Dear Institutional Investor,

Systemic changes in the financial markets have largely eliminated sell side research coverage for all but the largest and most actively traded stocks. This leaves some of the most promising equity investment opportunities unknown to most investors.

This monthly research report was created to find and follow these promising companies. The net result is a crisp summary of companies that we think can experience a dramatic increase in value with awareness. We apply a scientific analysis of firms, those with the most promising science, addressing large and unmet clinical needs. On a monthly basis we provide:

- 2 page initiation reports summarizing companies to understand what they do and what makes them of interest to prospective sponsors
- ½ page updates. We check in with the company monthly to report.

Our objective is to deliver consistent, standardized, quality communications about these firms and to provide the OneMedPlace media infrastructure: OneMedTV, OneMedRadio, Global Database, OneMedSentinel, and OneMedForum investment conferences. The 5th Annual conference will be held January 9-12th in San Francisco.

Hope to see you there.

Brett Johnson
Executive Editor
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Companies Profiled In This Issue:

- Advaxis [ADXS.OB] With proof-of-concept, phase II data for their cancer vaccine platform due imminently, 2012 could be a watershed year for ADXS.

- NanoViricides [NNVC.OB] is developing products for viral diseases that could be game-changing in that they simply soak up the virus in the circulation making it unavailable to mount an infection.

- Provectus [PVCT.OB] Working quietly for almost 10 years, PVCT had waded thru phase-I, -II and -IIB clinical trials of their drug PV-10 (Rose Bengal 10%) in metastatic melanoma. Now in final stages of their discussions with the FDA, company management could announce a phase III program imminently.

- Tianyin [AMEX.TPI] Now in a year of quiet consolidation, including first revenues from the new manufacturing plant, upgrading standards and yields at existing plants, getting 2-3 new drugs approved in a year, and improving margins by subtly changing their commercial game plan, TPI is all set to grow its top-line robustly starting in fiscal 2013.

Company Profiles Followed By Member Updates

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A modern spin on the age old vaccine mantra use a good bug to end a bad disease

Rationale to follow ADXS: With proof-of-concept, phase II data for their cancer vaccine platform due imminently, 2012 could be a watershed year for ADXS. This phase II trial will report preliminary data in early 1Q2012 and final data by 1Q2013. Enough will be gleaned from these results to determine the viability and future of ADXS’ flagship cervical cancer vaccine program. While the 1Q2012 preliminary data may provide some optics into the success of the trial, an unequivocal win on final results will be needed to ink partnerships, draft phase III protocols and change valuation. At the current stock price the downside (from phase II failure) is small and finite but the upside (from phase II success) may be significant.

Background: ADXS is a $45MM New Jersey based biotech company whose modern cancer-vaccine technology platform is based on the age-old and proven mantra in vaccine biology--to use a live but attenuated (weakened, nonpathogenic) bug to activate a person's own immune system. Since human immunity has evolved thru millions of years of combating disease, and pathogens, this is a more potent and long-lasting approach to medicine than any chemical drug known to man. Listeria monocytogenes (Lm) is the "bug of choice" at ADXS; Lm is a ubiquitous pathogen and yet rarely do people get sick with its infection. This is because the immune system, after millennia of co-existing with Lm, has learnt to outsmart it. The human body is born with the ability to recognize certain motifs (PAMPs') on Lm instantly such that even a low-grade attack with an attenuated strain of Lm can lead to (i) a strong activation of innate and adaptive immune cells like macrophages, monocytes, dendritic cells, and cytotoxic/killer-T cells, (ii) a reduction in immune inhibitory cells that weaken immune attacks e.g. regulatory T cells (Tregs) and Myeloid Derived Suppressor Cells (MDSC). Together these effects destroy the bug and stop its spread.

The ADXS cancer vaccine technology uses an Lm based platform to make cancer vaccines against (i) human papilloma virus (HPV)- the causative agent of cervical cancer and upper head and neck cancer, (ii) HER-2 neu- a protein overproduced in breast cancer cells and (iii) PSA- a protein associated with prostate cancer. The cervical cancer vaccine (ADXS-HPV) is the flagship agent at ADXS and the focus of this report.

ADXS-HPV is an attenuated strain of Lm, whose DNA has been genetically altered to carry and secrete an HPV E7 DNA fused to an immunogenic fragment of the Lm protein listeriolysin (LLO) DNA. The LLO and E7 DNA/proteins has been chosen because the former is the business end of the Lm infection and can activate host immune cells, and the latter (E7) is a very oncogenic protein that is conserved across all strains of HPV such that an immune attack against E7 is a sure-shot way of targeting all forms of HPV seen in women. When cervical cancer patients are injected with ADXS-HPV, the LLO protein acts as the adjuvant to awaken the host immune cells; these cells quickly recognize that the fused E7 protein is also an offending agent and mounts a second, more potent wave of attack on the E7 protein.

This host attack on the LLO-E7 is further extended to all E7 bearing cells i.e. all the HPV infected cervical cancer cells. The LLO protein has a second effect: it reduces the cells that suppress an immune attack by over 80%. It is broadly believed that the inability to suppress these cells has been the key cause of the failure of past immunotherapy approaches. Since this immune elimination of the virus is considered to be at a grass-roots level (versus surgery where HPV infected cells may still be left in the surgical margins) the likelihood of HPV return and cancer relapse maybe reduced when using cancer vaccines; however no human clinical trial has been performed for a long enough time to prove this preclinical finding. Other preclinical research has shown that Lm therapy can create an immune effect that encourages the immune system to select other, new antigen targets from dying cancer cells, preventing "escape mutations" that may result in resistant to recurring immunotherapy.

KEYPOINTS:

Cervical cancer marketplace: Since ADXS is running clinical trials in different patient pools thru different stages of cervical disease, understanding the entire continuum is important. Through their annual pap-smears >500,000 US women are annually diagnosed with cervical intraepithelial neoplasia
(CIN). This is an early precancerous condition where the HPV infected lesion is still in-situ and has not yet penetrated the underlying cervical tissue. CIN is classified in stages 1-3, where patients with CIN stage 2-3 are recommended for surgical removal (250-300K CIN surgeries/yr) of their lesion and maybe some portion of the underlying cervix. ADXS is running a CIN stage 2-3 stage trial with low dose ADXS-HPV (the US trial) as an alternative to surgery which is an invasive procedure, does not eliminate HPV and often results in such women not being able to sustain pregnancies. Post surgery CIN patients stay in remission for a variable amount of time after which the HPV may recur in a more aggressive cancerous form (cervical cancer). The annual incidence of cervical cancer in the US is 15000 patients; all patients are treated with 1st-line cisplatin which has a success rate of 50%. Today there is no therapeutic option for (i) the 7500 women who quickly demonstrate no benefit from cisplatin and (ii) for the women who are in need of 2nd-line therapy when their cancer progresses after initial "control" by cisplatin. ADXS is running another trial of ADXS-HPV in this late stage recurrent metastatic cervical cancer patients (the India trial). If the India trial is successful ADXS will embark on a phase III trial in such patients in 2013.

**What can be gleaned from Phase I trials of ADXS-HPV:** In 2009 ADXS published results of its phase I study in 15 women with recurrent metastatic cervical cancer (PS 1-4) treated with increasing doses of ADXS-HPV (every 3 weeks; 2 doses total) and demonstrated that live vaccines could be administered to patients safely. Patients demonstrated an easily treatable flu like system indicating that the agent was working. A max. tolerated dose of $1 \times 10^{10}$ cfu of ADXS-HPV was established. In 13 evaluable patients 1 PR and 7 SD were observed for a 1-year survival of 53%. If reproducible, these results are impressive in the light that the GOG has run 16-phase II trials to equivocally demonstrate an MOS of 6-months and a 1-year survival of 5% in this very patient population.

**Design of the phase II India trial:** Armed with results from phase I, ADXS is running a phase II study in India in women with recurrent metastatic cervical cancer (PS 1-2). A total of 110 women will be randomized 1:1 to receive either the vaccine or the vaccine+cisplatin combo-therapy. These patients receive injections of $1 \times 10^9$ cfu of ADXS-HPV (every 4 weeks; 3 doses total) and weekly IV cisplatin (5 doses total). All patients are given NSAID and antihistamine prophylactically and antibiotics post dosing. The primary and secondary endpoints are overall survival (OS) and response rate (ORR), respectively. Patients will be monitored almost real time for OS, with 3-monthly follow-ups for a period of 1 year. The trial DSMB has an interim analysis for OS and ORR at 6-months after 50% patients have started dosing. This analysis is schedule in Jan 2012 and ~46 patients will be available for analysis at that time.

**Benchmark for a good outcome in the India trial:** Given that immunotherapies work by having to wake up the host immune system, they are slow to show benefit at outset--in light of this we wonder how much benefit the India trial can demonstrate within a mere 6 months. However, given the moribund nature of this patient pool with 1-yr survival at 5%, 6-months is a long window of time in an individual patient’s life, which makes the timing of the interim analysis meaningful. Both angles considered, we think that showing survival benefit (versus historic GOG values) at the Jan 2012 interim analysis is a high hurdle; if reached it will speak to marked activity of this agent. Tumor response (PR, SD) in the vaccine-alone arm is the earliest marker for efficacy we will assess when reviewing interim results. Oncologists and ADXS management concur that by the time the data matures for 1Q2013 final analysis, a median OS of 9-12 months will be a meaningful achievement warranting phase III trials. Preliminary safety and anecdotal efficacy data appended: Full interim analysis available 1Q12.

**Patents:** Immunotherapy agents, being so unique, usually have no intellectual property issues. The ADXS technology platform has been allowed patent issuance by the USPTO for the use of Lm to combat specific cancers, the DNA construct of LLO-HPV or LLO-Her 2 *neu* or LLO-PSA, production and purification of the recombinant LM etc. Globally, 39 patents have been granted, with 38 pending. This technology platform was developed by scientists at University of Pennsylvania and licensed to ADXS for a 2% royalty.

**Catalysts:**
- Interim 6-mo results from the India trial 1Q2012
- Final 1-year survival results from the India trial 1Q2013
- “Go/no-go” decision on phase III trial in cervical cancer; partnerships 1Q2013

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Disclaimer: While the company is the source of the factual data, the analyses and interpretation of these data represent the work of the OMP Research Team.
ADXS-HPV IMMUNOTHERAPY: PRELIMINARY SAFETY DATA FROM A PHASE 2 STUDY IN RECURRENT/REFRACTORY CERVICAL CANCER

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Abstract
ADXS- HPV is an attenuated live Listeria monocytogenes (Lm) immunotherapy currently in clinical trials for HPV-associated dysplasia and malignancy. The use of the Lm vector has distinct advantages in immunotherapy. Being a gram positive intracellular bacterium, the vector serves as its own adjuvant and infects antigen presenting cells (APC) where it naturally cross-presents, mobilizes myeloid precursors, upregulates chemokines, and inhibits T and MDCS activity within the lesion but not elsewhere. Since antigen-specific specific T-cells to Tggs cellulating the lesion reversing immunosuppression.

Here we describe the incidence rate and pattern of adverse events associated with ADXS-HPV administration in Lm-LLL-E7-015, a Phase 2 study in Indian women with recurrent cervical cancer who have failed cytotoxic therapy. Patients are randomized 1:1 doses of ADXS-HPV 1x10^9 CFU or 4x10^10 CFU with or without cisplatin. The study is phase 2b and consists of 2 phases, 1 and 2. Patients received pap smear and oral prophylaxis as premedications. A course of ampicillin is given in 3 days after infusion followed by subsequent nodal evaluation and an additional 3 doses. The study immunotherapy can be safely administered to patients with advanced cancer and presents a predictable and manageable safety profile. Evaluation of clinical response and overall survival is ongoing.

Lm-LLL-Based Immunotherapy - ADXS-HPV is a live Listeria monocytogenes (Lm) based immunotherapy for the treatment of human papillomavirus (HPV) associated dysplasia and malignancy. ADXS-HPV secretes an antigen-avavirus fusion (Lm-LOO) protein consisting of a truncated fragment of the Lm protein lactocystin (LLO) linked to HPV E7. Lm-LOO agents redirect the potent immune responses to Lm which are inherent in humans, to the tumor associated antigen (TAA).

- Not toxic cytokine, relies on immune response in the patient.
- The immune response is a live, metabolically competent pathogen enables a more comprehensive immune response with multiple complimentary mechanisms.
- Strong innate stimulation
- Strong adaptive immune response
- Stimulates synthesis of new immune cells, maturation of existing cells
- Potential for memory generation after a short exposure to antigen
- Primarily a cellular immune response
- Antibiotics given prophylactically at 72 hours
- No evidence of listeriosis
- Reslolve with symptomatic treatment
- In Phase 1 trials in CIN 2/3, ADXS-HPV was administered to 30 patients (15 patients each in 3 dose levels: 1x10^9 CFU, 4x10^9 CFU, and 1x10^10 CFU). A total of 176 doses were administered where 75 subjects received 176 doses in this trial.

Observations common to immunotherapies:
1. Tumor responses (including 1 CR and 3 PR’s) observed in both treatment arms.
2. In advanced cancer, stabilization of disease that translates to prolonged survival is real clinical benefit, immunotherapy can alter the slope of tumor progression by increasing the ability of a patient to resist the progression of cancer.
3. Inflamation in the lesion and lymphoid tissue within 12 weeks of treatment can make the tumor measurements initially larger before the tumors begin to shrink. (Need to confirm apparent progression or take clinical factors into account).

4. Inflammation in the lesion and lymphoid tissue within 12 weeks of treatment can make the tumor measurements initially larger before the tumors begin to shrink. (Need to confirm apparent progression or take clinical factors into account).

5. In Phase 1 trials in CIN 2/3, ADXS-HPV was administered to 30 patients (15 patients each in 3 dose levels: 1x10^9 CFU, 4x10^9 CFU, and 1x10^10 CFU). A total of 176 doses were administered where 75 subjects received 176 doses in this trial. 5. Although the study is still enrolling, signs of clinical benefit have been observed.

- Complete response and 3 partial responders have been seen in the first 31 patients to reach day 94.
- Responses have been seen in both treatment arms (10 patients) in whom who have previously been treated with chemotherapy (including platinum) and/or radiation therapy.
- Responses have been seen in local recurrence (stage 2b), as well as metastatic (stage 4b) disease.
- While the primary efficacy endpoint is overall survival, early tumor responses are encouraging.

4. Clinical trials are ongoing to evaluate the activity of this agent in early and late-stage HPV-associated diseases.

Safety Summary: Lm-LLL-E7-015
(As of December 5, 2011)
75 patients received 176 doses of ADXS-HPV at 1x10^9 CFU.
- 29 patients (39%) report 72 Grade 1/2 AEs overall
- 48 patients (64%) have reported 54 AEs (no SAEs)

- ADXS-HPV has not been associated with any serious (grade 3/4) events in any Phase 2 clinical trial to date.
- Chemotherapeutic agents with activity in this disease setting selected by the GOG for evaluation in combination therapy are typically associated with a relatively high incidence of treatment-related toxicity.
- In most studies with chemotherapy the number of serious events observed meets or exceeds the number of patients treated.
- ADXS-HPV may be combined with other agents without adding serious toxicity.

Conclusions
- Incidence and severity of AEs lower than chemotherapy.
- In clinical trials to date (P1 and P2), 133 subjects have received 318 doses of ADXS-HPV. AEs are acute, Grade 1 (50% SAFAs), transitory, non-cumulative, and common of flu-like symptoms that respond to symptomatic treatment or resolve on their own.
- Activity alone or in combination
- Clinical benefit observed in refractory disease setting.
- Tumor responses (including 1 CR and 3 PR’s) observed in both treatment arms.
- This early to assess survival. Early tumor responses are encouraging.

Poster Board C45

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The P2 clinical trial is sponsored by Advaxis, Inc., Princeton NJ.
A bet on the future of the virology industry in the US

**Rationale to follow NNVC:** HIV, influenza drugs and other anti-virals together currently make up a $40+ B industry. Most of the current well-established brands in these virology marketplaces will lose their patents over the next decade. NNVC is developing products for these and other viral diseases that could be game-changing in that they simply soak up the virus in the circulation making it unavailable to mount an infection. Contingent on phase I/II success, the implication of this technology is so huge that it makes NNVC a definite acquisition target by any/all large pharma's in the virology space including Gilead, Roche and Bristol-Myers once patents of blockbuster HIV/flu agents start to expire.

**Background:** NNVC is a $95MM virology company whose technology consists a very small (nanometer size) patented polymer material called a nanomicelle that has on its surface a replica of the receptors expressed on the surface of the target cell of the virus. The nanomicelle and the surface receptors are together called a nanoviricide. These are then flooded into circulation at a very high concentration and literally soak up the virus in the blood, making the virus unavailable to enter the human host, replicate and mount an infection. A nanoviricide is usually a virus-specific polymer that has the following properties/stages (i) its surface bears the viruses "natural" receptors/co-receptors that have been somewhat engineered to increase their binding affinity (versus that for receptors on the human host cells). So a nanoviricide for HIV will bear CD4 and CXCR4/CCR5 receptors on its surface, while one for flu will bear modified sialic acid on its surface. The virus recognizes these surface receptors on micelles and preferentially binds to these, leaving the human host cell uninfected (ii) next the "neck of the micelle" will wrap itself around this tethered virus and complete the viral entrapment ("velcro effect"). For this purpose the neck region is made of a flexible biopolymer that can spread over to cover a virus bigger than itself "like a dewdrop spreading on a leaf" (iii) now the "mouth of the micelle" opens to engulf the tethered and entrapped virus. The physical reaction that ensues causes the viral envelope and capsid to be ripped apart sequentially and the nucleic acid (DNA/RNA) to be released and destroyed. This renders the virus dead and ineffective. (iv) these micelles bear polyethylene glycol (PEG) side chains which increase their life in circulation by allowing them to evade the immune system.

The simplest description of the nanoviricides technology is that there is a concentration-based competition (for virus binding) between the receptors on the micelle and those on the human host cells. Since trillions of micelles are injected/infused that bear surface receptors with greater affinity to the virus, they will invariably win the competition and the virus will tether to the micelle preferentially, avoiding the human host cells hence averting an infection. This anti-viral approach targets the virus at the very first step after entry into the body, preventing all contact between the virus and human cells and literally soaks it away from the circulation. Taken together this methodology may prove to be more advantageous than cocktails of drugs used today that inactivate different viral enzymes/proteins at later stages of infection. Furthermore, the nanoviricides technology is versatile in that it can delivered orally, intravenously, intramuscularly, intraocularly or topically. The physical reaction that ensues causes the viral envelope and capsid to be ripped apart sequentially and the nucleic acid (DNA/RNA) to be released and destroyed. This renders the virus dead and ineffective. These micelles bear polyethylene glycol (PEG) side chains which increase their life in circulation by allowing them to evade the immune system.

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**KEYPOINTS:**

**Why the choice to proceed with FluCide first:** After carefully analyzing novel strains of the flu virus, the Centers for Disease Control (CDC) has recently issued a warning of another imminent pandemic flu outbreak over the course of this decade. The CDC fears that the newly emergent mutant virus will be both high contagious and lethal. During the 2009 pandemic flu attack treatment options were limited to commercial Tamiflu and Ralenza and clinical trial agent Peramivir that received approval for emergency use despite of not being a commercial product. Preclinical data demonstrate that FluCide is far more efficacious and safe than existing agents (next section). Also in case of a pandemic flu outbreak, FluCide will continue to work across multiple mutant strains of influenza virus A because viruses cannot mutate at the receptor
binding site. All things considered, NNVC wants to move FluCide into the FDA as quickly as possible in order to position themselves appropriately, should this agent be required during another pandemic attack.

Treatment of the flu also offers two very interesting attributes when making corporate prioritization plans: (i) affects >35M Americans every year including 250,000 hospitalized, so the patient base is significant; showing efficacy in this indication can quickly validate the NNVC platform allowing for partnerships to be inked for this lucrative and recurring marketplace (ii) the flu (unlike HIV) is a self-limiting disease and runs its course in 5-7 days, hence clinical trials in flu will generally include short-duration trials where patients may be treated with only one dose of the drug and then monitored for the 5-7 days of disease and a month/few months of follow-up for safety.

Currently Tamiflu (Gilead-Roche) is the leading product in the flu market, but its key patents will expire by the end of this decade. Should NNVC be able to show good efficacy and safety in their upcoming phase I and II clinical trials, their technology maybe be well-received by these pharma companies trying to rekindle their influenza business forecasting lost of revenues post Tamiflu patent loss.

**What pre-clinical data do NNVC have so far:** In preclinical studies where mice with treated lethal doses of the influenza virus to simulate severe flu, co-treatment with FluCide resulted in such mice living for 529 hrs (22 days) versus Tamiflu treated or control mice that lived for 193 hrs and 125 hrs, respectively. In the same study when viral load was measured in the lung, FluCide and Tamiflu treated mice demonstrated a 1000-fold and 2-fold reduction in viral load, respectively (versus controls). Cytokine production, which marks onset of flu-symptoms, was also significantly reduced in FluCide treated mice. Clearly FluCide is superior to Tamiflu in these models. NNVC and its third party testing sites have dosed ~3000 animals with different formulations and concentrations of their nanoviricides against a host of different viruses (flu, HIV, dengue, adenovirus of the eye, herpes of the skin and genitals, Ebola) and always found it to be safe, free from any side-effects, with no dose limiting toxicities (DLT). Such results will need to be reproducible in human clinical trials.

**How will phase I/II development of FluCide proceed:** Pending consultation with the FDA in 1H2012, NNVC will finalize the toxicology and phase I/II development. Tentatively, when NNVC is able to start producing clinical grade drug, they will first embark on long term (9-12 month) toxicology studies in animal models. In parallel, NNVC will start a 20-30 patient strong phase I study where healthy volunteers will be treated with single ascending doses of FluCide (maybe from 10 mg/adult to 1g/adult) and monitored for adverse events and DLTs. Once a max. tolerated dose (MTD) is established, a phase II trial of ~50-75 flu patients will be run at doses spanning the MTD. Given the deduced half-life of the agent (8 days) and the time course of a typical flu (5-7 days), patients will be given a single dose of FluCide and monitored towards a primary endpoint of either viral load reduction or symptom resolution or both. Typical phase II trials for flu can recruit patients that either (i) have an ongoing attack of influenza but not severe (outpatient) (ii) hospitalized in-patients with severe flu or (iii) healthy people challenged with attenuated flu virus to simulate flu like conditions. These are all short course clinical trials and can be completed in ~9-12 months from enrollment of first patient to release of final results.

**What is the rate-determining step:** NNVC is in the throes of constructing an 18,000 sq ft research laboratory and cGMP manufacturing plant in Shelton, CT. When ready and validated in 2013, this plant will manufacture clinical trial grade FluCide (and all other agents) for the upcoming phase I/II clinical trials. Eventually if FluCide receives marketing approval, this plant has enough throughput to supply FluCide for 100K-1M adult doses/year. While NNVC will complete pre-IND meeting with the FDA in 1H2012, no clinical trial can start without this plant being completed.

**Patents:** NNVC does not divulge information on their patent estate that is licensed (with exclusivity) from TheraCour-a sister company specializing in drug development and headed up the co-inventors of nanoviricide technology. NNVC will pay 15% royalty on sales to TheraCour.

**Catalysts:**
- pre-IND meeting with the FDA to formalize phase I/II plans 1H2012
- GMP certified manufacturing plant starts making FluCide 1H2013
- Start of phase I/II trials for FluCide 2H2013
FDA recommendations and out-licensing decisions make for an interesting 2012

**Rationale to follow PVCT:** With some key catalysts around the corner, 2012 could be a transformative and outperforming year for PVCT. Working quietly for almost 10 years PVCT had waded thru phase-I, -II and -IIB clinical trials of their drug PV-10 (Rose Bengal 10%) in metastatic melanoma. Now in final stages of their discussions with the FDA, company management could announce a phase III program imminently. Because melanoma is a cancer type where drug development has been historically tricky, pharma interest maybe high with suitors lurking around to assess the complexity and feasibility of an FDA endorsed phase III design before pulling the trigger to in-license PV-10 or acquire PVCT.

In parallel, PVCT is negotiating with multiple companies to out-license their early stage phase I drug PH-10 (Rose Bengal 0.01%) for psoriasis and atopic dermatitis (AD). This is a more imminent but a smaller royalty deal, but since the dermatology marketplace has a backlog of ~10MM under-served patients in the US alone even a small percentage royalty may imply significant revenues for PVCT.

**Background:** PVCT is the story of one "old" molecule, three scientists, one businessman, and a decade of clinical development. This molecule, Rose Bengal (RB), was known for 30 years as an a liver diagnostic agent, but previously no one had looked into its chemical structure closely enough to determine its potential use as an anti-cancer agent. Not only did the founders of PVCT deduce this but they also realized that being a diagnostic agent RB was already FDA approved for IV therapy and at much higher doses than what would be needed for cancer. Furthermore, thru decades of use, its safety is well established and all preclinical and animal toxicity studies have already been performed historically and are on-file at the FDA. Now as PVCT proceeds with clinical work in cancer and dermatology indications, their FDA dossier will be significantly easier than if RB was a brand new agent.

**KEYPOINTS:**

**Mechanism of action:** RB is a unique cancer agent--in being a chemical moiety it is a chemotherapy but in being specific in its ability to concentrate in cancer cells (but be excluded from normal cells)--it resembles a targeted therapy. Furthermore unlike any current cancer therapies, RB is injected intra-tumorally and acts in-situ. RB undergoes partitioning and preferential uptake in the plasma membrane of cancer cells where it gets proteinated and localizes to/accumulates in the lysosome of cancer cells. Being a bulky proteinated moiety, RB can split the lysozyme resulting in necrosis like cell destruction within an hour. This cell ablation not only kills the cancer cells but also reveals antigenic conformations of the ablated cells, which then triggers host immune system. This dual approach of cell-destruction and immune triggering is very potent.

**PV-10 in melanoma and other cancers:** A large part of PVCT’s valuation is based on the successful phase II trial of RB in metastatic melanoma (MM). In this trial of 80 patients with Stage III/IV MM, intra-tumor injection of PV-10 on weeks 0, 8, 12, 16 lead to a 24% complete response (CR; n=19), and 25% partial response (PR; n=20) on target lesions. Surprisingly, 37% of those patients with good responses on target lesions (CR+PR; n= 39) also showed a positive response on non-target bystander cells. This is impressive and unprecedented since PV-10 is delivered intra-tumorally not systemically. Over and above its effect on the tumor itself, PV-10 was shown to increase progression free survival (PFS) to 8.2 mo versus historic comparable patients with 4-5 months; patients with CR and PR had an impressive PFS 11.7 months. PV-10 was also shown to be somewhat more efficacious in patients with nodal and cutaneous disease that those with stage IV M1c disease with distant metastases (PFS 8.7 mo Vs 6.2 mo).

In light of these results and the historic long-term safety database of RB, PVCT has approached the FDA with a draft phase III trial design wherein ~300 patients could be treated with PV-10 (or control [standard of care]) for a primary endpoint of modified PFS. Should the trial demonstrate success on PFS the sponsors will apply for accelerated approval of PV-10 but keep the trial running to completion for an overall survival (OS) endpoint. It may be several years until the OS endpoint is achieved but in
the meantime PVCT will be able to market the agent under the accelerated approval based on statistically and clinically superior PFS results.

It is our impression that management is unlikely to take on the financial onus of running a large phase III clinical trial without a partner. While they admit to pharma/biotech companies interest in partnering the cancer indications of PV-10, we believe that no deal can be struck without PVCT getting a consent from the FDA regarding their phase III trial design. It has taken PVCT two years to design and seek FDA consent on the phase III trial, but however long the wait, only when the design is FDA endorsed, can partnerships be inked.

A potential partnership for PV-10 will include all oncology indications including hepatocellular carcinoma (HCC) and recurrent breast cancer (BC). PV-10 has been tested in both these indications in 6 and 12 patients, respectively in phase I trials. In both trials 10% RB was found to be safe and well tolerated and demonstrated tumor ablation in a majority of patients. The FDA has designated PV-10 as an orphan drug for the HCC indication and PVCT has established a compassionate use program for PV-10 in HCC. The company is also designing a phase 2/3 randomized clinical trial of Sorafenib+PV-10 Versus Sorafenib alone with a PFS endpoint. Given how vast the HCC opportunity is worldwide (ex-US), non-US pharma companies may also be quite interested in PVCT.

**PH-10 in dermatology indications:** PH-10 is a diluted hydrogel formulation of PV-10 applied topically in patients with either atopic dermatitis (AD; including patients with recurrent eczema) and psoriasis. A 20-patient, phase II trial of daily PH-10 in AD, demonstrated a 94% improvement in the Eczema Index, and a generally clean side-effect profile. A 30-patient, phase II trial in psoriasis indicated a 79% improvement in the psoriasis scoring index, an 83% freedom from itching and clean side effect profile. To better hone the optimal dose of PH-10 in psoriasis, PVCT has started a 90-patient, multicenter, phase IIC trial with four dosing cohorts of PH-10; trial data are awaited and would set the stage for an optimal phase III design.

While on paper AD and psoriasis are large potential marketplaces for PH-10 with 30MM and ~8MM US prevalence, respectively, "market positioning" with a large sales force is the key to unlocking that potential. PVCT does not have financial capability or commercial acumen to achieve this. All things considered, PVCT has decided to out-license the derm indications in return for a royalty. A licensure decision appears to be near-term.

**Patents and competitors:** RB has an "old" agent; the composition of matter patent has expired but PVCT has recently filed a synthesis patent that spells a method to manufacture this agent that is devoid of any impurities and is the only formulation that meets the FDA's ICH guidelines. This patent maybe as robust as a composition of matter patent because without using this synthesis protocol, medicinal grade RB can never be synthesized. Additional "picket-fence" is provided by use, indication, formulation and mechanism of action patents.

**Balance Sheet:** With a cash position of $14.4MM and three large pivotal trials in the design stage (MM, phase 2/3 in HCC versus sorafenib and psoriasis), it seems logical that PVCT will require additional capital imminently, yet management insists that they are well capitalized thru YE2013. This indicates that management has its sight-set on one or more large licensing deals in 2012. The upfront payments from such deals will provide funds for phase III trials to start, and the partners will continue to fund development in a joint venture.

**Catalysts:**
- FDA consent on phase III trial design in MM 2012
- Disclosure of final phase III design in MM; triggering partnering talks for cancer 2012
- In-licensing deal for dermatology indications 2012
- Partnership deal for cancer indication; funds to start phase III MM trial YE2012

**Disclaimer:** While the company is the source of the factual data, the analyses and interpretation of these data represent the work of the OMP research team.
A year of quiet consolidation prior to reinvigoration of growth in 2013

Rationale to follow TPI: At a market-cap of $22MM against a $100MM revenue guidance and $33MM in cash, TPI seems a bargain. The management has come under pressure from investors for the past year due to (i) delays in getting a new manufacturing plant ready on time and (ii) as US based investors re-examine accounting principles of other Chinese companies. Now in a year of quiet consolidation, including first revenues from the new manufacturing plant, upgrading standards and yields at existing plants, getting 2-3 new drugs approved in a year, and improving margins by subtly changing their commercial game plan, TPI is all set to grow its top-line robustly starting in fiscal 2013.

Background: TPI is a Chinese drug manufacturer that currently markets 58 SFDA approved drugs throughout China. Their drugs' portfolio includes patented biopharmaceutical medicines, branded generics and modernized versions of traditional Chinese medicines (TCM). TPI's flagship product, generating ~$15 - 20MM in sales (approximately 20% of total revenues), Gingko Mihuan Oral Liquid (GMOL) is a modernized TCM for brain ischemic disorders (stroke, TIA). GMOL apparently has neuroprotective effects superior to western blockbuster brands like heparin. 42% of TPI's products meet such high clinical standards and unmet medical needs that they are on the national medical insurance program (NMRL) and reimbursed at 80-100% to patients. The "margin" savvy TPI management, gains access to raw materials (active pharmaceutical ingredients; API) either thru its own extraction plants (for the herb derived-TCM products) and thru its three major vendors (for western drugs). To improve net margins TPI sells its products thru its own distribution channel, Tianyin Medical Trading (TMT), comprising 730 sales reps across China.

KEYPOINTS:

The Chinese FDA, and drug reimbursement landscape: The SFDA (like the US FDA) bases drug approvals on phase I (50-100 patients), phase II (200-250 patients) and phase III (300+patients) clinical trial results that sponsors submit. Phase III clinical trials are somewhat simplified (than the US) yet equally stringent for TCM products because the API is a naturally occurring herb, whose safety has been known for generations. This permits faster phase III studies as the SFDA is satisfied with surrogate markers for efficacy, and monitors safety in phase IV settings 5 years post-launch. The SFDA then decides, based on the efficacy of the drug and the prevalence of the disease it treats, whether the drug belongs in the NMRL and ought to be fully (Essential drug list [EDL] at100% ) or largely (80%) reimbursed under the universal healthcare program of China. NMRL and EDL drugs are prescribed preferentially over non-NMRL drugs to treat a condition and generally dispensed only at hospital pharmacies under tight purchase price control. Twenty-four of TPI's drugs are on this list.

In contrast, many of the western pharmaceutical drugs and branded generics that TPI sells are not on the EDL or even NRML. Such drugs have to be aggressively marketed by sales reps in a US-like fashion and are prescribed (i) either when a condition has become recalcitrant to the free NMRL drug or (ii) for its overwhelming superior efficacy to an NMRL or (iii) when a wealthy patient proactively opts for it. Because the SFDA does not control the selling price of these drugs, TPI can make better margins on non-NMRL products; 34 of TPI's drugs are non-NMRL.

Gross and Net Margins: TPI managements "cost-of-goods" value orientation is striking. Over the years, TPI has taken over the entire manufacturing process for TCM drugs, which allows for tight control of production costs. Currently at their Chengdu facility TCM API is derived from herbs in the pre-extraction plant, then API is formulated, the drug product is manufactured and "fill-and-finish" is completed at their Longquan facility. For those drugs like TCM generics where the API is created in-house the gross margins are ≥50% versus ≤ 35% for western generics requiring 3rd party vendor API.

Over the last few years, in an attempt to further improve their control of the API, TPI has built a GMP certified, macrolide antibiotic (azithromycin) API facility called the Jiangchuan Macrolide Facility (JCM).
This plant will not only supply the API for TPI's own azithromycin franchise (3rd most lucrative franchise) but also allow the company to sell API to other companies. TPI will track and update investors on JCM API sales on a quarterly basis, which is a new leg to their growth story in 2013.

Another near-term margin booster is that TPI will change the formulation of their flagship GMOL from a liquid to an oral capsule. A liquid formulation has significant "bottling" and storage costs; the oral capsule will improved gross margins on GMOL to 75% (from 65% currently) and increase shelf-life from 2 yrs to 3 years and will probably qualify for a patent extension on this very lucrative platform. Capsule GMOL could become available by 2013.

In addition to production cost, sale price of a drug also plays a key role in the margin discussion. Within the Chinese reimbursement paradigm TPI's 24 NMRL drugs are high volume drugs but under price control; however by avoiding the "middle-man" and selling directly to hospitals through their TMT division, TPI can make a "respectable" 20% markup on the NMRL. On its 34 non-NMRL/EDL products, since the government does not dictate price point, TPI can make a 50% markup on price. Simply put, NMRL/EDL drugs are high-volume, lower margin products, while non-NMRL drugs are lower-volume, high-margin products; High margin product development is one of growth initiative for TPI.

**Commercial implication of Chengdu rezoning:** TPI's manufacturing plants are located at Chengdu, the Capital of Sichuan Province of China; this region has seen expanding population and industry growth in the last five years. The provincial government is now interested in planned townships with discreet biotechnology, automotive, residential etc zoning of Chengdu. The current plant of TPI is not located in the newly designated biotech zone and will need to relocate. At first blush this seems detrimental to capex. However, by YE2012, with a capital expenditure of $25MM, TPI will not only have moved to their brand-new plant (at a renewed GMP compliance standards), but will also have increased production capacity by 30%. The growth stimulating effect of the one-time capex will probably manifest in sustained margin improvement. Should a few of TPI's 10 pipeline drugs get approved by the SFDA in 2012, TPI will need this 30% excess manufacturing capacity, if not more. In fact TPI may take on an additional $10MM capex to increase production capacity to 200% of its current levels at the new facility, ascertaining manufacturing capacity for multiple pipeline drugs awaiting SFDA approval. The Chinese government will then reimburse TPI a "some portion" of the projected $25MM relocation cost, as it was done at the behest of the government (re zoning). The net effect of this transaction is a significant capacity increase and quality (GMP) improvement for current and future drugs without a very significant bill for TPI.

**Altering the commercial gameplan:** As management prepares for the next leg of growth starting 2013, TPI has indicated its intent to expand its footprint in the innovative drugs business that is the high priced, non-EDL marketplace. Pipeline drugs awaiting approval are for high-incidence diseases in China like brain ischemia and Alzheimer's, both of which indications already have approved NMRL drugs (including GMOL). TPI's new drugs will be used as "add-on" co-therapy products without cannibalizing its own franchise, but likely to not be an NMRL agent. This is a "win-win" for TPI as they can continue to sell their high-volume/low-price NMRLs like GMOL and add high priced, high efficacy, non-NMRL drugs in the same indications. This will allow TPI's 730 sales reps to detail their doctors about multiple, high-efficacy drugs for the same disease (although at different price points), thus making each sales call higher impact and worth higher revenue generation. To sell its expanding portfolio of higher priced, non-NMRL drugs, TPI may need to increase its sales force and target more doctors at "Class 3" urban hospitals, with greater wealth and volume of patients.

**Product exclusivity and the GMOL patent:** TPI's flagship GMOL, is the only truly patented drug of the company. GMOL patents run thru 2026, and could be extended with the GMOL capsule formulation. Since TPI has a large suite of TCM drugs, these are often un-patentable due to their API being a naturally occurring substance. However, in China once a drug is SFDA approved, a five-year exclusivity period is triggered during which the agency will not approve any comparable drug substances. This exclusivity serves as a defacto patent for most of TPI's products.

**Catalysts (calendar quarters not fiscal):**

- Initiation of API sale revenues from the JCM plant: YE2011
- SFDA approves at least two new TPI drugs: YE2012
- GMOL capsule enters the market: YE2013
- TPI relocates to new manufacturing plant: YE2013

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The Monthly Update on DATATRAK (DATA. PK)

- CEO Larry Birch was emphatic about the power of eClinicaltrials platform, and that on average using an electronic platform reduce clinical trial duration by 6-months.

- DATA can truly say that they serve the entire spectrum of clinical trials as they have recently inked clinical trial software sales deals with a biologics company.

- Current clients include biotech-, pharma-, medtech- companies and the clinical trials conducted with DATA software run from phase I through phase IV.

- While DATA continues to sell software thru its US and world-wide network of CRO's running individual clinical trials, the company has recently brought in its own business development/sales team to enter into direct multi-year partnerships with individual biotech/pharma companies running multiple trials for them across different CRO's rather than on an ad-hoc basis.

- Backlog business (revenue yet to be recognized because software have not yet been fully deployed) remain unchanged between 2Q and 3Q 2011.

- 3Q2011 revenues continue to validate the platform with a 8-9% sequential organic revenue growth.

- 2Q2011 revenues were a mix of organic revenues and a lump-sum payment from the NTT DATA enterprise deal-hence final revenue was somewhat inflated.

- Larry Birch provided more color on the NTT DATA deal.
  - NTT is a Japanese technology company that buys the trial software from DATA and then sells it to Japanese pharma companies. NTT essentially acts as the middle-man but exposes DATA software to its large Japanese pharma clientele.
  - DATA software are now being deployed by Daiichi Sankyo, one of Japan's largest pharma companies.
  - NTT is also paying for development of new software to be sold in Japan by NTT but world-wide by DATA. This is a new phase IV software and will be released by YE2012.

- DATA is in the process of tapping the Chinese market with NTT type deals. Currently in discussions with two technology companies in China. Presently, software sales for Chinese trials are done through local CRO's. DATA has now started to provide eClinical Solutions in simplified mandarin.

- While India is a huge clinical trials market with one billion naive patients, local business has been hard to tap because of the excessive reliance on paper-based data collection.
The Monthly Update on Novadaq Technologies (NDQ.TO)

- The most significant development at NDQ over the last month has been the extension of the LifeCell/KCI commercialization (revenue sharing) agreement for SPY systems
  - Historically, NDQ had a North American commercialization agreement with LifeCell (owned by KCI) for the sale of SPY Elite Systems for gastrointestinal-, head-and-neck-, plastic-, and reconstructive surgeries. Under this deal SPY Elite was sold by LifeCell salesforce under a revenue sharing model.
  - The success of the LifeCell deal and the growing awareness of the importance of monitoring tissue perfusion led to the KCI (the parent company of LifeCell) signing another commercialization deal with NDQ. This deal extends the use of a newer, smaller, portable SPY device (which is still 18-months to market) to the wound care market. Under this agreement the KCI salesforce will call on:
    - Wound clinics, burn wards, geriatric care centers, to implement the new SPY device to measure tissue perfusion and the extent of debridement to make treatment decisions for individual patients with the goal to shorten time to wound healing
    - Hospital based vascular surgeons to incorporate the use of the SPY Elite (with new software) when treating advanced wound care patients (e.g. diabetics ulceration) to measure the extent of perfusion of open wounds to guide amputation decisions

- While historically the SPY platform was first validated in cardiology using perfusion monitoring during coronary artery bypass graft (CABG) and percutaneous stenting, today cardiology segment sales only account for 25% of total segment, while the rest of 75% come thru the collaborations with Intuitive Surgical and LifeCell.

- Management also explained the reason that the 3Q2011 revenue was far exceeded expectations (165 SPY systems sold versus 3Q guidance of 80) was because their partner Intuitive Surgical (who integrate the SPY camera unit and LED light source into their Da Vinci surgical robots) started a full-fledged launch of the combined product in 3Q2011.

- 4Q2011 System sales guidance is set at 75-100 systems but OMP analysis suggests that positive trickle effect from the Da Vinci-SPY platform launch will be felt in 4Q2011 as well.

- While NDQ management refrained from discussing a revenue guidance for 2012, they will have system sales guidance in place as in previous years.

- NDQ management also indicated that while they opportunistic and secured a revolving line of credit of $2.5MM and has a low enough share count to tap equity markets, at the current time they had no need to raise cash for the base business (current cash: $10MM; cash burn/quarter: < $1MM).

- The next leg of NDQ growth is to come thru the PINPoint SPY endoscope, the only endoscope in the market today with perfusion monitoring capabilities. The PINPoint SPY is currently in clinical trials and should it be approved for US sales, NDQ intends to market this device themselves.
The Monthly Update on PLC Medical (PLCSF.OB)

- In the last month, they key focus of PLC management has been the initiation of the phase III clinical trial of RenalGuard in the US
  - In this trial patients with renal insufficiency who underwent cardiac or perivascular catheterization are randomized to receive RenalGuard therapy for half-day or overnight hydration. The primary endpoint of this study is incidence of catheter-induced nephropathy (CIN) after 4 days of therapy.
  - Trial has a very intelligent staggered enrollment plan that maximizes chance of a favorable outcome (read Nov 2011 issue of OMP Research)
  - PLC is on target to announce first patient enrolled/treated in the clinical trial before YE2011

- Also in the last month PLC management attended the Transcatheter Cardiology Therapeutics (TCT) conference in San Francisco where they had a very favorable turnout at their booth. European cardiologists were very keen to learn how RenalGuard since it is already being marketed in EU. Other cardiology companies and investors also took good interest in the RenalGuard device and US phase III trial, respectively.

- 4Q11 sales have been proceeding as planned; and will see some boost from a shipment that could not be recorded as revenues in 3Q11

- The Italian distributor of RenalGuard continues to make progress and about 50+ Italian interventionists now use RenalGuard in their practices (previous management comment was 30-40)

- The distributor in Germany and France has finished sales force training and is now starting to sign contract with hospitals to place these units. It is somewhat unclear if we will see sales from Germany and France in 4Q11

- Management will not be providing 2012 RenalGuard sales guidance on their FY2011 earning call. This is because the EU launch is still too incipient to predict sales targets.

- PLC will need to raise money in 2012 to roll-out the phase III US clinical trial.
The Monthly Update on Vasomedical (VASO.PK)

- In the last few months there has been an increase in the level of public awareness about Vasomedical’s FDA cleared non-invasive Enhanced External Counterpulsation (EECP®) therapy. Much of this public awareness is the result of doctors speaking out to inform patients about the availability of a therapy that has demonstrated scientifically, the cost-effective clinical benefits to patients who suffer from the symptoms of angina and heart failure.
  - There have been many live radio and TV interviews with Dr. Debra Braverman, Director of EECP® at the Albert Einstein Medical Center in Philadelphia, PA, author of the book “Heal Your Heart With EECP Therapy”.
  - Dr. Ozlem Soran, Director of Cardiovascular Research at the University of Pittsburgh Medical Center in Pittsburgh, PA was interviewed on FOX News in Orlando, Florida at the American Heart Association meeting after her abstract presentation on EECP therapy.
  - Dr. Alan Sosin, Irvine CA, Institute for Progressive Medicine, Irvine, CA was interviewed on local CNN Charter News
  - Dr. Clayton Bredlau, Heart and Vascular Center of Sarasota, FL was interviewed live on ABC-TV in Sarasota.

- EECP data was presented at the Annual American Heart Association (AHA), Nov 2011 by Dr. Ozlem Soran. The abstract was entitled Long Term Clinical Outcomes and Major Adverse Cardiac Event Rates of Enhanced External Counterpulsation Therapy in the Real World Settings in Patients with Coronary Artery Disease and Left Ventricular Dysfunction.
  - This study of 1276 cardiac patients demonstrated the reduction and elimination of symptoms for over 75% of the patients and for whom these initial benefits lasted a minimum of two years.

- As part of Medicare's commitment to reduce expensive invasive procedure significant rate cuts to interventional cardiology procedures are expected when 2012 Medicare Rate schedule is released. This trend has positioned EECP® therapy to benefit from an increase in consideration of proven safe and effective alternative to palliative invasive procedure such as bypass surgery or stenting.

- Vaso Diagnostics, a VASO owned third party sales channel for GE Healthcare imaging products, has now expanded its sales effort to all 48 contiguous US states.

- The increased marketing of their new FDA cleared ECG Holter and Ambulatory Blood Pressure Monitoring products have increased awareness and sales for Vasomedical in the office based physician and international sales markets.
The Monthly Update on Wound Management Technologies (WNDM.PK)

- WNDM acquired a medical device distribution company called Juventas to expand the distribution platform of their flagship product, CellerateRx.
  - Juventas is a new distribution company that has been carved out of BioMet Texas and boosts a wide network of sales reps and distribution contracts.
  - Juventas has been selling CellerateRx powder in the hospital channel since April 2011 thru an exclusive agreement with WNDM-so this acquisition makes a lot of sense because the Juventas distributors and sales force are already trained to sell CellerateRx and will now be able to sell both gel and powder formulations.
  - WNDM acquired Juventas for initial 12.5MM shares of WNDM, 5MM of which are in exchange of $500,000 of an immediate bridge loan to WNDM. Another 10MM WNDM shares to Juventas management are subject to their meeting CellerateRx revenue goalposts.

- WNDM also struck an impressive deal with a large US conglomerate of assisted living, nursing home and hospice facilities called Golden Living Healthcare Network whereby CellerateRx will be stocked in their 300 US assisted living/nursing home and 68 hospice/home health facilities as the preferred wound healing agent.
  - Golden Living takes care of 30,000 patients daily and while WNDM is not free to disclose projected revenues from this deal, we believe this deal could be worth $1MM of CellerateRx sales in the very first year.

- WNDM also made some strides in getting their second-line of products one step closer to commercialization. WNDM owns sizable intellectual property on resorbable bone wax and bone void fillers to make orthopedic bone remodeling products; these products are early in development and have not entered the clinic. Recently WNDM has a struck a deal with CA-based BioStructures, LLC to out-license the clinical and commercial development of some of these potential bone remodeling products. Under the terms of this contract WNDM received a $100,000 upfront payment and royalties starting 2013, when the products hit the market.

- Sales of CellerateRx has looked robust thru 4Q11 and company is on target to meet their projected $3M CellerateRx sales guidance for 2011 (3x over 2010).

- With multiple moving parts including Juvents and Golden Ventures deals WNDM management is considering how best they can provide 2012 revenue guidance.