a Next Generation Photodynamic Therapy (NGPDT)—for the treatment of various cancers, atherosclerosis, and infectious diseases.

Photodynamic Therapy (PDT) is a medical approach that employs a photosensitising compound, oxygen, and light to generate destructive reactive oxygen species (ROS). This process selectively kills cancer cells and stimulates an anticancer immune response. FDA-approved for certain cancer types, PDT is a less invasive alternative to surgery, with minimal side effects. It has proven to be an effective strategy for ablating tumour tissues, offering an alternative treatment option that can lead to tumour regression and long-lasting remissions.

What is Next Generation Photodynamic Therapy?

NGPDT, also known as Photosoft™ technology, is a chlorin-based PDT photosensitiser initially developed by the Cho Group over a decade ago. This ground-breaking technology aims to overcome the shortcomings of current PDT technologies, with the goal of transforming the treatment landscape for a wide range of cancers. It represents a minimally invasive modality for cancer treatment, specifically identifying and destroying cancer cells while leaving the rest of the body's normal cells unharmed. Photosoft™ is water-soluble and can be administered topically or intravenously, offering patient convenience when appropriate.

Invion's Photosoft™ technology and INV043

Invion is developing Photosoft™ technology as a novel NGPDT for the treatment of multiple cancer types since 2017. The Photosoft™ technology finds its utility in PDT therapy with several key advantages. The company's current lead compound for cancer from the Photosoft™ technology is PDT photosensitiser – INV043.

INV043: a promising new cancer treatment

Invion's lead cancer drug candidate – INV043 has the potential to become the best-in-class PDT in the oncology

Invion has made substantial progress through its collaboration with research partners, such as the Hudson Institute and Peter MacCallum Cancer Centre, for the development of INV043, an improvement over previous API. Serving as Invion's lead drug candidate, INV043 represents the Next Generation Photodynamic Therapy (NGPDT) designed to treat various types of cancers. It is an enhanced version of the original Photosoft™, demonstrating greater cancer-killing potential and eliciting an anti-cancer immune response in animal models.

Proof of Concept (PoC) studies for INV043 have revealed its selective absorption by cancer cells, effectiveness in regressing multiple cancer types in vivo, and its ability to stimulate the body's natural immune response. Furthermore, it synergistically works with blockbuster Immune Checkpoint Inhibitor (ICI) drugs. INV043 is non-toxic, safe, with limited side effects, supporting its translation into successful clinical trials.

In FY23, the company achieved significant progress in substantiating the potential of its API INV043, positioning it for advancement to clinical trials. INV043 exhibits various characteristics, including activity against multiple cancers, high potency and selectivity, a robust therapeutic profile, and theragnostic potential.

The commercialisation pathway for Invion with PDT involves multiple cancer therapies

The Photosoft™ technology is likely to be useful across a wide range of cancers including skin cancer, ovarian cancer, Anal cancer SCC, T-cell lymphoma, Triple Negative Breast Cancer (TNBC), pancreatic cancer, ano-genital cancer and colorectal cancer.

Invion licensed for the commercial development of Photosoft™ technology in multiple territories

Invion holds the exclusive license for the application of Photosoft™ technology in cancer treatment across Australia, New Zealand, and all Asia Pacific countries except China (including Hong Kong), Macau, Taiwan and Japan.

The Cho Group, known for successfully commercialising unique and advanced technologies, appointed Invion to lead the Research and Development (R&D) program for Photosoft™ technology's expansive application in various cancers and the associated light device. This strategic partnership allows the Cho Group to contribute its existing intellectual property and know-how related to the Photosoft™ technology for applicable cancer indications.

In FY22, Invion's initial exclusive licensing agreement with the Cho Group was expanded, aiming to provide the company access to markets encompassing more than 2.8 billion people. PDT, demonstrated to be effective across various disease conditions, further strengthens Invion's position.

Invion also possesses the rights to develop Photosoft™ for atherosclerosis and infectious diseases in the Asia Pacific region (excluding Greater China, Middle East, and Russia). Notably, a recent deal has expanded these territories for infectious diseases to include the United States, Canada, and Hong Kong.

Encouraging pre-clinical results along with strong partnerships in cancer bodes well for Invion

Pre-clinical experience of Invion's PDT products in cancer

Invion has collaborated with Peter MacCallum Cancer Centre (PMCC) and Hudson Institute on the pre-clinical development of Photosoft™ products. In October 2021, the company reported favourable pre-clinical results in TNBC with INV043. In December 2021, Hudson Institute released findings from its follow up PoC II studies. The studies utilised Invion's API INV043 for the treatment of immunocompetent mice that had been implanted with TNBC. The results of the PoC pilot work showed complete tumour regression with no recurrence of disease in the treatment of mice with photoactivated INV043. The non-establishment of new tumours suggested the development of protective immunity (following treatment of INV043), which is a key requirement to maintain long term remission.

Combination of INV043 and ICI for enhanced efficacy

The Hudson Institute successfully completed its third PoC study examining the use of INV043 in combination with immune checkpoint inhibitors (ICIs). The third PoC study discovered that combination therapy (for the ICI market which is likely to grow from US$35bn in 2021 to US$155.1bn by 2031 at a CAGR of 16.1%) enhanced the effectiveness of the treatment by around 65% in mice with TNBC as compared to standalone ICI therapy. We believe that the combination of INV043 and ICIs is likely to enhance anti-tumour efficacy compared to monotherapy alone, as the treatment will result in direct tumour cell death and improve anti-tumour immune responses. The combination of

INV043 and ICIs is further likely to open possibilities for partnerships. This can be attributable to INV043 providing scope to pharmaceutical companies with ICI drugs for enhancement of clinical outcomes and extension of the patent life for ICI therapies.

Squamous cell carcinomas (SCCs)

In September 2022, Invion was able to show that INV043 could work against SCCs associated with anal cancers *in vitro*. Successful in-vitro studies conducted by PMCC demonstrated INV043's effectiveness against six SCC cell lines. The main objective of the studies was to assess the relative cytotoxicity of light activated INV043 of human anal SCC cell lines. The results were consistent with the promising outcomes achieved by Hudson Institute on other cancer types.

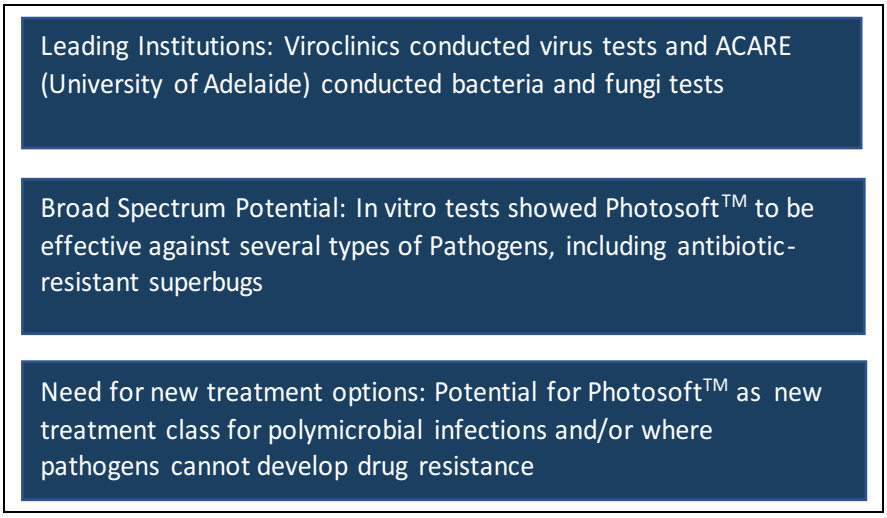
In vitro tests for atherosclerosis and infectious diseases

Recently, Invion started preparatory and early-stage preclinical work using Photosoft™ to treat atherosclerosis and infectious diseases, including Zika Virus, dengue, bacteria and fungi.

- **Viruses**
  - **Zika –** Many Photosoft™ compounds had >100x the activity of Monensin (selected control) in vitro.
  - **Dengue** – In vitro studies of the Photosoft™ technology resulted in positive screening results to inhibit the Dengue virus.
  - **SARS-CoV-2 –** The Photosoft™ technology has shown encouraging results against the Delta and Omicron BA.1 variants of SARS-CoV-2 (the virus behind COVID-19) during in vitro tests conducted in FY2021.
- **Bacteria and fungi** - In-vitro tests using Photosoft™ are effective against multiple strains of antibiotic-resistant MRSA bacteria, Escherichia coli bacteria and Candida albicans fungus in tests undertaken at the Australian centre for Antimicrobial Resistance Ecology (ACARE) in the University of Adelaide (Figure 1).

Photosoft™ technology proved to be effective against several types of pathogens including antibiotic resistant superbugs

Figure 1: The Photosoft™ technology has broad-spectrum anti-microbial potential



Source: Company, Pitt Street Research

Invion has made significant progress in the past few months

Invion has made substantial progress in its development of its Photosoft™ technology.

IP protection receives a boost from grant of new patent

In July 2023, a new Australian patent was granted to Invion's Photosoft™ technology which includes the lead compound INV043. The patent builds upon patents granted previously to the technology in Australia and other territories that Invion has exclusive rights to. The new patent extends intellectual property (IP) protection to the Photosoft™ technology for two decades until at least late 2041 with original patents set to expire in 2033. It also strengthens IP protection as Invion embarks on its commencement of its clinical trials.

Photosoft™ technology expanded to include South Korea for cancer indications

In September 2023, Photosoft™ technology's perpetual license and distribution rights for cancer indications expanded to include South Korea. This expansion opens up a significant opportunity for Invion, aligning with expectations of substantial growth in the South Korean oncology drugs market—from US$2.9 billion in 2022 to a projected US$7.4 billion by 2030, reflecting a Compound Annual Growth Rate (CAGR) of 12.5%. Market research by Insights10 suggests a rising cancer incidence in South Korea, attributed to an aging population and evolving lifestyles, a trend observed in many countries within Invion's exclusive territories.

To support the development in the South Korean territory, Invion is poised to contribute A$0.9 million towards prior development costs incurred by RMW Cho Group for cancer indications. Additionally, Invion is expected to share 50% of upfront fees, milestone payments, and royalties received from RMW Cho Group for sub-licensing the technology in South Korea. Future non-clinical work will be financed 25% by Invion and 75% by RMW Cho Group, while future clinical work will be funded at a ratio of 75% by Invion and 25% by RMW Cho Group in South Korea.

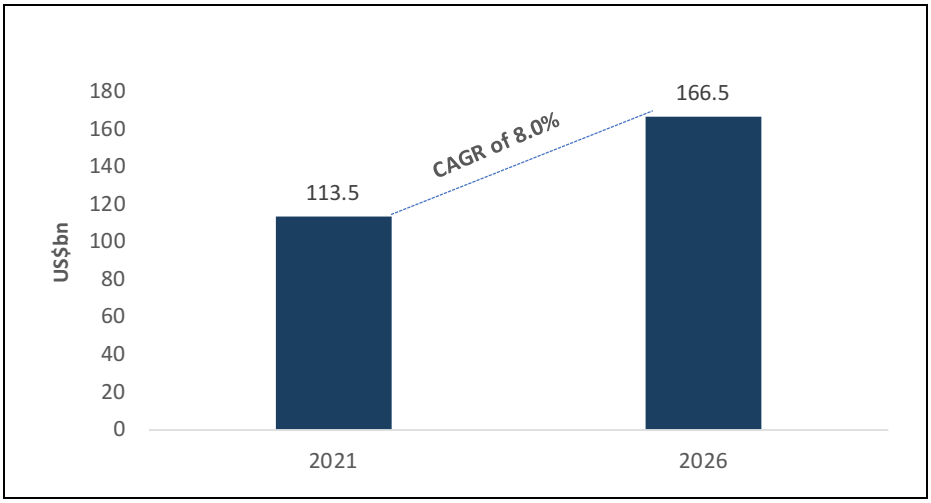
Expansion of Photosoft™ technology's license and distribution rights to South Korea is likely to boost the technology's potential as a key cancer treatment option

We anticipate that this agreement will offer Invion the opportunity to broaden its territories in the Asia Pacific region. As the company continues to enhance shareholder value through the development of Photosoft™ technology, poised to become a pivotal cancer treatment option, this expansion is timely. Invion is now embarking on human clinical trials for cancers, following promising results from its pre-clinical studies.

Significant market opportunity for cancer and other disease indications

Invion is planning on conducting further pre-clinical studies and clinical trials for cancer indications and atherosclerosis and infectious diseases (AID). The global market for infectious diseases is likely to grow from US$113.5bn in 2021 to US$166.5bn in 2026 at a CAGR of 8%, with the global pandemic signalling the need for new treatments (Figure 2).

Figure 2: Global infectious diseases market is likely to grow to US$166.5bn by 2026



Source: Company, Pitt Street Research, medgadget

The cancer indications for which clinical trials are being conducted include Non-Melanoma Skin Cancer (NMSC), solid tumour cancer indications, Anogenital Cancers (Topical) and additional international indications. AID includes oral microbial diseases, wound healing and atherosclerosis. Currently, a significant opportunity exists in the market for NMSC and oral microbial diseases.

1. NMSC

Need for a less invasive treatment has emerged from side effects associated with existing treatment options

NMSC is the world's most common type of skin cancer (Figure 3 and Figure 4). The epidemiology and risk factors for NMSC involve exposure to UV-rays, with genetics playing a significant role, primarily linked to a family history of skin cancer. NMSC predominantly affects older individuals, with more men than women being affected, and is associated with Human Papilloma Virus (HPV) and certain chemicals.

The standard treatment for NMSC is surgery; however, this approach can lead to scarring, pain, and inconsistent treatment outcomes. In recent times, alternative treatments for NMSC have been explored, including radiotherapy, brachytherapy, and chemotherapy, each having its set of side effects. This has underscored the pressing need for more effective and less invasive treatment options, particularly for advanced cases.

Figure 3: Australia has the highest incidence of skin cancer globally

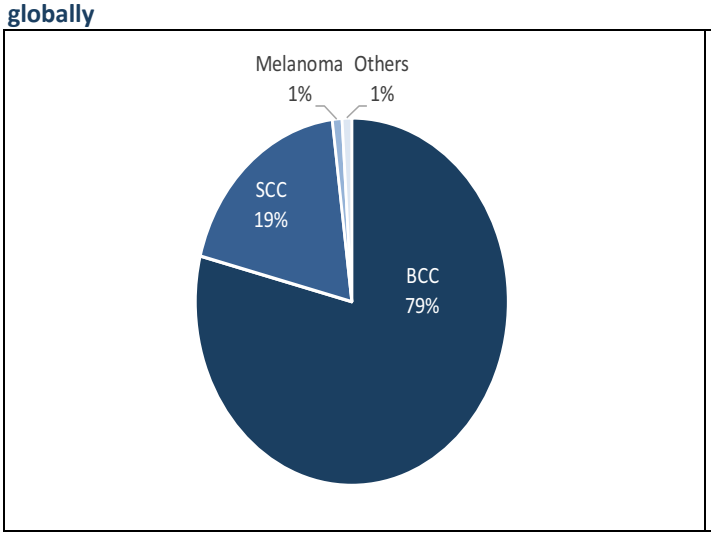
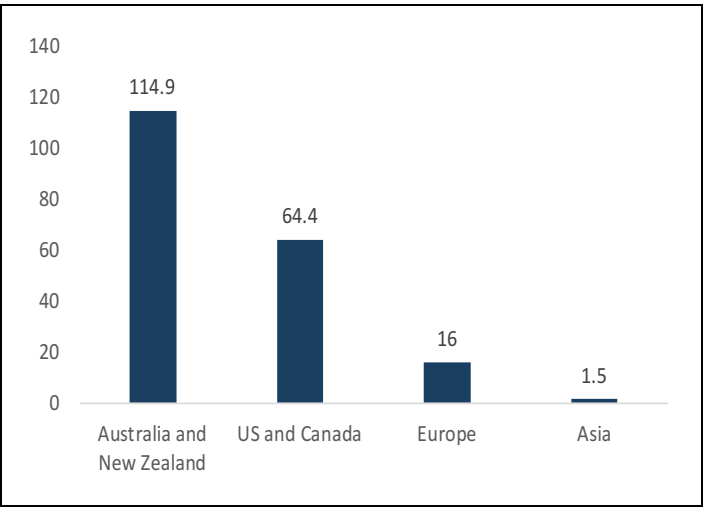


Figure 4: NMSC Incidence rates (2020) per 100,000



Source: Company, Pitt Street Research

2. Oral Microbial diseases

Globally 3.5bn people suffer from some type of oral microbial disease. These include:

- **Bacterial infections**

  Bacterial infections, such as dental caries and periodontitis, present significant challenges. The primary treatment for periodontitis involves non-surgical intervention, focusing on controlling bacterial growth to prevent the condition from advancing to a stage requiring invasive procedures for soft tissue and bone repair. Antibiotics play a crucial role in non-surgical gum disease treatments, combating bacterial development and preventing tissue destruction.

  Despite the effectiveness of non-surgical treatments, they are not fool proof. Some antibiotics lose their effectiveness, failing to inhibit bacterial growth and leading to the emergence of antibiotic resistance. Recognising this challenge there is a growing demand for preventive or minimally invasive treatments. These alternatives address concerns about antibiotic resistance and its associated side effects. Additionally, they show promise in tackling biofilms, a menace that antibiotics alone struggle to treat due to their antibiotic-resistant nature.

- **Viral infections**

Though current antiviral medicines shorten the duration of the HSV-I outbreak, they are accompanied by some severe side effects and risk of recurrence

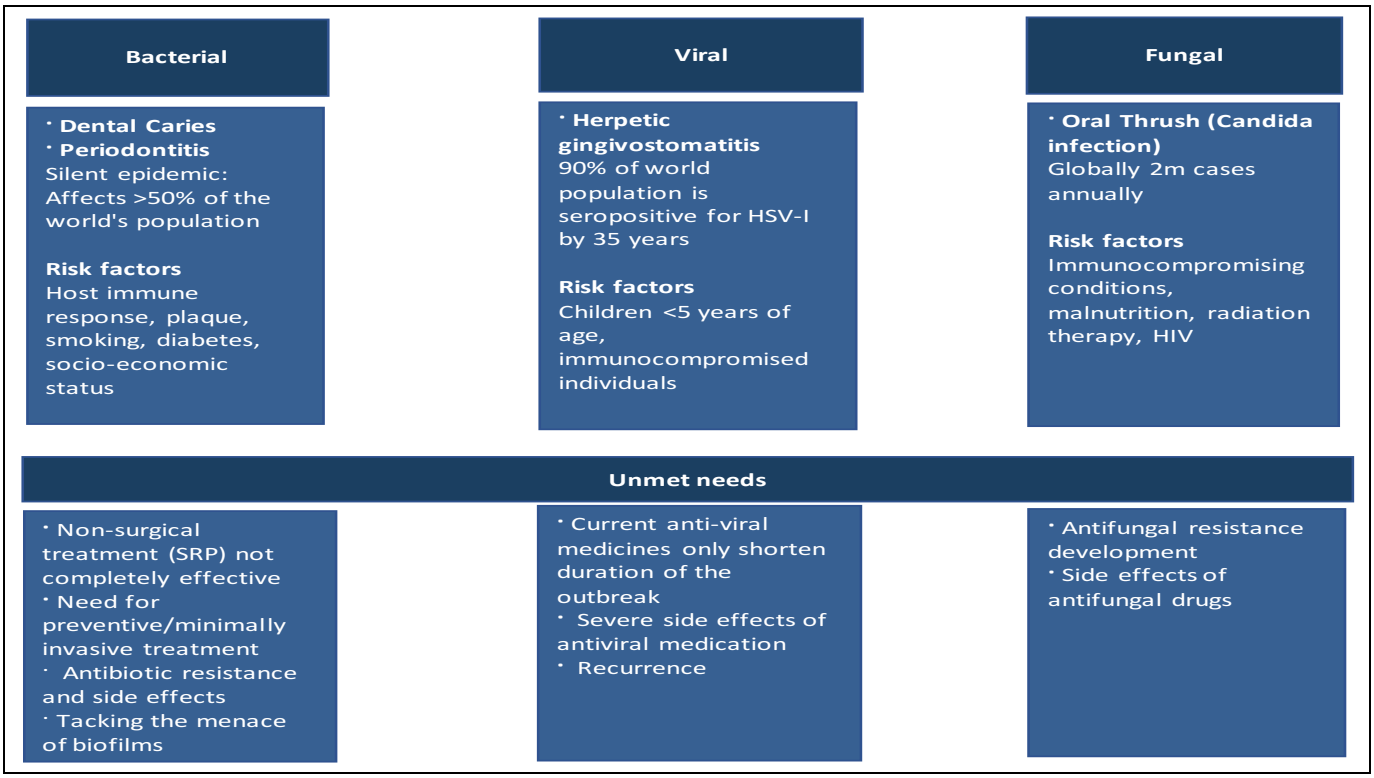
  90% of the world's population is seropositive for Herpetic gingivostomatitis (HSV-I) by 35 years. Current antiviral medicines shorten the duration of the outbreak. They also help relieve symptoms of some viruses as the disease passes. Antiviral medications can either prevent the virus from reproducing or boost the host's immune system to counter the effects of the virus. However, they are accompanied by some severe side effects such as influenza-like symptoms, hematologic abnormalities and neuropsychiatric symptoms, and risk of recurrence. Against this backdrop, an unmet need has arisen to mitigate the side effects associated with antiviral medicines.

- **Fungal infections**

  Fungal infections include oral thrush or Candida infection, with 2m cases being registered globally. Antifungal drugs help in the prevention of

topical or invasive fungal infections by stopping growth of fungi or by killing of fungal cells. However, the fungi successfully develop resistance against conventional drugs that are designed to kill or stop them from multiplying. Antifungal resistance refers to the phenomenon when a fungus no longer responds to antifungal drug treatments and continues to grow. Fungi develop resistance to antifungal drugs in the same manner that bacteria develop to antibiotics. Currently, only a few antifungal drugs exist. Thus, any resistance could severely limit treatment options. Some types of fungi such as Candida auris develop resistance to all antifungal drugs normally used for the treatment of infections. The antifungal drugs are also accompanied by some side effects. Against this backdrop, there is an unmet need to resolve the issue of resistance to antifungal drugs (Figure 5).

Figure 5: Common oral microbial diseases



Source: Company, Pitt Street Research

Invion is making strong headway in various clinical programmes

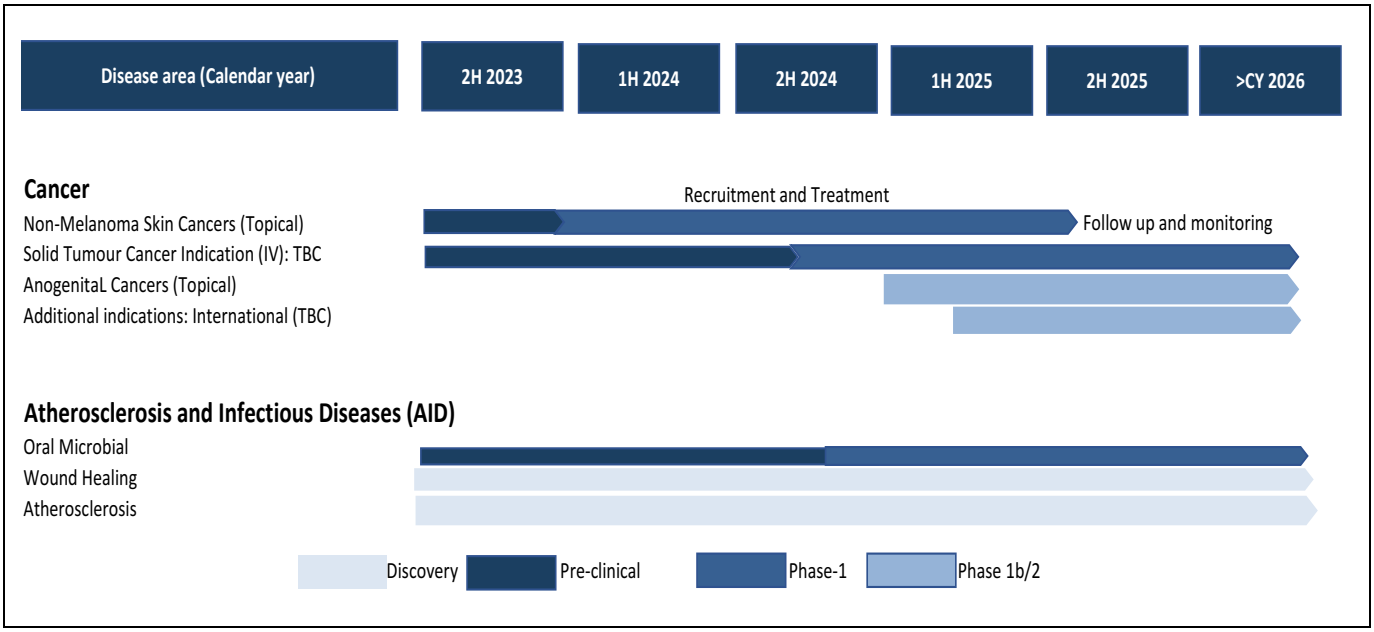
Invion is working with research partners towards clinical trials in NMSCs and ano-genital cancer

Invion is currently on track to initiate its Phase I adaptive platform protocol (APP) clinical trial for NMSCs in the coming months. The company plans to submit its application to the Human Research Ethics Committee (HREC) by the end of 2023, marking the official commencement of the trial. Recruitment and patient treatment are expected to begin in CY24.

Furthermore, Invion anticipates the ano-genital cancer trial to progress to a Phase 1b/2 trial, contingent on the Phase I NMSC trial meeting its primary safety endpoints through the design of APP. This is facilitated by the similarity in topical formulations of Invion's photosensitising agent for the treatment of both cancer types.

Furthermore, Invion is planning to commence two other Phase I trials in FY2024 – one being for a tumour using an intravenous (IV) formulation of its drug and another for oral microbial diseases (Figure 6).

Figure 6: Timelines for multiple clinical trials, indications and formulations



Source: Company, Pitt Street Research

Valuing Invion

We reiterate our valuation for Invion at A$0.016 per share base case and A$0.021 per share optimistic case (Figure 7), using a DCF-based approach. We believe that it is a conservative estimate as growth assumptions for the addressable market are highly subdued. Given that Invion is a young business operating in a growing industry vertical, a three-stage FCFF has been deployed as our valuation framework.

Figure 7: Our valuation of Invion

Invion Valuation (A$ m)	Base Case	Bull Case
Enterprise Value (A$ m)	**97.4**	**155.5**
Net debt (cash)	(5.1)	(5.1)
Equity value	**102.4**	**160.5**
Shares Outstanding	6,420.1	6.420.1
Implied price (A$ cents)	**0.016**	**0.021**
Adjusted Current price (A$ cents)	0.005	0.005
Upside (%)	*220%*	*320%*

Source: Pitt Street Research

Key share price catalysts

Invion's stock is currently trading below our base case valuation. We think the stock can re-rate to our valuation range based on positive news flow surrounding successful clinical trials, regulatory approvals, signing of major research partnerships, distribution deals in remaining geographies and value-enhancing acquisitions.

Risks related to Invion

Risks specific to Invion. We see five major risks for Invion as a company and as a listed stock:

- **Clinical risk**: There is a potential risk that the clinical studies of INV043, may fall short of their primary or secondary endpoints. The success rate for clinical trials varies significantly across technologies.
- **Market acceptance/ Competition risk**: Another risk is the possibility that INV043 might struggle to gain strong acceptance from oncologists. Despite Invion's unique proposition in cancer treatment, the presence of numerous small to medium-sized players developing different Photodynamic Therapies (PDTs), alongside established larger players, poses a competitive challenge. Establishing a competitive edge, particularly in terms of usability, becomes imperative for the company.
- **Timing risk**: There is a risk that Invion's clinical program may take longer to execute than the timing suggested in the note. This delay could potentially have a negative impact on investor sentiment towards Invion.
- **Licensing risk:** Another consideration is the risk that RMW Cho Group may opt to license its NGPDT technology to groups in other parts of the world or choose not to license it in certain markets. Such decisions could impact Invion's potential global market share.
- **Forex risk**: Once commercialised, Invion's earnings will be in the local currency of applicable markets. Currency fluctuations can affect the company's total earnings in AUD. Assuming a 1.5 AUD/USD exchange rate, fluctuations can impact valuation. For example, assuming parity between AUD/USD, the base case valuation drops to A$0.008, and the bull case drops to A$0.012 ceteris paribus. On the other extreme, if we assume US$1=A$2, the base case valuation will be A$0.01520, and the bull case will be A$0.023

Appendix I – Glossary

Active Pharmaceutical Ingredients – component of an over-the-counter (OTC) or prescription medication that produces its intended health effects.

Atherosclerosis - a disease where there is a build-up of plaque inside arteries and is a major contributor to cardiovascular diseases which is the largest cause of deaths worldwide.

Bioavailability – The quantity of a drug that can make it to its target once inside the body. High bioavailability is an important component in a drug's prospects for commercial success.

Biofilm – is a complex structure of microbiome having different bacterial colonies or single type of cells in a group. The cells are embedded in extracellular polymeric substances. The latter is a matrix composed of eDNA, proteins and polysaccharides, showing high resistance to antibiotics.

Brachytherapy – is a type of internal radiation therapy wherein seeds, ribbons or capsules containing a radiation source are placed in the body in or near the tumour. Brachytherapy is a local treatment and treats only a specific part of the body.

Dental caries – is a term referring to both the disease and resulting lesion. The caries process occurs in the biofilm which is permanently active with every pH fluctuation and the lesion manifests in the dental hard tissue.

Hemotologic diseases – are disorders of the blood and blood-forming organs. Along with cancers of the blood cell, hematologic diseases include rare genetic disorders, anaemia, sickle cell disease and complications from chemotherapy or transfusions.

Herpetic gingivostomatitis (HSV-1) - is a manifestation of herpes simplex virus type 1 (HSV-1) and is characterised by high-grade fever and painful oral lesions.

Immune checkpoint inhibitors (ICI)– A type of a drug that blocks proteins called checkpoints made by some types of immune cells such as T cells and some cancer cells. The checkpoints help to keep the immune responses from being too strong and sometimes can keep the T cells from killing the cancer cells. Blockage of the checkpoints can result in better killing of cancer cells.

Non-Melanoma skin cancer (NMSC) – refers to a group of cancers that slowly develop in the upper layers of the skin. Several types of cancer fall within the broader category of NMSC, with the most common types being Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC)

Periodontitis – is also called gum disease. It is a serious gum infection that damages the soft tissue around teeth.

Photosensitiser – A molecule that undergoes a chemical reaction when exposed to light at a certain wavelength.

Reactive oxygen species (ROS) – is a type of unstable molecule containing oxygen and which easily reacts with other molecules in a cell. A build-up of ROS in cells may cause damage to DNA, RNA and proteins and may cause cell death. ROS are free radicals also called oxygen radicals.

SCC – A cancer of the squamous cells in the epidermis.

Seropositive – shows a positive result of a blood test for a particular antibody. Antobody is a substance in the blood that fights disease.

Appendix II – Analyst Qualifications

Stuart Roberts, lead analyst on this report, has been covering the Life Sciences sector as an analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research specialty at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months in 2015 and 2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Science companies
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Science companies.

Nick Sundich, lead analyst on this report, is an equities research analyst at Pitt Street Research.

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

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