

MicroCap.com

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YM Biosciences

YM.T \$0.42 (TSX) / YMI.Z \$0.33 (AMEX) / YMBA (AIM in London)

Net Cash: \$44 million (\$0.76/share)

Cash Estimate 1 year from now: \$30 million or \$0.52/share

Ground breaking drug license carries (negative) value in the stock price

Biotechs (especially smallcaps and microcaps) are one of the most overlooked sectors anywhere. While investing in them goes against the herd, biotechs if successful can also yield one of the largest % gains of any investment.

YM is not a story about curing cancer, but improving (and extending) **QUALITY OF LIFE** - until a cure for cancer is found, this is the next most important factor in the fight against cancer.

FACT vs. FICTION

YM is a classic example of how cash rich microcap stocks are a burden and an opportunity. The burden because they don't need money so most brokerage firms won't bother with them. If they can't make money on financing fees or analyst coverage, rarely will they recommend them to clients when they can push their own portfolio of biased recommendations (a sad reality). We've seen this for years and its part of the reason retail investor portfolios perform so poorly when managed by other people. The second problem stems from institutional investors and funds. Many of these stocks are just too small (thinly traded) to be purchased in quantity - so they ignore them below a certain price or liquidity level.

Many investors look to the share price and because they (incorrectly) believe the markets are efficient, they feel the share price reflects the true value (or problems) associated with a small stock. If you don't believe this, simply look at the recent example of Nova Chemicals (NCX.T). The market beat them down to \$1.28 in February. Within 30 days the stock jumped to \$7 on a buyout offer. While North American investors wrote them off, Abu Dhabi saw value in a share price 400% higher.

We are seeing this disconnection between share price and value continually in the cash rich stocks we follow - so don't be tricked into thinking the "street" is correct. Associating share price with current value or future potential, is a huge mistake investors often make - in both good and bad markets.

CORPORATE PRESENTATION - www.ymbiosciences.com

To fully understand and appreciate the potential, please view the corporate presentation (bottom left of their home page). This important report was only made available mid March. The images are disturbing but necessary for proper due diligence.

A lot of the data is difficult to understand. However, if nothing else, view pages 15 through 18 to understand the importance of "Quality of Life" and also pages 22 to 24.

It is very sad to see what people must endure in the late stages of cancer - especially at the point in their life where little hope is left for a cure. Human interaction with their family and friends (or even going out in public) is critical to their mental and physical well being. This is a need that is not being addressed through current treatment programs - but one that would hopefully be resolved using YM's Nimotuzumab.

Most people don't understand the importance of a drug like this - until you know someone who is affected. Take a moment to view the presentation - if not from an investment perspective, from a point of Empathy. Its critical they get better drugs like this into the system as people in their last year deserve the dignity and respect that seems to be missing from current treatment regimes.

INTRODUCTION

The company's lead drug candidate Nimotuzumab, is direct competition (but it appears without the harsh side effects) to Erbitux®, Vectibix® and Tarceva® - all owned by the major pharmaceutical companies.

<http://en.wikipedia.org/wiki/Nimotuzumab>

The drug appears highly effective against 10 tumor types - tested (or testing) in more than 30 trials

Nimotuzumab was developed at the Center of molecular immunology (CIM) in Havana, Cuba over a decade ago. CIM with YM Biosciences and its licensees are committed to the clinical development and subsequent marketing of Nimotuzumab. These include Daiichi-Sankyo in Japan, Oncoscience AG in Europe, Kuhnle Pharmaceutical in South Korea and Innogene in South East Asia. In addition, several other biotechs around the globe form part of a consortium working with the drug. YM to date has spent over \$50 million.

CIMYM is the corporation (joint venture partnership with Cuba) registered under Canadian Law. YM owns 80% and holds the license to use the technology (research, development, marketing) - 4 countries including Canada and U.S. plus they have sublicensed rights in Japan, Korea, SE Asia and the European Union. The Cuban Council of State is directly associated with the Center of Molecular Immunology in Cuba (where the drug and research originate) and this in turn is directly controlled by Raul Castro who runs Cuba.

<http://www.redherring.com/Home/2899> - history of YM in Cuba 2001

POTENTIAL

Biotechs require a lot of patience but that is also why we discount (estimate) their cash position one year from now. Assuming a Q1/2010 range of \$30 million or \$0.52/share, we know a lot can happen in that time frame - from a perspective of the stock market, the global economy, corporate developments, etc. If a person is buying any stock below its cash value a year from now, it leaves a lot of room for managing risk.

In November 2008 a failed attempt was made by someone to try and buy YM for \$0.50 U.S. or \$29 million - this was a joke as they held CDN \$50 million in cash. Given the huge buyouts we have seen in the past on biotech companies and the proven potential we are seeing around the world with their

drug, there is no possible way YM shareholders would even consider an offer of this nature within a 1 year window.

Of particular importance - Nimotuzumab interacts significantly less with normal tissues resulting in a much lower incidence of debilitating toxicities (see images on corporate presentation). Erbitux which is the world's leading application in most instances of cancer treatment (used with chemo and radiation) can result in significant side effects that target the skin.

The drug has been administered to more than 2,000 patients worldwide. To date there have been no reports of any severe incidents of skin rash or other side-effects commonly observed with EGFR-targeting monoclonal antibodies or small molecule inhibitors.

In primary YM markets (where they have a license) there is a very large need - Estimates on an annual basis: Europe 600,000 patients, Japan 200,000 patients, North America 300,000 patients. Potential revenues could be several hundred million dollars per year.

The major pharmaceutical companies from the United States cannot license or even consider buying out YM (at this time) because of ties to Cuba - although that may all change in 2009 with Obama in power. It should also be noted that YM was cleared by the US FDA in August 2007 to run Phase II trials in children with inoperable brain cancer. The first time in which a company with Cuban origin has received FDA clearance.

If Nimotuzumab continues to show this kind of benefit in clinical trials (after all it is in more than fifteen late stage trials in different countries around the world) then the shares of YM have the prospect of becoming extremely valuable.

IMPORTANCE OF APRIL 20TH

Important data is being presented April 20th in Denver and while this may have little direct impact on share price (because these are not investors), it could/should be an awakening moment for the scientific community and hopefully the large pharmaceutical companies.

www.aacr.org - American Association for Cancer Research
100th Annual Meeting in Denver April 18 to 22 - YM presenting scientific data

#2763 Binding properties of the anti-EGFR monoclonal antibody, Nimotuzumab, limit interaction with the EGFR in renal and epidermal cells - Greta Garrido, Ailem Rabasa, Elias Gracia, Ilia A. Tikhomirov, Rolando Pérez. Center of Molecular Immunology, Havana, Cuba, National Institute of Oncology and Radiobiology, Havana, Cuba, YM BioSciences Inc, Mississauga, ON, Canada

Presentation Start/End Time: Monday, Apr 20, 2009, 1:00 PM - 5:00 PM

"To the best of our knowledge, this is the first report to characterize binding of Nimotuzumab and cetuximab to HRCE and HEC. This translational research demonstrates that, unlike cetuximab, attachment of Nimotuzumab requires bivalent binding. This leads to the Nimotuzumab discriminating between cells that over-express EGFR, while minimizing interaction with healthy tissue, such as renal and skin cells, that express normal EGFR levels. This intrinsic property of Nimotuzumab may be responsible for sparing of healthy tissues by the mAb observed in clinical studies."

MARCH 22nd DATA OUT OF CUBA (not reported in North America)

Cuba: Survival Rate Up of Children with Brain Tumors

Camagüey, Cuba, Mar 22 (Prensa Latina) Children operated from brain tumors receiving therapy with Cuban product Nimotuzumab (CIMAher) combined with conventional therapy, increased their life expectancy and curation in this Cuban eastern province.

Since 2008, that oncopediatrics service participates in the program of clinical expanded use of the monitoring CIMAher product, applied to over 60 patients over the nation.

In about one year, the effect is significant, as 67 percent of the patients increased their survival rate to six months, doctor Juan Carlos Arranz told Prensa Latina.

He extolled the quality of life of a surviving infant with Supratentorial Astrocytoma, who benefited in 2004 with the monoclonal product, created by the Cuban Center of Molecular Immunology.

Today Cuba continues researching on its efficiency and security for the treatment of breast, colon and rectum, esophagus, lung, pancreas, prostate cancers and other solid tumors.

INDIA VERY IMPORTANT

Established in 1978, Biocon is one of India's premier biotechnology companies. Their research is cutting edge and aggressive. In a recent press release, they highlight the fact that "... Biocon launched the world's first recombinant human insulin, INSUGEN in November 2004 using Pichia expression and India's first indigenously produced monoclonal antibody BIOMAb-EGFR."

BIOMAb-EGFR is the commercial name of their license for Nimotuzumab (they own the license direct from Cuba similar to YM). Biocon recently opened a fully dedicated research and development facility with Bristol-Myers Squibb.

The following provides an excellent review of the work being done in India. It is titled: BioSpectrum Asia Pacific Awards 2009: BIOMAb-EGFR

<http://www.biospectrumasia.com/Content/090309IND8787.asp>

Important excerpts below:

The **path breaking monoclonal antibody, BIOMAb-EGFR** is a product from the Indian biotech major Biocon Limited and was granted regulatory marketing and manufacturing approval in India in September 2006. The product is a therapeutic monoclonal antibody-based drug for treating solid tumors of epithelial origin, such as head and neck cancers. This novel drug is engineered to specifically target and block the epidermal growth factor receptor (EGFR) responsible for the proliferation of cancer cells.

The drug is the first of its kind to be clinically developed in India and is the first anti-EGFR humanized monoclonal antibody for cancer to be made available commercially, anywhere in the world. **The product has shown consistent response in clinical trials initiated both in India and globally**

Dr Kiran Mazumdar-Shaw, CMD, Biocon Limited says, "This product spearheads Biocon's foray into proprietary immunotherapeutics and today **we join the exclusive league of monoclonal antibody developers worldwide.**

The Genesis

Development of BIOMAb was a joint venture between Biocon and the Center of Molecular Immunology (CIM), Cuba. CIM has done the molecule research for the drug and also provided the initial human data. "Antibodies are a new class of therapies and Cuba was doing R&D and innovation in this area. Since we needed to be innovative, we took the risk of partnering with CIM as we believed in the cutting edge work being done there and they also had human data. We joined hands for developing the product, invested in the clinical development and technology for antibody production, and finally brought it to the Indian market at a very affordable price," shares Dr Shaw.

She further adds, "It was interesting to bring the first true proprietary immuno-therapeutics to the Indian market. **It has the potential to be a billion-dollar product.** Importantly, in terms of affordability and quality we score much higher than the multinationals, and our mission is to bring an innovative drug at an affordable price."

Biocon has made an investment of more than \$30 million on BIOMAb-EGFR including the clinical development programs and the manufacturing facility. The investment in the clinical development program is still in progress for other cancers and each clinical trial is costing around \$3—\$4 million. BIOMAb-EGFR is indicated for use in combination with radiation therapy or chemotherapy.

.... **Immuno-therapeutics is a new class of drugs that effectively address unmet needs, particularly in oncology and autoimmune diseases such as rheumatoid arthritis, psoriasis, and lupus.** Immuno-therapy is the most recent form of treating such diseases wherein use of antibodies and vaccines play a key role in disease management.

.... **A dramatic absence of skin toxicity (rash) has been noted when patients are treated with BIOMAb-EGFR as compared to any other EGFR targeting therapies.** In particular, grade 1/2 skin rash (no grade 3/4) has only been reported in about six percent patients, compared to the high frequency often seen with both cetuximab and panitumumab. Furthermore, no significant hypomagnesemia occurred in patients treated with Nimotuzumab.

.... The total number of registered patients for BIOMAb is almost 1500 in India, which is much higher than any other similar product from the multinational companies. Multiple other clinical trials led by the global consortium of partners for the development of BIOMAb-EGFR are either planned, ongoing or completed. **These include trials in head and neck cancers, cervical cancer, esophageal cancer, diffuse intrinsic pontine glioma, pediatric glioma, pancreatic cancer and colorectal cancer.**

CONCLUSION

Take a few moments to read through the backgrounds on the people behind YM Biosciences (under Profile on their website). **Their management, board of directors, and scientific advisory board are all Blue Chip.** I was going to highlight a few but that wouldn't do justice to them all. After reading the level of expertise here, it's hard to imagine the stock trades so far below cash value.

I had a great conversation with YM's CEO David Allan and while he was very careful to only disclose what was public knowledge (through clinical studies, etc.), it was very insightful. In particular, he was able to take a very complicated industry and put it into layman's terms so you don't need a biology degree to understand the drugs application. **The big picture is presented below - note the last sentence and remember that this is the same company that is barely worth 1/2 its CASH value right now.**

THE BIG PICTURE

In a presentation at the American Academy for Cancer Research (AACR) in September 2008 YM demonstrated definitively that Nimotuzumab, it's member of the important family of anti-cancer drugs called Epidermal Growth Factor (EGFR)-targeting monoclonal antibodies (Erbix® and Vectibix® are both in the market), acted differently from the two marketed drugs.

Whereas Erbix® and Vectibix® have such a very high affinity for the EGFR-target, Nimotuzumab has a moderate affinity. This moderate affinity causes it to have a similar target profiling as another well known drug called Herceptin®. The affinity of both Herceptin® and YM's Nimotuzumab results in both those drugs being effective when there is a high density of the target and a condition called "bivalent binding" occurs. The marketed drugs, by contrast, stick to their target both bivalently and monovalently. Monovalently means that just one arm of the antibody is sufficient to stick whereas bivalently means that both arms of the antibody are required.

The positive consequence of only bivalent binding is that the drug sticks to the tumour. The negative consequence of monovalent binding is that the marketed drugs will stick to any amount of the target. Since Epidermal Growth Factor is what it sounds like – a protein that is in normal tissues such as skin, stomach and other organs – the high affinity of the marketed drugs results in them targeting those normal cells in the body resulting in awful toxicities which are intolerable for patients.

These toxicities include rash that covers the patient's face and torso in acne-like pustules as well as numerous other toxicities including severe diarrhea and a condition called hypomagnesemia which can require a patient to visit a hospital daily for up to eight weeks for lengthy infusions of magnesium.

Nimotuzumab has none of the severe forms of these toxicities and the reason is that, like Herceptin®, it only sticks to the target when there is a considerable amount of it. What happens on tumours is that, unlike normal skin and kidney and gut, they have an enormously increased density of this target and consequently Nimotuzumab must be as effective as the marketed drugs in those indications where there is this medium-to-high density of EGFR.

Nimotuzumab's very benign side-effect profile has also been its challenge because the companies marketing Erbix® and Vectibix® have, for ten years or so, made a big point about correlating the rash, that their patients suffer, and the other toxicities with the effect that those drugs are having on the cancer. They have been saying that a patient is getting no benefit without rash.

YM's breakthrough discoveries in 2008, which the upcoming poster at the 100th anniversary of AACR on April 20th, 2009 in San Diego, will amplify and confirm, as already described in the published abstract, should terminate the debate about rash being required for Nimotuzumab and show why **Nimotuzumab is effective against the majority of solid tumours while having none of the serious toxicities of the marketed drugs.**

Because the rash and other toxicities do correlate to the marketed drugs with effect on the cancer (but also hitting the skin, kidney and gut) the absence of the toxicities with Nimotuzumab would position it to be the “best-in-class” of this EGFR family. In the pharmaceutical business best-in-class invariably ends up dominating the market. Good examples of this are **Lipitor® and Crestor® which was, respectively, seventh and eighth in the cholesterol-lowering market.**

Notwithstanding that, Lipitor® became the biggest selling drug in the history of pharmaceuticals.

Nimotuzumab's challenge in proving its efficacy without the toxicity that the marketed drugs claim is required was, by great irony, intensified by YM's own trial in colorectal cancer for which YM put out data in mid-2008. If patients who have become resistant to treatment for colorectal cancer with the standard chemotherapy, irinotecan, are then treated with an EGFR-targeting drug approximately 20% of them would expect to be re-sensitized to irinotecan and get some benefit from further treatment.

The YM trial showed that significantly less than 20% of the patients treated with Nimotuzumab were re-sensitized to irinotecan and the street then attributed these inferior data as confirming that Nimotuzumab was ineffective.

The irony is that, of all the indications which YM could have chosen, this indication – refractory colorectal cancer – is about the only one where, first of all, most colorectal cancer cells have low density of EGFR to begin with and then to compound the situation, irinotecan preferentially kills off any high-EGFR cells leaving only the low ones.

At the time that YM launched its trial in refractory colorectal cancer it had no reason to know what it has now discovered. As we now know, and have shown definitely, Nimotuzumab requires a high density as does Herceptin®. This high density is found in many cancers and, in addition, any cancer treated with radiation or chemoradiation – the great majority.

They know that Nimotuzumab is effective because in thirty clinical trials of ten different tumour types, the drug has shown itself to be efficacious. In fact, it is already marketed in thirteen secondary markets which include India, Argentina, Brazil, and China, and to confirm its safety, there have been no reports of the severe side-effects in the more-or-less 4,000 patients treated worldwide.

Further data from the Indian public company, Biocon Limited, which is also being presented at the same AACR conference in April 2009, describe the efficacy to date of Nimotuzumab in head & neck cancer which supported its approval for marketing in India by the Drug Controller General.

ImClone was recently purchased by Eli Lilly for US\$6 billion and their principal asset is the currently marketed, but toxic, version of Nimotuzumab.”