Research Coverage Report

Emerging growth company investment opportunities for sophisticated healthcare investors

onemedplace RESEARCH

Companies in this issue:

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

Dear Investor,

Our focus is on the creative disruptors shaping the future of health and medicine. Here are some interesting companies and happenings that have crossed our desk recently.

This letter is followed by progress reports of companies currently being covered by OneMedResearch.

The JOBS Act (Jumpstart Our Business Startups)[1] was signed into law in response to moribund job creation. Congress passed the rare bipartisan legislation to make it easier for small companies to raise capital. The Act will help firms like **Second Market** and **Sharespost**, which facilitate trading in private companies. Reed Smith attorney Gerry DiFiore summarized the key elements nicely in a recent bulletin, which OneMedSentinel published.

CrowdFunding [2] is now a buzz word likely to become a popular concept. Numerous crowdfunding sites (as well as legal, accounting and consulting services) are springing up, promising to help companies solicit capital from non-accredited investors. Earlier this month, OneMedSentinel published an investor-directed summary of crowdfunding and its impact on healthcare. This brave new world of growth company finance will be the subject of a panel at our 3rd Annual **New York** OneMedForum on **July 12th**.[3]

Upcoming Events

May 2nd
New York Biotechnology Association (NYBA) Annual Meeting

July 12th
3rd Annual OneMedForum New York Trans-Atlantic Conference

Wall St. continues to evolve for the worse. We have seen decreased trading volume recently as strategic and financial investors have headed for the exits in response to high frequency trading. This and other market conditions have hammered the world of growth company funding. Structural changes have led to the death of the traditional IPO as well. In short, Wall St. is sick, and possibly dying. To understand why, see the OneMedTV interview with former NASDAQ Vice Chairman **David Weild**, [4]

Declining economics are driving small broker dealers from the business of supporting companies. Others are changing their business models. **Rodman & Renshaw**, for example, seeing the inevitable disintermediation that technology is having on the finance business, launched **DirectMarkets** [5] in March, an attempt to capitalize on this trend. They provide an online platform to match secondary offerings with institutional investors without the traditional investment banking middleman and expense structure. OneMedRadio interviewed **CEO Kevin Lupowitz** about this new venture.

OneMedPlace is producing an **Investor Guide to Regenerative Medicine**, which will include a comprehensive list of firms in the space alongside resources and editorial analysis. As such, we were interested to see the presentation of **BioTime** [AMEX: BTX] at the recent **Maxim Conference**. When asked about whether stem cells would deliver on the promise to investors, CEO **Michael West, M.D.,** referenced Monoclonal Antibodies and Recombinant DNA, which at one time many called "science fiction," but later delivered terrific returns to investors. West is the founder of two prominent stem cell companies, **Geron** and **ACT.** With five separate operating companies, and interest in additional acquisitions, **BioTime** is looking like a rollup.

OneMedTV will provide coverage of the 21st Annual NYBA meeting on May 2nd

Also at the Maxim Conference, **Provectus** [OTCBB: PVCT] [6] presented some compelling results on cancer treatment. The company specifically discussed data from research conducted at the **Moffit Research Center** in Tampa, Florida, which duplicated and validated Provectus' findings. The study found that the company's PV-10 chemoablation of melanoma lesions leads to systemic anti-tumor immunity. CEO **David Dees PhD** showed before and after slides from a very aggressive type of **melanoma** in which Provectus' therapy appears to have stopped the cancer in its tracks.

We will be publishing an **Investor Guide to Oncology** and dedicating a panel to the topic at New York OneMedForum. In light of these efforts, we have begun coverage of **Advaxis** [OTCBB: ADVX] [7], which is addressing **Cervical Cancer**, a leading cause of death among women under 40. Advaxis is progressing in its clinical trials, and is one of a number of companies in the emerging area of immunology for various cancers. Advaxis is the first non-surgical approach to cervical cancer, which kills 275,000 women worldwide each year. [8]

SAVE DATE:
July 12th
3rd Annual
OneMedForum
New York
Trans-Atlantic
Conference

Panels on:

- Diagnostics
- Regenerative Medicine
- Health Information
- Oncology
- Biotechnolgy
- Medical Devices

Also sessions on:
- Crowdfunding
- China

Presentations by over 50 emerging growth companies

OneMedResearch will be initiating coverage of **OncoSec Medical Inc** [OTCBB: ONSC],[9] also appearing in the Oncology Investor Guide. The company, which recently raised $7.5 million, develops localized anti-cancer therapies against solid tumors to overcome the significant side effects associated with oncology surgery. OncoSec uses the technology of electroporation – a method of cell membrane stimulation – to deliver targeted chemotherapy or immunotherapy to the localized site. The company's minimally invasive therapies selectively destroy cancer cells while preserving healthy tissue, optimizing required dosage and potentially reducing post-treatment complications.

Autoimmune Technology. OneMedResearch will be initiating coverage of **Opexa Therapeutics, Inc** [NASDAQ: OPXA],[10] an autoimmune disease biotechnology company focused in the area of advanced **secondary progressive Multiple Sclerosis**. We find it interesting that there has been very little developed for this debilitating disease, which affects more than 350,000 in the US and almost 2.5 million worldwide. Opexa's lead product candidate, currently a completed phase IIb clinical study, is a personalized T-cell vaccine that is specifically designed to each patient's disease profile. The vaccine requires only a handful of injections a year and uses autologous immunotherapy to improve efficacy, safety and comfort. Another company working in this field is Nanoviricides (for more information on Nanoviricides, continue to our company progress reports).

Health Information Disruptors. Tablets to Change Healthcare Delivery. We see this as inevitable. A recent study indicated that the tablet saves physicians in a hospital setting one hour daily. We think another big opportunity may be the use of tablets to implement targeted, interactive education and advertisement campaigns to patients. This technology may curb the vast inefficiency of pharmaceutical marketing, where estimates reach $57 billion on each year. [11]

Epion Health,[12] is a start up company focused on tablet technology to increase patient-healthcare provider communication. Its software can educate patients on specific health issues during the 34 minutes (the national average) they spend in the waiting room. It provides patients with specific health education, information about new treatments and drugs, and interaction with third-party providers. The company is now seeking funding to implement a rollout with a major pharmaceutical manufacturer.

Web-based treatments is another interesting evolution of health information**. Aetna** recently added to coverage a depression treatment developed by a San Francisco-based company, **Brain Resource** [ASX: BRC].[13] Their concept is simple: positive thoughts reduce depression, so train your brain to increase positive thoughts. Brain Resource sees a large opportunity using Internet games to provide this therapy to consumers. OneMedRadio interviewed the company's top management earlier this month.

These companies and others will be included **Investor Guide to Health Information**, currently in development. We have also begun a survey on this subject, which will include a listing of companies and resources alongside interviews and contributions from leading healthcare information experts, including Dr. Cynthia Haines, Chief Medical Officer of HealthDay. In a recent OneMedRadio interview, Dr. Haines discussed the increased need for an informed patient population in combating the shortcomings of the healthcare system.

Also of note is the upcoming 21st annual **New York Biotechnology Association** meeting. In addition to bringing together industry leaders, NYBA has engaged OneMedPlace to help with its company showcase, which provides an exceptional opportunity for companies to reach industry leaders.

OneMedPlace Media

Visit these links to learn more about:

OneMedResearch

OneMedForum

OneMedRadio

OneMedTV at NYBA

Endnotes & Disclosures

1. Excellent highlights of the legislation provided here by Gerry DiFiore, Reed Smith. Look for a OneMedRadio interview on the subject in mid-April.
2. Crowdfunding is the process of getting a larger group of smaller investors (now legal) to use tools such as websites to raise capital for firms, spawning a new financial sector and in theory unleashing private capital into the startup world.
3. OneMedForum is the '3rd Annual OneMedForum in New York.' It is the east coast, midyear complement to the OneMedForum in San Francisco that occurs each January during the JP Morgan Healthcare week.
4. Weild also headed equities at Prudential. He has impacted legislation and was a keynote speaker at OneMedForum San Francisco in 2012. Watch this video on his outlook on capital markets.
5. DirectMarkets was formed by Rodman & Renshaw in March. Its platform seeks to supplement secondary market trading.
6. The **Investor Guide** will provide thought leaders a comprehensive list of companies and resources in the space. It will be released at the July 12th OneMedForum. Guides are also planned for Oncology, Diagnostics and Health Information.
7. OneMedResearch initiated coverage of Advaxis in the December issue. See the full December research report here.
8. According to the World Health Organization.
9. Last year, San Diego-based Oncosec licensed electroporation technology from Inovio.
10. OneMedResearch will be initiating coverage of Opexa in April of 2012.
11. A 2008 NYU study estimated the industry spends nearly a quarter ($57.5 billion) of annual sales $235 billion) on marketing, and devotes 13 percent to research and development. A 2004 study published by McGill University determined the breakdown of marketing: 56 percent of marketing funds are devoted to free samples, 25 percent to detailing of physicians, 12.5 percent to direct user advertising, 4 percent to hospital detailing, and 2 percent to journal ads.
12. Epion Health is based in New Jersey. Epion's founders come from the Pharma industry. The company has already made some intriguing progress. OneMedResearch is currently producing an analysis of this field.
13. Brain Resource, trading on the Australian Securities Exchange, is focused on depression and ADHD. The company has reached $7 million revenues run rate, primarily serving the research market.

Recent OneMedRadio Interviews:

- Dr. Evian Gordon, CEO and Dan Segal, COO of Brain Resource
- Punit Dhillon, CEO of OncoSec
- Dr. Steve Perrin, CEO of ALS TDI
- Asa Cox, Publisher of New Pharma Magazine
- Cameron Loper and Brian Scrivens of MPR Associates
- Kevin Lupowitz, CEO of DirectMarkets, a subsidiary of Rodman & Renshaw

The following are progress reports of companies currently under research coverage

With Tailwinds from Strong 2011 Revenues Novadaq Enters 2012 with Divestiture of Their Legacy Heart Laser Business, CMS Recognition of SPY Procedures, Nasdaq Listing And a Secondary Offering

NVDQ
52 wk: $5.75-$7.75
Apr 10: $6.25
Mkt Cap: $203.82MM

- In February, NVDQ (formerly NDQ.TO) reported 4Q and FY 2011 earnings. Total revenues for 4Q2011 was $5MM—a 119% increase annually and a 19% increase sequentially
- NVDQ vastly exceeded their 4Q2011 guidance (75-100) for system sales with 130 new SPY or FIREFLY systems shipped out
- Entering 2012, 300 US hospitals are using NVDQ imaging systems
- Of the $5MM in 4Q2011 revenues, $2.4MM represented recurring revenues from repeat users of the SPY products. Recurring revenues has increased 67% percent annually
- Taken together, these data indicate that old customers are happy with the SPY/FIREFLY systems and continue to generate recurring revenues for the SPY procedural kits while new customers continue to be added on, requiring newly installed systems
- The company also indicated that its YE2011 cash and burn to be $9.6MM and $0.3MM, respectively
- Being fully focused on its imaging business, NVDQ was also able to divest out its legacy therapeutic (not imaging) product, CO2 Heart Laser, to a specialized cardiovascular hospital sales distributor called MAQUET Cardiovascular
    - NVDQ continues to consolidate their second partnership with LifeCell/KCI
    - The MAQUET 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
- Novadaq continued its positive news flow spree as the Centers for Medicare & Medicaid Services (CMS) announced that the SPY Vascular angiography had been granted a favorable outpatient reimbursement code, effective April 1, 2012
    - While the vast majority of SPY guided procedures are in-patient and surgical in nature, this recognition of SPY imaging as a standalone reimbursable procedure by the CMS bodes well for upcoming launches of the portable SPY system in wound care, the SPY Elite in vascular procedures and the PINPOINT device in minimally invasive surgeries—all of which are performed in out-patient settings
- On the heels of this positive earnings, divestiture, consolidation and reimbursement news, Novadaq was successful in securing a NASDAQ listing for itself. Novadaq shares began trading on the NASDAQ on Mar 1, under the ticker symbol "NVDQ." This successful US listing underscores the growing popularity and investor base of this company in the US
- At press-time, NVDQ is tapping its "eager" US investor base for a secondary offering through Piper Jaffray and Stifel Nicolaus Weisel

At the OneMedForum 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)

Major turnaround in Company Leadership, Collaborators and Strategy

WNDM.PK
52 wk: N/A
Apr 10: $0.20
Mkt Cap: $11.61MM

- On Mar 22, WNDM announced a complete change in the leadership of the company. Scott Haire and Deborah Jenkins-Hutchinson, former CEO and President of WNDM, respectively, have stepped down and were replaced by Robert Lutz Jr., who will now be the President & CEO of the company
- The events leading up to this marked turnaround remain unclear as the company went into a "silent period" soon after the acquisitions of Juventas in YE2011
- Robert Lutz Jr is believed to have extensive management and leadership experience, having worked with subsidiaries of Liberty Corp, AMEX, and AMRESCO. However, Mr Lutz lacks relevant biotech/medtech experience
- Another surprising decision by Mr. Lutz was the termination of the Juventas acquisition that had been completed when Mr. Scott Haire was the CEO
- As a reminder, Juventas is a large hospital/hospice based distributor that was acquired by WNDM in YE2011 to market Cellerate Rx in the hospital channel
- The new WNDM CEO, Mr Lutz, presumably terminated the Juventas deal because it was poorly conceived. Also, Mr. Lutz would like to create an internal sales team to market CellerateRx rather than have Juventas do the marketing for this agent
- OneMedResearch continues to reach out to new WNDM management for more clarity on strategic direction and re-alignment of the company. We will provide updates as the team learns more

Executing on PV-10 in Melanoma and PH-10 in Psoriasis for News Flows in 2012-2013

PVCT.OB
52 wk: $0.67 - $1.23
Apr 10: $0.82
Mkt Cap: $90.97MM

- On Mar 26 2012, non-clinical data presented by Moffit Cancer Center at the 2012 Society of Surgical Oncology Annual Meeting confirmed that PV-10 chemoablation of melanoma lesions leads to a systemic response and the induction of systemic anti-tumor immunity
- On Mar 19 2012, PVCT reported phase II results of PH-10 Rose-Bengal hydrogel formulation for patients suffering from mild-to-moderate plaque psoriasis. Approximately 1-2% of people in the United States, or about 5.5 million, have plaque psoriasis
- Overall across all doses, 23-29% PH-10 treated patients (versus 0 for placebo) demonstrated complete/near complete resolution of all the three components of the PSI (erythema, induration and desquamation). This speaks to the overall activity of the agent. Side effects were local and mild.
- The study found the lowest dose, 0.002% PH-10, to be most efficacious with 38% patients reporting no itching versus 14% in placebo. While the lack of a clear dose response curve for PH-10 poses a conundrum, it is possible that the agent will be investigated a few other doses in phase III for a viable dose response curve
- The 0.002% dose also demonstrated a statistically significant ($p<0.001$) improvement in the plaque response assessment
- If approved, PH-10 will compete with topical steroids and vitamin creams in the psoriasis market—most of which are used off-label and have no clear cut clinical data. The full clinical data package for PH-10 will quickly make it the preferred agent in this segment of the psoriasis topical agents
- A potential out-licensing deal could occur in the 2012-2013 timeframe
- However, investor interest in PVCT is predicated largely on the PV-10 franchise in metastatic melanoma
- Based on successful agreements with the FDA in Jan 2012, PVCT is likely to seek a special protocol assessment (SPA) for the phase III trial of PV-10 in metastatic melanoma. This should occur by 3Q2012 for a start of the phase III trial by YE2012 and final results by YE2014. It is unclear at this time whether the phase III study will have an interim analysis in 2013. OneMedRadio interviewed CEO, Dr. Craig Dees on Jan 20, 2012
- Key catalysts for PVCT continue to be partnering of PV-10 for oncology indications and out-licensure of PH-10 for dermatology

NNVC.OB
52 wk: $0.52 - $1.65
Apr 10: $0.68
Mkt Cap: $103.01MM

NNVC Meets the US FDA For Pre-IND Meeting on FluCide. "All Hands on Deck" for 2013 Launch of a Worldwide Clinical Program for FluCide.

- On Mar 29 2012, NNVC met the US FDA for a pre-IND meeting for the clinical development of their nanoviricide product FluCide for the treatment of seasonal and endemic flu
- FluCide differs from currently available treatment options, like Tamiflu or Relenza, by sequestering the entire virus and removing it from circulation, rather than inactivating one viral protein at a time
- At its FDA meeting, NNVC presented all available "proof-of-concept" materials including preclinical efficacy and safety and preliminary animal toxicology data that they have collected so far
- In this meeting , NNVC sought the FDA's guidance on the following items:
    - What additional toxicology studies are required: (i) types of animal species to test FluCide in, (ii) number of animals/species that need to be exposed (iii) duration of exposure
    - Design of the phase I-III program and the need to use randomized trials against standard-of-care even in phase I/II stage
    - The exact approval strategy in the US and the FDA's overall blessing on the ex-US approval strategy
- **Ex-US strategy:** NNVC's internal vision is that there be a combined phase I/IIa study, probably conducted by a US based CRO with subjects (N =~50) in Europe. Since the timing of the flu season in Europe is different from the US, conducting a study there allows adequate setup/legwork time for the CRO and provides a lower cost but equally robust option to NNVC
- NNVC also envisions that if the European trial is successful, a phase III program could be started in Australia, allowing the company to capitalize on the staggered flu seasons in different countries. This will be a much larger trial and may need to treat over 500-1000 patients

- **US strategy:** Since GMP approval standard for investigational drugs are more stringent in America than in EU or Australia, it is likely to take until mid-2013 for US trials to start
- The FDA advices NNVC to start US trials (maybe phase II/III) under an orphan drug program treating the sickest tranche of flu patients who are also immuno-compromised at outset
- Given that there are 250,000 hospitalizations for flu each year in the US, and a significant number of such patients are immuno-compromised, it is very clear that this sickest patient pool is an orphan designation (≤ 200,000 incidence/year)
- We believe this is a very interesting path to follow because FluCide's mechanism of action is by physically trapping the virus and making it unable to infect human cells; hence the presence or absence of a functional immune system should have no bearing on the efficacy of the drug. If proven, FluCide maybe the only flu agent that can work on such immuno-compromised patients—which could be a huge marketing leverage for NNVC

- **Manufacturing plant:** However, the important and **rate-determining step** towards the start of any clinical program for FluCide is the construction of the production plant in Connecticut
    - NNVC has decided to hire contractors and builders who build the framework at their own plants, then deliver to the site in a modular fashion and then integrate on-site
    - This ex-location production is both cost- and time- efficient and could be completed in five months from start date
    - To oversee the construction and integration process, NNVC has retained a former head of worldwide manufacturing from Merck who is presently working with GMP consultants to seek their clearance before the proposed plan is sent off for modular construction
    - NNVC management believes this plant will be ready to produce FluCide by YE2012 or 1Q2013
    - At its optimal production capacity this plant will make 1 kilogram of GMP certificated FluCide/year, which is sufficient to supply 1MM doses of the drug/year

We believe that after the FDA meeting, toxicology studies will continue in parallel with the construction of the manufacturing plants. Both will conclude at the same time by YE2012 allowing for production of drug materials

ADXS-HPV CIN2/3 Phase II Trial Completes First Dose Cohort. Key FDA meeting likely in 2Q12.

ADXS.OB
52 wk: $0.09 - $0.25
Apr 10: $0.13
Mkt Cap: $35.81MM

- In February 2012, ADXS announced early results in the CIN 2/3 (cervical intraepithelial neoplasia) trial
  - This is a Phase II, single-blind, randomized trial where 120 women with very early stage cervical cancer are treated with three escalating doses of ADXS-HPV (n=30/dose cohort); 10 women are treated with placebo
  - In this setting of very early stage cervical disease, ADXS-HPV, if successful, could be used as a neo-adjuvant therapy or as an alternative to surgery all together
  - ADXS reported that in women treated with lowest dose the severity of CIN demonstrated 52% regression to either CIN 1 or normal cells. This compares to 40% regression in placebo treated patients
  - O'Shaughnessy et al (*Cancer Clin Res. 2002*) have set the bar of efficacy in this setting to 50% regression to CIN1 or normal cells.
  - While the lowest dose cohort ($50x10^7$ cfu) did achieve this level of efficacy, the fact that 40% of the placebo treated women also did the same, tells us that while the drug maybe active, at this early dose the curve for the drug and the placebo effects have not diverged markedly
  - All eyes are now on the drug effect at two higher doses; phase I studies did demonstrate better effect of ADXS-HPV at higher doses. We continue to monitor this study for more robust drug effect with higher doses
  - The next higher dose cohort is 75% recruited and the company expects to report results in 4Q2012
- Separately, the recent interim results from phase II India study of ADXS-HPV in patients with metastatic recurrent cervical cancer has been receiving good press from investors and KOLs
  - ADXS in concert with the Gynecologic Oncology Group (GOG) is now contemplating an extension to this phase II study using a chemo doublet (cisplatin/paclitaxel) in the control arm
  - The original phase II India study randomized recurrent cervical cancer patients to ADXS-HPV versus cisplatin (chemo-singlet) + ADXS-HPV
- ADXS will likely seek audience with the FDA imminently and will probably get to meet the agency in 2Q2012 to discuss a fast-track designation for ADXS-HPV in recurrent cervical cancer.
  - At the same meeting ADXS will seek the FDA guidance on all ongoing and future phase II and III trials to decide if the chemo-doublet phase II study that the KOLs are proposing is congruent with what the FDA wants to see
- In the absence of any current agents for cervical cancer, a compassionate use program for ADXS-HPV will also be discussed. If granted, then ADXS will have to increase their manufacturing capability at their current production facility
  - This may include longer runs or more production shifts to make more doses of the drug but does not entail new capital expenditure
- Separately, based on the interim results of the phase II recurrent cervical cancer (India study) there has been some interest amongst pharmaceutical companies to perform due-diligence on the data for potential licensure at a future time
- ADXS hopes to meet some potential licensure companies over the next two months and allow the due diligence process to begin.

for the seamless start of the clinical program in 2013

BiovaxID's Future Plans Remain Positive As Management Signals to Robust Pre-NDA Meeting with Drug Approval Agencies Worldwide

BVTI.PK
52 wk: $0.32 - $0.77
Apr 10: $0.53
Mkt Cap: $76.69MM

- OneMedResearch initiated coverage of Biovest International (BVTI.OB) in Jan 2012. See initiation report here
- BVTI's key asset, BiovaxID is an idiotype-targeting personalized immunotherapy for the treatment of follicular lymphoma (FL)
- BiovaxID has completed one statistically significant phase III clinical trial in this patient population and is currently conducting pre-NDA filing meetings with regulatory agencies worldwide to get a consensus on whether their phase III data is robust enough for the company to initiate regulatory filings
- While the phase III design and results were clinically meaningful at the time the trial was started in 2000, the treatment landscape in FL has changed significantly since then. This puts some doubt in the minds of investors, whether this trial alone is sufficient to get the agent approved, or should another phase IIIB trial be performed that incorporates the current standard-of-care, Rituxan for FL
- BVTI management contends parallel BVTI studies have demonstrated that the efficacy of BiovaxID is not altered in any way (increased or reduced) in the presence of Rituxan. So the agent should be approved and a phase IV study evaluating Rituxan treated patients be conducted
- BVTI has gone on record to say that had key pre-NDA meetings recently. OneMedResearch conjectures that these meetings were held with the:
    1. EMEA
    2. Regulatory agencies in few different EU nations who will need to propose and second the BiovaxID filing to the EMEA
    3. FDA
    4. Health Canada
    5. Regulatory agencies of individual countries, maybe Israel, India etc
- The OneMedResearch team also conjectures that such meetings have gone "well" for BVTI given the enthusiasm that their management continues to demonstrate
- BVTI management also indicates that to clear any investor confusion and controversies, it intends to press release key takeaways of their minutes of meeting-of-meeting with such agencies. This decision makes OneMedResearch more confident of the success of the meetings

In the meantime, BVTI continues to expand and solidify its scientific advisory board (SAB). Oncologists and consultants of the SAB will advise BVTI about the NDA filing for BiovaxID, commencement of a Rituxan containing phase IIIB or phase IV and eventually launch of this agent worldwide

PLCSF.OB
52 wk: $0.07 - $0.35
Apr 10: $0.33
Mkt Cap: $9.86MM

PLC Receives Distribution Approval in Brazil and Israel; Ramp-up of U.S. Pivotal Trial Underway Alongside Increased R&D Initiatives

- On March 30, 2012, PLC announced it had received approval from the Brazilian government to market its innovative RenalGuard System™ in that country
  - PLC's exclusive distributor in Brazil, DISCOMED Comercio de Produtos Hospitalares Ltda., Porto Alegre, Brazil, secured approval for both the RenalGuard® system and its single use sets through ANVISA, the Brazilian registration authority
  - DISCOMED is now beginning launch efforts in Brazil, including placing an initial stocking order, scheduling training sessions and promoting RenalGuard to medical professionals in the market
- The company reported fourth quarter and full year 2011 results
  - As of Dec 31, 2011, PLC reported $2,585,000 in cash and equivalents, an increase of $1,261,000 from the company's cash position of $1,324,000 as of Dec 31, 2010. The increased cash position reflects the net proceeds from the sale of the TMR business and the secured convertible debt financing
  - During the fourth quarter of 2011, PLC shipped 963 single-use RenalGuard disposable sets and 21 RenalGuard consoles internationally, compared to 90 RenalGuard single-use disposable sets and two consoles that shipped in the fourth quarter of 2010 and 25 single-use sets and two consoles shipped in the third quarter of 2011
  - As expected with the ramp-up of the company's U.S. pivotal trial, Operating Expenses increased to $1,049,000 in the fourth quarter of 2011 from $472,000 in the same quarter of 2010. Sales, General and Administrative costs were $596,000 in the fourth quarter of 2011, lower than the $621,000 recorded in the fourth quarter of 2010. Research & Development expenses were $453,000 in the fourth quarter of 2011, an increase from the credit of $150,000 associated with the impact of the R&D grant of $244,000 from the Qualifying Therapeutic Discovery Project Program reported in the fourth quarter of 2010
  - For the full year 2011, PLC reported total revenues of $671,000, compared to total revenues of $587,000 in 2010. Net loss from continuing operations for 2011 was $6,990,000, or a loss of $0.21 per basic and diluted share, compared to a net loss from continuing operations of $3,109,000, or a loss of $0.10 per basic and diluted share, in 2010
- The company is currently seeking strategic partners for financing

TPI
52 wk: $0.56 - $2.68
Apr 10: $0.86
Mkt Cap: $24.60MM

Tianyin's Qionglai Facility Project Initiated, Company Targets Q4 2012 Completion Date

- Tianyin Pharmaceuticals presented and participated in the panel discussion on healthcare reform and pricing at the 32nd Cowen's Healthcare Conference on Monday, March 5th, 2012 at the Boston Marriott Copley Place Hotel. The updated corporate presentation is available here
- On February 13, 2012, TPI announced the official start of the Qionglai Facility project following the initial planning period. The Phase I of QLF project will be the construction of the pre-extraction plant, which is targeted for completion by the end of 2012 calendar year.
- The QLF occupies 80 mu, or 53,000 square meters. Both the pre-extraction plant and the formulation plant are to be relocated. The re-location and construction cost for the QLF is estimated at $25 million for Phase I, which will expand the current capacity by 30%. For Phase II QLF, an additional $10 million may be employed to double the current capacity by 2013 begun after the initial planning stage
- The company is reaffirming the guidance for the fiscal year 2012 to the $100 million top-line and $11 million net income. They have recently received the approval of High Tech valuation of their Jiangchuan Facility, which should be able to be carried over to the Qionglai Facility, and could effectively reduce their tax rate from the current 25% or 30% down to around 15% to 20%

Vasomedical Announces Record Operating Income of $5.2 Million and 169% Increase in Revenue for the Seven Months Ended December 31, 2011

Vasomedical

VASO.PK
52 wk: $0.18 - $0.74
Apr 10: $0.24
Mkt Cap: $31.13MM

- On March 30, 2012, Vasomedical announced its operating results for the seven months ended December 31, 2011
    - These results include the operation of its Chinese subsidiaries for the four months since their acquisition in Sept 2011. The results for the seven month period are based on the change in 2011 of their fiscal year end from May 31 to Dec 31
- The Company recorded revenue of $23.49 million for the seven month period ended December 31, 2011, compared to revenue of $8.74 million for same period in 2010, an increase of 169%. The increase is primarily due to an increase in commission revenue at the wholly-owned subsidiary Vaso Diagnostics, Inc., d/b/a VasoHealthcare, as its agreement with GE Healthcare, which began mid-year 2010, was in full operation in 2011
- They continue to record substantial amounts of deferred revenues, which will be recognized once the underlying equipment or service is accepted or performed. As of Dec 31, 2011, total deferred revenues were approximately $15.23 million, an increase of $3.31 million from May 31, 2011
- As of March 29, 2012, the company had cash, cash equivalents and short term investments of approximately $13.1 million
- Net income for the seven months ended Dec 31, 2011 was $5.11 million, compared to a net loss of $2.41 million for the same period in 2010. Income attributable to common stockholders was $3.89 million or $0.03 per common share for the seven months ended Dec 31, 2011, compared to a net loss of $2.60 million or ($0.02) per common share for the seven months ended December 31, 2010
- The net income in 2011 and net loss in 2010 applicable to common stockholders were after reduction for preferred stock dividends of $1.22 million and $191,000 for the seven months ended December 31, 2011 and 2010, respectively
- These dividends for preferred stock, all of which were converted to shares of common stock during the reporting period, are noncash items resulting principally from the value of the imbedded beneficial conversion feature in the preferred stock

DATA Reports Strong FY2011 Results With Marked Increase In Client Base. Poised for a Successful 2012

DATA.PK
52 wk: $0.21 - $0.80
Apr 10: $0.40
Mkt Cap: $5.84MM

- On Mar 15, 2012 DATA reported FY2011 financial results with a top-line revenue of $7.9MM (a 7% Y-o-Y increase)
    - In a year where the fear of a "double dip recession" has decelerated worldwide purchase patterns across different industries, an increase in annual sales underscores the stability of the DATATRAK ONE platform, and client demand
    - The reported 7% increase in sales came despite two major contract cancellations (because these clinical trials were held back midway for scientific reasons), leading a $2MM total loss of realized and backlog revenues
- For FY2011 DATA reported $11.6MM of backlog revenue versus $11.2MM in 2010 which is yet another metric to gauge the stability and relative success of DATA eClinicalTrial unified software solutions
- Using a combination of their own sales reps ("inside sales") and CRO's that supply their software to drug/device companies, DATA demonstrated
    - New contract sales increased 15% Y-o-Y and 130% since 2009
    - New CRO partners increased 267% including a top-10 US CRO that is using DATA's software to validate its entire suite of offerings to the healthcare industry
- CEO Larry Birch indicated that this was a "tip of the iceberg," as the market for electronic clinical trials still remains untapped with 40% of all US-trials still being done in a paper-based format
- DATA software have also started permeating to the fast growing Asian markets:
    - Their Chinese partner, TigerMed, has translated the entire eClinicalTrials software in simplified Chinese and is now deploying this in Chinese clinical trials
    - DATA has inked its first deal with an Indian CRO, which will most likely gradually phase out their pen-and-paper based data collection and replace with DATATRAK ONE
- CEO Larry Birch also spoke about the growing footprint of Apple devices in the field of clinical trials and DATA being a “pioneering provider” of software that are/have been completely web-based and "Cloud"-enable, accessible across any Mac or PC based platform
- Despite all the relative financial success that DATA has achieved in 2011, the patent ligation with competitor Medidata (MDSO) remains as overhang
    - In 2011 OneMedResearch had written about DATA suing MDSO on grounds of patent infringement to the former's primary US patent 7,464,087
    - Subsequently, and in an attempt to shift the "burden of proof" to DATA, MDSO submitted potential "prior art" documents that pre-date the '087 patent and suggest that DATA platform is not novel and should not be patentable
    - In Oct 2011, based on this "prior art" submission the USPTO granted MDSO request for *ex parte* re-examination of the '087 patent
    - The re-examination process in ongoing and may lead to some results in 2012
    - DATA attorneys have studied MDSO's prior art paperwork and intend to vigorously defend the '087 patent as they believe that the submitted prior art is not relevant
        - Should the '087 patent stand the test of re-examination, MDSO will likely have to pay punitive damages and seek a license from DATA to continue to sell products
        - Should the USPTO find the prior art to be meaningful, it may choose to reduce the scope/claims of the '087 patent (a negative development for DATA)
    - CEO Larry Birch believes that even this latter, low-probability incident would not hurt new client acquisition and new revenues because DATA's customer base cares for higher-performing products and not just patent status
- Looking forward, 2012 marks the beginning of another strong year for DATA. We sense a strong 1Q2012 in the works. While DATA does not prefer to give annual revenue guidance, OneMedResearch projections suggest a ~15% top-line growth