Company Report Update

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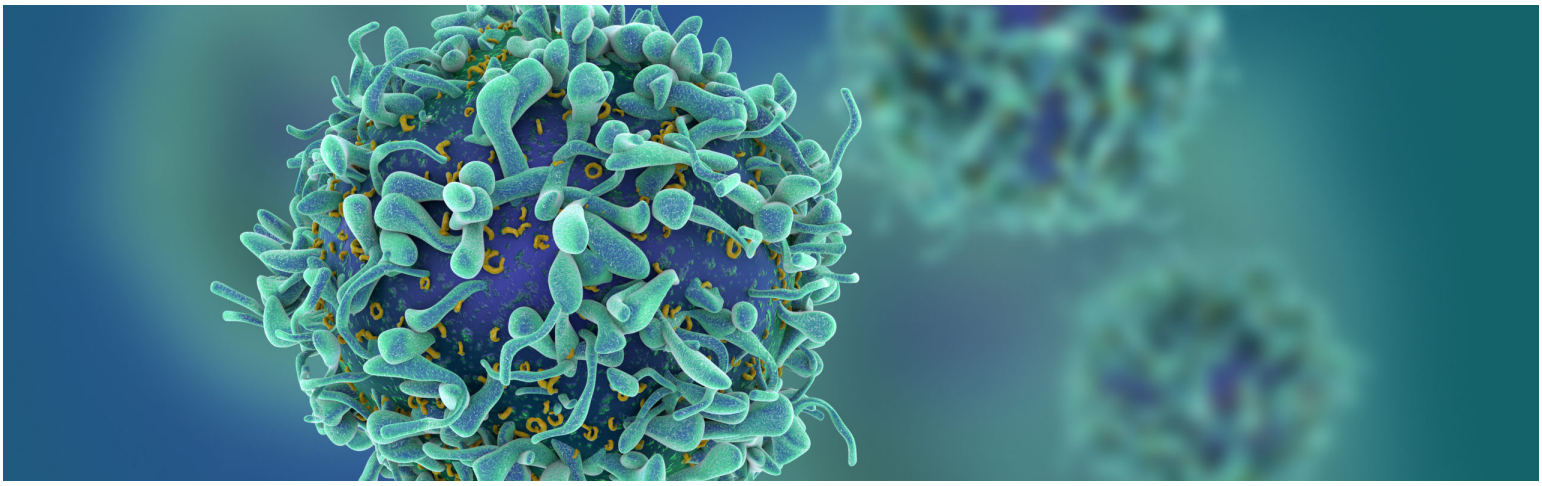
June 10, 2021

Industry: Biotechnology



NASCENT BIOTECH INC.

Taking a step forward towards filling an unmet need in brain cancer treatment as Phase I trials commence

NASCENT BIOTECH, INC. (OTC-NBIO-$0.0808)	Rating: Speculative Buy	Price Target: $0.39-$1.99

COMPANY SUMMARY

Incorporated in 2014, Nascent Biotech, Inc. is a clinical-stage biopharmaceutical company which develops monoclonal antibodies for the treatment of various forms of cancer. It is currently developing Pritumumab (PTB), a monoclonal antibody to primarily treat patients with brain cancer malignancies, such as glioblastoma and malignant astrocytoma for which there remains an unmet demand for more effective treatment than is currently available. The company has recently opened Phase 1 human trials at Hoag Presbyterian.

KEY STATISTICS

Price as of 6/9/2021	$0.0808
52 Week High-Low	$0.0437-$0.1595
Share Count	107.1MN
Market Value	$8.65MN
Average Daily Volume	396,666
Primary Exchange	OTCQB
Fiscal Year	March 31
Inception Date	2014
Addressable Market Size (US)	$1.1BN
NPV Based Valuation Est.	$42MN to $213MN

INVESTMENT HIGHLIGHTS

- Nascent Biotech is developing a targeted immunotherapy drug, Pritumumab (PTB), a monoclonal antibody which has shown early promise as a long-awaited breakthrough therapy in the fight against brain cancer, one of the most challenging cancers with relatively low survival rates. Successful development of new treatments for this type of cancer has proved rare with the FDA having approved only four brain cancer therapies over the last three decades.

- PTB's target, Ecto-Domain Vimentin is a 'first of a kind' conserved target on the surface of brain and other epithelial cancer cells. In previous human clinical studies conducted in Japan more than 20 years ago, as well as in more recent pre-clinical trials on animals, PTB has been shown to consistently breach the blood-brain barrier enabling it to attack brain cancer cells more efficaciously than existing therapies.

COMPANY INFORMATION

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- In April 2021, Nascent consummated a landmark licensing agreement with Bioray Pharmaceutical worth $5MN in non-dilutive funding, including a $1MN upfront payment enabling the company to start its long-awaited Phase I human clinical studies on PTB in the US in March. Promised funding gives Nascent a funding runway through to the start of Phase II trials, with Bioray also insisting on first right of refusal to fund the cost of completing the Phase II studies.

- PTB's orphan drug designation opens up the possibility of an expedited drug trial process and FDA approval process if clinical outcomes at least replicate the Japanese trial results. In such a scenario, PTB could be commercialized by late 2024 or early 2025. If successfully commercialized, we would anticipate rapid adoption of the PTB.

- Our 10 Year Risk-Adjusted NPV assessment models based around two scenarios indicate a rNVP based valuation range of $42MN to $213MN for Nascent versus the company's current capitalization of ~$8.65MN. Our assessed values do not take into account potential approvals for the use of PTB in the treatment of other epithelial cancers, including breast, colon and pancreatic cancers which would substantially expand PTB's potential addressable market and Nascent's value.

COMPANY OVERVIEW

NASCENT BIOTECH, INC.

Filling the gap in the fight against brain cancer

Nascent Biotech was incorporated on March 3, 2014 to continue the development of a human monoclonal antibody, known as Pritumumab (PTB), to treat epithelial (tissue-related) cancers. While the long term goal is to bring PTB to market to treat a variety of such cancers including pancreatic, lung, colon and breast cancer, Nascent's primary focus is to bring PTB to toward regulatory approval and commercialization for treatment of brain cancer for which there remains an unmet demand for more efficacious treatment than is currently available.

PTB is not actually a new development, and has already been clinically tested in Phase I and Phase II trials in 249 human brain cancer patients in Japan during a 14-year time period between 1988 and 2002. The objective of those Phase I and Phase II human clinical trials was to determine the safety of PTB in humans and its efficacy in eliminating tumors or reducing tumor size in patients with brain cancer. These trials not only showed that PTB was well tolerated, but also produced data showing that PTB, administered as a single agent to brain cancer patients intravenously and directly into the tumor, demonstrated positive biological activity even with the very low dose regimens administered. The trials were conducted around two dosage regimens— 1x1mg dose per week and 2x1mg doses per week—with both regimens set well below the typically approved mAb dosage of 5mg/kg plus (350mg plus per patient) for approved mAb therapies, and designed for these trials to elicit only a minor immune response. The data from these trials showed a collective rate of partial remission (tumor volume reduction greater than 51%) plus complete remission (including a glioblastoma patient) of 15%, and a stable disease rate of an additional 50% (stable disease defined as +25% to -50% change in tumor volume) as measured by a standard formulary from MRI and X-ray imaging. The overall response rate to PTB in the 74 follow up patients was ~65%.

The sponsor of those trials in Japan was the Hagiwara Institute of Health (HIH) where all pre-clinical development was performed. At the end of the Phase II trials, the Japanese Ministry of Health & Welfare (MHW) approved HIH for expanded Phase III trials of PTB in humans in 2004. However, further clinical development of the drug was suspended following the death of HIH's founder in the same year. In spite of the positive momentum behind PTB, its development was subsequently abandoned by his surviving heirs with the major concern at that time being the ability to manufacture enough quantity of PTB to continue clinical trials due to manufacturing technology limitations.

But, the promise of PTB has been revived after Dr. Mark Glassy, who had initially discovered the antibody in 1982 while he was a faculty member at the University of California San Diego's Department of Medicine, Hematology/Oncology division before a visiting member of the faculty from Japan took it back to his country and had it licensed there, succeeded in recovering the license on his discovery in 2009. Dr. Glassy went on to cofound Nascent in 2014 with its primary mission to resume the development of PTB. While Dr. Glassy has recently retired from Nascent, the company has achieved key milestones that have enabled the development of PTB to move significantly forward culminating so far in the commencement of Phase I clinical trials in May 2021.

NASCENT'S LEADERSHIP

Experienced management backed up by a top-rated investigative science team

Experienced Management

Sean Carrick – CEO, President and Director - More than 25 years' success building and leading Life Sciences Companies in large, mid-cap and venture-backed stages, including Pfizer, Conmed and Maquet.

Boris Shor, Ph.D. - Science Advisor - More than 20 years' experience leading oncology discovery programs and external R&D partnerships at large pharmas (Wyeth, Pfizer) and biotech companies, with specific focus on preclinical discovery and development of small molecule kinase inhibitors, biologics and nanoparticles.

Ivan Babic, Ph.D. – VP, Research and Development - More than 12 years' experience in translational oncology; has been actively involved in drug discovery and development for the last 6 years. Held positions at UCLA and UCSD, was Assistant Professor at the John Wayne Cancer Institute and a Research Scientist at the Pacific Neurosciences Institute.

Lowell Holden – Chief Financial Officer, Treasurer and Director - More than 50 years of business and financial accounting experience, including public company auditing and SEC reporting requirements.

Dr. Santosh Kesari, Md, Ph.D. – Chief Medical Advisor - An experienced researcher and NeuroOncologist, John Wayne Cancer Institute.

Source: Nascent Biotech

KEY MILESTONES

Nascent's landmark Phase I trial begins

In April 2015, Nascent achieved its first major milestone when the US Food and Drug Administration (FDA) granted PTB orphan drug designation for treatment of patients with glioma, opening up the possibility of an expedited drug development and FDA approval process. This was followed by a similar designation in April 2016 for the treatment of pancreatic cancer.

On March 31, 2017 Nascent filed an Investigational New Drug (IND) submission with FDA for clearance to begin Phase I clinical trials to test the value of PTB in the treatment of advanced brain cancer. In December 2018 the company received clearance from the FDA to begin phase 1 clinical trials albeit subject to a partial clinical hold, allowing Nascent to use a specific lot of drug substance, but requiring the company to present additional product testing criteria to the FDA before being allowed to perform all the clinical work requested under its IND.

In August 2019, Nascent entered into a clinical trial agreement with Hoag Memorial Hospital in Newport Beach, CA where the company will conduct clinical trials to initially evaluate PTB on patients with brain cancer.

In December 2020, Nascent received a letter from FDA removing the partial clinical hold on PTB, giving the company full clearance to commence Phase I Human Clinical Trials proposed under the terms of its IND without restriction.

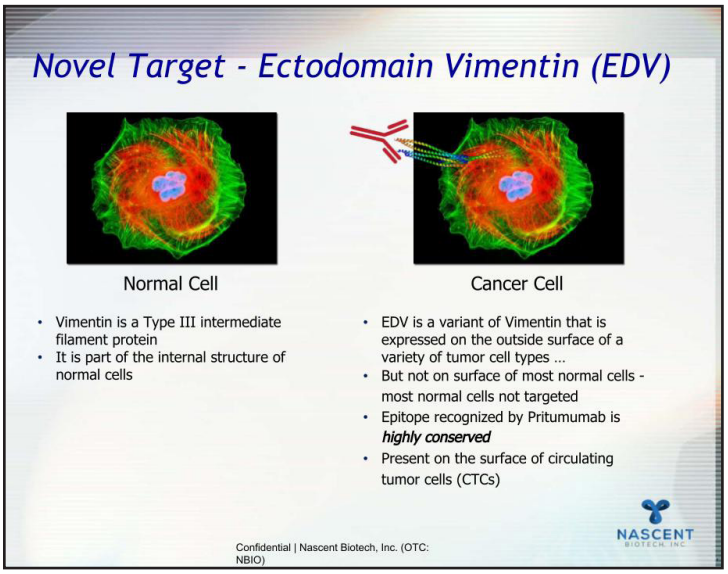
In March 2021, albeit approximately one year behind plan, Nascent officially opened its Phase I human trial to evaluate PTB as a treatment option for brain cancer, including malignant primary brain tumors and adult brain metastases. Patients have been enrolled and initial dosing has been applied to three patients so far in the trial. To meet FDA requirements, the trial continues to recruit new patients for participation in what is scheduled to be a 42 patient Phase1/II study that tests the safety, side effects, and best dose of the treatment and how well a certain type of cancer or other disease responds to a new treatment.

WHAT IS PRITUMUMAB (PTB) & HOW IT WORKS

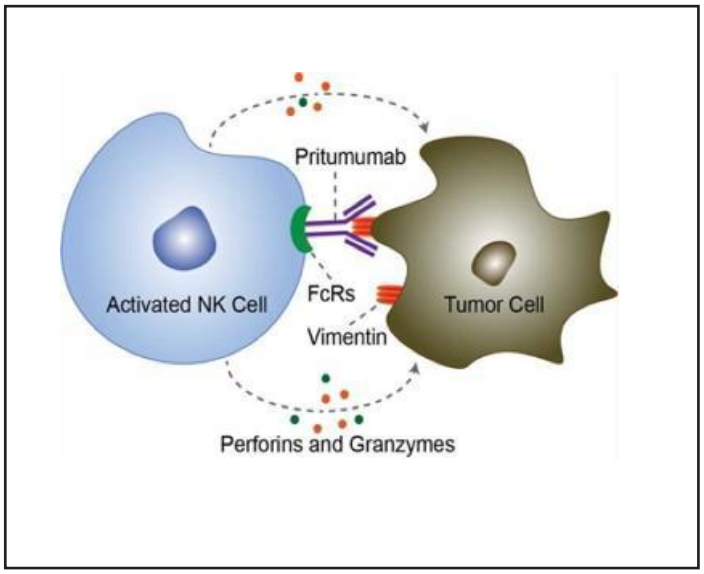
A potential breakthrough targeted therapy treatment for brain cancer

PTB's primary targets are Gliomas, which are the most prevalent among malignant primary brain tumors, include all tumors— glioblastoma, ependymomas, astrocytomas, and oligodendrogliomas—arising from the gluey or supportive tissue of the brain. This tissue, called glia, helps to keep the neurons in place and functioning well. However, three types of normal glial cells can produce tumors—astrocytes, oligodendrocytes, and ependymal cells. Tumors that display a mixture of these cells are called mixed gliomas. The most common type of glioma is glioblastoma (also known as glioblastoma multiforme (GBM) or grade IV astrocytoma) which accounts for approaching 60% of all diagnosed gliomas, close to half of all malignant primary brain tumors and ~15% of all primary brain tumors. It is also the most aggressive form of brain cancer which can arise in the brain de novo or evolve from lower-grade astrocytomas or oligodendrogliomas. While overall 5-year brain cancer survival rates are approximately one-third, within that figure, the prognosis for GBM patients is far worse with the 5-year survival rate at only 5%. In fact, average survival rates for GBM patients rest somewhere in the 11 to 15 months post diagnosis time frame.

PTB (also known as CLNH11, CLN-IgG, and ACA-11 in the scientific literature) is a natural fully-human monoclonal human antibody (MaB) that was originally discovered from a draining lymph node of a cervical cancer patient. Specificity analysis of the antibody showed that it recognizes the altered form of Vimentin or Ecto-Domain Vimentin (EDV) that is expressed on the cell surface of epithelial tumor cells. Studies have shown the target antigen to be highly restricted to various epithelial cancers and not to normal cells and tissues. Vimentin is an intracellular cytoskeletal protein overexpressed during epithelial-to-mesenchymal transition (EMT), a process integral to cancer cell metastasis. PTB has been demonstrated to bind cell surface expressed Vimentin (referred to as EDV) on the surface of the cancer cells inducing tumor cell death by antibody-dependent cell-mediated cytotoxicity (ADCC), a mechanism of cell-mediated immune defense in which antibodies, by coating the target (tumor) cells, makes them vulnerable to attack by immune cells, known as natural killer (NK cells).



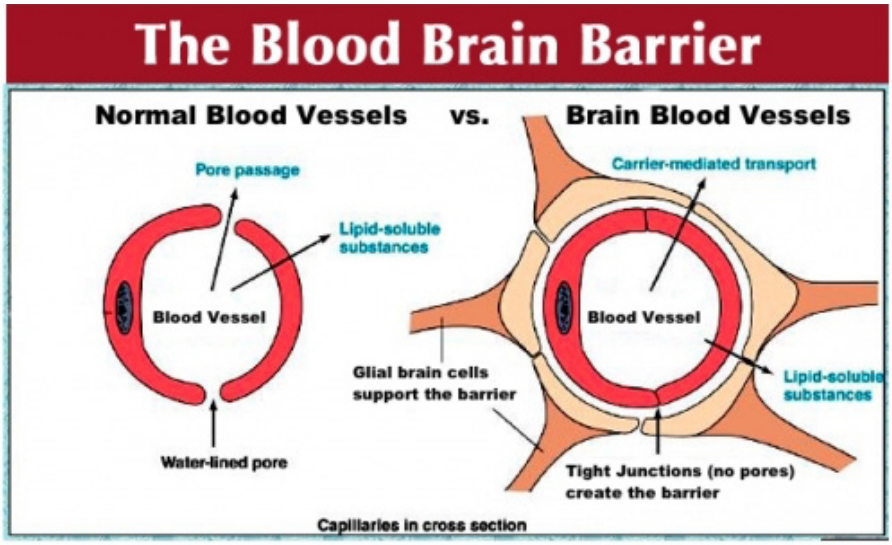
Source: Nascent Biotech



Source: Creative Biolabs

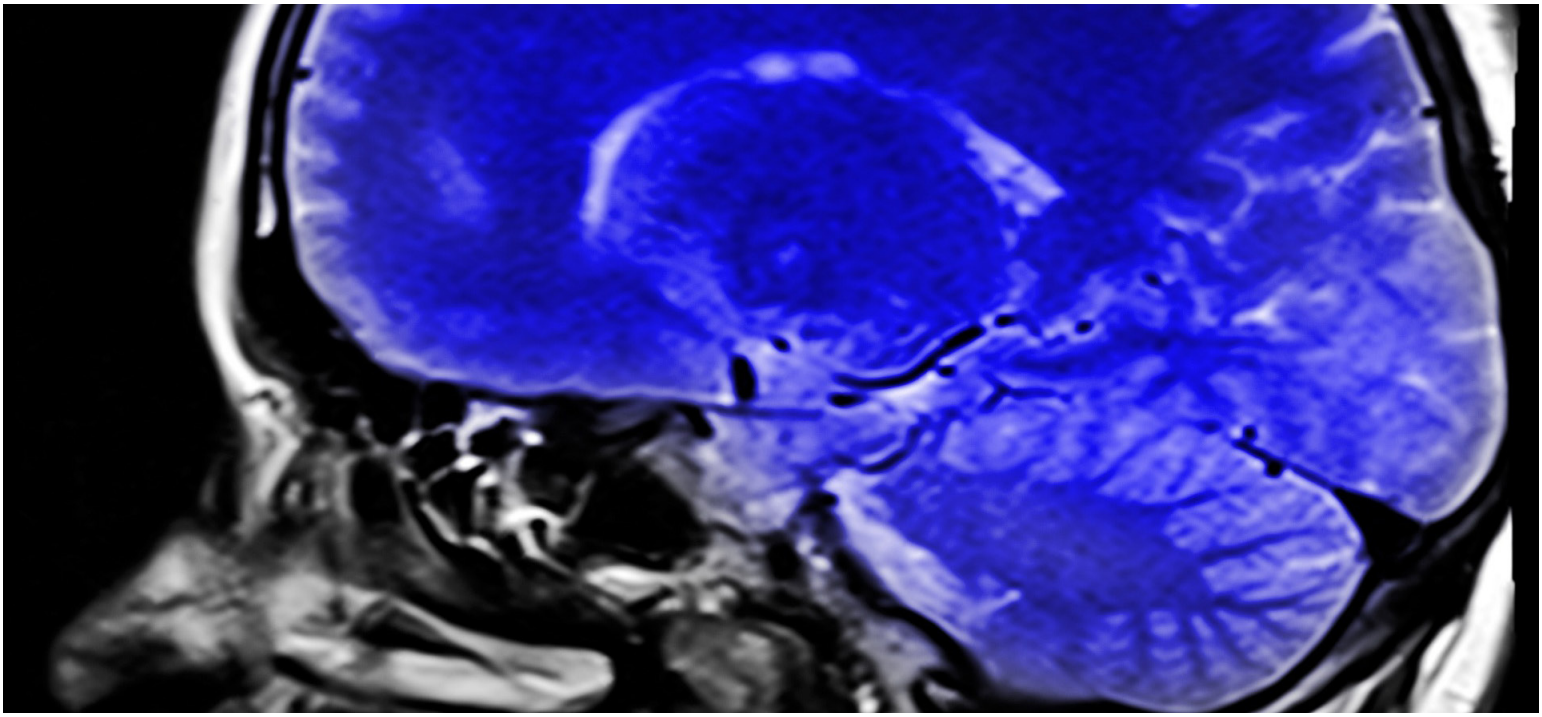
One of the limitations of targeted therapies is that they tend to be targeted at a specific population of cells. Unlike other cancers where there is only one mutation to consider providing the environment for targeted therapies to be effective, brain tumors are made up of different sub-populations which can neutralize the impact of targeted therapies. However, a positive aspect of PTB in this regard is that its antigen target is quite broadly expressed, which potentially deals with the problem of tumors with multiple sub-populations.

Another impediment in the treatment of brain cancer is the blood-brain barrier. The brain is the only organ in the body that is known to have its own security system which is known as the blood–brain barrier. This is a barrier between the brain's blood vessels (capillaries) and the cells and other components that make up brain tissue - describing it as a barrier may be somewhat misleading because the blood brain barrier is not a static wall, but instead, actively pumps selected molecules into or out of the brain. Whereas the skull, meninges and cerebrospinal fluid protect against physical damage, the blood–brain barrier provides a defense against disease-causing pathogens and toxins that may be present in our blood. Similar to all other blood vessels in the body, the brain's blood vessels are lined with endothelial cells which serve as an interface between circulating blood and the vessel wall. However, unlike other blood vessels in the body, the endothelial cells in the brain are tightly wedged together, creating a nearly impermeable boundary between the brain and bloodstream. Extensive scientific research has found that compounds that are very small and/or fat-soluble, such as antidepressants, anti-anxiety medications, alcohol, morphine, and many hormones are able to slip through the endothelial cells that make up the blood-brain barrier without much effort. In contrast, larger molecules, such as glucose or insulin, must be ferried across by proteins. These transporter proteins, located in the brain's blood vessel walls, selectively snag and pull the desired molecules from the blood into the brain. For reasons not yet fully understood at this time, the barrier does allow metastatic cancer cells to slip in from the bloodstream, but most chemotherapy drugs have a tough time getting through the brain's gatekeeper.



SOURCE: CHRISTOPHER & DANA REEVE FOUNDATION

Studies have reported that antibodies with a high isoelectric point can spontaneously cross the blood-brain barrier. PTB's high isoelectric point (defined as the pH at which the antibody has no net electrical charge and therefore does not migrate in an electric field) increases its potential efficacy in the treatment of brain cancer. Indeed, the drug had been found to cross the blood-brain barrier in the Japanese human trials. More recently, Nascent has demonstrated in its experiments with mice that had been bred without an immune system in order to be able to grow the cancer tumors in the animal that the drug got through the blood-brain barrier. The body of evidence to date has convinced the US Patent and Trademark Office (USPTO) to grant Nascent allowance for a "Method-of-Use" patent for PTB in March 2021. Specifically, this patent approval is related to PTB's ability to cross the blood-brain barrier. The 13 year patent number is expected to be issued in this month and will be a unique feature of Nascent's primary asset which can only enhance the company's future fund raising efforts.



THE MARKET OPPORTUNITY

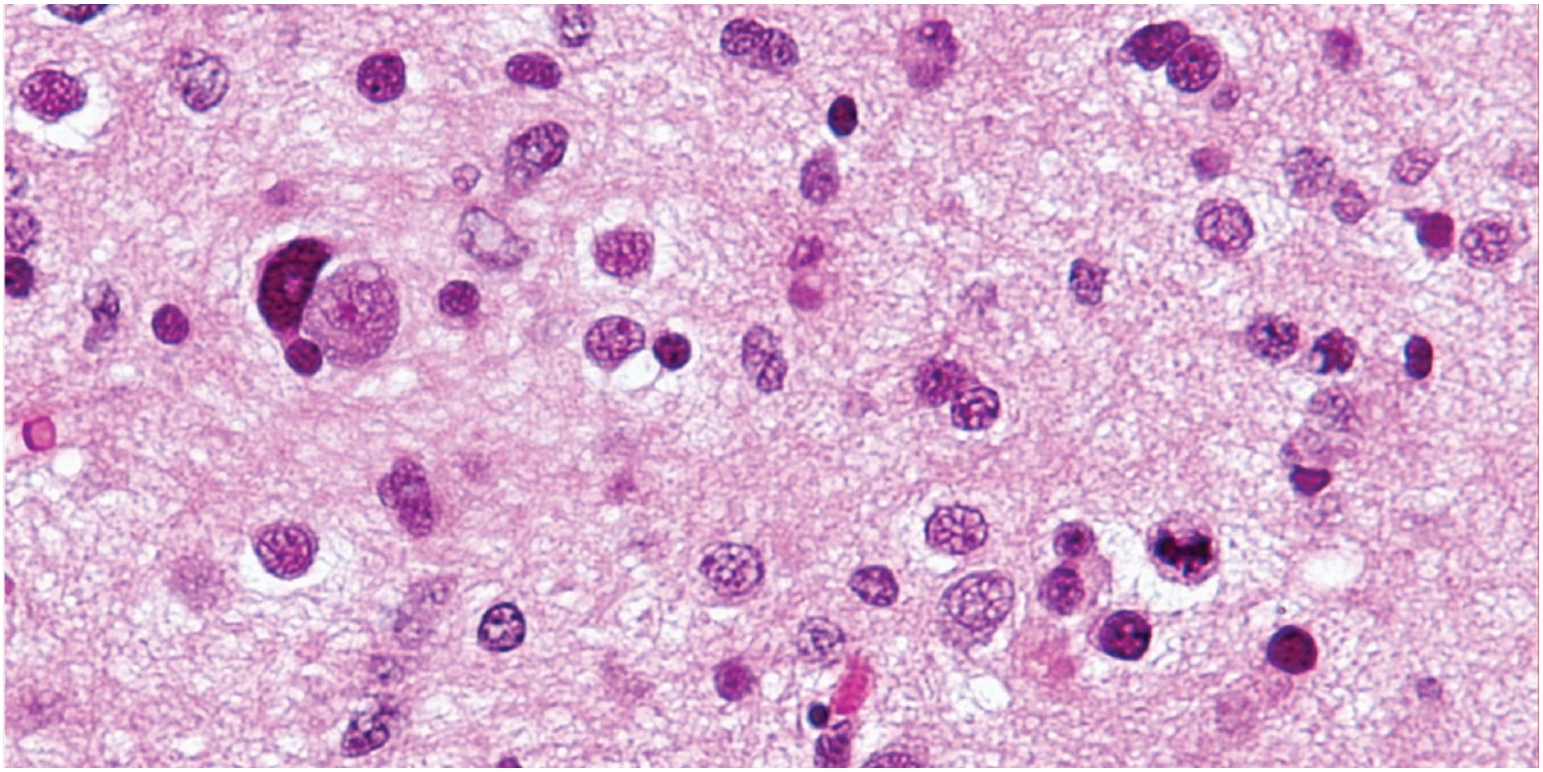
Primary brain cancer may be a small opportunity in the oncology universe, but PTB's treatment net can draw substantially broader

Cancer is the second leading cause of death in the US behind heart disease, but malignant brain and other central nervous system (CNS) cancers are considered a rare disease being 16th in the list of the most common cancers in the US, and accounting for just 1.3% of estimated new cancer cases expected to be diagnosed in 2021. The National Brain Tumor Society estimates that ~24K-$25K adult Americans are diagnosed with a malignant primary brain tumor in 2021. For the record, there are also ~4K new malignant pediatric cases that are diagnosed in the US each year According to consulting and market research firm Fortune Business Insights (FBI), the brain cancer oncology market in North America was worth ~$1.1BN in 2020 (almost half the global market of $2.35BN). However, this represents less than 2% of the total size of the North American oncology market estimated at somewhere between $65BN and $70BN.

However, while the incidence of malignant primary brain cancer among adults may be less prevalent than many other cancers, looking beyond the raw numbers, it unfortunately counts itself among those with the lowest survival rates based on statistics provided by the National Cancer Institute (NCI).These show that only about one third of the brain cancer population remain alive 5 years following diagnosis with only pancreatic (another target indication for PTB), liver, lung and stomach cancers indicating worse survival rates among the prevalent cancers in the US. Drilling down further, survival rates for GBM, the most aggressive form of glioma, which accounts for approaching 60% of all diagnosed gliomas, close to half of all malignant primary brain tumors and 15% of all primary brain tumors, has a 5-year survival rate of just 5%. Moreover, malignant brain tumors kill more people under the age of 40, the most productive or potentially productive section of society, than any other cancer.

Add metastatic brain cancer (i.e., cancer in the brain arising from distant organs such as breast and colon), PTB's addressable market multiplies with something over 200,000 new cases diagnosed each year in the US. But, while PTB potentially addresses an important unmet need in the treatment of one of the most complex and deadly cancers known, its properties allow it to treat other epithelial cancers. This substantially expands PTB's addressable market further as there are 1.1MN new diagnoses of epithelial cancers in adults in the US each year, led by breast, prostate, lung, colon, bladder and pancreatic cancers. Epithelial cancers account for nearly 60% of new adult cancer diagnoses each year in the US.

The market opportunity, of course, goes beyond North American shores. As indicated above, Nascent has recently struck a 20 year (from commercialization) licensing agreement with Bioray which can potentially yield significant overseas sourced income for the company. According to data from Fortune Business Insights, the brain cancer oncology market outside of North America was slightly bigger in 2020, at $1.2BN. Based on these numbers, PTB's calculated that PTB's addressable market would be ~$111MN as things stand (i.e., 9% of sales). Furthermore, this addressable market could be significantly higher should PTB make it to commercialization as FBI predicts that the global brain oncology market could grow at a CAGR of ~11% to ~$5.64BN by 2028 from $2.35BN in 2020.



TREATMENT LANDSCAPE

Currently available treatment options do not result in prolonged remission in high-grade gliomas

The relatively poor survival rates associated with malignant brain tumors speaks to the fact that brain cancer is one of the most challenging cancers to treat effectively, let alone cure. Treatment options depend on the size, type and grade of the tumor as well as whether the tumor is pressing on vital parts of the brain or has spread to other parts of the CNS. Surgery to remove as much of the tumor as possible is usually the first step in treating most types of tumors including gliomas. Gliomas that are small and easy to separate from surrounding healthy brain tissue, makes complete surgical removal possible. In other cases, tumors cannot be separated from surrounding tissue, or they are located near sensitive areas in the brain which make surgery risky. Surgery is often the only treatment needed for a low-grade brain tumor especially if all of the tumor can be removed, but at the other extreme, there are tumors which are unable to be removed surgically because of their location in the brain or because there are multiple tumors. In these cases or if there is a visible tumor remaining after surgery, radiation therapy and chemotherapy are typically used. For high-grade gliomas, such as GBM, treatment usually begins with surgery, followed by radiation therapy and chemotherapy. Surgery to remove a glioma carries risks, such as infection and bleeding. Other risks may depend on the part of the brain in which the tumor is located. For instance, surgery on a tumor near nerves that connect to the eyes may carry a risk of vision loss. For GBMs, the primary objective of surgery is to remove as much of the tumor as possible without injuring the surrounding normal brain tissue needed for normal neurological function (such as motor skills, the ability to speak and walk, etc.). However, the complicating characteristic of GBMs is that they are surrounded by a zone of migrating, infiltrating tumor cells that invade surrounding tissues, making it impossible to ever remove the tumor entirely.

Radiation therapy usually follows surgery in the treatment of gliomas, especially high-grade gliomas, when the wound is healed. Radiation therapy for gliomas uses high-energy beams, such as X-rays or protons from a machine (called a linear accelerator) outside the body (external beam radiation). The goal of radiation therapy is to selectively kill the remaining tumor cells that have infiltrated the surrounding normal brain tissue. Multiple sessions of standard-dose "fractions" of radiation are typically delivered to the tumor site as well as a margin in order to treat the zone of infiltrating tumor cells. Radiation therapy along with the concurrent use of chemotherapy designed to slow down or kill rapidly dividing cells has become the standard of care for gliomas. However, while the concurrent use of radiation therapy and chemotherapy has shown to provide most patients with longer survival rates compared to surgery alone, currently available treatment options have not proven to result in a prolonged remission of high-grade gliomas such as GBM.

In the US, there has been an increase in the 5-year survival rate for many cancers over the last 20 years due to a variety of factors including improved diagnostics & screening and the availability of new & better treatment options. Unfortunately, brain cancer has not seen any improvement on this measure while mortality rates from the disease remain little changed over the past two decades or so. One reason given for this lack of progress is because the incidence of primary malignant brain tumors is relatively rare compared with other cancers, and as a consequence, R&D in new treatments for brain cancer has not attracted the size of budgets that support drug development in other cancers especially among the big pharma/biotech companies. Perhaps, a more profound reason is the unique complexity of treating gliomas leading to the high risk of failure in new treatment development for brain cancer. Between 1998 and 2014, of the 78 investigational brain tumor drugs that had entered the clinical trial evaluation process in that period, 75 failed those trials, translating into a 25:1 failure ratio in developing new brain tumor treatments over the past two decades. To highlight the challenge, the FDA has remarkably only approved 4 drugs for malignant brain tumors over the past four decades — *Bevacizumab, Temozolomide, Carmustine, Lomustine* — which have proven only to provide incremental improvements to patient survival.

Bevacizumab (Avastin) is a tumor-starved (anti- angiogenic) therapy by injection. Unlike chemotherapy that attacks the cancer cells, the purpose of Avastin, a vascular endothelial growth factor inhibitor (VEGF is a signal protein produced by cells that stimulates the formation of blood vessels), is to block the blood supply that feeds the tumor in order to stop the tumor from growing. Developed by Genentech (now a subsidiary of Roche), Avastin was granted accelerated approval by the FDA for the treatment of recurrent GBM in May 2009. A Cochrane review in 2018 concluded that while Avastin slows tumor growth there is a lack of evidence of a survival advantage for the anti-angiogenic therapy over chemotherapy in recurrent GBM. Moreover, the use of anti-angiogenic therapy shows no evidence of significantly improving overall survival in newly diagnosed patients with GBM. In 2018, Avastin is also used to treat advanced colorectal, breast, lung, kidney, cervical and ovarian cancers. The cost of brain cancer treatment using Avastin runs at ~$10k per month per patient, but the drug has recently gone generic with the availability of biosimilar MVASI in the US. Branded Avastin generates annual sales of ~$7 BN, but we would estimate that the brain cancer indication contributes between $800-MN-$1BN.

Temozolomide (Temodar) is an oral chemotherapy drug used in the first-line treatment of GBM as well as for recurrent anaplastic astrocytoma (a rare grade III malignant brain tumor accounting for 1%-2% of all primary brain tumors). It is an alkylating agent which binds to the DNA in cells and interferes specifically with cell growth and division to prevent the tumor from growing. Temozolomide was granted FDA approval in the treatment of recurrent anaplastic astrocytoma in 1999, with approval for the first-line therapy of GBM received in 2005. The agent has also shown some activity in patients with metastatic melanoma. Temozolomide is the frontline drug typically given along with radiation therapy to treat GBM as it sensitizes the tumor to the radiation to make the latter more effective. Temozolomide has demonstrated modest efficacy in about 20% of patients with high grade brain tumors in conjunction with radiation therapy. In the Temozolomide final clinical trial performed before submitting for FDA approval (573 patients), overall survival was only improved by 2.5 months versus radiation alone. The cost of brain cancer treatment using the branded

Temodar runs at ~$5k per month per patient with annual worldwide sales running at ~$200 MN.

Carmustine and Lomustine are the generic names for chemotherapy drugs BCNU and CCNU which were approved by the FDA in the late seventies for brain tumors. They offer limited efficacy and for GBM, they are used as second line or later treatment options. They have shown to have a response rate of ~15% at best with an average progression-free survival rate of 2 to 3 months. They are the standard with or without Avastin (though the combination has proven no better than using either drug alone). Lomustine is used as part of a regimen called PCV where it has proven beneficial in a relatively rare tumor type called Oligodendroglioma, a type of glioma which occurs primarily in adults accounting for ~9% of all primary brain tumors.

CHALLENGES TO THE DEVELOPMENT OF EFFECTIVE BRAIN CANCER THERAPIES

The road to prolonging survival rates in patients, particularly with high high-grade malignant brain tumors more meaningfully is beset with several high hurdles to surmount. Oncologists will point to the blood-brain barrier as the primary reason for the lack of progress on this front. As we discussed earlier in this report, data from the Japanese trials and more recent preclinical experiments that PTB can get through the blood-brain barrier on a sufficiently consistent basis to earn a specific US patent for that reason, which is a unique feature of Nascent's core asset versus the few existing treatments and competing developments.

Even if the newer targeted therapies do succeed in circumventing the blood-brain barrier, there are other issues to consider. Unlike other cancers where there is only one mutation to consider, brain tumors are made up of multiple different sub-populations which is akin to treating multiple diseases in one tumor. Thus, for example, a specific targeted therapy might be able to successfully treat one part of the tumor, but other parts of the tumor may be growing on the basis of different protocols or mutations. Some of the high-grade brain tumors such as GBM are also good at hiding out in the folds of the brain and protecting themselves from intervention before storming back when the treatment is over. Glioma stem cells (GSC) represent a subpopulation of cells within GBM that have been found to be particularly resistant to chemotherapy and radiotherapy, with the ability to self-renew. Therefore, GSCs are considered a relevant target for GBM therapy. But, as we have indicated above, PTB's antigen target is quite broadly expressed, which potentially deals with the problem of tumors with multiple sub-populations

NASCENT IS BANKING ON PTB'S PROMISE AND ADVANTAGES OVER EXISTING TREATMENTS AND COMPETING DEVELOPMENTS

Nascent does not yet make claims about the curative potential of PTB in the fight against high-grade malignant brain tumors such as GBM, but it does already have a body of positive data behind it from Phase I & II human clinical trials, albeit conducted more than 20 years ago in Japan, which it will hope to at least replicate in its current round of clinical trials. According to data from Citeline's Pharma R&D Annual Review 2020, there are some 460 drug therapies for brain cancer treatment under active investigation, but the chances are that most of those therapies, if not all, will not see the light of day in view of the challenges cited above. These investigations embrace a variety of approaches that have been long pursued including:

Immunotherapy, a therapy that has proven to be very successful against various aggressive cancers, such as triple-negative breast cancer, but so far the immunology approach has resulted in failure with regards to brain cancer;

Cellular type of approaches such as CAR (chimeric antigen receptors)-T cell therapy aimed at targeting multiple antigens in an attempt to address tumor antigen heterogeneity in recurrent GBM. But, while this approach used in treating liquid (notably blood and bone marrow) cancers has resulted in strong overall response rates and significant cancer regressions, results in the treatment of hard tumors has been relatively underwhelming so far with relapses occurring. Moreover, given that the therapy is an immunotherapeutic modality, the main limitation with respect to the

treatment of high-grade brain cancer is that that the tumor microenvironment in GBM is immunosuppressive, and this has shown to become even more dramatic when CAR T cells are administered;

Vaccine and biological therapies, but studies in brain cancer have yielded little in the way of positive results to date;

Therapies targeting metabolic transformation of energy in the tumor - Brain tumors, like most malignant tumors, depend heavily on glucose and glycolysis for their metabolic energy that most tumors rely upon for growth. Thus, changing the energy metabolism of the brain tumor could be a pathway to reduce tumor growth. However, it is very early days for this approach and there is nothing in the foreseeable horizon from this new approach with respect to the treatment of gliomas.

The main FDA approved frontline drugs currently deployed against malignant brain tumors are a chemotherapy drug (i.e. Temozolomide) and a targeted therapy (i.e.Bevacizumab).The probability that the next breakthrough therapy comes from these tried and familiar therapeutic sources may be higher than other strategies mentioned above. In chemotherapy, one promising development is a drug being developed by CNS Pharmaceuticals (NASDAQ: CNSP) which was IPOed on November 28, 2019. Its lead development is called Berubicin, developed at the MD Anderson Cancer Center. Berubicin is an anthracycline, a member of the most widely used class of chemotherapy drugs in the world.

As noted earlier, most chemotherapy drugs are not able to get through the blood-brain barrier and so have limited efficacy, but the major claim for Berubicin, is that it is the first anthracycline that has ever been shown to cross the barrier in adult patients and kill tumor cells in early stage trials, albeit based on limited clinical data. The drug is specifically designed to be invisible to the brain-blood barrier. Some 44% of GBM patients enrolled in Phase I trials (completed in February 2009 by its previous developer, Reata, to whom the drug was initially licensed) are reported to have shown a clinically significant response to Berubicin. The drug has also shown to improve overall survival beyond the median survival rate of ~15 months, with one of those patients from Phase I remaining cancer-free 14 years after treatment with Berubicin, encouraging CNSP to proclaim the curative potential of its lead development. Of course, this is a unique case which may not be indicative of the overall effectiveness of the anthracycline when results from Phase II and later stage clinical trials are assessed. With CNS's IND for Berubucin finally cleared by the FDA in December 2020, CNSP has targeted to commence Phase II trials in both the US and Poland in the current quarter.

Whether such trials will validate CNSP's claim of Berubicin's curative potential, remains to be seen. The use of a powerful anthracycline can be best described as a shotgun approach to treating cancer. However, although the Phase I trials indicated a promising toxicity profile with a low side effects, anthracyclines are known to have significant toxic effects, notably cardiotoxicity. For example, Doxorubicin, an older, very effective chemotherapy drug used to treat many types of cancer, can decrease the heart's pumping ability, which in the most severe cases can lead to heart failure. Although Doxorubicin is not indicated for brain cancer where it has limited efficacy due to its poor penetration through the blood-brain barrier, it is noteworthy that Berubicin shares with it a similar chemical structure.

Should PTB proceed to FDA clearance and commercialization, this does not mean it will be involved into a zero sum game. It is very likely that PTB will be applied as part of a cocktail with existing or other therapies.

THE ROAD TO PTB'S COMMERCIALIZATION

After COVID delay, initial funding is now in place to allow Phase I trials to begin

Our coverage initiation of Nascent published in January 2020 indicated that the company had originally been targeting to begin Phase I trials on PTB in 1Q 2020, albeit acknowledging that the proposed timeline was somewhat of a moving target dependent on a variety of factors, not least access to capital. Having raised $8MN since its inception in 2014, which had got the company through the preclinical stages to partial IND clearance, Nascent was looking to raise an additional $10MN to $15MN to get it through the Phase I study and the start of the Phase II trials. It is only now that Nascent is in a position to begin Phase I trials, approximately one year later than had been originally targeted.

There are two principal reasons to explain this delay. The primary reason is the advent of the pandemic which limited Nascent's ability to raise funds. In this respect, the company received a major setback early on during the pandemic when the two principal investors that it had lined up to meet some of the expenses to begin the trials last year, were forced to withdraw due to the surge in financial markets volatility. The second reason, which is somewhat connected to the financing environment, is that Nascent's initial FDA clearance which was subject to a partial clinical hold did not in reality allow the company to complete its Phase I trials. As a consequence of Nascent's funding limitations in a pandemic impacted financing environment, it took longer than expected for Nascent to provide the FDA with the necessary data and responses to questions the latter had requested in order for the partial clinical hold in those trials to be lifted. A full FDA clearance, as indicated above, was finally received in December 2020.

Nascent's ability to move forward and commence enrollment for its Phase I trials for initial dosing was effectively guaranteed in 1Q 2021 when the company entered a licensing agreement with Bioray Pharmaceutical, a one-time core business division and the platform for the R&D, manufacturing and sales of biologic antibody-based drugs of China's

Zhejiang Hisun Pharmaceutical Company with whom Nascent has history. Back in 2016, Nascent and Hisun entered into an exclusive agreement whereby Nascent agreed to license development, manufacture and commercialization rights for PTB to Hisun, for the treatment of epithelial cancers in China, in a deal worth $16MN plus 10% royalty payments for 20 years. Although Nascent received $3MN in upfront payment from Hisun which was invested in pre-clinical requirements as well as in manufacturing processes in preparation for clinical trials, the licensing agreement effectively went into abeyance as Hisun Pharmaceutical fell into financial difficulties.

In September 2019, Hong Kong based PAG, a leading Asia-focused private equity firm with ~$40BN of assets under management, acquired a controlling 58% interest in Hisun's Bioray business for ~$540MN, leading to a new licensing agreement with Nascent which became effective in March 2021. Under the new arrangement, Nascent has agreed to give Bioray exclusive rights for 20 years to manufacture and commercialize PTB outside of North and Central America as well as the Caribbean in return for pre-commercialization funding of $5MN plus 9% (of net sales) royalty upon commercial approval.

Nascent has already received an upfront payment of $1MN, part of which has gone towards paying off toxicity, but most of which will go towards funding the Phase I trials. Nascent is promised an additional $750K once it has enrolled its 12 Phase I trial patients. Should PTB be approved to proceed to Phase II trials, PAG backed Bioray will pay Nascent an additional $2.5MN plus a further $750K once the Phase II trials actually begin. The total $5MN of funds promised by Bioray is expected to be sufficient to take Nascent through to the start of Phase II trials. Furthermore, should the PTB development achieve that milestone, Bioray has requested first right of refusal to fund the remaining cost of Phase II studies which could amount to an additional $12MN-$15MN. This potentially de-risks Nascent's ability to raise the necessary funds to move PTB towards FDA clearance and commercialization.

CLINICAL STUDY REQUIREMENTS AND TIMELINE SCENARIOS

So far three patients have been enrolled and have received initial dosing in the Phase I trial. Additional patient enrollment continues as to complete the Phase I portion of the clinical study data from 12 dosed patients are required to be submitted to the FDA to demonstrate the safety of the trial drug. Following FDA review of the data, the expectation is that the regulator will request the trials be expanded to Phase II with an additional 30 patients to be tested. The data collected from the full complement of 42 trial patients are then to be submitted for review by the FDA to determine how well the treatment has worked in its patient population. The best outcome of the review would be for the FDA to declare that PTB has breakthrough status which will enable Nascent to accelerate PTB to commercialization. The next best outcome would be for the FDA to request Nascent expand its trial patient population, typically by 20 to 60 persons depending on the strength of the data submitted, or approval to proceed to Phase III trials which would require clinical study on 250 to 300 patients.

PTB benefits from its orphan drug status as FDA approval timelines for pipeline treatments with such a designation, typically granted to those targeting rare diseases, of which brain cancer is considered one, tend to be abbreviated. The FDA created the Orphan Drug Act to encourage and provide special incentives to drug companies that undertake the development of drugs that target diseases affecting fewer than 200,000 people in the US. Nevertheless, one major challenge to the actual conduct of Nascent's clinical studies is the time it might take to enroll and dose the appropriate patients. The trial population is made up of brain cancer patients who have been treated with other medications and must be off those medications for 30 days before they can be treated with PTB. Moreover, many of these patients are put onto steroids to help soften the tumor and relieve searing headaches, and as long as they remain on steroids, they cannot receive any monoclonal antibody because this would counteract the impact of the steroid.

While it may be feasible to assume that enrollment and dosing of the first 12 trial patients can be completed by the end of 2021. On this timeline, it is unlikely that Nascent will be in a position to submit its first set of data to the FDA much before the end of 2Q 2022 since each patient must be monitored for a subsequent period of 6 months following treatment. However, should the Phase I study, which is primarily tasked with assessing the drug's toxicity, also demonstrate positive indications of tumor shrinkage, this could accelerate PTB's progress to the Phase II study given its orphan drug designation. But, barring this or any unforeseen issues on the negative side (given the supportive body of evidence from the clinical studies in Japan), we would expect the FDA to approve the expansion of those trials to Phase II in 3Q 2022, which would likely take approximately 24 months to complete. This would indicate that the most reasonably optimistic timeline for the start of commercialization of PTB would be late 2024 going into 2025, should the FDA assign the new treatment breakthrough status. The other outcomes mentioned earlier including the expansion of Phase II or move into Phase III studies, would potentially delay commercialization by a further 2 to 3 years.

VALUATION ASSESSMENT

The Net Present Value Approach – We arrive at a $42MN to $213MN valuation range

Pre-clinical or early-stage clinical trial biopharmaceutical companies are notoriously difficult to value. These are companies that typically fall into the high risk/high reward paradigm as there is a plethora of moving targets to consider as discussed above. 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 de-risking of the product. The further the drug progresses through the clinical trial process from Phase I through to Phase III, the lower the risk of the product getting to FDA approval and getting to market, the higher the value attributed to the product.

The table below is an amalgamation of various studies showing the approximate success probabilities of each stage, starting from clinical, in the drug development process (upper row) as well as the cumulative probability of getting the drug approved (lower row) So, for example, the probability of passing phase I is approximately 65%, but the overall probability of making it from the start of phase I to an approved drug is 90% × 65% × 40 × 65% = 15%, as shown in the lower row. The NDA (New Drug Application) is the formal final step taken by a drug sponsor involving application to the FDA for approval to market the drug in the US.

SUCCESS PROBABILITIES AT EACH DRUG DEVELOPMENT STAGE

Illustrative Probabilities	Phase I	Phase II	Phase III	NDA
Success Probability of Stage	65%	40%	65%	90%
Success Probability of Drug Approval	15%	23%	59%	90%

SOURCE: UCSD DRUG DEVELOPMENT MOOC, TUFTS CSDD, NATURE

Nascent trades on the Over-The-Counter Market where it is currently being valued at $8.65MN. We believe that this represents a fraction of Nascent's potential value should its lead candidate drug, PTB, which has finally embarked on its clinical studies journey in the US, deliver on its promise as a breakthrough therapy for one of the toughest cancers to treat out there today.

We present a risk adjusted Net Present Value (NPV) analysis based around two scenarios. The first scenario assumes that PTB follows the typical drug development process of 3-stage clinical trials, while the second scenario incorporates the very reasonable possibility that PTB will be granted breakthrough status afforded to drugs with orphan status designation should Phase II trials deliver positive indications. Our models are premised only on the commercialization of PTB for brain cancer treatment – primary and metastatic. Our models do not take into account the commercialization prospects of PTB in the treatment of pancreatic and other epithelial cancer indications which are expected to be targeted by Nascent over time.

For both scenarios, we have assumed an NPV discount rate 25% given that Nascent is currently at the early stage of its clinical trials. This discount rate reflects the cost of equity as Nascent starts with a clean balance sheet. The upfront payment of $1MN in April from its licensing agreement with Bioray has been deployed in part towards the elimination of Nascent's toxic debt and dilution risk in the form of outstanding Convertible Notes. In May, Nascent preemptively settled $115K of convertible notes. As of today, only one convertible note with a redemption value of $135K remains outstanding and will be redeemed in August 2021 when due.

For both scenarios, we have applied an approval success probability rate of 12%, which is lower than the 15% indicated above for a drug entering a Phase I clinical trial. Oncology drugs, and as we have noted, brain cancer drugs in particular, have been shown to carry a higher risk of FDA approval failure than other therapeutic drugs.

Below, we present our 10 Year Risk-Adjusted NPV based assessments and the assumptions behind them under the two scenarios. On this basis, we arrive at a valuation assessment for Nascent based on its single pipeline drug, PTB, of $42MN to $213MN or $0.39 to $1.99 per Nascent Biotech share.

PHASE III PROGRESSION SCENARIO – NPV $42MN ($0.39/SHARE)

Nascent Biotech (Pritumumab) - Revenue Model: Phase III Progression Scenario										
Year Ending March 31	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**
Indication 1 -Primary Brain Cancer										
Total Market Size (# Potential Patients)	24,500	24,500	24,500	24,500	24,500	24,500	24,500	24,500	24,500	24,500
Patients On PTB Medication at End of Year							1,225	6,125	11,025	14,700
Average # of Patients Throughout the Year							400	3,675	8,575	12,863
Year-End % of Market on PTB							5%	25%	45%	60%
Average Annual Reimbursement Per Patient ($'000)							$90.00	$90.00	$90.00	$90.00
Net Revenues ($MN)							**$36.00**	**$330.75**	**$771.75**	**$1,157.63**
Indication 2 -Metastatic Brain Cancer										
Total Market Size (# Potential Patients)	200,000	200,000	200,000	200,000	200,000	200,000	200,000	200,000	200,000	200,000
Patients On Medication at End of Year				-				4,000	16,000	24,000
Average # of Patients Throughout the Year				-				2,000	10,000	20,000
% of Market on Pritumumab								2%	8%	12%
Average Annual Reimbursement Per Patient ($'000)								$90.00	$90.00	$90.00
Net Revenues ($MN)								**$180.00**	**$900.00**	**$1,800.00**
International TAM ($MN)	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200
PTB Market Share									1%	5%
Royalties @9% of International Revenue ($MN)									**$12.00**	**$60.00**
Total Net Revenues ($MN)							**$36.00**	**$510.75**	**$1,683.75**	**$3,017.63**
Nascent Biotech (Pritumumab) - Expense Model: Phase III Progression Scenario										
Year Ending March 31, $MN	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**
Manufacturing	$0.60	$1.50	$2.50	$7.00	$7.00	$7.00	$8.74	$123.94	$405.68	$717.72
% of Revenue							*24%*	*24%*	*24%*	*24%*
Storage	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03
Regulatory	$0.20	$0.50	$0.50	$0.50	$0.50	$1.00				
Development	$0.50	$0.50	$0.50	$0.75	$0.75	$1.00	$0.72	$10.22	$33.68	$60.35
% of Revenue							*2%*	*2%*	*2%*	*2%*
Other Phase 1 Related Expenses	$0.30									
Other Phase I/II Related Expenses		$3.50	$3.50							
Other Phase III Related Expenses				$6.00	$6.00	$6.00				
Corporate Overheads/ Other	$1.25	$1.25	$1.50	$2.50	$3.00	$4.00	$5.40	$76.61	$252.56	$452.64
% of Revenue							*15%*	*15%*	*15%*	*15%*
Total Cash Expenses	**$2.88**	**$7.28**	**$8.53**	**$16.78**	**$17.28**	**$19.03**	**$15.14**	**$211.06**	**$692.21**	**$1,231.00**
Net Free Cash Flow From Operations, $MN	**-$2.88**	**-$7.28**	**-$8.53**	**-$16.78**	**-$17.28**	**-$19.03**	**$20.86**	**$299.69**	**$991.54**	**$1,786.62**

Commercialized Manufacturing Cost Assumptions		
Per gram of Substance	$4,200	
Per miligram of Substance	$4.2	
Quantity Per Vial	100mg	
Cost Per Vial	$420	
Average Number of Vials Per Treated Patient Per Year	52	One 100 mg vial per patient per week

Source: Marble Arch Research

Nascent Biotech (Pritumumab): Risk Adjusted NPV Valuation Model - Phase III Progression Scenario										
Year Ending March 31	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**
Total Net Revenues, $MN							36.00	510.75	1,683.75	3,017.63
Total Cash Expenses, $MN	2.88	7.28	8.53	16.78	17.28	19.03	15.14	211.06	692.21	1,231.00
Net Free Cash Flow, $MN	**(2.88)**	**(7.28)**	**(8.53)**	**(16.78)**	**(17.28)**	**(19.03)**	**20.86**	**299.69**	**991.54**	**1,786.62**
NPV Discount Factor	**25%**	Cost of Equity								
NPV of Free Cash Flow, $MN	**$351**									
Phase I Risk Adjustment	**12%**	Probability of PTB Commercialization								
Risk Adjusted NPV of Free Cash Flow, $MN	**42.09**									
NBIO Share Count, MN	**107.11**	As at May 30, 2021								
Implied NBIO Share Price, $	**0.39**									

BREAKTHROUGH STATUS SCENARIO – NPV $213MN ($1.99/SHARE)

Nascent Biotech (Pritumumab) - Revenue Model: Breakthrough Status Scenario										
Year Ending March 31	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**
Indication 1 -Primary Brain Cancer										
Total Market Size (# Potential Patients)	24,500	24,500	24,500	24,500	24,500	24,500	24,500	24,500	24,500	24,500
Patients On PTB Medication at End of Year				1,225	6,125	11,025	14,700	15,925	15,925	15,925
Average # of Patients Throughout the Year				400	3,675	8,575	12,863	15,313	15,925	15,925
Year-End % of Market on PTB				5%	25%	45%	60%	65%	65%	65%
Average Annual Reimbursement Per Patient ($'000)				$120.00	$110.00	$100.00	$90.00	$90.00	$90.00	$90.00
Net Revenues ($MN)				**$48.00**	**$404.25**	**$857.50**	**$1,157.63**	**$1,378.13**	**$1,433.25**	**$1,433.25**
Indication 2 -Metastatic Brain Cancer										
Total Market Size (# Potential Patients)	200,000	200,000	200,000	200,000	200,000	200,000	200,000	200,000	200,000	200,000
Patients On Medication at End of Year					4,000	16,000	24,000	30,000	30,000	30,000
Average # of Patients Throughout the Year					1,500	10,000	20,000	27,000	30,000	30,000
% of Market on Pritumumab					2.0%	8.0%	12.0%	15.0%	15.0%	15.0%
Average Annual Reimbursement Per Patient ($'000)					$110.00	$100.00	$90.00	$90.00	$90.00	$90.00
Net Revenues ($MN)					**$165.00**	**$1,000.00**	**$1,800.00**	**$2,430.00**	**$2,700.00**	**$2,700.00**
International TAM ($MN)	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200	$1,200
PTB Market Share							1%	5%	8%	10%
Royalties @9% of International Revenue ($MN)							**$12.00**	**$60.00**	**$96.00**	**$120.00**
Total Net Revenues ($MN)				**$48.00**	**$569.25**	**$1,857.50**	**$2,969.63**	**$3,868.13**	**$4,229.25**	**$4,253.25**
Nascent Biotech (Pritumumab) - Expense Model: Breakthrough Status Scenario										
Year Ending March 31, $MN	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**
Manufacturing	$0.60	$1.50	$2.50	$8.74	$113.02	$405.68	$717.72	$924.11	$1,003.00	$1,003.00
% of Revenue				*18%*	*20%*	*22%*	*24%*	*24%*	*24%*	*24%*
Storage	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03	$0.03
Regulatory	$0.20	$0.50	$1.00							
Development	$0.50	$0.50	$0.50	$2.40	$11.39	$37.15	$59.39	$77.36	$84.59	$85.07
% of Revenue				*5%*	*2%*	*2%*	*2%*	*2%*	*2%*	*2%*
Other Phase 1 Related Expenses	$0.30									
Other Phase I/II Related Expenses		$3.50	$3.50							
Corporate Overheads/ Other	$1.25	$1.25	$1.50	$7.20	$85.39	$278.63	$445.44	$580.22	$634.39	$637.99
% of Revenue				*15%*	*15%*	*15%*	*15%*	*15%*	*15%*	*15%*
Total Cash Expenses	**$2.88**	**$7.28**	**$9.03**	**$18.59**	**$210.04**	**$721.72**	**$1,222.84**	**$1,581.97**	**$1,722.26**	**$1,726.34**
Net Cash Flow From Operations, $MN	**-$2.88**	**-$7.28**	**-$9.03**	**$29.41**	**$359.21**	**$1,135.78**	**$1,746.79**	**$2,286.15**	**$2,506.99**	**$2,526.91**

Source: Marble Arch Research

Commercialized Manufacturing Cost Assumptions		
Per gram of Substance	$4,200	
Per miligram of Substance	$4.2	
Quantity Per Vial	100mg	
Cost Per Vial	$420	
Average Number of Vials Per Treated Patient Per Year	52	One 100 mg vial per patient per week

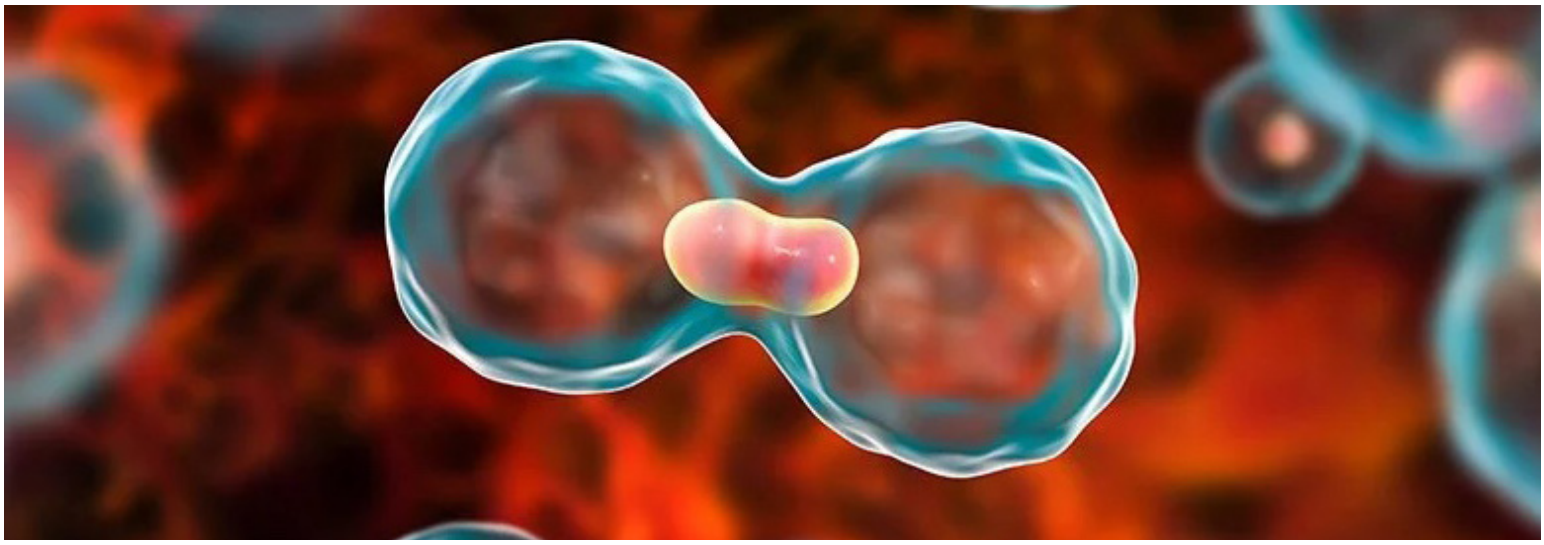
Nascent Biotech (Pritumumab): Risk Adjusted NPV Valuation Model - Breakthrough Status Scenario										
Year Ending March 31	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
Total Net Revenues, $MN				48.00	569.25	1,857.50	2,969.63	3,868.13	4,229.25	4,253.25
Total Cash Expenses, $MN	2.88	7.28	9.03	18.59	210.04	721.72	1,222.84	1,581.97	1,722.26	1,726.34
Net Free Cash Flow, $MN	**(2.88)**	**(7.28)**	**(9.03)**	**29.41**	**359.21**	**1,135.78**	**1,746.79**	**2,286.15**	**2,506.99**	**2,526.91**
NPV Discount Factor	**25%**	Cost of Equity								
NPV of Free Cash Flow, $MN	**$1,774**									
Phase I Risk Adjustment	**12%**	Probability of PTB Commercialization								
Risk Adjusted NPV of Free Cash Flow, $MN	**212.83**									
NBIO Share Count, MN	**107.11**	As at May 30, 2021								
Implied NBIO Share Price, $	**1.99**									

COMPARATIVE VALUATION APPROACH –BENCHMARK POINTS TO A VALUATION APPROACHING $50MN IN THE NEXT 12 TO 15 MONTHS

On a comparative basis, the most direct comp and valuation reference point to evaluate Nascent is, in our view, CNS Pharmaceuticals (NASDAQ:CNSP). Like Nascent, CNSP is a clinical-stage company targeting the brain cancer market as we highlighted earlier in this report. Like Nascent, CNSP's lead pipeline drug, Berubucin, has been designated orphan drug status. From a valuation perspective, the main difference is that CNSP appears to be about 12-15 months ahead of Nascent in the clinical trial process. While Nascent has just commenced its Phase I clinical study of PTB, CNSP is preparing to embark on the Phase II study of Berubucin. To this end, CNSP announced last month (May 2021) that it had commenced patient enrollment in a potentially pivotal study to evaluate efficacy of Berubicin in the treatment of adult GBM. CNSP intends to enroll approximately 210 subjects across 35 clinical sites in the US and also plans to expand the trial into Western Europe.

CNSP was IPOed on the NASDAQ in November 2019, raising ~$9MN of net proceeds from the sale of ~15% of its outstanding equity to contribute towards the funding of Phase II clinical studies of its lead pipeline brain cancer drug Berubucin. Although CNSP's intention was to start those trials in the second half of 2020, CNSP only received FDA approval for its re-submitted IND application for Berubucin in December 2020 (Reata to whom Berubucin was originally licensed had conducted a Phase I clinical trial on Berubicin in 2009, but subsequently allowed their IND with the FDA to lapse for strategic reasons).

CNSP currently has a market value of ~$47MN (albeit down from the $66MN IPO value) as it enters the Phase II clinical study stage of its lead candidate for the treatment of GBM. Given the parallels between CNSP and Nascent, it is not unreasonable to consider CNSP's valuation as a benchmark for Nascent's potential value in the next 12 to 15 months should Nascent hit its Phase I milestones and be in a position to embark on Phase II trials as discussed above.



RISK FACTORS

PRODUCT DEVELOPMENT SUCCESS & COMMERCIALIZATION TIMELINE RISKS

There is always uncertainty over the success of a product going through clinical trials, and even more so with one targeting a category such as brain cancer which has seen virtually no success in new drug development in decades. Although PTB can boast a body of positive data behind it from previous Phase I & II clinical trials conducted in Japan more than 20 years ago, product success is not guaranteed. There are examples of drug developments that have failed in Phase III trials (which involve larger trial populations than earlier stage clinical trials) even after generating positive results in Phase 1/II trials. Even if PTB successfully navigates clinical trials, it may take several years for the drug to commercialize and generate revenue for Nascent. That said, the FDA has an accelerated approval program to allow faster approval of drugs for serious conditions that fill an unmet medical need. This factor could come into play in PTB's case if the trials at least replicate the results seen in Japan showing evidence of tumor shrinkage and improvement in survival rates versus the current standard care. Orphan designated drugs treating cancer or rare diseases can often get approval on just Phase II data. But, even under those circumstances, we would not realistically expect to see PTB start to commercialize and generate revenue for Nascent before late 2024 or early 2025 at the earliest.

FUNDING RISK

The primary challenge of an early-clinical stage, one product pipeline biopharmaceutical company and particularly one targeting one of the most challenging cancers, is its ability to raise funds, let alone funds without toxic or dilutive terms. For Nascent, the risk associated with its early stage clinical funding needs have been allayed by its recent $5MN licensing agreement with PAG backed Bioray Pharmaceuticals including an initial upfront non-dilutive payment of $1MN in cash which will in part be deployed to eliminate Nascent's existing convertible debt. As indicated earlier, the remaining capital promised by Bioray is non-dilutive and is expected to provide Nascent with sufficient funding to take the company through to the start of Phase II trials. Although Nascent will require additional funding of up to $12MN-$15MN to complete the Phase II clinical study, Bioray has requested first right of refusal to fund the remaining cost of Phase II studies as part of its licensing agreement with Nascent, which potentially de-risks Nascent's ability to raise the necessary funds to move PTB towards FDA clearance and commercialization. Furthermore, positive progress in the clinical studies process, particularly from the Phase II stage, has a good chance of attracting the interest of the bigger pharmaceutical companies willing to invest in or acquire a promising new breakthrough therapy.

CONCLUSION

Key Investment Considerations –Speculative BUY

PTB's target, Ecto-Domain Vimentin is a 'first of a kind' conserved target on brain and other epithelial cancers which are undertreated due to the current lack of effective therapies on the market.

PTB already has a body of data from the previously conducted Phase I/Phase II clinical studies in Japan which provide positive indications for the drug relative to the current standard care of gliomas with respect to safety and biological activity. Evaluation of the efficacy of PTB indicated that ~15% of glioblastoma patients, ~27% of malignant astrocytoma patients, and 44 % of astrocytoma patients benefited from therapy conducted , either through tumor shrinkage or . Importantly, no major adverse drug effects were seen and no severe host reaction to the administered antibody was observed making long-term repetitive treatment reasonable. These results provide solid grounds to expect positive results as PTB progresses through its clinical studies in the US.

PTB's orphan drug designation for brain cancer opens up the possibility of an expedited drug development and FDA approval process if clinical outcomes at least replicate the Japanese trial results. This is reflected in our Breakthrough Status Scenario.

While PTB's initial target indication (i.e., malignant brain tumors) is a relatively small cancer therapy category, its properties allow it to treat other epithelial cancers led by breast, prostate, lung, colon, bladder and pancreatic cancers. This substantially expands PTB's potential addressable market as there are 1.1MN new diagnoses of epithelial cancers in adults in the US each year which account for nearly 60% of new adult cancer diagnoses in the US each year.

We believe that there is a reasonable investment thesis at hand to indicate that the company's market value can rise significantly as its lead development drug, PTB progresses through its clinical studies journey which has just begun. We rate the stock a Speculative BUY.

SENIOR ANALYST: ROBERT SASSOON

Robert Sassoon has been an equity analyst for more than two decades focusing primarily on global special situations. Robert has worked in research for several large sell-side institutions in London, Hong Kong and New York, including Credit Suisse, Natwest Capital Markets and Societe Generale. In 2017, Robert founded AlphaSituations, an independent idea-generating special situations investment research service, joining forces with Marble Arch Research in 2019 to head the research team responsible for producing and delivering comprehensive institutional quality research on early stage/emerging publicly traded and privately owned companies with the goal of telling an underappreciated or unknown story to relevant investors.

Robert has developed a uniquely broad and deep knowledge base of multiple industries and global perspective and in recognition of his institutional quality research and excellent track record of service to clients, has received citations and achieved top 5 rankings in various analyst surveys. Robert holds an MSc in Economics from the London School of Economics and Political Science, and has held Finra licenses, Series 7, 63, 86, 87 and 24.

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