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COVERAGE INITIATION

February 11, 2020
INDUSTRY: BIOTECHNOLOGY

BERONI GROUP, LTD.

TAKING ON THE CHALLENGE IN SOLID TUMORS

Analyst: Gregory Aurand, CFA gdaurand@gmail.com

BERONI GROUP, LTD. (OTCQX-BNIGF-$2.15)	
Rating: Speculative Buy	Price Target Range: $2.30-$3.05

COMPANY SUMMARY

Since inception in 2014, Beroni has become a diversified global biopharmaceutical enterprise with a differentiated business model encompassing an Innovation/R&D Pathway and a Commercial Pathway. Innovation research and development is led by PENAO, a unique anti-cancer therapy being studied in pancreatic, brain, breast and ovarian cancers, and Allogeneic Gamma Delta T Cell anti-cancer therapy. Commercial is led by its healthcare product focused E-commerce platform.

KEY STATISTICS

Price as of 2/11/2020	$2.15
52 week High-Low	$1.50-$2.15
Share Count	72.54mm
Market Value	$155.9mm
Average Volume	----
Primary Exchange	OTCQX
Fiscal Year	31-Dec
Inception Date	2014
Funds Raised	----
Addressable Market Size	$3 billion
Fair Market Value $ million- Low/High	$73-$224
Funding Sought	$55mm

COMPANY INFORMATION

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Sydney NSW 2000 Australia

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Email: enquiry@beronigroup.com
Website: www.beronigroup.com

INVESTMENT HIGHLIGHTS

Beroni Group is developing a targeted anti-cancer drug, PENAO, which has shown promise as a therapy against solid tumor cancers in, among others, pancreatic and brain cancers that have low 5 year survival rates.

PENAO is a unique small molecule and is the only ANT inhibitor in clinical development. PENAO has shown activity in several solid tumor cancers, including ovarian, breast and pancreatic.

mTOR inhibitors, shown to further enhance the apoptotic effects of PENAO, will be used in combination therapy as the therapy moves to clinical multi-center Phase II trials in Q1-Q2 2020.

Initial clinical trial targets include pancreatic and brain, but, given PENAO's method of action, could eventually expand to other solid cancers in breast and ovarian.

As part of its clinical plan, Beroni plans to file PENAO for Orphan Drug Status in the United States by mid-2021.

A promising therapy in solid tumors, a Gamma Delta T cells trial is in planning stages. Gamma Delta T cells kill cancer cells and are shown to be safe. Beroni is developing a clinical trial plan.

Already approved by the FDA for emergency use, Beroni has a commercial-ready exclusive license viral detection platform with the CII-Arbo ViroPlex rRT-PCR Assay. There is no similar alternative for detection of Zika, dengue, chikungunya and West Nile virus.

Listed on the OTCQX and NSX, Beroni is in early stages seeking listing on NASDAQ and NYSE to enhance liquidity and visibility.

A cost-based +discounted revenue valuation comparing Beroni to other similar early-stage biopharmaceutical companies suggests that Beroni could be worth 40% more than current market value.

BERONI GROUP

COMPANY OVERVIEW

Beroni Group Limited, based in Sydney Australia, is a differentiated biopharmaceutical company with four core businesses – advancement of anti-cancer therapies, development of cell therapies and infectious disease detection and diagnosis tests, bolstered by a revenue producing E-commerce healthcare products group.

INNOVATION

ANTI-CANCER

The leading anti-cancer therapy, PENAO, is moving into Phase II studies in 2020. PENAO is a second generation drug developed over more than 10 years by Professor Philip Hogg, the inaugural director of the Lowy Cancer Research Centre at the University of New South Wales. PENAO is novel compound with an active arsenic molecule. The compound has shown anti-cancer, tumor shrinking potential in various cancers including pancreatic, breast, ovarian and brain tumors.

CELL THERAPIES

In pre-clinical trials, Beroni has discovered allogenic gamma delta T cells for solid tumors have a good safety profile. Moving to Phase I with a proprietary formula that should improve the tumor killing capability of gamma delta T cells, the company will focus on lung and breast cancers, large market opportunities.

Gamma delta T cells are uniqueT lymphocytes, able to attack target cells directly, or indirectly through activation of other immune cells.

COMMERCIAL

INFECTIOUS DISEASE DETECTION AND DIAGNOSIS –VIRAL DETECTION

Beroni holds an exclusive 20 year license, obtained in April 2019, from Columbia University to market the CII-Arbo ViroPlex rRT-PCR Assay worldwide. For the licensing right, Beroni shall pay royalties to Columbia University based on net sales of the products. Columbia University secured test patents in six countries: USA, India, Saudi Arabia, China, Australia and Japan.

Approved in the US during August 2017 with an Emergency Use Authorization (EUA), this is the first assay to test simultaneously for Zika virus, dengue virus, chikungunya virus and West Nile virus. Specifically, the test detects viral RNA matching Zika, dengue types 1-4, chikungunya, and West Nile virus from either human serum or urine (Zika) samples. In February 2016, Secretary of Health and Human Services (HHS) Sylvia Burwell determined there was a significant public health emergency potentially affecting US national security and the health and security of US citizens living abroad. Based on this determination, the Secretary authorized emergency use of in vitro diagnostics for Zika virus detection and infection.

E-COMMERCE HEALTHCARE PRODUCTS

The China E-commerce platform will expand into Japan with the closing of the Medline Plus acquisition. This acquisition will provide further access to large market opportunities in medical products, health foods, cosmetics and household goods. In 2018, Beroni entered into a binding agreement to acquire Medicine Plus Co., Ltd, a pharmaceutical company based in Osaka, Japan for JPY1.178 billion (about $10.8 million) via a combination of cash and shares. In October 2018, Beroni issued 2,067,900 shares at $1.75 AUD to the owners of Medicine Plus as partial settlement for the acquisition of the latter company. The original settlement price of $10.8 million was increased by 10% to approximately $11.9 million as a result of extending the settlement date.

GENE DETECTION PLATFORM

In collaboration with ThorGene, Beroni established a gene detection platform. Invention patents (23 to date) have been filed and software copyrights (32 to date) have also been filed. Tumor detection, data platform, analysis algorithm and life data service are the four categories within medicine and data analysis that have invention patents.

BERONI GROUP LTD.'S LEADERSHIP

Seasoned Management Team

JACKY ZHANG – CHAIRMAN & CEO

Jacky Zhang has more than 20 years of experience in life science industry, maintaining collaborative relationships with universities and institutes to promote advancements. Jacky Zhang is founder of Tianjin Beroni Biotechnology Co., Ltd. Mr. Zhang is a biotech graduate from Tianjin University of Commerce, with an MBA from Nankai University, a Masters degree in International Management from the University of Sussex. He is currently studying another MBA from Tsinghua University. He is also Executive Director of Medical Health Committee, The Silk-road Industry and Finance International Alliance.

PETER WONG – CFO

Mr. Wong is 30-year veteran in accounting, finance and banking with Deloitte, PWC, Citibank, Hong Kong Stock Exchange, Hong Kong Telecom, and Shanghai Pudong Development Bank and has gained experience across a wide spectrum of functions, including audit, taxation, finance, operations, technology, HR, risk management, compliance and control. He is a Chartered Accountant with the Institute of Chartered Accountants in England and Chartered Accountants Australia and New Zealand. Mr. Wong obtained his BSc degree from University of Manchester and MBA degree from Henley Business School.

HAI HUANG – EXECUTIVE DIRECTOR

Hai Huang is one of the founders of Tianjin Beroni Biotechnology Co., Ltd. Mr. Huang has over 15 years experience in cross border business with a global Fortune 500 company. He has extensive international trade experience and more than 10 years of experience in business franchising and e-commerce business planning, implementation and team building. He has a Bachelor's degree in business management from the Capital University of Economics and Business.

Highly Regarded Scientific Research Team

ZHINAN YIN – CHIEF SCIENTIST

Dr. Zhinan Yin graduated from Hubei Medical University in 1984 and finished his Master's Degree in immunology from Shanghai Second Medical University in 1988. He later obtained his Doctorate degree from the Free University of Berlin in 1997, and his academic dissertation won the Excellent Paper Award. Dr. Yin is a current Dean, Professor and PhD Tutor at Biomedical Translational Research Institute of Jinan University and Visiting Professor at Yale University School of Medicine. Dr. Yin's main research area is the differentiation and development of Gamma Delta T cells and their roles in the regulation of tumor immunity, hepatitis, and intestinal flora. He has published 52 academic articles where he is the first author, communication author, or co-corresponding author.

PHILIP HOGG – CHIEF SCIENTIST

Professor Philip Hogg graduated with a PhD in biochemistry from the University of Queensland in 1987. Following post-doctoral training in the USA and Sweden he returned to UNSW as a NHMRC RD Wright Fellow. He is now a NHMRC Senior Principle Research Fellow and was the inaugural director of the Lowy Cancer Research Centre at UNSW. He has won several national and international awards for his research, which focuses on a fundamental chemical modification of proteins he discovered. Professor Hogg's research has led him to make novel, small-molecule inhibitors of mitochondrial adenine nucleotide translocase (ANT), GSAO and PENAO, that are currently being trialed in solid tumor cancer patients. He maintains visiting professorships at Children's Hospital, Harvard University and the Dunn School of Pathology, University of Oxford.

WALTER IAN LIPKIN – CHIEF SCIENTIST

Dr. W. Ian Lipkin is an international authority on the use of molecular methods for pathogen discovery. Dr. Lipkin has over 30 years of experience in diagnostics, microbial discovery and outbreak response. He and his team implicated West Nile virus as the cause of the encephalitis epidemic in New York in 1999 and have discovered or characterized more than 500 infectious agents including Borna disease virus, West Nile virus, LuJo virus and human rhinovirus C. Dr. Lipkin assisted the WHO and the Peoples Republic of China during the 2003 SARS outbreak and currently advises the Kingdom of Saudi Arabia in addressing the challenge of MERS. Dr. Lipkin is the Director of the Center for Infection and Immunity at Columbia University and Director of the World Health Organization Collaborating Center for Diagnostics in Zoonotic and Emerging Infectious Diseases.

STRATEGIC GOALS

"Beroni is at the epicenter of major themes in healthcare: oncology, cell therapies and large addressable markets such as China."

- Jacky Zhang, CEO

ADVANCE PENAO AND CELL THERAPIES THROUGH THE REGULATORY AND COMMERCIAL PROCESS

In August 2019, Beroni and a subsidiary of the University of New South Wales (UNSW) jointly took over the PENAO drug development and licensing rights from Cystemix Pty Ltd., a company established by UNSW. Beroni will invest a total of $10.4 million in stages over a two year period until the end of the Phase II trial. Phase II trials are expected to start Q1-Q2 2020 in a multi-center trial, enrolling 50 patients. Phase II trials will initiate in Sydney Australia, expand into Japan, with potential in the US. Beroni expects to apply for US Orphan Drug Status in 2021

Beroni has a deep pipeline in allogenic gamma delta T cells for lung and breast cancer, and drug-resistant TB, WT-1 tumor vaccine in lung and breast cancer and other small molecule and delivery vehicles in pre-clinical. Gamma delta T cell trial plan is being developed with expectations to begin Phase I in 2020. A Phase I for the WT-1 tumor vaccine could also start in 2020.

EVALUATE COMMERCIALIZATION STRATEGIES

Beroni has several products where their advancement through the pipeline into commercialization could benefit from different strategies. Beroni's strategic options include joint development, particularly in the US markets, as well as licensing development to another pharmaceutical company that could shepherd products to market, paying Beroni development milestone royalties and/or royalties.

EXPAND COMMERCIAL REVENUE GENERATING AVENUES

Viral Detection

Already approved by the FDA for emergency use, Beroni has a commercial-ready exclusive license viral detection platform with the CII-Arbo ViroPlex rRT-PCR Assay. There is no similar alternative for detection of Zika, dengue, chikungunya and West Nile virus. Beroni USA will commercialize the assay and develop new business opportunities. Patents have been registered in China, United State, Australia, Saudi Arabia, and India.

E-commerce

The China E-commerce platform will expanded into Japan with the Medline Plus acquisition. Medicine Plus markets over 63,000 different products through Rakuten, Yahoo!, and Amazon, among others. This acquisition will provide further access to large market opportunities in medical products, health foods, stem-cell cosmetics and household goods. Beroni currently markets smoking cessation, pollution filtration, health and cosmetic supplements.

Gene Detection

In conjunction with ThorGene, Beroni has established a leading technological platform for early-stage tumor detection. The platform will provide precision detection and post-analysis services. Invention patents have been filed in four categories: tumor detection, data platform, analysis algorithm and life data service The liquid biopsy gene detection technology could offer much-needed early-screening for lung, breast, and colorectal cancer.

AN OPPORTUNITY IN BRAIN AND PANCREATIC CANCERS

Pancreatic Cancer Overview

The pancreas serves a vital function in digestion and glucose control. The pancreas secretes enzymes into the small intestine aiding digestion. About 95% of the pancreas is exocrine tissue, producing the digestion enzymes. The remaining 5% are endocrine cells, producing insulin to lower blood sugar and glucagon to raise blood sugar.

Although not the most prevalent form of cancer (ranked 15th globally), pancreatic cancer is one of the most deadly, with 5-year survival rates after diagnosis below 10%. Incidence rates are increasing, possibly due to environmental risk factors like smoking, obesity, family history and type II diabetes. The incidence level varies with higher rates in developed countries but males are more susceptible than females.

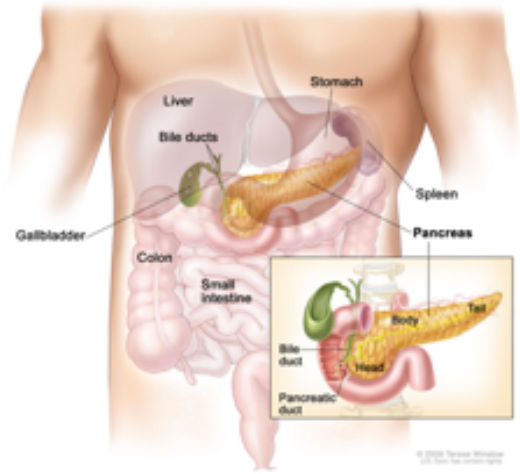


FIGURE 1 - PANCREAS; SOURCE CANCER.GOV

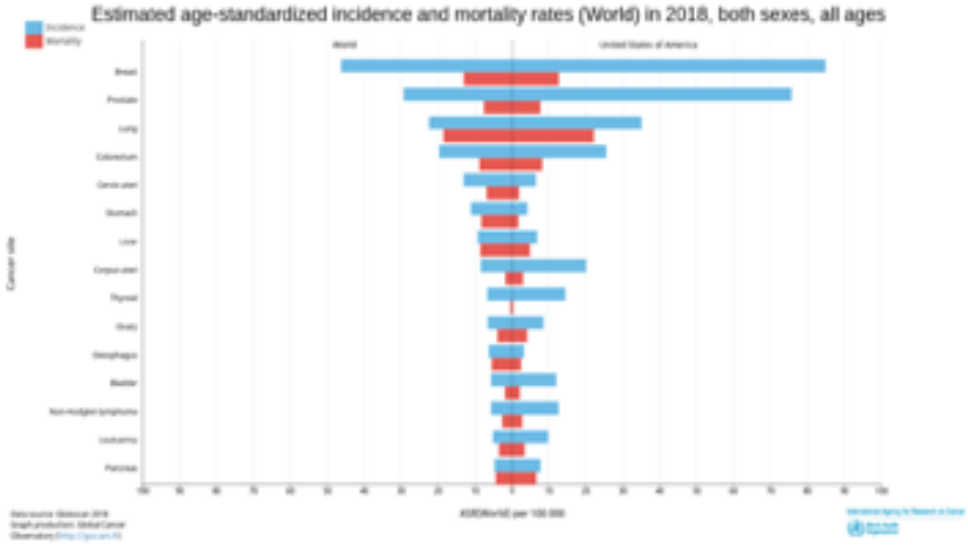
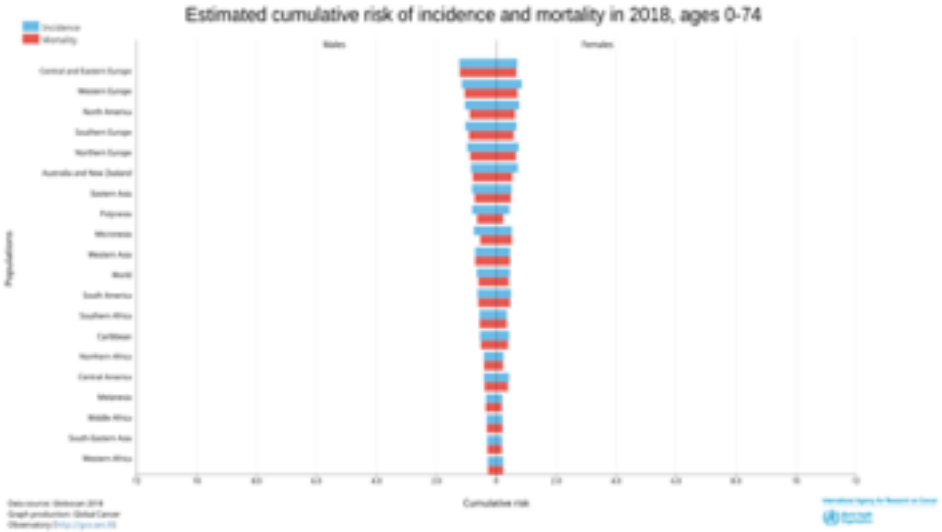
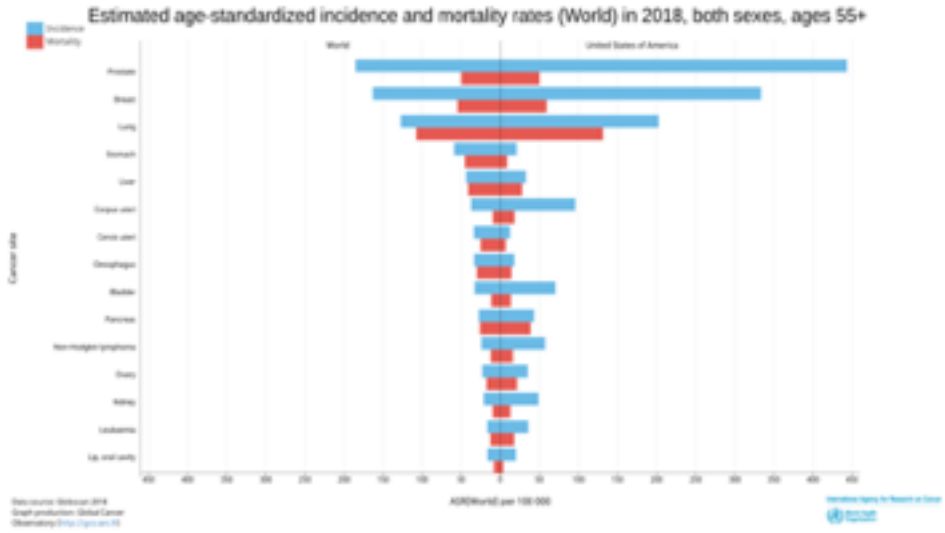


FIGURE 2 - ESTIMATED INCIDENCE AND MORTALITY RATES (WORLD AND US); SOURCE GLOBOCAN 2018



Pancreatic cancer is a disease predominantly attacking older people, incidence correlating with an increasingly aging populace. Diagnosis is rare below the age of 30, and about 90% diagnosed are 55 years of age or older. At 55 years or older, pancreatic cancer becomes the 10th highest incidence level cancer. Worldwide, incidence levels are higher in men than women.

FIGURE 3 - ESTIMATED CUMULATIVE RISK OF PANCREATIC CANCER INCIDENCE AND MORTALITY, CUMULATIVE, MALE VS. FEMALE; SOURCE GLOBOCAN 2018



While the pancreas can suffer from non-cancerous treatable disease like pancreatitis (those diagnosed with chronic pancreatitis are at increased risk to develop cancer), cancerous disease is increasingly difficult to treat with the vast majority of pancreatic cancers starting in exocrine cell tissue.

FIGURE 4 - ESTIMATED INCIDENCE AND MORTALITY RATES (WORLD AND US), AGED 55 OR OLDER; SOURCE GLOBOCAN 2018

Pancreatic cancer survival is impacted by stage at time of diagnosis. If the cancer has not spread and is only found near where it started, it is known as localized or Stage I and attempts can be made to have the tumor surgically removed. About 10%-15%% of patients are diagnosed at this stage. If it has moved (or become metastatic) to lymph nodes regionally nearby, the cancer has become Stage II (lymph nodes are small organs located throughout the body to fight infection and disease). If the cancer has moved to nearby arteries and veins, as well as regional lymph nodes, it is now considered Stage III. Once the cancer has spread to other parts of the body as well as distant lymph nodes, it has become Stage IV. When it has metastasized, pancreatic cancer has been most commonly found in the liver, abdominal cavity (peritoneum) and the lungs.

The highest curative rate is when the tumor is localized. The National Cancer Institute's 2009-2015 data showed a 5-year survival rate of 37% at Stage I discovery when resection or tumor removal is still possible. However, at Stage II-III, the survival rate declines to 12%. Stage IV patients have a survival rate of 3% and over 50% of patients were diagnosed at Stage IV.

5-Year Relative Survival (Percent) 2009-2015 by Stage at Diagnosis			
Stage at Diagnosis	All Races,Both Sexes	All Races,Males	All Races,Females
All Stages	9.3	9.4	9.2
Localized	37.4	39.6	35.5
Regional	12.4	13.2	11.6
Distant	2.9	2.9	3
Unstaged/Unknown	5.6	6.4	5

FIGURE 5 – 5-YEAR PANCREATIC CANCER SURVIVAL AT DIAGNOSIS STAGE;
SOURCE: NATIONAL CANCER INSTITUTE SEER CANCER STATISTICS REVIEW 1975-2016

The frequent late diagnosis of pancreatic cancer is due to difficulty detecting and diagnosing a tumor. Early stage cancer typically has no signs or symptoms alerting a patient. There are no effective screening tests that can find non-symptomatic cancer. Developing symptoms can mask the problem, presenting as other another disease like an ulcer or pancreatitis. Imaging the pancreas is also difficult given its location behind the stomach.

BRAIN CANCER OVERVIEW

BRAIN CANCER IS A CHALLENGING, DEADLY DISEASE

The brain controls all body functions. As the command center organ, the brain receives signals from the body's sensory organs and pushes out information to the muscles through the nervous system. The brain is composed of three main sections within the skull known as the cerebrum, cerebellum and the brain stem. The cerebrum is the largest section, composed of the frontal lobe, temporal lobe, parietal lobe, and occipital lobe.

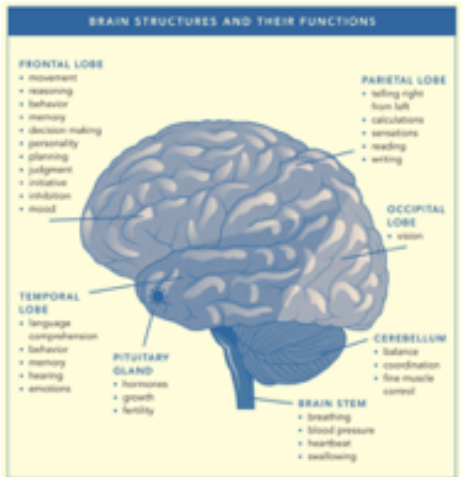


FIGURE 6 - BRAIN STRUCTURES AND FUNCTIONS;
SOURCE - NATIONAL BRAIN TUMOR SOCIETY

Brain cancer is termed as either Primary (cancer originating in or near the brain) or Secondary (the cancer is metastasized and originated elsewhere). Primary brain and CNS tumors can be benign or malignant. Although found elsewhere, most tumors occur in the frontal, temporal, and parietal lobes of the brain.

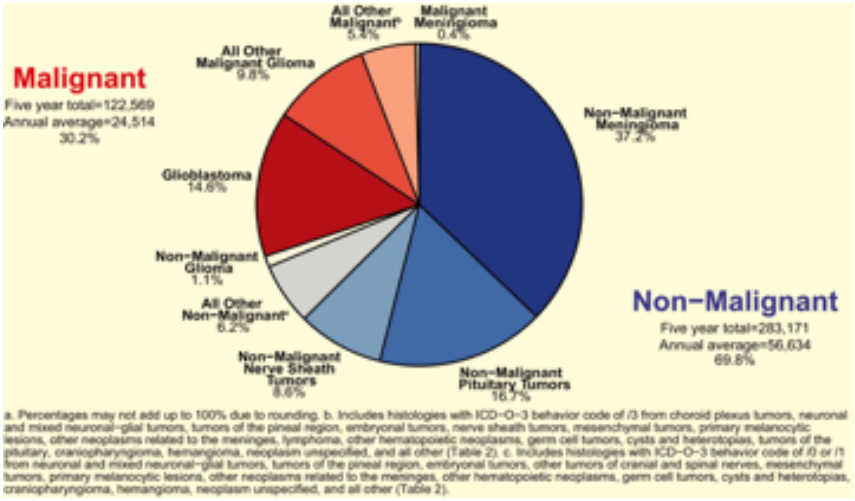


FIGURE 7 - DISTRIBUTION OF PRIMARY BRAIN AND OTHER CNS TUMORS BY BEHAVIOR (FIVE-YEAR TOTAL = 405,740; ANNUAL AVERAGE CASES = 81,148), CBTRUS STATISTICAL REPORT: US CANCER STATISTICS - NPCR AND SEER, 2012–2016

According to The Central Brain Tumor Registry (CBTRUS) annual US incidence of all primary brain and CNS tumors averages 23 per 100,000 people. Approximately 70% are non-malignant or approximately 16 per 100,000. Brain tumors typically have accounted for 85% or more of all primary CNS tumors, so US statistics suggest about 6 persons per 100,000 develop malignant brain tumors or approximately 25,000 each year.

Globally, primary incidence rates vary due to environmental risk factors including radiation exposure or genetics.

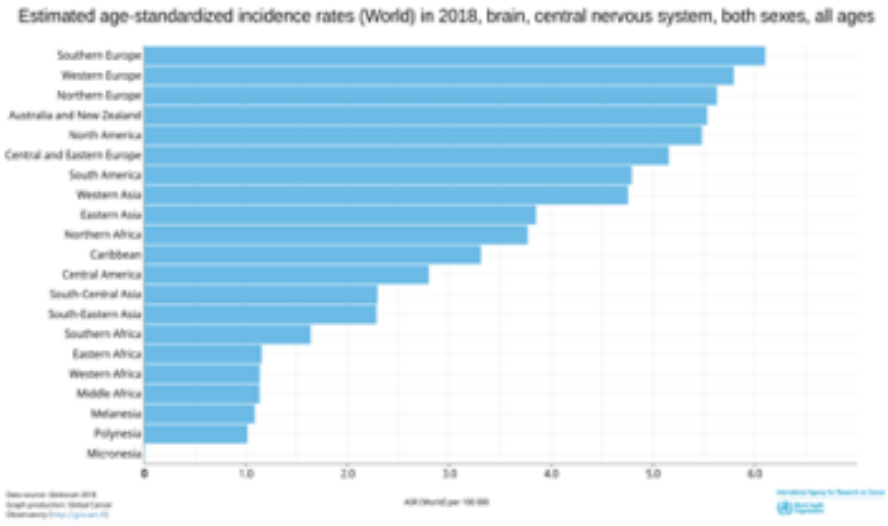


FIGURE 8 - ESTIMATED INCIDENCE BY GLOBAL REGION;
SOURCE GLOBOCAN 2018

Globally, brain and central nervous system (CNS) cancers are 18th in incidence. Due to the importance of the brain and its functions, the numbers might be smaller than other cancer incidence rates but the importance to treat brain cancer cannot be overstated. Males are also more susceptible to brain and central nervous system cancers.

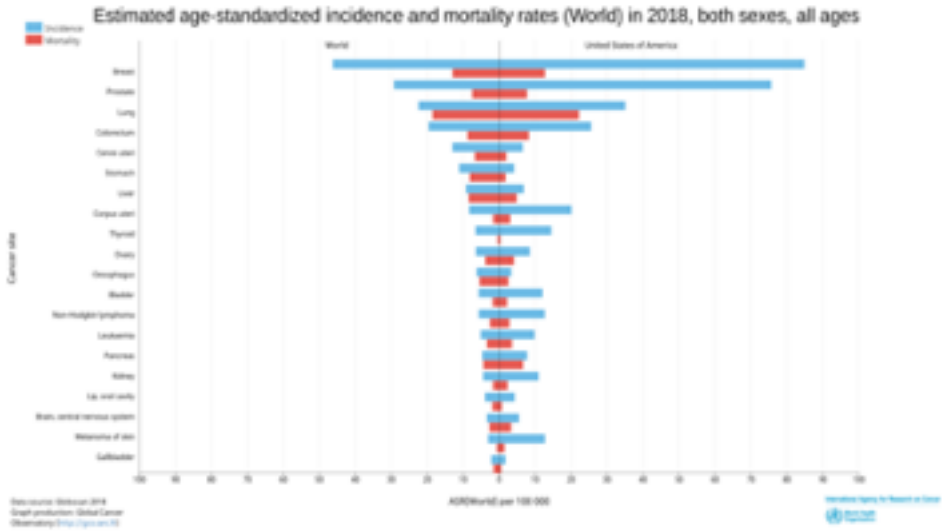


FIGURE 9 - ESTIMATED INCIDENCE AND MORTALITY RATES (WORLD AND US);
SOURCE GLOBOCAN 2018

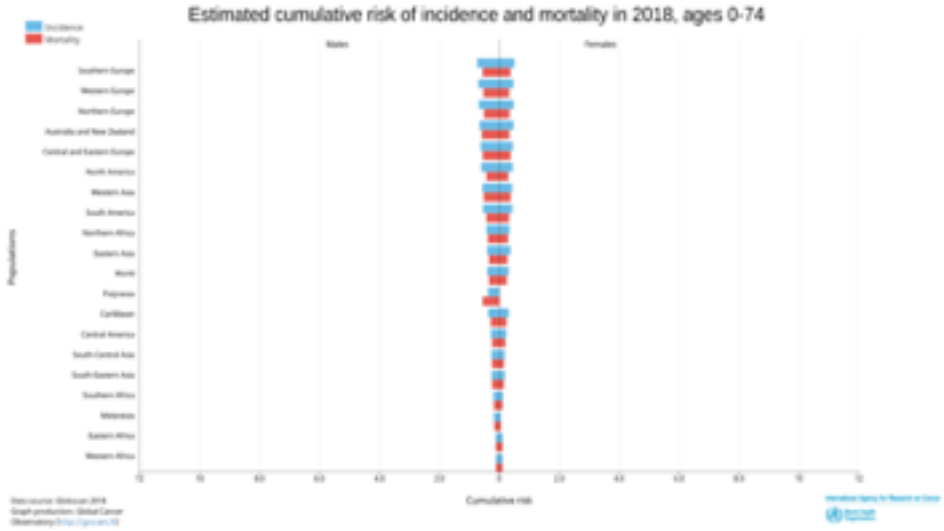


FIGURE 10 - ESTIMATED CUMULATIVE RISK OF BRAIN AND CNS CANCER INCIDENCE AND MORTALITY, CUMULATIVE, MALE VS. FEMALE;
SOURCE GLOBOCAN 2018

Secondary or metastasized brain and CNS tumors are not called brain cancer, but rather named after the location the cancer originated. Partly due to this, the incidence of metastatic or secondary brain tumors is not known but is estimated at 200,000 - 300,000 in the US annually. The metastatic tumor typically contains the same type of cells in the brain as the origination or primary site. According to The American Brain Tumor Association, lung, breast, skin cancer, colon and kidney cancers commonly spread to the brain.

Localized brain cancer shows only slightly better 5-year survival compared to later stage cancer. A number of factors affect survivability in treating brain cancer, with surgical attempts to remove these small tumors completely one important factor. Location within the brain or nearness to sensitive sensory organs creates hurdles as well. Age and general condition of the patient also impacts survival. Tumors not completely removed might continue to migrate, advance or invade, especially aggressive glioblastoma forms.

5-Year Relative Survival (Percent) 2009-2015 by Stage at Diagnosis			
Stage at Diagnosis	**All Races,Both Sexes**	**All Races,Males**	**All Races,Females**
All Stages	**32.9**	**31.6**	**34.6**
Localized	**35.7**	**34.3**	**37.6**
Regional	**20.2**	**19.6**	**21**
Distant	**32.4**	**29.3**	**36.8**
Unstaged/Unknown	**28.2**	**27.4**	**28.9**

FIGURE 11 – 5-YEAR BRAIN CANCER SURVIVAL AT DIAGNOSIS STAGE;
SOURCE: DATA DERIVED FROM NATIONAL CANCER INSTITUTE SEER CANCER STATISTICS REVIEW 1975-2016

PANCREATIC AND BRAIN CANCER TREATMENT LANDSCAPE

THE PRESENT OPTIONS ARE NOT LONG-TERM EFFECTIVE FOR SUCH CHALLENGING CANCERS

Current Pancreatic Treatment

Pancreatic Cancer, in the US market, has the worst 5-year survival of any cancer. Pancreatic cancer, when detected early, has a higher chance of successful treatment. That said, a cancer diagnosis typically has come when the cancer has advanced. Available diagnostic tests are non-specific and may miss patients with early-stage disease.

Primary Sites	5-Year Relative Survival (%) 2009-2015
Pancreas	**9.3**
Liver and intrahepatic bile duct	18.5
Lung and bronchus	19.4
Esophagus	19.9
Stomach	31.5
Brain and nervous system	**32.9**
Ovary	47.6
Larynx	60.3
Leukemia	62.7
Colon and Rectum	64.4
Oral cavity and pharynx	65.3
Cervix uteri	65.8
All Sites	67.1
Non-Hodgkin lymphoma	72.0
Kidney and renal pelvis	74.8
Urinary bladder	77.1
Hodgkin lymphoma	86.6
Breast(females)	89.8
Melanoma	92.2
Testis	95.2
Prostate	98.0
Thyroid	98.2

FIGURE 12 - 5-YEAR RELATIVE SURVIVAL MOST COMMON CANCER TYPES;
SOURCE: DATA DERIVED FROM NATIONAL CANCER INSTITUTE SEER CANCER STATISTICS REVIEW 1975-2016

Surgery to remove the tumor is the first option, followed by radiation and chemotherapy. Radiation therapy uses high-energy x-rays or other particles to destroy cancer cells. External-beam radiation is the most often type of therapy used. Stereotactic body radiation (SBRT) and proton beam therapy is also used. Chemotherapy drugs, like capecitabine (Xeloda) or gemcitabine (Gemzar), are often used concurrently with radiation due to treatment benefits attacking the tumor. Chemotherapy drugs can be given as a monotherapy, but also used in combination with other chemotherapy agents. The following chemo drugs are approved by the US Food and Drug Administration (FDA) for pancreatic cancer:

Capecitabine (Xeloda)
Erlotinib (Tarceva)
Fluorouracil (5-FU)
Gemcitabine (Gemzar)
Irinotecan (Camptosar)
Leucovorin (Wellcovorin)
Nab-paclitaxel (Abraxane)
Nanoliposomal irinotecan (Onivyde)
Oxaliplatin (Eloxatin)

Some targeted chemo therapies, depending on genetic makeup of the pancreatic tumor, are also being considered. Mentioned above, Erlotinib (Tarceva) is the only approved treatment for advanced pancreatic cancer patients, in combination with gemcitabine. Erlotinib is an EGFR (epidermal growth factor receptor) inhibitor, targeting the growth protein that causes cells to divide. In certain forms of pancreatic cancers, olaparib (Lynparza) might be used in a maintenance setting. Although olaparib was FDA-approved in January 2020, lackluster data did not show overall survival benefit but did show progression-free survival. Olaparib is a PARP inhibitor, a pathway that repairs damaged DNA in cells. For cells with mutated BRCA genes (also involved in DNA repair), blocking the PARP pathway makes it difficult for BRCA mutated tumors to repair damaged DNA, leading to possible cell death. Other solid tumor types of targeted therapy include larotrectinib (Vitrakvi) and entrectinib (Rozlytrek) that target proteins in mutated NTRK genes.

Immunotherapy helps boost the body's immune system to fight off cancers and some forms might work in pancreatic cancers Checkpoint inhibitors, a form of PD-1 (programmed death receptor) antibody, work by releasing the brakes on the immune system so it can fight and kill cancer cells. Another immunotherapy known as adoptive cell transfer (ACT) engineer a patients' own immune cells, like T cells, to treat the cancer. Vaccines, another form of immunotherapy, attempt to stimulate the immune system to attack cancer cells. These types of treatments were developed originally for other forms of cancer and results have been underwhelming so far in pancreatic cancer.

There has been one approval in pancreatic cancer in the U.S. more recently. Pembrolizumab (Keytruda), a PD-1 inhibitor, received FDA accelerated approval in 2017 for solid tumor patients, including pancreatic cancer, in a subset of patients with a certain tumor genetic biomarker. However, pitfalls remain as, in 2019, Durvalumab (Imfinzi), a PD-L1 checkpoint inhibitor monoclonal antibody, failed in Phase II, alone or in combination with tremelimumab, failing to elicit a sufficient response rate.

Despite the poor outcomes and relative small incidence level, pancreatic cancer therapies currently are a $2 billion market, so development continues. According to Citeline Pharma R&D Annual Review 2019, 438 therapies are currently under development. While large in numbers, chances are high that most of these development treatments will fail. Nucana's Acelarin (a gemcitabine prodrug) failed in mid-2019 due to lack of efficacy. Abbvie's Imbruvica failed in Phase III early 2019. Also in early 2019, Celgene's Abraxane combined with gemcitabine, although showing some benefit in metastatic pancreatic cancer, did not achieve its primary endpoints for patients undergoing surgical resection.

DEVELOPMENT OF SUCCESSFUL THERAPIES REMAINS CHALLENGING

There are major issues needing resolution for successful new pancreatic cancer therapies.

LATE DIAGNOSIS

Pancreatic cancer disease is usually asymptomatic in the early stages, and without the use of invasive procedures, current screening methods are unable to achieve an effective early diagnosis. Only about 10-15% of patients are diagnosed at Stage 1 when the disease is confined. Diagnosis usually comes late when the disease has spread, raising the hurdle for most new therapies. Even when diagnosed early and surgery is involved, some of the tumor or pancreas is left behind and can re-grow quickly. If some of the tumor is missed, it can move to other organs like the liver.

THE PANCREATIC CANCER GENOME IS COMPLEX

Most targeted agents developed have been ineffective to date, partly due to the heterogeneity of the disease. Tumor cells escape treatment, hide out, and then return. Similar to brain cancer, pancreatic cancer exhibits resistance to conventional therapy and possesses a highly immunosuppressive tumor microenvironment. Dense connective tissue and disorganized blood vessel growth decreases effectiveness of therapies to reach their target.

RESISTANCE TO RADIATION AND CHEMOTHERAPY

As indicated above, tumors can survive resection and rebound or re-grow. In addition, pancreatic cancer cells display radiation and chemotherapy resistance due to an ability to create alternative pathways.

CURRENT BRAIN TUMOR TREATMENT

Brain tumor treatment depends on the type, location and size of the tumor. Gliomas are the most common form of malignant primary brain tumors, representing nearly 81% of tumors. Gliomas are a broad category of brain and CNS tumors that originate from the glia (short for "neuroglia") that support neurons and provide insulation. Glia are the most abundant cell type within the CNS and originated from the Greek word for "glue". Glioblastoma multiforme (GBM) is the most aggressive and most common primary brain tumor, representing nearly half of all malignant brain tumors.

Primary Sites	5-Year Relative Survival (%) 2009-2015
Pancreas	**9.3**
Liver and intrahepatic bile duct	18.5
Lung and bronchus	19.4
Esophagus	19.9
Stomach	31.5
Brain and nervous system	**32.9**
Ovary	47.6
Larynx	60.3
Leukemia	62.7
Colon and Rectum	64.4
Oral cavity and pharynx	65.3
Cervix uteri	65.8
All Sites	67.1
Non-Hodgkin lymphoma	72.0
Kidney and renal pelvis	74.8
Urinary bladder	77.1
Hodgkin lymphoma	86.6
Breast(females)	89.8
Melanoma	92.2
Testis	95.2
Prostate	98.0
Thyroid	98.2

FIGURE 13- 5-YEAR RELATIVE SURVIVAL MOST COMMON CANCER TYPES; SOURCE: DATA DERIVED FROM NATIONAL CANCER INSTITUTE SEER CANCER STATISTICS REVIEW 1975-2016

While overall 5-year brain cancer survival is close to 33%, it remains one of the most deadly forms of cancer. Importantly, the outcomes for GBM patients are much lower, with 25% surviving more than one year and less than 5% surviving five years. Median survival is about 15 months.

Treatment options usually start with surgery to remove the tumor. Surgery success is dependent on the size, location and type of tumor. As mentioned previously, tumor location within the brain or near sensitive sensory organs might make complete removal difficult. As well, surgical risks include bleeding and infection. For most aggressive spreading forms like GBMs, surgery is the first option followed by radiation therapy. Radiation is intended to kill leftover tumor. Chemotherapy is also an option in treating tumors, sometimes alongside radiation therapy. However, brain cancer success rates measured by survival have shown only modest improvement in the past thirty years.

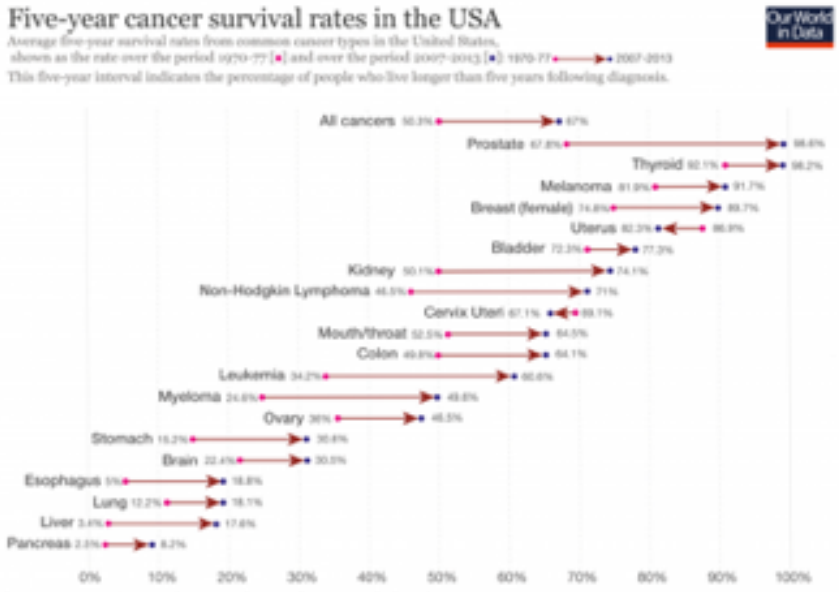


FIGURE 14 - 5-YEAR US CANCER SURVIVAL CHANGES 1970-1977 VS. 2007-2013; SOURCE MAX ROSER AND HANNAH RITCHIE (2020) - "CANCER". PUBLISHED ONLINE AT OURWORLDINDATA.ORG. RETRIEVED FROM: 'HTTPS://OURWORLDINDATA.ORG/CANCER' [ONLINE RESOURCE]

Much like pancreatic cancer, despite the relatively small incidence level, brain cancer therapies currently are a $1+ billion market, so development continues. Much like the pancreatic cancer market, there has been a lack of new treatments approved for brain cancer, although over 350 are in development, according to Citeline Pharma R&D Annual Review 2019. This can be attributed to the relative small size of the brain cancer market compared to the overall cancer therapy market with large drug company development funds being siphoned to other areas. While there have been a number of new cancer drugs developed and approved, none recently have been indicated specifically for brain cancer. Secondly, the lack of new treatments available is also due to the tremendously high risk of investigational failure for brain tumor drugs. Treatments like immunotherapy Opdivo (although receiving FDA approval for other cancers), and Abbvie's Depatux-M for GBM, were late stage failures in 2019.

The few brain tumor therapies approved include older therapies like bevacizumab (Avastin), a vascular endothelial growth factor inhibitor (VEGF). Bevacizumab starves the tumor, blocking needed blood flow. Avastin was first approved in 2004 as anti-cancer therapy for metastatic colon cancer. Subsequent approvals came for metastatic breast cancer in 2008, for lung cancer in combination with chemotherapy in 2006, accelerated FDA approval for GBM in 2009 and full approval for recurrent GBM in 2017. Despite the approval, Avastin did not meet its primary endpoint of overall survival. MVASI, an Avastin biosimilar, was approved September 2017.

Chemotherapy drugs have been approved and are available, including:

temozolamide
procarbazine
carmustine (BCNU)
lomustine (CCNU)
vincristin
PCV
(a combination of procarbizine, vincristine, and lomustine)

As in pancreatic cancer, immunotherapy treatments like CAR-T cell therapy, are being investigated. These treatments have shown good response rates in non-solid or liquid cancers, but results thus far have been poor in brain cancer.

DEVELOPMENT OF SUCCESSFUL THERAPIES REMAINS CHALLENGING

There are three major issues to resolve to increase chances for successful new brain cancer therapies.

THE BLOOD-BRAIN BARRIER (BBB)

The brain has a natural defense barrier against toxins and unwanted material floating in the bloodstream. Tightly packed endothelial cells lining brain capillaries create a boundary or barrier between the brain and the blood-stream. Small fat-soluble substances like alcohol and caffeine are able to cross; Water-soluble substances like penicillin have problems getting through the barrier. Substances the brain needs like glucose are carried across the barrier by transport proteins.

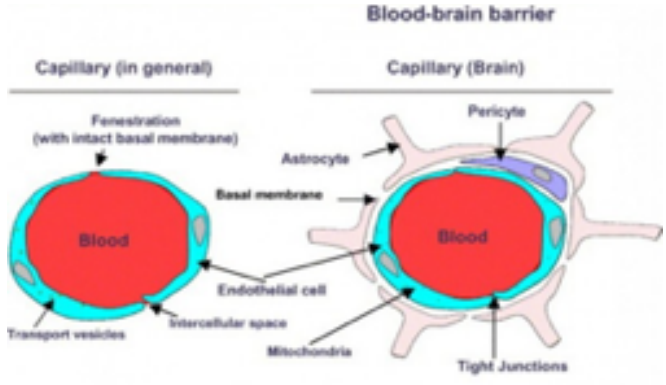


FIGURE 15 - GENERAL CAPILLARIES COMPARED TO BRAIN CAPILLARIES; SOURCE - HOPES.STANFORD.EDU

MUTATION AND DIFFERENT TYPES OF BRAIN CANCER CELLS

Mutations in genes have been identified in brain cancers. Numerous tumor sub-types exist, making targeted therapy much more difficult. Some mutations, like in the gene IDH1 that exists in about 12% of patients, have been theoretically shown to improve survival outcome. Nonetheless, brain cancer is typically heterogeneous. This biological heterogeneity often means a tumor that, at first glance, may appear to be the same, might actually require a different approach to treatment. The reverse exists as well (tumors that may look different under the microscope may have common elements genetically).

RESISTANCE TO CURRENT FORMS OF RADIATION AND CHEMOTHERAPY

Tumors can survive the initial therapies and rebound or re-grow. In particular, certain types of GBMs called glioma stem cells (GSC) display higher radiation and chemotherapy resistance not only through genetic heterogeneity but also through hiding in adaptive resistance pathways that cannot all be blocked effectively.

PENAO HAS UNIQUE POTENTIAL BREAKTHROUGH TO OVERCOME THE CHALLENGES

HOW DOES IT WORK?

PENAO (4-(N-(S-penicillamine acetyl)amino)-phenylarsen-oxide) is a mitochondrial arsenic poison. The arsenic molecule cross-links two amino acids on the enzyme adenine nucleotide translocase (ANT) a mitochondrial transporter. Mitochondria is the cell battery, making most of the cell's supply of adenosine triphosphate (ATP), a molecule that cells use as a source of energy. ANT is a key component of energy transmission, exchanging “high-energy” adenosine triphosphate (ATP) for “low-energy” adenosine diphospate (ADP) across the mitochondrial membrane pore. PENAO is an ANT inhibitor, triggering inactivation of ANT during mitochondrial energy transfer, resulting in cell death.

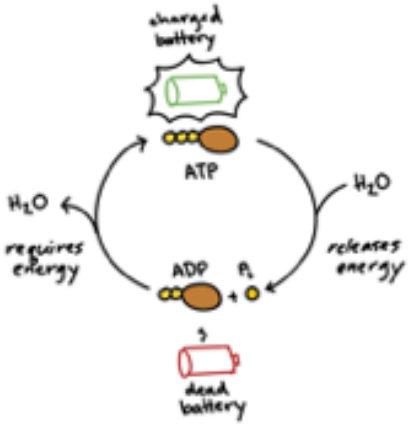


FIGURE 16 - ATP/ADP MITOCHONDRIAL ENERGY CYCLE; SOURCE: KHAN ACADEMY

In pre-clinical mice models, pharmacokinetic analysis demonstrated that PENAO readily crossed the blood-brain barrier and accumulated specifically in tumor tissue. PENAO was 440-fold more potent than temozolomide, the frontline chemotherapeutic used clinically for glioblastoma. There were also no signs or symptoms of treatment toxicity.

mTOR INHIBITORS

mTOR (mechanistic Target Of Rapamycin) has been found to regulate cell growth, proliferation and survival. The study of Rapamycin originated from an expedition to Easter Island (known locally as Rapa Nui) in the 1960's. Bacterium discovered there were found to contain anti-fungal as well as immunosuppressive and anti-cancer properties. Rapamycin was first approved by the FDA as a immunosuppressant following kidney transplants. Eventually, the mammalian rapamycin target was discovered (mTOR) in the 1990's.

Increased activation of mTOR has been found to contribute to development of tumors including breast, prostate, lung, bladder and brain tissue cancers. One of the most common reasons for increased mTOR activity is known to be mutations in the tumor suppressor PTEN gene.

Since mTOR is a central pathway for metabolism and tissue function, mTOR inhibitors disrupt this process. Early combined PENAO and mTOR Inhibitor data in primary pediatric diffuse intrinsic pontine gliomas (DIPG) cell cultures showed efficacy in this type of brain tumor that has been resistant to clinically available therapies.

THE COMBINATION ENHANCES CYTOTOXIC ACTIVITY

Glioma development is associated with metabolic reprogramming, redox state disruption and resistance to apoptotic pathways. The mitochondrion is an attractive target as a key organelle that facilitates these critical processes. As indicated previously, PENAO targets mitochondrial function by inhibiting adenine nucleotide translocase (ANT). The resistant tumor cultures in early stage clinical expressed high levels of ANT2 protein and were sensitive to the mitochondrial inhibitor PENAO through oxidative stress, while its apoptotic effects were found to be further enhanced upon co-treatment with mTOR inhibitor temsirolimus. This combination therapy was found to act through inhibition of PI3K/AKT/mTOR pathway, HSP90 and activation of MAPK (mitogen-activated protein kinases).

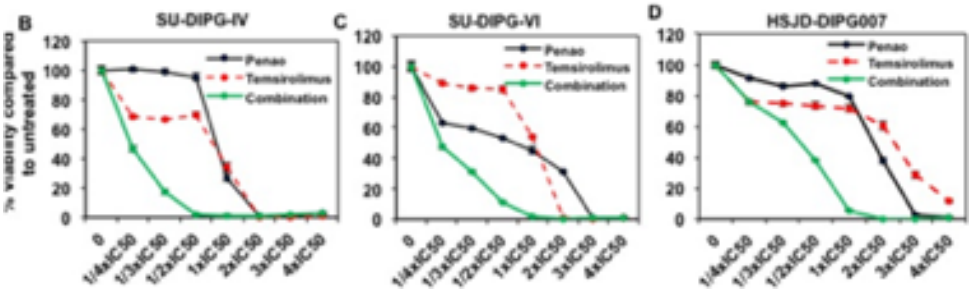


FIGURE 17 - CYTOTOXIC EFFICACY OF PENAO COMBINED WITH MTOR INHIBITOR TEMSIROLIMUS TESTED IN 3 CELL LINES; SOURCE BERONI

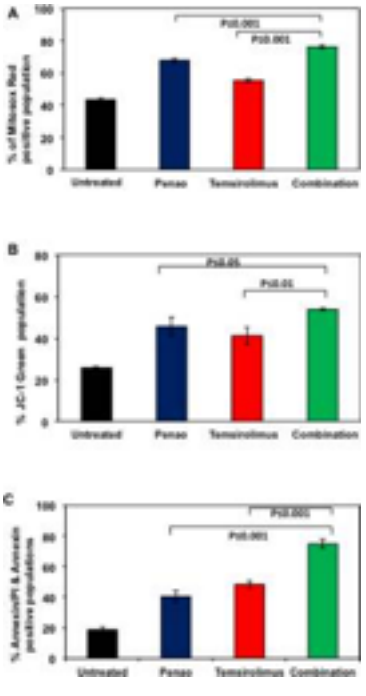


FIGURE 18 -COMBINATION OF PENAO WITH TEMSIROLIMUS INCREASES MITOCHONDRIAL DYSFUNCTION AND ENHANCES APOPTOSIS; SOURCE: IMPACTJOURNALS.COM/ONCOTARGET

PENAO DEVELOPMENT

PENAO is the result of more than a decade's work by Professor Philip Hogg, the inaugural director of the Lowy Cancer Research Centre at the University of New South Wales. In August 2019, Beroni and a subsidiary of the University of New South Wales (UNSW) jointly took over the PENAO drug development and licensing rights from Cystemix Pty Ltd., a company established by UNSW. Beroni will invest a total of $10.4 million in stages over a two year period until the end of the Phase II trial.

Pre-clinical trials found that PENAO cell-killing effects increased with mTOR inhibitors. A Phase I trial demonstrated safety. The multi-center Phase II trials will combine PENAO with an mTOR inhibitor based on demonstrated effectiveness in combination. Although moving four solid tumor indications into Phase II, the company expects to focus on brain and pancreatic tumors, with the initial trial enrollment in Australia and possibly expanding to Japan and eventually to the United States.

The company also expects to apply for Orphan Drug status in the United States by mid-2021.

WHAT'S NEXT FOR PENAO?

Beroni anticipates that, based on project and expected funding timeline, it is anticipated that the best case scenario is for the Phase II clinical trial to commence in first half 2020 with the recruitment of trial patients The expected duration of the clinical trial will be between 18 and 24 months. For the Phase II clinical trial, the PENAO drug will be combined with an mTOR inhibitor of the rapalog class. Three potential trial sites in Sydney, Australia have been identified. Once the trial has started, Beroni will monitor the progress of these trial sites and, if needed, more trial sites will be added to accelerate progress of the clinical trial, particularly in jurisdictions with suitable drug regulation, unmet market need and strong existing collaboration This may include Japan as Beroni has collaboration with a medical group in Japan with extensive hospital and clinical trial facilities. Conducting part of the clinical trials in Japan will strengthen Beroni's application for Japan PMDA's approval of the PENAO drug. Dependent on enrollment timing, the Phase II analysis will be conducted second half 2021. Beroni is also considering clinical trials in the United States and has begun discussions with Clinical Research Organizations. As part of its clinical plan, Beroni plans to file PENAO for Orphan Drug status in the United States by mid-2021.

RISK FACTORS

FUNDING ENVIRONMENT

As an early-clinical stage biopharmaceutical company targeting challenging cancers, Beroni faces a number of hurdles, including product development success, timelines and access to capital. The primary risk, at present, is the ability to raise the $10.4 million in funds on acceptable terms. The funds Beroni hopes to raise could be more difficult than originally expected. Funding needs could increase as the number of patients or the number of clinical sites expand. Another limitation to getting the funding is that the pancreas and brain cancer markets are relatively small and might not attract as much investor interest compared to other larger cancer markets.

As an expanding E-commerce company, Beroni also faces revenue hurdles until the Medicine Plus acquisition is closed.

PRODUCT DEVELOPMENT SUCCESS & COMMERCIALIZATION TIMELINE

There is always uncertainty over the success of a product going through clinical trials, and even more so with one targeting risk categories such as pancreatic and brain cancers. There has been limited success in new drug development in these therapeutic categories. While approval odds improve as therapies successfully advance through early-stage clinical trials, failures in late-stage trials are numerous. Another risk is the time needed to make it through the trial and approval process to reach commercialization. Unique serious disease unmet need small patient market therapies could accelerate approval, especially if Beroni is successful obtaining U.S. Orphan Drug Status. Orphan status drugs treating cancer or rare disease can often get approval on just Phase II data. But, even under those circumstances, it is not realistic to expect commercialization until late 2023.

E-COMMERCE OPPORTUNITY

Medicine Plus began operations in 2005 and sells a wide range of medical drugs, health foods, supplements, cosmetic products and household goods in the Japanese market. Its products are sold to various clinician, supermarket and other retail outlets. The company has a significant presence on the popular e-commerce sites in Japan such as Rakuten, Yahoo and Amazon. In addition to selling its own branded products, Medicine Plus also markets a wide range of third party branded products. Medicine Plus has an established wholesale network of over 2,000 distributors and 7,500 sales outlets. Roughly half of the business sales are through the wholesale network. The other half, e-commerce business is the fastest growing channel. Beroni expects to expand the sales and distribution of the e-commerce platform.

Closing of the Medicine Plus acquisition has been held up but is the agreement is still binding. Upon acquisition closing, Medicine Plus could greatly expand Beroni's existing business into Japan and other markets. The market represents a current market $35 million opportunity with solid growth potential.

VALUATION AND CONCLUSION

COMPARATIVE COST-BASED BIOPHARMACEUTICAL + E-COMMERCE REVENUE ASSESSMENT SUGGESTS BERONI HAS 40% UPSIDE FROM CURRENT VALUE

Early-stage clinical trial biopharmaceutical companies are extremely difficult to value.

Biopharmaceutical companies typically fall into the high risk/high reward group. While in most other industries it is growth of revenue and profit that drives value creation, in drug development companies the key value driver is the moving toward commercialization. The further the drug progresses through the clinical trial process from Phase I to Phase III, the lower the risk of the product getting approval and getting to market, and equating to product value attribution.

Risk is represented by time and success probability. The graphic and table below indicate the amount of time and the success probabilities of various studies of a therapy to move to the next stage, starting with Phase I in the drug development process. While it can take upwards of 15 years to become commercialized, the overall probability of making it from the start of phase I to an approved drug is just under 10%. Moving from Phase II to Phase III carries the highest risk since Phase II typically tests for safety and efficacy against a control arm.

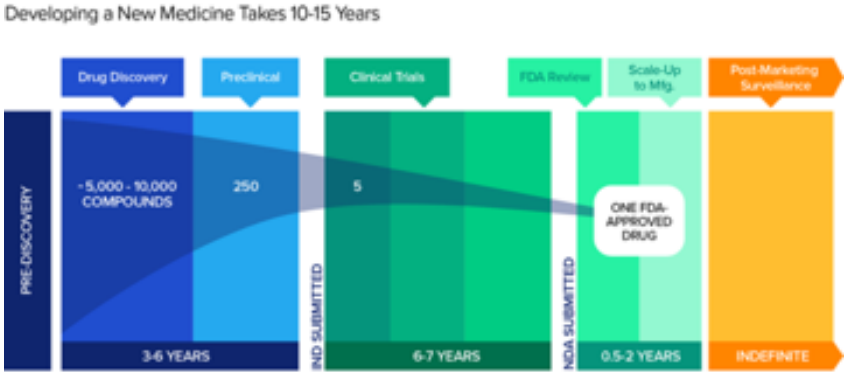


FIGURE 19- DRUG DEVELOPMENT TAKES TIME; SOURCE UCSD DRUG DEVELOPMENT MOOC

Beroni is trading on the OTC Best Market where it is being valued at ~$156 MN. Given the pipeline, supplemented by possible expansion and revenue opportunities in the commercial pathway, it is our belief a reasonable investment case could be made that the company could be worth a bit more than its current value. PENAO will be a significant driver of value as it advances through clinical trial phases. Key considerations:

PENAO is a unique apoptotic therapy with potential to address the current cancer drug development challenges. The current pancreatic and brain cancer markets, despite relatively small incidence (compared to other cancers) and limited effectiveness, still generate ~$ 3 billion worldwide, so the opportunity for PENAO is tremendous. With its method of action, combined with mTOR inhibitors, PENAO could be effective in current anti-cancer markets with limited effective therapies.

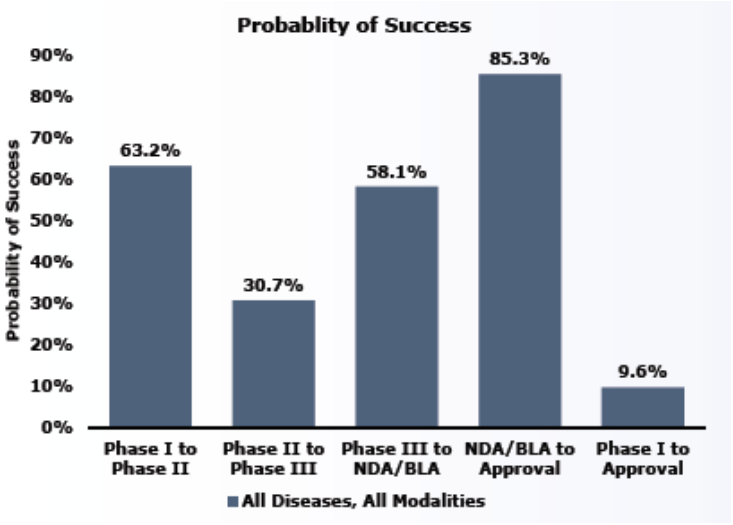


FIGURE 20 - DRUG DEVELOPMENT PROBABILITY OF SUCCESS FROM PHASE I TO APPROVAL;
SOURCE - BIO REPORT CLINICAL DEVELOPMENT SUCCESS RATES 2006-2015

As PENAO transitions to Phase II trials targeted to begin in first half 2020, the development drug data from the previously conducted pre-clinical and Phase I studies provide positive indications for the drug.

A potential Orphan Drug designation improves the possibility of an expedited drug development. Beroni is seeking indications in pancreatic and brain cancer markets, addressable worldwide revenue markets over $3 billion currently.

The commercial pathway offers some revenue growth and support, especially if the Medicine Plus acquisition is closed. There will be revenue needs as the company advances other commercial pathways in infectious disease and gene detection, in addition to requirements toward PENAO and other pipeline therapies.

On the biopharmaceutical business, good direct comparison and valuation reference points to make are Nascent Biotech and CNS Pharmaceuticals, which are clinical-stage companies targeting similar brain cancer markets as Beroni. CNS (CNSP) traded publicly on NASDAQ at $4/share in November 2019 valuing the company at ~$66 million. CNS is currently trading at $4.35 per share (as of January 30, 2020) with a market value of ~$72 million. Nascent (NBIO) is currently trading at $0.143 per share (as of January 30, 2020) with a market value of ~$4.51 million. CNS is preparing to begin its Phase II trial while Nascent is just moving to Phase I (but has received FDA Orphan Drug status).

However, a revenue component should be also valued. In the table below, we compare the three companies using 2019 OPEX and 2020 revenue estimates which have been calculated by estimating annual expenses for each company reported to date, and assuming the Medicine Plus acquisition closes near-term. The calculation shows that CNS's EV/OPEX at ~41X is nearly 2 times greater than BNIGF's EV/OPEX of ~24X. In two scenarios applying a 50% and 35% discount to CNS's valuation, a $133-$175 million fair market value range for BNIGF can be implied. Based on the share count, a $1.00-$1.30 per share value is derived based solely on the EV/OPEX valuation (the discount is applied given CNS's slightly advanced clinical trial status). However, adding in revenue from anticipated e-commerce expansion, expected to be profitable in 2020, increases the company overall valuation. As the e-commerce expansion is not yet profitable (and the Medicine Plus acquisition has not closed but could close by mid-2020), a discounted .3x-.5x revenue multiple range is warranted for half year 2020 expected revenue contribution.

2019, US$ million	CNSP	NBIO	BNIGF (cost-based only)	BNIGF (cost-based + revenue)
Revenue	--	--	--	19.00
COGS	--	--	--	18.00
SG&A	1.25	0.97	0.70	0.70
R&D	0.49	0.27	0.16	0.16
OPEX	1.75	1.25	3.50	8.00
Share Price 1/30/20)	4.35	0.14	2.15	2.15
Share Count , millions	16.45	33.77	72.54	72.54
Market Value, $ millions	72.00	4.72	155.90	155.90
Net Cash	0.63	0.01	2.41	2.41
Enterprise Value	71.37	4.71	153.49	153.49
EV/OPEX	40.78	3.77	43.85	19.19
Share Fair Value Scenarios, US$ millions				
@ 50% discount from CNSP EV/OPEX		20.39	20.39	20.4
Implied EV		25.5	71.4	163.1
@ .3 x revenue multiple				5.7
Implied MV		25.5	73.8	171.2
Implied $ Per Share		0.76	**1.02**	**2.36**
@ 35% discount from CNSP EV/OPEX		26.5	26.5	26.5
Implied EV		33.1	92.8	212.1
@ .5 x revenue multiple				9.5
Implied MV		33.1	95.2	224.0
Implied $ Per Share		0.98	**1.31**	**3.09**

FIGURE 21 -SOURCE MARBLE ARCH ESTIMATES AND COMPANY FILINGS

SENIOR ANALYST: GREGORY AURAND, CFA

Greg Aurand has been a research analyst for more than 15 years, working on the buy-side and sell-side, including Munder Capital Management, Zacks Investment Research and Orbitex Management. His focus in healthcare has encompassed a broad spectrum of large-, mid- and small-cap situations in medical technology, pharmaceuticals, biopharmaceuticals, healthcare facilities and services, and health information technology.

ANALYST CERTIFICATION

I, Gregory Aurand, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report.

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