

Research Coverage Report



Companies in this issue:

Biovest [BVTI] *
 Vasomedical [VASO]
 PLC Systems [PLCSF]
 Novadaq [NDQ]
 Tianyin Pharma [TPI]
 DATATRAK [DATA]
 Nanoviricides [NNVC]
 Provectus [PVCT]
 Wound Mgmt. [WNDM]
 Advaxis [ADXS]

*Initiation Report

OneMedRadio Interviews*

[QLida](#)

[Neovasc](#) [NVC]

[Anavex](#) [AVXL]

[Thermalin](#)

[Stentys](#) [STNT]

*To hear full audio interviews, please visit onemedplace.com/blog

At the 5th Annual OneMedForum San Francisco January 9-11 Former Vice Chairman of NASDAQ announced the formation of the **New Markets Movement** (NMM) to address the fundamental structural flaws in the US equity markets. As he pointed out, Wall Street doesn't need to be occupied. It needs to be fixed. Specifically, the stock market needs to be fixed to incent capital formation, job growth and dampen speculation.

The insightful analysis by David Weild IV presented hard data that point to a US equity market that no longer adequately supports growth companies. His series of sobering graphs included one which showed that the number of listed companies have dropped a staggering 43% in the last 14 years. Clear evidence of how the US stock market has gone from first to last compared to other major countries during this period. During this time, short-term high-frequency trading has gone from nowhere to 70% of trading volume, and market volatility has risen to unprecedented levels that undermine investor confidence. The IPO's, once the brass ring of entrepreneurship and a metaphor for attaining the American Dream is fast joining the horse and buggy as a historic relic.

He pointed out that unless something is done to fix stock market structure to better support small companies, that **the IPO market (that we once knew) will never come back**. An improved global economy won't matter. His detailed research into the history describes **systemic** changes which are the result of a "perfect storm" that began in 1996. Online trading, the collapse of trading spreads (Regulation ATS in 1998), and the collapse of retail brokerage commissions (1996-2000 due to the internet) resulted in a **market structure** that eliminated the economics needed to support small companies. Small broker dealers went out of business and Wall Street became a business dominated by a handful of large investment and commercial banks. Decimalization (2001) and Sarbanes Oxley (2002) happened well after the fact and merely added two more nails to the coffin.

So, the message is: expect continued depressed returns, lower levels of economic activity, fewer options for investors and entrepreneurs, dramatically lower compensation for financial professionals, and continued high unemployment for main street America. Growth company exits are no longer through offerings, rather through acquisition. Expect reduced investment returns, reduced innovation, higher unfunded pension fund liabilities, reduced tax revenues and higher than necessary unemployment.

The good news is that he and his team have come up with concrete ways to fix the system. One simple idea is to let companies determine the "tick" size (the difference in price between where a stock may be bought or sold at a particular point in time) on their stock. Pretty simple fix, but it involves...continued

Research Coverage Initiated In this issue:

Biovest [OTCQB.BVTI] Over the next several months, BVTI's market position and stock profile could change dramatically as the company prepares for key pre-filing regulatory meetings that will determine the approval pathway forward for its personalized cancer vaccine targeting the treatment of follicular lymphoma (FL), an incurable form of NHL blood cancer.

legislation. And we know that Washington is also broken. The system can work again, but only if YOU do something. Start by understanding what is really happening.

A more hopeful note from the conference was presentations from over 100 high-quality public and private company during the two days of the conference. OneMedTV captured the company presentations, which are available subscriber to the Intelligence Services of OneMedPlace. You can watch these presentations as well as other content from the conference by visiting www.onemedplace.com.

Brett Johnson
Editor in Chief

New Companies & Technologies in this issue:

Expanded summaries of the following emerging healthcare technology companies can be found on the New Companies & Technologies section of this Research Report. Intelligence Services subscribers can view profile of these firms by referencing the company ID# at the OMP Global Database found at OneMedPlace.com.

Gene expression tests for cancer treatment

[Earlier stage, oncology](#)

Offers tests that identify patients' genetic risk of developing cancer.

Blood volume expander that reverses capillary leakage

[Earlier-stage, hematology](#)

A treatment that prevents further leakage from damaged capillaries and allows the body to heal.

Cardiac ablation systems with accurate temperature feedback

[Later-stage, cardiology](#)

Physicians can measure the temperature of heart tissue during cardiac ablation procedures.

Heart stabilization during cardiac procedures

[Earlier-stage, cardiology](#)

A technology for the opening, stabilization, and closure of the heart during various cardiac procedures.

Blood pressure and cardiac output technology

[Later-stage, cardiology](#)

Produces technologies that offer precise data on finger arterial pressure and cardiac output.

Cardiac stem cell therapies

[Earlier-stage, cardiology](#)

Stem cell therapies for heart regeneration using cells derived from the heart itself.

Replacement for the aortic side-biting clamp during bypass surgery

[Earlier-stage, cardiology](#)

Surgeons can perform cardiovascular bypass surgery without leaving traces of metal within patients.

Direct cardiac compression device

[Earlier-stage, cardiology](#)

A device that restores normal cardiac motion after heart failure.



Biovest International

OTCQB: BVTI
52 wk: \$0.32-0.79
Jan 31: \$0.75
Mkt Cap: \$108MM

Cash: \$1.2MM
Debt: \$37.04 MM
Shares Outstd: 144.6 MM

Founded: 1981
Employees: 36



Samuel S. Duffey,
President & General
Counsel

Francis E. O'Donnell, Jr., M.D.,
Chairman

Carlos F. Santos, Ph.D., SVP,
Product Development &
Regulatory Affairs

Douglas W. Calder, VP,
Strategic Planning & Capital
Markets

Mark Hirschel, PhD, Chief
Scientific Officer

For more information, see
profile on [OMP global
database](#).

NOTE: This summary was produced by OneMedPlace (OMP). Research based on information provided by the company and other sources. The mission of OMP Research is to identify promising investment opportunities in healthcare and life sciences

The next personalized cancer vaccine to market?

Rationale to follow: Over the next several months, BVTI's market position and stock profile could change dramatically as the company prepares for key pre-filing regulatory meetings that will determine the approval pathway forward for its personalized cancer vaccine targeting the treatment of follicular lymphoma (FL), an incurable form of NHL¹ blood cancer. Assuming positive upcoming meetings with various U.S. and international regulatory agencies including Health Canada, FDA (US) and EMEA (EU), BVTI will likely apply for licensure of their active immunotherapy vaccine in 2012, seeking approval for BiovaxID® for the treatment of indolent follicular lymphoma (FL).

Two Phase 2 clinical trials and one completed Phase 3 clinical trial already prove that BiovaxID is safe, non-toxic, non-immunosuppressive and efficacious therapy for patients with FL. However, the current valuation reflects an overly pessimistic perception that another pre-registration Phase III clinical will be required before BVTI can file applications for marketing approval. BVTI management points out that through their comprehensive pre-filing meetings with regulatory agencies worldwide they have been able to make a compelling and well-received risk -to-benefit argument for BiovaxID. The benign side-effect profile and marked prolongation of disease-free survival achievable in BiovaxID treated FL patients will likely intrigue regulators. Furthermore, expedited approval pathways are also potentially available (such as accelerated approval and/or conditional approval) for cancer therapies like BiovaxID that fill an urgent, unmet need. This expedited approval pathway is probably a more likely outcome for BiovaxID, which would be considered a major victory resulting in higher valuation for BVTI

Background: BVTI is an independently trading, but majority-owned subsidiary of Accentia Biopharmaceuticals (ABPI). BVTI's history dates back nearly three decades with its origin as a biomanufacturing contract manufacturer, most notably serving for 15 years as the National Cell Culture Center for the National Institutes of Health (NIH). Based on its relationship with the NIH, Biovest collaborated with the NCI² in the clinical development and manufacturing of BiovaxID and while this collaboration remains active, BVTI acquired the full commercial rights to BiovaxID from the NCI in 2004.

Since BiovaxID is a personalized vaccine, each patient's vaccine is individually manufactured from a tissue biopsy obtained from the patient's own tumor. This approach is used because there is a unique protein called an "idiotype" expressed exclusively on the cancerous B-cells. When a full length idiotype protein is linked to a foreign protein (KLH), and administered with an immune-enhancing agent (GM-CSF), the resulting vaccine can mount a highly-specific anti-lymphoma attack that "trains" the body's own immune system to solely recognize the idiotype as a "foreign invader". This recruits the patient's own immune system to destroy micro-pockets of cancer cells (bearing the same idiotype signature protein) that either remain following chemotherapy or are newly arising, thus potentially delaying or preventing cancer recurrence. As such, through its unique mode of action, and extraordinary safety record, BiovaxID represents a new therapeutic approach to treating FL and other B-cell NHLs.

KEYPOINTS:

Phase III results: BiovaxID is the first cancer vaccine targeting FL to demonstrate a disease-free survival benefit in a Phase III setting. Presented at the 2009 ASCO³ plenary session and published in the JCO⁴, this 8-year, randomized, multicenter, double-blind, phase III trial measured disease-free survival for two prospectively-defined patient populations: 1) all randomized patients and 2) all randomized patients that were vaccinated with either BiovaxID or a non-specific control vaccine. The statistically significant results ($p=0.045$) achieved by comparing patients treated with BiovaxID versus patients treated with control showed that patients who received BiovaxID experienced a median disease-free survival of 44.2 months compared to 30.6 months for those who received a control vaccine – a median increase of over a year. In the study, with a median follow-up of 4.7 years, patients receiving BiovaxID experienced a 38% lower risk of disease recurrence compared to patients receiving the control vaccine (HR = 0.62).

Furthermore, an unplanned analysis of patients that had a certain type of idiotype protein called "IgM" showed that those patients who were treated with IgM isotype-matched BiovaxID had significantly longer DFS (52.9 months, versus 28.7 months) than patients with IgM isotype tumors who received control vaccine. For patients with IgM biopsies, the IgM BiovaxID resulted in a 66% lower risk of disease recurrence compared to IgM biopsied patients in the control arm (HR=0.34)⁴. In other words, a key structural feature of the idiotype proteins expressed on lymphoma cells may allow physicians to predict with confidence in advance which patients are most likely to derive the greatest clinical benefit from vaccination.



Controversial Items

A. Is the current phase III study approval-worthy by itself without another lengthy phase III trial pre-filing? The current phase III trial has two caveats that may influence its approvability (i) the trial "failed to meet statistical significant for the intent-to-treat (ITT) population (all 177 patients) but rather in a modified ITT (mITT) population of 117 patients. This was because in the hiatus of 6-12 months between achieving CR and BiovaxID dosing, 60 patients relapsed, were rendered ineligible for BiovaxID and could not be included in the analysis; however mITT was always a pre-specified endpoint. (ii) the *p*-value of 0.045 is not highly statistically significant; when the FDA does their own data analyses and slices the data many different ways, this borderline significance may change

B. How will BiovaxID fit into a modern treatment regimen in which rituximab is universally used? This question assumes that BiovaxID would face a difficult, marketing challenge if its market penetration were dependent upon oncologists and patients being forced to choose between rituximab and BiovaxID. However, based on recently reposted clinical data at a major blood cancer conference, BiovaxID actually complements other B-cell lymphoma therapies as it employs a completely different mechanism of action. And while the market may not yet realize it, this question was definitively answered at the 2011 Annual ASH⁵ conference where a senior investigator from the NCI reported that Phase II data demonstrated that vaccination with BiovaxID following rituximab combination chemotherapy induced nearly universal immune responses which strongly correlated with overall survival (OS) in treated patients suffering from mantle cell lymphoma (MCL), a highly aggressive non-Hodgkin's lymphoma. These immune responses, moreover, primarily consisted of tumor-specific T-cell immune responses which complemented the effects of induction rituximab chemotherapy. Because rituximab destroys all B-cells (healthy and cancerous), but not T-cells and because BiovaxID works by stimulating T-cells, not only are the two therapies compatible, BiovaxID is additive representing an entirely new and unique T-cell based therapy for lymphoma.

Path Forward: In 2012 BVTI will apply for licensure in many geographies. It may garner conditional approval to sell BiovaxID immediately and run a phase IIIB trial in parallel to get full-approval in upcoming years. Such a phase IIIB trial will include FL patients whose B-cell cancers express IgM (not IgG) idiotypes and who are in remission after any induction chemo regimen; obviously a majority of such regimens will contain Rituxan.

Market Opportunity: In the US alone, the incidence of FL is approximately 22,500 cases/year, with virtually all patients receiving induction therapy with approximately 60% or 13,000 of these patients achieving remission, thus being ideal candidates for a lymphoma vaccine maintenance therapy. With a similar market opportunity in Europe, and the future opportunity to expand the indications for BiovaxID to include relapse/refractory and vaccination in early diagnosis ("watch and wait") follicular lymphoma settings, as well as targeting other B-cell subtypes of NHL such as mantle cell lymphoma and Waldenstrom's lymphoma, make BiovaxID a compelling opportunity.

Another Shot on Goal: Novel Biomanufacturing Systems: While BiovaxID is the "crown jewel" in Biovest's pipeline, the company's founding core competency is in the efficient, cost-effective cell culture production of biologics – human proteins for both therapeutic and diagnostic uses. Biovest holds the rights to an impressive line of patented hollow fiber (HF) bioreactor systems, including the AutovaxID™, that are capable of producing personalized medicines, such as the company's BiovaxID vaccine, as well as monoclonal antibodies and viral vaccines. We expect important news-flow on this front in 2012.

2012 Catalysts

- Announce results of pre-filing regulatory meetings with Health Canada, FDA/EMA 1H2012
- Announce decision "to file" formal regulatory application(s) for BiovaxID 1H2012
- Potential strategic collaboration with potential "big pharma / big biotech" partners 1H2012
- File formal BiovaxID regulatory application(s) seeking approval(s) 2H2012
- Announce new BiovaxID clinical studies for other B-cell NHL indications 1H2012
- Report validation of new BiovaxID manufacturing facility 1H2012

1. NHL-non-Hodgkin's lymphoma 2. NCI-National Clinical Institute 3. ASCO-American Society for Clinical Oncology 4. JCO-Schuster et al. Journal of Clinical Oncology; June 2011. 5 ASH- American Society for Hematology



The following are progress reports of companies currently under research coverage.



DATA.PK
52 wk: \$0.25-0.93
Jan 30: \$0.40
Mkt Cap: \$5.82MM

Founded: 1991
Employees: 52

Total revenues and revenue backlog are highest in DATA' s history. FY2011 results released in Feb 2012

- OMP Research initiated on DATA in Nov 2011, and compiled a monthly update of the company in the Dec 2011 issue of OMP Research
- DATA continues to expand its unified phase I-IV eClinicaltrial software platform across multiple different disease indications, types of biotech/medtech/pharma companies and geographies
- DATA CEO Larry Birch presented at the OneMedForum Conference in Jan 2012 and highlighted the reasons that the eClinical Trial platforms like DATA will continue to exceed expectations:
 - While overall NDA submissions have reduced annually, the rate of drug approval is at an all time high. This is because pharma companies are now using electronic systems (like DATA) such that their trials have no "loose-ends" or improperly analyzed information, anymore
 - While large pharma pipelines are stagnating, biotech products are quickly filling up the gap; amore biotech companies are willing to enter disease indications that are niched and not blockbusters
 - With multiple "billion dollar" agents losing patents over the next decade, the generic industry -who now have to conduct elaborate clinical trials even to get generic agents approved- are now starting to utilize electronic clinical trial systems for the first time
 - Most importantly the FDA has drafted a guidance document, eSOURCE, about running and reporting clinical trials on "unified" electronic platforms. Data come from such electronic trials can be analyzed by the FDA more easily and expeditiously



NDQ out licensed legacy product CO₂ Heart Laser Systems to a specialized cardiovascular hospital sales distributor called MAQUET Cardiovascular

NDQ.TO
52 wk: \$2.81-5.58
Jan 30: \$4.94
Mkt Cap: \$161.76MM

Founded: 2000
Employees: 75

- As a reminder NDQ's CO₂ Heart Laser System for Transmyocardial Revascularization (TMR) is indicated for use in patients suffering from severe angina who are not amenable to routine revascularization therapies. In such patients, during the TMR procedure, laser beams generated by the CO₂ Heart Laser create tiny channels in the cardiac tissue stimulating better oxygenation and blood flow to the heart. Annually ~ 30,000 US cardiac procedures use the CO₂ Heart Laser system
- MAQUET is a private subsidiary of a Swedish Gettinge Group and generates close to €1B in sales per annum; its 250 people strong US salesforce is largely comprised of former sales personnel from Guidant and Boston Scientific companies
- NDQ continues to consolidate their second partnership with LifeCell/KCI that we had written about in the Dec issue of OMP Research
 - This deal extends the use of SPY in a newer, smaller, portable device (which is still 18-months to market) for the wound care market. Under the 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 in simple wounds aiding 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
- NDQ will release FY2011 earnings in Feb 2012, we fully assume that they will meet or exceed the high end of their 4Q11 guidance range (75-100) for new systems shipped
- At the OMP Conference in San Francisco, in Jan 2012, CEO Dr. Arun Menawat indicated that in 2011 the revenue stream came from the use of SPY in breast, reconstructive and cardiovascular surgeries. In 2012 the mix is also going to include robotic surgeries (partnered with ISRG) and gastrointestinal surgeries (approved Oct 2011; partnered with LifeCell)



PLCSF.OB
52 wk: \$0.06 – 0.24
Jan 30: \$0.17
Mkt Cap: \$5.16MM

Founded: 1990
Employees: 8

PLC Medical Initiates pivotal Phase III trial of RenalGuard in the US. First patient treated on Jan 23, 2012

- In this trial patients with renal insufficiency who underwent cardiac or perivascular catheterization are randomized to receive either RenalGuard therapy for half-day or standard-of-care with overnight hydration. The primary endpoint of this study is the incidence of catheter-induced nephropathy (CIN) after 4 days of therapy.
- The trial has an intelligent staggered enrollment plan (to enroll anywhere from 326 to 652 patients pending an interim analysis at 163 patients) that maximizes the chance of a favorable outcome (read Nov 2011 issue of OMP Research)
- PLC received consent from the FDA to start the study as recently as mid Oct 2011, we are encouraged by the expeditious start of the trial and patints being treated
- Another key news release from PLC Medical in late Dec 2011 was the start of the process of marketing approval for RenalGuard in Japan
- PLC Medical also continued to stay in the news in Jan 2012 because its investigator-sponsored 170 patient MYTHOS study of RenalGuard in Italy was published in the Journal of the American College of Cardiology-Cardiovascular Intervention in Jan 2012
 - This trial was conducted in patients who already suffer from chronic kidney disease and are clearly at risk for CIN when they have to undergo percutaneous coronary interventions. In such a refractory patient population RenalGuard demonstrated a 74% reduction in the risk of CIN versus standard-of-care hydration therapy
 - The publication of this trial is an important marketing tool for the EU marketplace; RenalGuard is currently sold in Italy, France and Germany.
- Furthermore the US pilot study of 23 patients on RenalGuard was also published in the International Journal of Cardiology in late Dec 2011



OTCPK.VASO
52 wk: \$0.18 – 0.75
Jan 30: \$0.22
Mkt Cap: \$33.85MM

Founded: 1986
Employees: 109

VASO records net income for first time in history

- In the 2Q of FY2012, VASO recorded total revenues of \$9.95MM versus \$3.8MM in 2Q FY2011 (y-o-y) and \$4.33MM in 1QFY2012 (q-o-q)
- This doubling of revenues sequentially marks the success of the commission business of VasoHealthcare who provide third party sales for products and devices of GE Healthcare
- For the first time in his history VASO recorded + net income of \$2.4MM for 2Q FY2012 versus 1QFY2012 when VASO report a net loss of \$1.74MM
- On the clinical side, the Journal of Applied Physiology published results from an open-label clinical trial conducted at the University of Florida, demonstrating the success of VASO's counterpulsation technology (EECP) in diabetic and pre-diabetic patients with abnormal glucose tolerance.
- Currently in the US EECP is used to treat patients with refractory angina who are contraindicated for angioplasty or "bypass" surgery (CABG); this indication is both FDA approved and reimbursed by Medicare and other major insurers
- The new clinical data showing improvements in diabetic patients may provide a path for the company to initiate pivotal studies for FDA approval of EECP for diabetic patients
- VASO CEO, Dr. Jun Ma presented at the OneMedForum in Jan 2012 and highlighted the clinical benefits and cost savings for angina patients who receive EECP therapy. He reiterated the company's desire to expand EECP's applications to new indications including paralysis after a stroke (based on experience in China where EECP is routinely used in such patients) and in diabetics (based on the University Of Florida experience)



WNDM in a period of internal consolidation of the multiple new players that have been recently engaged to sell CellerateRx

WNDM.PK
52 wk: \$0.21 – 0.80
Jan 30: \$0.33
Mkt Cap: \$19.15MM

Founded: 2001
Employees: 11

- As a reminder, WNDM acquired a medical device company called Juventas who will now use their widespread distribution channel to sell CellerateRx (powder and gel forms) in both hospitals and direct-to-consumer settings
- Juventas had already been selling CellerateRx powder in the hospital setting since April 2011, consequently this acquisition by WNDM allows for an easy integration of Juventas' salesforce that is already trained in selling CellerateRx
- Also as a reminder, in Nov 2011, WNDM 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 company management is not free to disclose projected revenues from this deal, OMP research believes this deal could be worth \$1MM of CellerateRx sales in the very first year
- Sales of CellerateRx have looked robust thru 4Q11 and company is on target to meet their projected \$3M CellerateRx sales guidance for 2011 (3x over 2010)



PVCT announced consensus between the FDA and PVCT, regarding the trial design for the phase III trial of Rose-Bengal (PV-10) in metastatic melanoma [Jan 18, 2012]

PVCT.OB
52 wk: \$0.67 – 1.23
Jan 30: \$0.88
Mkt Cap: \$96.48MM

Founded: 2002
Employees: 4

- OneMedRadio interview with CEO, Dr. Craig Dees from Jan 20, 2012
<http://www.onemedplace.com/blog/archives/10032>
- In 2011, PVCT had met the FDA on two occasions (end-of-phase II-meetings) to seek the agency's blessings on the phase III trial design
- On Jan 18, 2012, the FDA indicated to PVCT that no further meetings were required and the company should now submit their final/consensus protocol to the agency for signatures either through the "special-protocol-assessment (SPA)" or the "regular" categories
- An SPA is probably the best way to proceed for a novel agent like Rose-Bengal whose clinical trial will be somewhat different from traditional oncology clinical trials
- If all things go as planned we assume a trial start before YE2012 for an NDA filing around YE2014
- Under confidentiality, PVCT management is now discussing this phase III clinical trial and company's overall strategy (in oncology and dermatology) with other larger healthcare companies who may be interested in either in-licensing Rose-Bengal for oncology/dermatology, or an outright acquisition of PVCT.
- Whatever be the outcome, PVCT management indicates their own clinical acumen and financial ability to start the phase III melanoma trial with or without any signed partners.



ADAXIS

ADXS released interim analysis results from its phase II trial of ADXS-HPV in women suffering from recurrent metastatic cervical cancer [Jan 25, 2012]

ADXS.OB
52 wk: \$0.11 – 0.25
Jan 30: \$0.15
Mkt Cap: \$37.71MM

Founded: 2004
Employees: 14

- OneMedRadio interview with CEO, Tom Moore from Jan 26, 2012
<http://www.onemedplace.com/blog/archives/10040>
- As a reminder, for this interim analysis 88 of the total 110 enrolled women were evaluated, as they were the first tranche of enrolled patients
- Side effect profile of ADXS-HPV seemed benign with flu-like conditions in 34% patients that resolved quickly. 1 case of grade 3 but transient hypertension was reported
- On the efficacy side: 1-yr, 9-month and 6-month survival of patients treated with ADXS-HPV was 40%, 41% and 62% respectively, an unprecedented result given that the current standard of care in cervical cancer (cisplatin) shows a 1-yr survival of only 5%
- After ~1-yr of followup, median overall survival has not been reached at this time
- 3 patients demonstrated complete response (100% tumor shrinkage) and 4 patients showed partial response (≥30% shrinkage)
 - While usually anti-cancer effects of immunotherapies are seen on late aspects of the disease like overall survival and not on early aspects like tumor shrinkage, the fact that patients treated with ADXS-HPV shows CRs and PRs bodes well for final results from this trial
- The final analysis of the full trial population is awaited in 1Q2013
- The Gynecology Oncology Group (GOG) of the Natl. Cancer Inst. announced that they have started dosing patients in a second phase II trial run of ADXS-HPV in patients with recurrent cervical cancer.
 - This trial is being run by GOG and not ADXS and the trial population is comparable to women from the India study whose interim results were reported recently.
- Separately the company raised ~\$1MM in convertible notes due Jan 2015



NanoViricides
Incorporated

NNVC continues to prepare their initial dossier for a pre-IND meeting with the FDA to receive the agency's blessings to start of their phase I study of FluCide

NNVC.OB
52 wk: \$0.52 – 1.65
Jan 30: \$0.57
Mkt Cap: \$83.75MM

Founded: 2005
Employees: 10

- As a reminder, FluCide is an engineered nanoviricide molecule that binds to the Flu virus preferentially (versus the binding affinity of a human host cell). Once bound to a nanoviricide the Flu virus is trapped, destroyed and rendered incompetent to carry out an infection of the human cells
- Please read NNVC initiation in the December 2011 OMP Research report
- NNVC will likely meet the FDA for this pre-IND meeting in late 1Q2012
- However, the rate determining step in the initiation of the phase I study of FluCide is not the FDA meeting rather the construction of a new NNVC manufacturing facility in Connecticut, that will provide the drug material to be used in all upcoming phase I/II/III studies.
- This state-of-the-art manufacturing plant will become ready in 2011

**天 银****TPI reiterated its FY2012 guidance of total; revenues of \$100MM and net income of \$11MM.**

TPI

52 wk: \$0.68 – 3.28

Jan 30: \$0.68

Mkt Cap: \$20.42MM

Founded: 2003

Employees: 1300

- At the OneMedForum in Jan 2012, TPI reiterated its FY2012 guidance of total; revenues of \$100MM and net income of \$11MM. This margin compression versus previous years should be alleviated by 2013, when the Qionglai plant, GMOL capsule, azithromycin JCM plant, and two agents to be approved in 2012, all start generating revenues.
- TPI is in a period of internal consolidation at this time. Their primary pre-extraction manufacturing plant is relocating from Chengdu to a new biotech belt in Qionglai-China in 2013, where TPI will receive certain tax breaks as a result of the relocation.
- TPI is also currently launching a brand-new manufacturing facility (called the Jiangchuan Macrolide Facility (JCM) that will bulk produce the API for the antibiotic, azithromycin. 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
- In 2013, TPI will boost margins on its flagship GMOL drug by changing the formulation of from a liquid to an oral capsule. The oral capsule will improved gross margins on GMOL to 75% (from 65% currently), increase shelf-life from 2 yrs to 3 years and probably qualify for a patent extension
- TPI is also expanding its footprint in the innovative high-efficacy drugs business that are high-priced agents not on the Chinese governments "Essential Drugs List". For such agents, TPI will not have to be restricted by government dictated selling price, and will be able to > 50% gross margins.

The New Companies & Technologies Section of this Research Report offers summaries of emerging and disruptive healthcare companies and technologies sourced by our Research team which they felt were worthy of a full profile on our global database. Intelligence Services subscribers can view profile of these firms by referencing the company ID# at OneMedPlace.com.

Gene expression tests for cancer treatment

Earlier stage, oncology

Offers tests that identify patients' genetic risk of developing cancer.

Company #15006 provides standardized, proprietary gene expression tests to accurately diagnose, monitor, and inform cancer treatment. 15006's molecular diagnostics test is intended for chronic myeloid leukemia patients previously diagnosed with a fusion gene event, and monitors treatment efficiency, minimal residual disease, and follow-up for disease relapse. 15006's lung cancer risk test identifies patients at highest genetic risk of lung cancer in order to prioritize them for CT screening, resulting in marked reduction of the annual cost of screening. This earlier-stage biotechnology company is also developing its nucleic acid platform, which can standardize any quantitative multigene expression test and is ready to be applied in any therapeutic area.

Blood volume expander that reverses capillary leakage

Earlier-stage, hematology

A treatment that prevents further leakage from damaged capillaries and allows the body to heal.

Company #14213 is a biomedical company that was created in 2008 when its three founders discovered that a blood volume expander they invented in response to a patient's death to hypovolemia could actually be applied to any condition that triggers capillary leak syndrome (CLS). CLS is a condition that can be onset by any serious injury, and is a leading cause of mortality among soldiers injured in battle in the U.S. military. Upon intravenous administration, this blood volume expander works immediately to prevent further leakage of blood proteins and plasma water from capillaries into surrounding tissue, and actually reverses CLS, thereby giving the body the critical time it needs to heal its damaged capillary vessel walls and to recover. This earlier-stage biotechnology company has its product under protection by three U.S. patents as well as three international patents, with further patent applications pending.

Cardiac ablation systems with accurate temperature feedback

Later-stage, cardiology

Physicians can measure the temperature of heart tissue during cardiac ablation procedures.

Company #14616 specializes in advanced irrigated cardiac ablation systems with proprietary temperature-sensing technology based on microwave radiometry. Cardiac catheter ablation procedures involve advancing a catheter into the heart and selectively ablating certain areas of tissue in order to prevent the spread of electrical signals that give rise to a patient's specific cardiac arrhythmia. Most catheter ablation procedures are conducted with a saline-irrigated catheter in order to prevent the tip from overheating; however, this results in loss of temperature feedback, while the usage of power settings to drive ablation creation brings the issue of poor lesion quality. 14616's cardiac ablation catheter enables the measurement of tissue temperature with an irrigated catheter by continually reading the temperature in the tissue below the heart wall surface, thereby providing EP Physicians with greater control and real-time information that is more accurate regarding validity of lesion creation and completeness. This later-stage medical device company is the first to enable knowledge of temperature measurement at depth with saline-irrigation through its technology, which recently received CE mark clearance.

Heart stabilization during cardiac procedures

Earlier-stage, cardiology

A technology for the opening, stabilization, and closure of the heart during various cardiac procedures.

Company #14990 is a privately-held medical device company developing large hole access, stabilization, and closure technology. The system is a platform for beating heart delivery of Transcatheter Heart Valves for Aortic Valve Replacement (TAVR), Mitral Valve Repair (MVR), and implantation of Left Ventricular Assist Devices (LVAD), without loss of blood via a sealed conduit. The system improves patient safety and reduces technical challenges associated with large access site management for these new minimally invasive procedures with a projected \$2B market opportunity by 2014. This earlier-stage medical device company raised \$5.1M in Series A financing in December 2010.

Blood pressure and cardiac output technology

Later-stage, cardiology

Technologies that offer precise data on finger arterial pressure and cardiac output.

Company #9710 is a technology-based, market-driven company that focuses on finger arterial pressure and cardiac output technologies. While 25 million patients annually could benefit from a new beat-to-beat, noninvasive advanced hemodynamic monitoring device, only 16% of patients in the US are monitored 'hemodynamically' for cardiac output during surgery, because the available medical equipment is invasive, costly, intermittent, or unreliable. Now, 9710 has developed products that support physicians in preventing unnecessary complications for their patients and reducing the lengths of their hospital stays. Moreover, 9710's products can be applied by a nurse, minimizing healthcare costs. The first product is a non-invasive blood pressure and cardiac output monitor that offers precise, real-time profiles of data within a minute of application. It obtained CE and FDA clearance in 2007, and 9710 is building a network of strong distributors with its launch, leading toward physicians' usage of it in patient diagnosis. This later-stage medical device company brings over 30 years of research and development experience to customers and works with medical centers and universities all over the globe in joint research projects.

Cardiac stem cell therapies

Earlier-stage, cardiology

Stem cell therapies for heart regeneration using cells derived from the heart itself.

Company #15022 is developing cardiac stem cell therapies for cardiovascular regeneration, using a proprietary mixture of cells from the heart itself. While these cells are genetically programmed to work in concert together and support one another, most investigations of stem cells for usage in the heart involve deriving the cells from non-cardiac tissues, which possess limited clinical usage due to inappropriate differentiation that can cause tumor formation. 15022's cardiac-derived cells (CDCs) therapeutic program is its front line treatment for patients with a recent myocardial infarction or heart attack, and offers a coronary catheter-infusible formulation of CDCs. Cardiospheres are the Company's 3-D product that are de facto "biological factories" that stimulate cardiac regeneration when reintroduced to the heart, with the stem cells inside a protected environment that increases effectiveness; this study is currently targeted at the heart failure patient with low-ejection fraction. Both CDCs and CSp can be applied either autologously or allogeneically. 15022 is conducting a Phase I trial studying CDCs, which is the first to use heart-derived stem cells in human subjects, with a Phase II/III clinical trial set to enroll in early 2012. This earlier-stage biotechnology company is currently in a B round of financing.

Products that replace the aortic side-biting clamp during bypass surgery

Earlier-stage, cardiology

Surgeons can perform cardiovascular bypass surgery without leaving traces of metal within patients.

Company #14353 develops products that enable surgeons to either minimize or completely eliminate the aortic side-biting clamp during coronary artery bypass grafting (CABG), thereby leaving no traces of metal within patients. 14353's system lets surgeons use their standard suturing techniques without the addition of foreign materials, without the introduction of permanent rigid connectors or stents, and with minimal disruption to the inner aortic surface. Either venous graft or arterial graft can be loaded onto the product for measurement prior to usage of the system's coil and aortic cutter; after a circular cut is made in the aorta, the surgeon can easily begin sewing the proximal anastomosis. This earlier-stage medical device company's product also supports multiple anastomoses, including hand-sewn anastomoses and angled anastomoses.

Direct cardiac compression device

Earlier-stage, cardiology

A device that restores normal cardiac motion after heart failure.

Company #11407 has developed a breakthrough technological platform for the treatment of heart failure. Congestive heart failure is a gradually progressive condition in which the heart muscle weakens, leading to a decrease in contraction force and inadequate delivery of oxygen-rich blood to the body. Utilizing the knowledge that aberrant cardiac motion leads to congestive heart failure by causing abnormal growth and remodeling of the heart, 11407 has developed a product that is a minimally-invasive, direct cardiac compression device that restores normal cardiac motion to the heart through the application of gentle pressure. This product will be the first heart assist device on the market that promotes healthy cardiac motion, rather than simply heart ejection or blood flow. This restoration of normal cardiac motion enables the reversal of muscle damage, allowing the heart to remodel itself back to a normal, healthy state. Additionally, the device is bi-ventricular, does not contact the blood, and can be turned on and off safely, thereby overcoming complications of bleeding and stroke that are inherent to left ventricular assist devices. This earlier-stage medical device company's technology is poised to replace or work in conjunction with already-existent treatments including invasive surgery, pharmaceuticals, and electrical and stem cell therapies.