**AVAILABLE PHARMACEUTICAL PRODUCTS**
May 2012

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AVAILABLE PHARMACEUTICAL PRODUCTS

This list is a periodic compilation of pharmaceutical products that are currently in licensing processes or where actual or potential M&A discussions are taking place. We have divided opportunities by therapeutic area. Items involving public companies are only listed where it is broadly understood that a licensing / sale process is underway or where a product that is an excellent candidate for outlicensing is available but no known active process is underway. This list is distributed to individuals with an interest in business development in the pharmaceutical industry. Occasionally, we include products where the owner has asked that their identity remain undisclosed or there is some sensitivity to wide disclosure. In most cases Torreya Partners can make an introduction to a party noted as “undisclosed” to qualified groups with an interest in the product.

To assist you, we highlight listings with the following tags:

- **NEW**: items flagged are NEW since the last listing of products.
- **UPDATE**: denotes a change on an existing listing.
- **COMPLETED**: denotes that a transaction was completed on a previously listed available product.
- **H**: High interest or likely to end up as a large deal. An indicator of one of the higher quality available assets.
- **$**: items denote marketed products

In many cases we also provide a web link to relevant information about a compound or company noted by (Link).

**ACTIVE COMPANY TAKEOVER SITUATIONS**

- **NEW**: Achillion - ACH-1625, a Phase 2 pan-genotypic protease inhibitor, has shown strong activity against HCV genotype 1 and 3. The company is also developing ACH-3102, a second generation NS5A inhibitor. The company’s CEO Michael Kischbach indicated that they are in “advanced discussions” with potential partners and acquirors.

- **COMPLETED**: Actavis – A number of media reports suggest a likely acquisition of this global pharmaceutical company by Watson for $5-6 billion. Update: Watson announced this acquisition on April 25, 2012.

- **UPDATE**: Abdi Ibrahim Ilac - largest Turkey drug maker with revenues over $800mm. Reported in May 2011 that was in discussions to sell a strategic stake. As of April 2012 it is understood that these discussions have not borne fruit.

- **UPDATE H**: Akebia –Positive Phase 2 with a HIF modulator for the treatment of anemia. Company reported impressive, positive Phase 2 data in pre-dialysis CKD patients in April 2012. Interested parties should contact Bill Daly (wdaly@akebia.com). (Link)
**UPDATE** Albireo - Positive IBS-c Phase 2 data on A3309 which modulates the enterohepatic circulation of bile acids by inhibiting the Intestinal Bile Acid Transporter (IBAT). Company starting Phase 3 studies. Albireo is rumored to be exploring a company sale with the assistance of a financial advisor. ([Link](#))

**UPDATE** Alexza – Developing ADASUVE (Loxapine) which recently met the primary endpoint in a Phase 3 Bipolar Disorder trial. On February 13, 2012, Alexza received preliminary feedback, the Day 80 Assessment Report, from the EMA regarding its MAA, which contained major objections to various aspects of extrapolating phase III of clinical trials in addition to practical concerns. An FDA approval decision is expected in early May 2012. Alexza announced in Dec 2011 that it had hired Lazard to explore strategic options.

**COMPLETED** Allos Therapeutics – Oncology marketer with Folotyn® for liquid tumors. After a recently failed merger attempt with AMAG, Allos is rumored to be continuing to explore strategic alternatives with the assistance of JP Morgan. Update: Apr 5, 2012 – Spectrum to by Allos in a deal valued at $206 million. ([Link](#))

$ AMAG - Feraheme IV iron product - Recently approved. Company is commercializing on its own. AMAG’s recent merger attempt with Allos was ended in November 2011. On Nov 17, 2011, AMAG announced that it had hired Jefferies to explore all opportunities to enhance shareholder value. Frank Thomas, interim CEO of AMAG indicated: “We will expeditiously complete this process, which will include a parallel review of a potential sale of the company and other strategic merger and acquisition transactions.”

**UPDATE** Amarin - Developing a pure omega-3 for reduction of triglycerides. Phase 3 data reported out very strong. Company has indicated that it has retained a financial advisor (Lazard) to explore a sale. Amarin is well positioned to be a takeover candidate in 2012 – particularly with recent clarity on its patent position and April 2012 media reports have rumored a pending transaction. ([Link](#))

Amoun Pharmaceutical - An Egyptian company that manufactures off-patent branded generic formulations. It is one of the largest pharmaceutical companies in Egypt. It sells over 135 human products in over 275 forms. Of these products, 33 occupy the top 2 positions in their respective therapeutic categories and subcategories. Open to a company sale or strategic stake purchase. Reuters - Dec 6, 2010: “CVCI is also preparing to sell Amoun, one of Egypt’s biggest drugmakers, people familiar with the matter told Reuters on Oct. 20. It owns Amoun with two other co-investors.” Bloomberg reported in Feb 2011 that the company has been looking for $1 billion in a sale price but that political upheaval in Egypt has hindered the sale.

**NEW** Amylin – marketer of Byetta® and Bydureon® for the treatment of diabetes has reportedly received an offer from Bristol-Myers Squibb and, according to Bloomberg in mid-April 2012 has hired a financial advisor to help find a buyer. Separately, Amylin is interested in finding a partner outside of the U.S. to distribute its products.


**UPDATE** Bioject Medical Technologies - Needle free delivery technology. Extends supply agreement with Ferring pharma. In Nov 2011, the CEO stepped down as a cost-cutting measure. As of February 2012, the company is reviewing its options with a financial advisor (Ferghana Partners), including a sale of the company. ([Link](#))

**COMPLETED** Biota - Looking to partner a once weekly inhalable long-acting neuraminidase inhibitors for the treatment of flu. Would compete against Relenza from GSK. Currently partnered with Daichi-Sankyo in Japan. One of two Phase 3 studies have reported out with positive data - large market. Recently received a large BARDA grant and has retained Piper Jaffray as financial advisor to maximize value of existing programs and help to enter the U.S. market on a commercial basis. Update: Biota merged into Nabi in April 2012 which lists the company in the U.S. ([Link](#))
NEW Ceptaris – Formerly Yaupon Therapeutics is filing an NDA for Valchlor, a gel formulation of mechlorethamine for the treatment of mycosis fungoides, a type of CTCL. This orphan disease impacts 80,000 persons in the Western world. Product launch in U.S. anticipated in Q4 2012. Company in active business development dialogue.

UPDATE China Nuokang -its lead products include Baquting for bleeding control, Aiduo, a cardiovascular stress imaging agent, and Aiwen, an anti-arrhythmic agent. The company has a value of $180mm. Biopharm Insight in November reported that this company hired Lazard for a sale process. On Feb 17, 2012 the company noted: “Although we remain open to strategic alternatives that enhance shareholder value, we are now focused on stabilizing our commercialization platform and achieving our goal of becoming one of China's leading, multi-product biopharmaceutical companies. Meanwhile, although we expect our revenues for 2011 to remain within our previously guided range of $40 million to $45 million, we expect a substantial decrease in our net income for 2011 due to one-time and non-operational charges such as costs associated with our exploration of strategic alternatives.”

$ Claris Life Sciences - Indian injectibles company has hired Rothschild to look at strategic options. Company has a rich pipeline of hospital generic injectibles using novel delivery methods. (Link)

UPDATE $ CNS Therapeutics - has introduced Gablofen, an AP rated intrathecal version of baclofen for control of severe spasticity among patients with movement disorders. This product has significant advantages over the existing marketed product and is likely to have significant revenue traction over the next several years. This product is promoted and the company is a suitable acquisition candidate for either a branded or generic company. Rumored to be in active sale discussions. (Link)

NEW Columbia Labs – recent issue with approval of its partnered product Prochieve. After FDA indicated that an additional trial is generated, the company indicated that it has hired Cowen to explore strategic alternatives. Columbia has a royalty stream, some cash and is a good candidate for a reverse merger transaction.

UPDATE Covidien Pharmaceuticals - According to the New York Times on June 7, 2011 “Covidien, the health care company spun out from Tyco four years ago, may seek to sell its pharmaceutical unit...” This division of Covidien (formerly Mallinckrodt) has a major business selling pain products (both branded and generics) and imaging products. Revenues are around $2 billion. Update: As of April 2012 no sale has taken place. Company is rumored to be interested in a sale of the whole business (rather than pieces) for a full price and is now thought to be more likely to be spun out. YE 2011 numbers reported on Nov 15, 2011 and were robust (sales up 9% yoy) with strong performance in generics.

NEW EpiCept Corporation - SunTrust Robinson Humphrey to assist in exploring strategic alternatives to maximize the commercial opportunity of AmiKet™ includes the evaluation of potential transactions involving the sale of the Company. AmiKet™ is the Company's prescription topical cream intended for the treatment of neuropathic pain. The engagement of SunTrust Robinson Humphrey will focus on the identification and implementation of a strategy designed to optimize AmiKet's value for the Company's shareholders. EpiCept recently announced that it has received further encouraging guidance for the Phase III clinical and nonclinical development and subsequent New Drug Application (NDA) filing of AmiKet™ in the treatment of chemotherapy-induced peripheral neuropathy (CIPN). (Link)

Exelixis - According to Bloomberg on April 12, 2011: "Exelixis Inc. is working with Goldman Sachs Group Inc. to prepare for potential takeover offers after its experimental drug helped prostate-cancer patients in a study.” Company’s XL-184 has reported dramatic data on reducing metastatic prostate lesions at ASCO. Update: company has hired a Chief Commercialization Officer with intention to introduce cabozantinib to the U.S. market and has reported strong data for cabozanitinib in the treatment of medullary thyroid cancer.

COMPLETED Gen-Probe - Widely rumored to be for sale with interest from Novartis. Well known diagnostics company. Process well underway but company viewed as expensive. Update: Wall Street journal reports on July
20, 2011 that “Novartis is no longer actively pursuing U.S. medical diagnostic-testing company Gen-Probe, meaning Gen-Probe could end its sales process…” Update: Apr 2012 – Hologic buying Gen-Probe for $3.7bn.

**COMPLETED** GlaxoSmithKline - running a process to divest non-core OTC brands with assistance from Goldman Sachs. The products to be divested, which are primarily sold in Europe and the United States, had sales in 2010 of approximately £500 million, 10% of GSK’s total Consumer Healthcare turnover. They include analgesics: Solpadeine, BC and Goody’s; vitamin and supplement product Abtei; feminine hygiene treatment Lactacyd; and alli for weight management. Reuters Update on Nov 14, 2011: “GlaxoSmithKline is assessing final bids for a clutch of its non-prescription drugs, keeping the process on track for the selection of a buyer by the end of the year, people familiar with the matter said on Monday.” Transaction completed in a sale of U.S. brands to Prestige Brands in Jan 2012, EU brands to Omega Pharma in March 2012 and other brands to Aspen Pharmacare in April 2012. Total consideration received was £425mm with revenue multiples in the 2-3X range. (Link)

Guangxi Golden Throat (Guang Xi Jin Sang Zi), a privately held manufacturer of healthcare products, is reportedly in sale talks. The company has annual revenues of around $47mm from its throat lozenges, which sell under the 'Golden Throat' brandname.

**NEW** Human Genome Sciences – Received an unsolicited takeover on April 19, 2012 offer from partner GlaxoSmithKline for $13 per share, or about $2.6 billion in cash. Human Genome, which said the offer did not reflect its “inherent” value, retained Goldman Sachs and Credit Suisse to assist in exploring strategic alternatives, including a potential sale.

**UPDATE** Ipsen – Completed a strategic review in 2011 with the theme of increasing focus and growing the footprint. The implications of this for potential partnerships or asset divestitures are threefold: (1) Ipsen looking for a partner in the French primary care arena, (2) Ipsen looking to find a buyer for its industrial site in Drex France which makes solid dose and liquid formulations and (3) “Ipsen will explore all options to maximize value (of its short stature franchise) while meeting its obligations to patients and partners. It will be managed directly by regions and countries.” Update: Ipsen sold off the rights to Apokyn in the U.S. for over 1X revenues on Nov 2, 2011. In a February 2012 investor update, the company emphasized goal of partnering French primary care business.

**COMPLETED** $ Ista – Strength in ophthalmologic and respiratory disease products. Company received an acquisition offer from Valeant and was ultimately acquired by Bausch and Lomb in March 2012.

**COMPLETED** $ Lipose - Viafill fat transfer system on the market with applications in aesthetics where traditional volumizers are not well suited - particularly for the face and breasts. Company assisted by Torreya Partners. Update: This company was sold to an aesthetic dermatology player in March 2012.

Meda - A Wall Street Journal Report on July 27, 2011 indicated that Valeant had approached Meda about a takeover offer. Meda responded indicating that its board of directors had not received an approach of the kind reported in the WSJ.

Mimetica - Has developed MTC896 as a topical gel for the treatment of excessive sebum production in subjects with acne and other skin conditions. MTC896 is a highly selective and potent antagonist (<10 nM) of the Melanocortin-5 Receptor (MC5R). There are currently no other approved topical products available on the market for the treatment of excessive sebum production. The company hired William Blair in October 2010 to seek a company sale. Update: no sale as of April 2012. (Link)

**COMPLETED** Mustafa Nevzat - Turkish generic pharmaceutical maker with revenues of approximately $250mm. According to Bloomberg (Jan 31, 2012), in talks to sell a strategic stake with help from Bank of America Merrill Lynch. Update: Amgen Inc. said it will acquire 95.6% of Mustafa Nevzat Pharmaceuticals A.S. (Istanbul, Turkey) in a cash deal that values the Turkish pharma at $700 million on April 25, 2012.
Myrexis - good candidate for a reverse merger transaction. Company has substantial negative enterprise value and has hired Stifel to explore strategic alternatives. Feb 15, 2012: “Myrexis, Inc. (Nasdaq: MYRX), a biotechnology company focused on the development of small molecule therapeutics, today announced that its Board of Directors has retained Stifel Nicolaus Weisel, an investment banking firm, to assist it in reviewing and evaluating a full range of strategic alternatives available to the Company to enhance shareholder value. Myrexis has also suspended development activities on all its pre-clinical and clinical programs. The Company will initiate an alignment of resources consistent with its decision to suspend further development activities.” (Link)

Nabi - good candidate for a reverse merger transaction following a recent Phase 3 failure with NicVax. On Nov 7, 2011, the company said: “Nabi Biopharmaceuticals today announced that its Board of Directors has retained Piper Jaffray to assist with its exploration of the strategic alternatives available to the company to enhance shareholder value.” Update: In March 2012 the company indicated that it plans to announce the result of its plans in Q2 2012. Update: Apr 2012 – company announced a merger with Biota.

Neurogesx - Qutenza is a patch that delivers synthetic capsaicin for PHN on the market in U.S. Recently approved. Partnered in the EU to Astellas in June 2009. Company looking for partnerships in Asia and Latin America. Announced in April 2012 that it is exploring a range of potential transactions with help from JSB Partners. (Link)

Newron - has failed with ralfinamide in Phase III for lower back pain. Market cap around $45mm. Has a solid pipeline of CNS candidates. Open to an M&A deal. Update: Had announced a merger with BioTie which was terminated on Oct 28, 2011. Company looking for alternatives. Update: As of April 2012 has signed a license for Asia rights with Meiji and rumored to continue in search for a partner or buyer elsewhere. In April 2012 Newron concluded a licensing deal for ralfinamide with Zambon for approximately $26mm.

Par Pharmaceuticals - Relational Investors filed a 13D showing 8.7% ownership of this company on November 25, 2011. In the 13D Relational indicated: “Despite these opportunities for improvement, the Reporting Persons believe that the Company may continue to trade at discounted prices because of industry challenges and the Company’s sub-optimal size and product scope. If the discount persists, the Reporting Persons believe that, in keeping with sound stewardship principles, the Company’s board will be required to consider broad strategic alternatives. Specifically, the Reporting Persons are confident that substantial cost savings could be achieved in a transaction with a strategic buyer.” Note: there is no evidence that Par Pharmaceuticals has received offers or is open to receiving such offers at present.

Onyx - rumored to be exploring strategic alternatives. Substantial value potential tied to a recently filed NDA for carfilzomib, a protease inhibitor, for the treatment of liquid tumors including multiple myeloma. Market rumors of an acquisition in April 2012.

Pfizer - has sold its nutritional business to Nestle in April 2012 for $11.5 billion. It is believed that the vet medicines business is most likely to be spun out.

Prestige Brands – major OTC marketer has received an offer from Genomma for acquisition at $834mm in Feb 2012.

Qualicaps - owned by Carlyle. Maker of gencaps (like Capsugel) is up for auction. UBS is rumored to be sellside advisor on business with approx. $350mm in EBITDA. As of April 2012 no sale had taken place.

Riemser - German vertically integrated marketer of generic and branded pharma products with strength in cardiovascular, dental and veterinary medicines. Revenues of this company exceed €100mm and EBITDA around €30mm. Active sale process underway according to Biopharm Insight.

Rottapharm - for sale according to the Wall Street Journal. Company has two Phase 3 drugs in development and a strong group of branded products in the market. Revenues over $850 million. Sale price could be over $2.5
billion. Company rumored to be using Credit Suisse to find a buyer. According to Bloomberg (3/15/2012) Mylan recently pulled out of a sale process. The article noted that “sources said the selling family has not been able to agree to give up control of the company and was not prepared to compromise enough on price either.”

**COMPLETED** $*Bio - In June, 2011 announced results from multiple Phase I/II clinical studies of JAK2 inhibitor Pacritinib which confirmed safety and efficacy. $*Bio has received the rights back to this program from Onyx Pharma. Has promising data on a Phase 1 HDAC inhibitor. Update: This compound was licensed on April 18, 2012 for $30mm upfront in cash and stock plus milestones and royalties.

San Raffaele del Monte Tabor- privately-held Italian pharmaceutical company, is soliciting offers other than the EUR 350m binding offer from Vatican bank IOR and Italian entrepreneur Vittoria Malacalza, according to Il Sole 24 on Dec 2, 2011.

Savient Pharmaceuticals - FDA approved KRSTEXXA (peglisticase) in Sep 2010, a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Company is seeking a commercial buyer and is using JP Morgan and Lazard in its search for an acquisition partner. Savient is now pursuing a launch of Krystexxa on its own and is building a 50-person plus sales force. (Link)

**UPDATE $** Shunfeng Pharmaceutical, a Chinese topical skin care drug manufacturer is exploring a sale. Revenues around $35mm. According to ChinaBio, this company has received an acquisition bid for a price of $110mm in Jan 2012.

**NEW** Somaxon – marketer of Silenor®, a sleep drug with a favorable label has hired Stifel to explore strategic alternatives. On March 8, 2012 Somaxon reported: “We will also continue to work with our strategic advisor, StifelNicolaus Weisel, to evaluate strategic alternatives with the goal of fully leveraging Silenor for the benefit of our stockholders.” Net product sales of Silenor in 2011 were $16.2 million. (Link)

**COMPLETED** Thrombogenics – completed Phase 3 studies for Microplasmin in Phase III clinical development for the non-surgical treatment of back of the eye diseases. Good evidence of efficacy with two positive Phase 3 trials reported. Expected to be on market by end of 2012. Would consider a sale. Note: Thrombogenics licensed the rights to this product to Alcon on March 16, 2012 for 75mm EUR upfront plus additional payments and royalties. Thrombogenics has retained the U.S. rights to this program and intends to self-commercialize. (Link)

**COMPLETED** Undisclosed player - player in drug delivery is searching for a merger or sale with assistance of a financial advisor. Company has expertise in both injectibles and controlled release solid dose. Substantial royalties and partnership deals signed. Update: Flamel instead merged with Eclat Pharma and the CEO of this company assumed the CEO role of Flamel and has an intention of building this company.

**COMPLETED $** Undisclosed player - process well underway for sale of company with a marketed but not promoted cardiovascular product with 2011 revenues around $9 million. Note: Santarus acquired rights to Fenoglide from Shore Therapeutics in Dec 2011 for $11mm plus royalties.

**COMPLETED** Undisclosed Player - U.S. generic company with more than $100 million in revenues is for sale. Company has a significant branded business and a manufacturing facility. Note: Takeda acquired URL Pharma’s generic and branded businesses on April 11, 2012 for $800mm plus contingent payments. The revenues of URL were approximately $550mm.

**COMPLETED $** Undisclosed player – US and European player in oncology and hospital products with revenue over $100mm is open to a change of control transaction. Note: EUSA Pharma was acquired by Jazz Pharma for approximately $700mm in April 2012.
Undisclosed player - dermatology company with more than $40mm in revenue has hired a financial advisor to restructure its debt that likely exceeds intrinsic value of assets. Update: Triax was acquired by PreCision Dermatology on April 30, 2012 for undisclosed consideration.

Undisclosed – UK generic pharmaceutical company with over $50mm in revenues. Expertise in liquids and “specials”. Open to a change of control transaction.

Undisclosed – Pan-European marketer of hospital pharmaceuticals is exploring strategic alternatives. The company has approximately $20mm in revenues. Interested parties should contact rodolphe.grepinet@torreyapartners.com.

Undisclosed dermatology player in the U.S. with strength in brands and generics open to a change of control transaction. Revenues > $70mm. Update: Fougera was acquired by Sandoz for $1.5bn on May 2, 2012.

Undisclosed – Marketer of branded hospital cardiology-oriented pharmaceutical products outside the U.S. with revenues over $50mm is open to a company sale or a strategic investment. Interested parties should contact tim.opler@torreyapartners.com.

Undisclosed – small dermatology player with expertise in OTC and Rx open to a change of control transaction.

Undisclosed – Indian CRO / drug developer with substantial infrastructure looking for a change of control or new investor. Substantial revenue base.

Undisclosed – Hospital focused company with a strong presence in China is exploring strategic options with assistance of a financial advisor.

Undisclosed – small U.S. marketer of respiratory pharmaceutical products seeks a buyer.

Undisclosed – US pediatric specialty pharma with expertise in ADHD open to a change of control

Undisclosed – UK generic player with strength in oral solid dose looking for an acquirer.

Undisclosed player – US generic player with revenue > $25mm with multiple ANDAs is looking at a potential sale.

Undisclosed player – US cardiovascular specialty pharma company with revenue > $50mm and a hospital sales force is seeking a buyer with assistance from Lazard. Transaction is expected soon.

Undisclosed player – US generics company with strength in injectibles and revenue > $80mm is seeking a buyer.

Undisclosed player – US antibiotics biotechnology company with a phase 2 program is seeking a buyer.

Undisclosed player – US urology therapeutics developer with a phase 2 program is seeking a buyer.

Undisclosed player – US critical care specialty pharmaceutical company is seeking a buyer.

Undisclosed player – bundle of several marketed mature pharma products in the neurology and pain areas. Revenue around $10mm.

Undisclosed player – US biotechnology company with a phase 2b program in autism / Fragile-X syndrome is seeking a buyer.

Undisclosed player - selling off $20mm revenue+ commercial product for narrow market with pediatric applications.
Undisclosed player - open to a merger or sale of $35mm revenue company with commercial presence in the U.S. pain market. Torreya Partners advising.

Undisclosed Player - U.S. generic company with approximately $60mm in gross revenue is searching for a buyer with the assistance of a financial advisor. Company has substantial presence in medicines for cough & cold, womens health and pediatrics.

Undisclosed - Chinese specialty pharmaceutical company with strength in anti-infectives. Good EBITDA and revenue over $70mm in 2011. Torreya Partners assisting in sale of majority stake. For details please contact rodolphe.grepinet@torreyapartners.com.

Undisclosed player - Division of Indian generic company that is focused on oral solid dose preparations is for sale. Revenues over $300mm. Company has strength in formulation work and manufacturing. Ships product to numerous global locations.

Undisclosed Player - U.S. generic company with more than $40 million in revenues is for sale via Torreya Partners. Company has a significant pipeline, high growth and a fully developed operating platform. For details please contact tom.babich@torreyapartners.com.

Undisclosed player - very promising Phase 2 product for treatment for OA using an alternative to Synvisc®. Using a financial advisor to find a buyer or partner.

NEW Warner-Chilcott – According to Bloomberg in April 2012, Warner-Chilcott has retained Goldman Sachs to consider potential strategic approaches.

Wockhardt - rumored to be in a process to sell its substantial nutrition business as part of a process to pay down external debt.

**ADDITION MANAGEMENT**

NEW Acino – Has a market ready transdermal buprenorphine system.

Alkermes - ALKS-33, a unique opioid receptor profile with strong efficacy data demonstrating rapid onset and extended activity beyond 24 hours. Broad applicability including treatment for reward/impulse control disorders. Multiple clinical studies conducted including Phase II for alcohol dependence. Interest in partners for rights outside of North America.

UPDATE BioDelivery Sciences is developing BEMA Buprenorphine/Naloxone for the treatment of opioid dependence. The product will combine a “high dose” of buprenorphine along with an abuse deterrent agent, naloxone. Phase 3 studies underway. BDSI recently started PK study of this product compared to Suboxone with data expected in Q3 2012. BDSI now anticipates an NDA filing in H1 2013. (Link)

Camurus - CAM2038 is a long-acting injectable buprenorphine in development for treatment of opiate addiction. A Phase Ila has recently been completed with positive data. Similar program at Titan Pharma.


Embera NeuroTherapeutics is developing EMB-001 which is designed to reduce craving for addictive substances. The product is a combination of oxazepam and metyrapone. In Phase 1 studies. Shown to be more effective in reducing craving than Chantix® in animal studies.

Medicinova - has reported positive efficacy data on ibudilast for the treatment of opioid withdrawal.
Omeros - in Phase 2 studies for a PPARgamma agonist for the treatment of addiction to prescription opioids. Open to partnering this program. (Link)

Orexo - OX219, buprenorphine, a partial opiate agonist, for managing heroin addiction. Orexo looking for a Japanese partner. (Link)

Psyadon Pharma - in a Phase 2 clinical study of ecopipam for pathological gambling.

**UPDATE** Titan Pharmaceuticals - Probuphine is a novel, subcutaneous implant formulation of buprenorphine designed to deliver six months of medication following a single treatment. This product has demonstrated strong positive results in a controlled Phase 3 study for the treatment of opioid addiction and an NDA filing is planned for Q3 2012. (Link)

**ANTIBODIES**

Ablynx - Has positive Phase 1b safety and efficacy data for a “nanobody” targeting RANK-L (compare to Amgen’s Prolia®). Dataset presented at EULAR in May 2011. (Link)

**UPDATE** Ablynx - ALX-0081 is a Nanobody targeting von Willebrand Factor (vWF), to reduce the risk of thrombosis in patients with acute coronary syndrome (ACS) and thrombotic thrombocytopenic purpura (TTP). Through Phase 1b. Phase 2 study is underway. Potential POC expected in H2 2013 which would lead to launch in 2015.

Ablynx - reported on November 5, 2011 that it regained rights ATN-103 a nanobody treatment for rheumatoid arthritis based on TNF-alpha modulation. Ablynx may develop this program further itself or partner out. (Link)

Access Pharmaceuticals - Searching for a partner an anti-proliferative antibody called Angiolix which targets Lactadherin. (Link)

Acumen Pharmaceuticals – anti-ADDL antibody for Alzheimer’s Disease that had been co-developed with Merck. This program has entered clinical studies. (Link)

ADIENTE Pharma - Begedina is a new murine monoclonal antibody directed against CD26 antigens, expressed on a small portion of CD4 T lymphocytes produced by haematopoietic progenitor cells. Begedina is being developed for the treatment of Graft Versus Host Disease. Promising Phase 2 data reported.

Affimed - Taking AFM13, with a novel tetravalent bispecific antibody structure, for the treatment of Hodgkin’s disease (HD) into Phase I. No approved treatments on market. Partnership discussions underway.

Affimed - Affimed's fully human antibody predominantly binds to the activated form of a receptor (GPIIb/IIIa) that plays a major role in the formation of blood clots. A better ReoPro. Company looking for a partner.

Alder Biopharmaceuticals - Phase 2 data from ALD518 investigational antibody therapeutic that targets interleukin-6 (IL-6) demonstrate a reversal of anemia in patients with advanced non-small cell lung cancer (NSCLC). After 12 weeks of treatment with the anti-inflammatory therapeutic, 58 percent of patients who received ALD518 experienced hemoglobin level increases from less than 11 g/dL to more than 12 g/dL, while no patients receiving placebo experienced this increase. Also saw improvements in lean body mass and reductions in fatigue. Note: this antibody is partnered to BMS for all indications except cancer. (Link)

Alder Biopharmaceuticals - ALD306 is a potent, humanized monoclonal antibody that targets PCSK9. This is a late pre-clinical asset. For cardiovascular patients who have trouble reaching target lipid levels with statins, this therapeutic is a promising alternative for lipid control. PCSK9 has been genetically linked to cardiovascular disease. Eliminating this protein in humans has been shown to profoundly alter LDL-C levels in a therapeutically significant way in a number of recent studies. (Link)
Alden Bio - ALD403 is a potent, humanized monoclonal antibody that inhibits calcitonin gene-related peptide (CGRP), a molecule shown to trigger migraine attacks. Previous therapeutic approaches targeting CGRP have centered on traditional pharmacology to alleviate migraine symptoms but were halted due to safety issues. Alder is pioneering a new treatment strategy with ALD403, which will be given to chronic sufferers on a monthly basis via a subcutaneous injection. The medicine will be present at the time of migraine onset—by far the most successful intervention point for treating migraines. A Phase I clinical study evaluating ALD403 in healthy volunteers will launch in early Q2 2012. (Link)

Ambrx –very exciting platform technologies which allow engineering of proteins developed in both eukaryotic and prokaryotic cells including an antibody drug conjugate program for oncology. (Link)

Anaphore - pioneering Altrimers®, a NEW class of protein therapeutics that has a trivalent structure. Better ability to lock on to a target. Working on a number of targets including a TRAIL-R antibody for oncology that is pre-clinical. (Link)

Anaphore - ATX3105, blocks the receptor complex engaged by interleukin-23 (IL-23), an immunoregulatory protein that has become a key target in strategies to develop better therapies for autoimmune disorders. This preclinical drug candidate is being prepared for an IND. (Link)

Apeiron Biologics - In Phase 3 for CH14.18, an antibody, for neuroblastoma. (Link)

Apogenix - in Phase 2 with APG101, a CD95 antibody, for GBM. (Link)

Aiveo Pharma – developing AV-299, an anti-HGF/c-MET antibody currently in Phase 2 development for NSCLC. Open to partnering this product. (Link)

Biocon - Would consider a partnership for its anti-CD6 humanized antibody, T1h. Has completed a Phase 1 study in RA and has two Phase 2 studies underway.

Biogen Idec - Looking to outlicense Galiximab, an anti-CD80 antibody, which has shown activity in B-cell lymphomas. Has gone through Phase 3 trials. Biogen looking to outlicense after a recent strategic review. (Link)

Biogen Idec - looking to outlicense Volociximab, a chimeric monoclonal antibody that inhibits the functional activity of a5α1 integrin, a protein found on activated endothelial cells. Blocking the activity of a5α1 integrin has been found to prevent angiogenesis. This product is jointly owned with Abbott’s Facet Biotechnology. (Link)

Biogen Idec - looking to outlicense BIIB015 which consists of Biogen Idec’s Cripto-binding antibody and Immunogen’s DM4 cell-killing agent. BIIB015 advanced into Phase I testing in the summer of 2008. This compound was slated for Phase 2 in 2011 until Biogen Idec decided to exit oncology after a recent strategic review.

Biogen Idec - looking to outlicense an anti IGF1-R antibody for solid tumors. Has progressed into Phase 2 studies. (Link)

BioInvent - In Phase 2 studies in multiple myeloma with an anti-CD54 antibody. Encouraging Phase 1 data.

Biotecnol - CAB051, an anti-HER2 antibody which is nearing readiness for clinical testing.

Biotie - Biotie initiated two clinical studies in rheumatoid arthritis and psoriasis patients with its fully human VAP-1 monoclonal antibody. Phase 1b studies were supportive of efficacy showing improvements in DAS28 versus placebo. (Link)

Cellidex - Their lead antibody-drug conjugate (ADC), CDX-011, is in Phase 2 development for the treatment of locally advanced or metastatic breast cancer (in Phase 2b) and stage III or IV melanoma. Saw 15% ORR in
melanoma Phase 2a study. CDX-011 targets glycoprotein NMB, also known as osteoactivin, an cell surface protein overexpressed in certain cancers. ([Link])

Chiome Bioscience - Can develop antibodies against rare and difficult antigens using its ADLlib technology. January, 2011 entered into NEW license agreement for joint invention with RIKEN, which allows Chiome to generate, develop, commercialize, or out license antibodies through preferential use of ADLlib system and to license out ADLlib for the life of the patent. ADLlib system is an innovative technology for preparing antibodies by activating homologous recombination in avian DT40 cells. Update: Chiome successfully went public in Dec 2011.

DSX Therapeutics - Developing a Mab that targets inducible nitric oxide synthase, which is involved in sepsis pathology. Pre-clinical program.

Elusys - Has positive animal data for Anthim, a high-affinity humanized monoclonal antibody targeting the anthrax toxin protective antigen. Recently received a U.S. government contract for up to $143 million. In active strategic discussions. ([Link])

Ganymed Pharmaceuticals – Good Phase 1 data with Claudiximab, an iMAB directed against the GC182 target, a gastric differentiation protein that is expressed at the cell surface of 70% of gastric cancers, 50% of pancreatic cancers, 30% of esophageal cancers, and 25% of NSCLC. Now in Phase 2a studies in gastro-esophageal cancer. ([Link])

Genesis Pharma - developing a CD-55 antibody against solid tumors. In Preclinical testing ([Link])

NEW Immune Pharmaceuticals – Has non-opthalmic rights to Bertilimumab, a Phase 2 antibody targeting eotaxin-1 with application to Crohns disease, ulcerative colitis and asthma. ([Link])

HImmunogen - Seen as one of the more exciting oncology players in the market. Has an unpartnered antibody drug conjugate that binds to CD56 Lorvotuzumab Mertansine for SCLC, multiple myeloma, MCC, Ovarian Cancer and other CD56+ Solid Tumors. A recent study showed a number of partial responses in the treatment of multiple myeloma. ([Link])

Immunomedics - In partnership discussions on the oncology indications for two monoclonal antibodies which are currently in Phase 2 trials ([Link])

InNexus - Next generation cancer antibodies at pre-clinical stage. Several highly potent anti-CD20 antibodies in development. Has engaged Dundee Securities to act as financial advisor. ([Link])

ISU Abxis - Biosimilar to ReoPro for adjuvant of PCI (Percutaneous Coronary Intervention) procedure. Clotinabl is anti-GPIIb/IIIa monoclonal antibody and Fab Protein which blocks platelet aggregation. On market in 7 countries.

Kenta Biotech - Outlicensing antibodies for HAP and pseudomonas infections, KBPA101 has completed Phase 2a studies and reported 100% survival in hospital-acquired pneumonia.

Morphosys - MOR103 is a fully human HuCAL antibody against GM-CSF that is in Phase 1 studies. Also see a similar antibody in development at Kalobios. ([Link])

Mymetics - Has hired Lazard to look at its strategic alternatives. Company developing mucosal antibodies to prevent HIV infection. Phase 1 data show safe and well tolerated. Also has a preclinical RSV vaccine. ([Link])

NasVax Ltd. - In a Phase 2a clinical trial in 36 subjects with NASH (Nonalcoholic steatohepatitis) or “fatty liver” and the metabolic syndrome, oral aCD3 antibody immunotherapy was generally very safe and induced positive trends in blood levels of two enzymes that are biomarkers for liver inflammation. ([Link])
Neogenix – In Phase 2 in CRC with Ensituximab, a novel antibody targeting an overexpressed cell surface antigen. Using biomarkers to assist in trial. (Link)

Novimmune - In Phase 2 with an anti-CD3 antibody for Crohn’s disease. Exploring potential as an immunomodulator in Type 1 diabetes and transplant rejection as well.

OMT - Fully Human antibodies from transgenic rats (Link)

Opsona Therapeutics - In preclinical development of an anti-TLR Mab for treatment of inflammatory diseases such as RA and lupus. (Link)

Patrys - developing antibodies for solid tumors. In Phase 1 with PAT-SM6 that binds to GRP78 that is found on the surface of cancer cells but not on the surface of healthy tissues. Also in Phase 1 with PAT-SC1 that binds to CD-55. (also see Genesis Pharma). (Link)

Peregrine Pharma - Positive data in a single arm Phase 2a trial evaluating Bavituximab in combination with carboplatin and paclitaxel in advanced breast cancer patients. Is currently in two phase 2b trials in NSCLC. Reported 12.4 month overall survival data from Phase II trial in non-small cell lung cancer in June, 2011. Would discuss partnership of this antibody outside of the U.S. - particularly after Phase 2 NSCLC data arrive in Q1 2012. (Link)

Philogen - L19-IL2 is well tolerated in patients and is being clinically developed in two registrational clinical trials in patients with metastatic melanoma. In addition, L19-IL2 is being studied in combination with gemcitabine in patients with pancreatic cancer.

Progenics - looking to outlicense its virology pipeline. Included is PRO-140, a Phase 2 antibody for HIV. Unlike small-molecule CCR5 antagonists, PRO 140 inhibits HIV entry at concentrations that in vitro do not appear to block CCR5's natural activity of directing the migration of immune cells towards sites of inflammation in the body. (Link)

Stromedix - STX-100 is being developed for the treatment of chronic allograft dysfunction in kidney transplant recipients. Also exploring IFP indication. Humanized monoclonal antibody to integrin αvβ6, going into Phase 2. Note: This company was bought by BiogenIdec in Feb 2012 for $75mm upfront and additional contingent payments of $487.5 million.

Symphogen - Rozrolimupab (Sym001) is a recombinant polyclonal composition of 25 different Rhesus D specific antibodies for the treatment of primary Immune Thrombocytopenia and for Anti-RhD prophylaxis (ADP) in prevention of Hemolytic Disease of the Newborn. Symphogen reported positive data from this drug at ASH in 2011 in immune thrombocytopenia patients. This product was returned to Symphogen from Biovitrum Swedish Orphan for strategic reasons on Dec 30, 2010. (Link)

Symphogen - Novel polyclonal antibody technology platform with a promising antibody in development for RSV (Sym003), still in the pre clinical stage.

Therapure - TBI 304 is a monoclonal antibody that mimics the natural ability of hemoglobin to stimulate stem cells to produce red blood cells. TBI 304 is in the preclinical stage. (Link)

ThromboGenics - TB-402 is a novel human antibody which partially blocks Factor VIII, an essential blood clotting factor. Reported positive Phase 2 data. ThromboGenics and its partner BioInvent plan to out-license TB-402 for its later stage development and commercialization. Currently dosing a P2b study. (Link)

Tracon Pharma - TRC105 is a human chimeric monoclonal antibody that binds CD105 (or endoglin), a target that is essential for angiogenesis. A Phase 1 trial of TRC105 for patients with advanced cancer is nearly complete and a Phase 1/2 trial of TRC105 for patients with prostate cancer is ongoing. (Link)
Viventia - Vicinium® has VB4-84, a humanized, single-chain antibody fragment specific for the EpCAM antigen. The antibody fragment is recombinantly fused to a truncated form of Pseudomonas exotoxin A, ETA(252-608), engineered to lack the cell binding domain, but to retain the active domains necessary to induce cell death. Has done well in Phase 2a studies in bladder cancer. (Link)

NEW Wilex - RENCAREX (INN: Girentuximab) is a targeted antibody for the treatment of solid tumours and binds specifically to the protein carbonic anhydrase IX (CA IX) expressed on the tumour cells, thereby triggering an immune reaction called Antibody-Dependent Cellular Cytotoxicity (ADCC). CA IX is expressed in over 90% of all clear cell renal cell carcinomas (ccRCC), but not expressed in normal kidney tissue. RENCAREX is currently in a pivotal Phase III trial with 864 patients in over 140 centres in 14 countries as an adjuvant therapy of patients with non-metastatic clear cell renal cell cancer (ccRCC).

Xencor - Developing an anti-CD30 (XmAB 2513) antibody for Hodgkin’s disease and T-cell lymphoma. Has finished Phase 1. (Link)

Xoma - XOMA 3AB, is a biodefense anti-botulism antibody candidate in Phase 1 studies.

Y’s Therapeutics - Anti-CD26 Humanized Monoclonal Antibody for solid tumors. Phase 1 ready.

YM Biosciences - Is developing an EGFR antibody targeting HER1, Nimotuzumab, for solid tumors. Late stage and on the market in developing countries. Believes that this drug could be introduced to the U.S. market in the next few years, depending on Cuba policy.

**ANTI-INFECTIVES**

2M Biotech - CBR-2092, a rifamycin-quinolone hybrid antibiotic, has been evaluated in two Phase 1 human studies. Based on data from animal models, CBR-2092 represents a unique agent for the treatment of MRSA. (Link)

Achaogen - Achaogen’s lead compound, ACHN-490 has displayed efficacy in research and nonclinical studies against systemic infections caused by multi-drug resistant (MDR) Gram-negative bacteria. Safety Phase 1 data at ICAAC looked good. Phase 2 studies are planned. (Link)

UPDATE Affinium Pharmaceuticals - AFN-1252 is a potent inhibitor of bacterial fatty acid biosynthesis under development (in Phase I) as an oral treatment for drug resistant staphylococcal infections like MRSA. This product was recently reformulated into an oral tablet form prior to starting a new Phase 1 study in October 2010. Update: Company raised $15mm in August 2011 and is launching a Phase 2 study with first patient dosed in Feb 2012. (Link)

AmpliPhi - Formerly Targeted Genetics. Preparing for a Phase 3 trial of Biophage-PA for the treatment of otitis media. Also effective in cystic fibrosis. Biophage-PA is a mixture of six bacteriophages that destroy Pseudomonas aeruginosa. Bacteriophage or phages are naturally occurring viruses that consist of an outer protein hull enclosing genetic material. (Link)

NEW Aridis Pharma - intravenous gallium nitrate citrate in cystic fibrosis patients in a Phase 1 study shows acceptable safety profile and suggestion of a biologic response with microbiology and lung function changes.

UPDATE Basilea - Ceftobiprole is a cephalosporin for the treatment of the increasing number of patients with severe methicillin-resistant Staphylococcus aureus (MRSA) infections. Has completed Phase 3 studies. Looking for a partner. Will apply in the second half of 2012 for approval of its antibiotic ceftobiprole in Europe. Also open to licensing rights to Isavuconazole for invasive fungal infections.
BioAlliance Pharma - searching for a U.S. Partner for Oravig. Oravig is miconazole buccal tablets for the treatment of oropharyngeal candidiasis (OPC), more commonly known as thrush, in adults and children age 16 and older. This drug was returned by Strativa Pharmaceuticals recently to BioAlliance.

BioRelix - BioRelix uses RiboSwitches as a new class of anti-infectives. (Link)

**UPDATE** Cempra Pharmaceuticals - Taking CEM-101 a highly potent macrolide into a Phase 3 trial in CABP after reporting positive Phase 2 data in March 2012. CEM-101 is active in vitro against M. pneumoniae, M. hominis and Ureaplasmas, including macrolide-resistant strains. Went public in Feb 2012. Open to partnering discussions. (Link)

Cempra - preparing CEM-102 (Fusidic Acid or Taksta®) for Phase 3 studies that is designed to show non-inferiority to linezolid in patients with acute bacterial skin and skin structure infections. (Link)

CG Pharmaceuticals - CG400549 is a potential first-in-class antibiotic targeting ENR (Enoyl-acyl carrier protein reductase) or FabI (Fatty acid biosynthesis type I). It is being developed for MRSA and VRSA. CG400549 recently completed Phase I studies in Europe and Phase 2a study will be initiated soon.

**UPDATE** Destiny Pharma - Novel antibiotics based upon dicationic porphyrins. XF-73 has shown safety and preliminary efficacy against MRSA. Has begun Phase 1 studies. (Link)

**NEW** Durata – completing a final Phase 3 study for Dalbavancin, a broad spectrum, relatively safe hospital antibiotic. Durata filed to go public in March 2012. (Link)

Enanta - Developing once a day bicyclolide (modified macrolides azithromycin) like for community acquired infections and hospital based MRSA. (Link)

F2G - FG3622 is currently in Phase 1 with a novel broad spectrum antifungal. (Link)

Furiex - regained rights to broad spectrum quinolone from J&J in May 2011. Interested parties should contact Sailash.Patel@furiex.com. (Link)

**NEW** Great Lakes Pharma – developing a catheter lock solution called B-Lock with high efficacy in the prevention of MRSA and other infectious disease from catheters.

IASO Pharma - developing zabofloxacin, a fluoroquinolone antibiotic, for Community Acquired Pneumonia. (Link)

Inimex - IMX942 is a broad spectrum immune defense activator in Phase 1 that targets bacteria such as methicillin-resistant Staphylococcus aureus (MRSA) or vancomycin-resistant Enterococcus (VRE). (Link)

Italfarmaco, ITF-2534 is a triazole enantiomer for fungal infections. This drug has completed a Phase 1 trial.

**NEW** Jina Pharma - Lipid based Amphotericin B Gel is indicated in acute, chronic and recurrent type of skin fungal infection and cutaneous leishmaniasis. Provides specificity to target fungal cells. Has longer PK than approved products such as Ambisome®. (Link)

Kenta Biotech - Outlicensing antibodies for HAP and pseudomonas infections, KBPA101 has completed Phase 2a studies and reported 100% survival in hospital-acquired pneumonia.

**UPDATE** Lytix Biopharma AS - Novel ultra-rapid bactericidal antimicrobial agent capable of killing highly resistant bacteria. Broad spectrum of action, Gram +, Gram -, fungi and yeasts. Two recent Phase 1b studies showed that this product was effective in the treatment of nasal MRSA / MSSA (methicillin-resistant and methicillin-sensitive Staphylococcus aureus) bacteria and in the treatment of Gram+ skin infections. (Link)
Mayne Pharma - Lozanoc™ (SUBA®-itraconazole) is an improved patent protected formulation of itraconazole to treat fungal infections. The bioavailability of SUBA®-itraconazole is twice that of the originator product (Sporanox®) and shows reduced intra- and inter-subject variation. A Marketing Authorisation Application (MAA) in the EU has been submitted (November 2010) and discussions with the FDA are underway regarding further requirements for 505(b)2 filing and US registration. Interested parties should contact andrew.dunbar@maynepharma.com.

McMaster University - Outlicensing a novel class of streptogramin antibiotics (Link). Preclinical.

Merlion - Developing finafloxacin, a best in class 4th generation fluoroquinolone being targeted against severe, life-threatening infections. Compound has successfully progressed through to mid-stage clinical development. Oral formulation demonstrated in PoC studies compelling efficacy in uncomplicated UTI and the eradication of Helicobacter pylori. IV formulation currently completing Phase I trials and Phase II studies in complicated UTI are planned for late 2011, as are clinical protocols in complicated respiratory tract infections. (Link)

UPDATE Methylgene –Developing oral Hos2 antifungal compound. MGCD290 targets the fungal Hos2 enzyme and was designed to be co-administered with azoles, in particular fluconazole, to potentiate and enhance activity against fungal infections. In a large Phase 2 trial against vaginal yeast infections. (Link)

Nabriva Therapeutics - Finished Phase 2 with BC-3205, is an oral pleuromutulin agent with activity against gram positive and gram negative bacteria and atypicals. Positive data reported out.

Nabriva Therapeutics - BC-7013 is a topical antibiotic active against resistant Gram-positive pathogens, including MRSA. It has completed Phase I. Company interested in partnering in second half of 2012.

NEW Pacgen - Reported positive results from its Phase IIb dose-ranging clinical trial for its lead product candidate, PAC-113, a novel anti-fungal drug for the treatment of immunocompromized patients. The Phase IIb study, which involved over 200 seropositive HIV patients, demonstrated that PAC-113 efficacy profile compares favorably to the efficacy of Nystatin, a current standard of care for topical treatment of oral Candidiasis. (Link)

Palau Pharma - Phase 2b trials complete for oral anti-fungal product, albaconazole in onychomycosis. Has also been in trials for vulvovaginal candidiasis and tinea pedis. (Link)

UPDATE Paratek Pharmaceuticals - Broad spectrum antibiotic with IV and oral forms for treatment of moderate to severe resistant and susceptible skin, respiratory tract and urinary tract infections typically requiring hospitalization. Phase 2 and 3 studies in cSSSI concluded. Registration trials planned and company received an SPA from the FDA in late March 2012. This product was returned by Novartis despite impressive data. Interested parties welcome to contact Dennis Molnar, Vice-President, Corporate Development (dmolnar@paratekpharm.com).

UPDATE Pergamum - Antimicrobial peptide DPK-060 to treat and prevent skin infections; lead indication skin infections (atopic dermatitis). Clinical Phase I/II, proof-of-concept study successfully completed. A Phase 2 trial in Swimmer’s ear was initiated in Jan 2012.

Phage Biotech - Preclinical work on phages as antibiotics. (Link). Also see related Biocontrol (Link).

UPDATE Polymedix - PMX-30063 is a novel Phase 1 broad spectrum amphiphilic antibiotic. Works as a mimetic of host defense proteins. Recently reported positive Phase 1 data and now in Phase 2 trials for cSSSI from staph aureus. Phase II data in patients with acute bacterial skin and skin structure infections (ABSSSI) showed that PMX-30063 led to similar clinical response rates compared to daptomycin, but was associated with more adverse events. Interested parties are welcome to contact shelmling@polymedix.com (Steffen Helmling, VP Business Development). (Link)

Polyphor - Looking to outlicense POL7080 which is a PEM compound with selectivity for Gram-negative bacterial strains, and for Pseudomonas in preclinical models. In Phase 1 studies.
Recombinogen - Outlicensing Rumycins which is in the pre-clinical stage – calcium dependent lipopeptide antibiotics. (Link)

UPDATE Rempex - planning to file an NDA in 2012 for an undisclosed antibiotic that shows high efficacy versus a tough to treat hospital infection type. In addition, the company is in Phase 1 with a very promising treatment for gram negative infection. (Link)

UPDATE Rib-X Pharmaceuticals - Developing Delafloxacin (next gen quinolone) and radezolid (oxazolidinone). Both in Phase 2 with impressive data. Looking to partner one or both compounds. Update: Rib-X has filed to go public and has recently set a pricing range. (Link)

Sequella - SQ109 also has excellent activity against H. pylori, and can kill 99.99% of these bacteria with concentrations easily achievable in stomach contents and tissues. Beginning a Phase 2 study. Also active against TB. Recently licensed rights to Russia and CIS. (Link)

TaiGen - In Phase 2 development Nemonoxacin, a novel quinolone, in MRSA/CAP infections for U.S. and China markets. (Link).

UPDATE Tetraphase Pharmaceuticals - Tetracyclines for using novel synthetic chemistry. Recently reported Phase 1 data for TP-434 activity in humans. Update: received a $67mm BARDA grant in Feb 2012. (Link)

Theravance - TD-1792 is a heterodimer antibiotic that combines the antibacterial activities of a glycopeptide and a beta-lactam in one molecule. In Phase 2, gets positive results. Interested parties should contact crogers@theravance.com.

NEW Theravance – Has full commercial rights to Vibativ (Televancin), an approved product, for the treatment of skin infections caused by MRSA and MSSA gram positive bacteria. This product was previously marketed by Astellas and was returned to Theravance in January 2012. Sales of Vibativ in Q4 2011 were $1.6 million. (Link)

Third Stream Bioscience - Developing a novel skin antimicrobial based upon a chemical composition developed by Procter & Gamble. Promising data in dermatology (acne) and a variety skin cleansing applications. Company is in an active sellside process. (Link)

Toyama - T-2307 is a novel broad spectrum antifungal which has shown potent activity against Candida and Aspergillus as well as Cryptococcus, for which few drug therapies are available. In Phase 1.

Trius Therapeutics - In Phase 3 with Torezolid phosphate, a second generation oxazolidinone antibacterial prodrug that is a potent inhibitor of Gram positive bacterial pathogens including MRSA. Company went public in 2010 and has a market cap of approximately $198mm. In a July 2011 deal, Bayer will commercialize torezolid in China, Japan and all other countries in Asia, Africa, Latin America and the Middle East. (Link)

COMPLETED $ Undisclosed - two marketed antibiotics in U.S. One is facing generic competition. Revenues total around $10mm. On March 7, 2012 Cornerstone Therapeutics announced the divestiture of product rights to Factive® (gemifloxacin mesylate) tablets and the Spectracef® (cefditoren pivoxil) family of products in a series of transactions with Merus Labs International Inc. and Vansen Pharma Inc.

$ Undisclosed - large pharma disposing of a marketed antibiotic with global rights. This product is off patent.

$ Undisclosed - marketed antifungal with revenues > $10mm. Hospital setting is where generally used.

University of Western Ontario - Novel antifungal agent with strong pre-clinical efficacy versus cindas. (link)

UPDATE Ventria - has developed a recombinant lactoferrin for the prophylaxis and treatment of infection in prematurely born children. Positive POC dataset for this product reported in March 2012.
Zurex - Zuragen used for prevention of catheterrelated bloodstream infections. Potentially of high value in the hospital setting. ([Link](#))

**BANKRUPTCY AND RESTRUCTURING SITUATIONS**

Altea Therapeutics - has agreed to shutter its operations according to a story published in the *Atlanta Business Chronicle* on Dec 9, 2011 ([Link](#)). Atlanta-based Altea Therapeutics Corp. was developing a proprietary, noninvasive method to deliver therapeutic proteins, conventional drugs and vaccines through the skin by creating “micropores” on the skin’s surface.

**NEW** Archemix – has gone into liquidation and has distributed assets back to investors.

Aryx Therapeutics - ATI-2042, an improved amiodarone like molecule, for reduction of atrial fibrillation. Also has tecfararin - an anticoagulant. GI candidate with promise. Update: Feb 19, 2010: Company retained Cowen to explore strategic options. Dec 15, 2010: “Over the course of the strategic process ARYx initiated earlier this year, the most significant interest, even in the absence of a binding offer, was shown in ARYx’s gastrointestinal product candidate, naronapride (ATI-7505), demonstrating the potential value of the asset. Also, interactions with the US Food and Drug Administration (“FDA”) in April 2010 substantially clarified the remaining clinical development requirements for the compound. As a result, the lead investors in ARYx encouraged the company to seek substantial additional funding to continue the development of naronapride internally, and such funding has been actively pursued since late summer without final resolution.” Company close to default on debt. Update: March 2011 - company went into a wind down of its operations. ([Link](#))

**UPDATE** Bionovo - Looking to partner a SERM with promising Phase 2 data for hot flashes. This is based upon a botanical product. Does not bind to estrogen receptor alpha. The company’s Phase 3 trial of this drug was halted on March 30, 2012 due to a lack of company funding. ([Link](#))

Ceragenix - in Chapter 11 bankruptcy with a skin cream and assets in the anti-infective area. ([Link](#))

**NEW** Cytos Has restructured its convertible bonds in Feb 2012 and is now pursuing a search for “strategic solutions”.

**NEW** Emisphere has a promising oral Vitamin B12 drug that is approved but reported in March 2012 that it does not have enough cash to make it through its Sep 2012 convertible bond payment. The company also has a promising platform technology and oral insulin collaboration with Novo Nordisk.

Orbus Pharma - Canadian generic drug maker is in bankruptcy. Has a variety of generic CNS drugs on the market. ([Link](#))

Undisclosed player - dermatology company with more than $40mm in revenue has hired a financial advisor to restructure its debt that likely exceeds intrinsic value of assets. Process has been underway for a month or two.

**COMPLETED** Vion Pharmaceuticals - Received an approvable letter for Onrigin, a late stage alkylating agent. Has > $15mm in cash but $60mm in debt. Filed for Chapter 11 bankruptcy and is being advised by Roth Capital. FDA has made it clear that a randomized Phase 3 trial will be required. Update: Nanotherapeutics acquires the compounds of Vion in 2011.

Vytexis - has closed operations. Several programs are in development at this company including patch products for women’s health and pain applications.

**BIG PHARMA / BIG BIOTECH PROGRAMS FOR OUTLICENSING**

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Biogen Idec - Looking to outlicense Galiximab, an anti-CD80 antibody, which has shown activity in B-cell lymphomas. Has gone through Phase 3 trials. Biogen looking to outlicense after a recent strategic review. (Link)

Biogen Idec - looking to outlicense BIIB021, an HSP90 modulator, targeted for GIST. (Link) (Link2). Also outlicensing BIIB028, an HSP90 modulator that is in Phase 1 studies.

Biogen Idec - looking to outlicense Volociximab, a chimeric monoclonal antibody that inhibits the functional activity of a5β1 integrin, a protein found on activated endothelial cells. Blocking the activity of a5β1 integrin has been found to prevent angiogenesis. This product is jointly owned with Abbott’s Facet Biotechnology. (Link)

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Biogen Idec - looking to outlicense an anti IGF1-R antibody for solid tumors. Has progressed into Phase 2 studies. (Link)

COMPLETED GlaxoSmithKline - running a process to divest non-core OTC brands with assistance from Goldman Sachs. The products to be divested, which are primarily sold in Europe and the United States, had sales in 2010 of approximately £500 million, 10% of GSK’s total Consumer Healthcare turnover. They include analgesics: Solpadeine, BC and Goody’s; vitamin and supplement product Abtei; feminine hygiene treatment Lactacyd; and alli for weight management. Reuters Update on Nov 14, 2011: “GlaxoSmithKline is assessing final bids for a clutch of its non-prescription drugs, keeping the process on track for the selection of a buyer by the end of the year, people familiar with the matter said on Monday.” Transaction completed in a sale of U.S. brands to Prestige Brands in Jan 2012, EU brands to Omega Pharma in March 2012 and other brands to Aspen Pharmacare in April 2012. Total consideration received was £425mm with revenue multiples in the 2-3X range. (Link)

UPDATE Ipsen – Completed a strategic review in 2011 with the theme of increasing focus and growing the footprint. The implications of this for potential partnerships or asset divestitures are threefold: (1) Ipsen looking for a partner in the French primary care arena, (2) Ipsen looking to find a buyer for its industrial site in Dreux France which makes solid dose and liquid formulations and (3) “Ipsen will explore all options to maximize value (of its short stature franchise) while meeting its obligations to patients and partners. It will be managed directly by regions and countries.” Update: Ipsen sold off the rights to Apokyn in the U.S. for over 1X revenues on Nov 2, 2011. In a February 2012 investor update, the company emphasized goal of partnering French primary care business.

COMPLETED Pfizer - has sold its nutritional business to Nestle in April 2012 for $11.5 billion. It is believed that the vet medicines business is most likely to be spun out.

NEW Prestige Brands – major OTC marketer has received an offer from Genomma for acquisition at $834mm in Feb 2012.

Sanofi / Genzyme - Outlicensing RDP58 (Delmitide), a clinical-stage D-amino acid decapetide with established anti-inflammatory properties. Proof of concept for this product opportunity has been demonstrated in models of inflammatory bowel disease (IBD).

Sanofi / Genzyme - Outlicensing tolevamer for CDAD which is in Phase 3 studies but missed the primary endpoint. (Link)

Sanofi / Genzyme - Looking to outlicense Genz-29155, a novel, small molecule, orally bioavailable, 1x daily novel inhibitor of TNF-α signaling. Proof of concept has been demonstrated in multiple models of transplantation rejection, multiple sclerosis (MS), sepsis, inflammatory bowel disease (IBD) and lupus. (Link)

$ Undisclosed - large pharma disposing of a marketed antibiotic with global rights. This product is off patent.
$ Undisclosed - large pharma disposing of a marketed oncology drug for NHL with revenues of around $5mm. Significant barriers to entry.

$ Undisclosed player – approved hospital anesthetic in the United States with differentiation from existing products. Also could be used in physician office setting where sedation required. Open to a product sale or other value creating arrangement. Global rights available.

Undisclosed - Large Pharma disposing of several late stage compounds for treatment of depression.

Undisclosed - Large Pharma disposing of several late stage compounds for treatment of hyperlipidemia.

Undisclosed - Pharma disposing of more than 20 compounds including several with commercial rights in EU and Asia.

NEW Undisclosed - Migraine asset – Phase 1b drug candidate in prophylactic migraine.

NEW Undisclosed – Bundle of ophthalmology assets in Phase 1 –3 of development.

NEW Undisclosed – Group of reproductive health drugs in development.

NEW $ Undisclosed – Big pharma selling mature cardiovascular product with sales of around $5mm.

Undisclosed - Pharma disposing of large mature product. Off patent with revenues over $80mm.

Undisclosed - pharma company is open to divesting a marketed specialty cardiology product with revenues > $30mm per annum.

Undisclosed - Large pharmaceutical company interesting in outlicensing a late stage program in wound care.

Undisclosed player - Partnering a Phase 2 progesterone modulator for uterine fibroids and endometriosis.

**BIGGER DEALS ($200MM+ IN VALUE)**

NEW Achillion - ACH-1625, a Phase 2 pan-genotypic protease inhibitor, has shown strong activity against HCV genotype 1 and 3. The company is also developing ACH-3102, a second generation NS5A inhibitor. The company’s CEO Michael Kischbach indicated that they are in “advanced discussions” with potential partners and acquirors.

COMPLETED Actavis – A number of media reports suggest a likely acquisition of this global pharmaceutical company by Watson for $5-6 billion. Update: Watson announced this acquisition on April 25, 2012.

UPDATE Abdi Ibrahim Ilac - largest Turkey drug maker with revenues over $800mm. Reported in May 2011 that was in discussions to sell a strategic stake. As of April 2012 it is understood that these discussions have not borne fruit.

UPDATE Akebia – Positive Phase 2 with a HIF modulator for the treatment of anemia. Originally developed at P&G Pharma. Company reported positive Phase 2 data in pre-dialysis CKD patients in April 2012. At a recent conference, its spin-out company Aerpio indicated that a change of control transaction is likely in 2012. Interested parties should contact Bill Daly (wdaly@akebia.com). (Link)

COMPLETED Allos Therapeutics – Oncology marketer with Folotyn® for liquid tumors. After a recently failed merger attempt with AMAG, Allos is rumored to be continuing to explore strategic alternatives with the assistance of JP Morgan. Update: Apr 5, 2012 – Spectrum to by Allos in a deal valued at $206 million. (Link)

$ AMAG - Feraheme IV iron product - Recently approved. Company is commercializing on its own. AMAG’s recent merger attempt with Allos was ended in November 2011. On Nov 17, 2011, AMAG announced that it had hired
Jefferies to explore all opportunities to enhance shareholder value. Frank Thomas, interim CEO of AMAG indicated: “We will expeditiously complete this process, which will include a parallel review of a potential sale of the company and other strategic merger and acquisition transactions.”

**UPDATE** Amarin - Developing a pure omega-3 for reduction of triglycerides. Phase 3 data reported out very strong. Company has indicated that is has retained a financial advisor (Lazard) to explore a sale. Amarin is well positioned to be a takeover candidate in 2012 – particularly with recent clarity on its patent position and April 2012 media reports have rumored a pending transaction. (Link)

Amoun Pharmaceutical - An Egyptian company that manufactures off-patent branded generic formulations. It is one of the largest pharmaceutical companies in Egypt. It sells over 135 human products in over 275 forms. Of these products, 33 occupy the top 2 positions in their respective therapeutic categories and subcategories. Open to a company sale or strategic stake purchase. Reuters - Dec 6, 2010: “CVC is also preparing to sell Amoun, one of Egypt’s biggest drugmakers, people familiar with the matter told Reuters on Oct. 20. It owns Amoun with two other co-investors.” Bloomberg reported in Feb 2011 that the company has been looking for $1 billion in a sale price but that political upheaval in Egypt has hindered the sale.

**NEW** Amylin – marketer of Byetta® and Bydureon® for the treatment of diabetes has reportedly received an offer from Bristol-Myers Squibb and, according to Bloomberg in mid-April 2012 has hired a financial advisor to help find a buyer. Separately, Amylin is interested in finding a partner outside of the U.S. to distribute its products.

$ Avanir - Launched Neudexta for the treatment of pseudobulbar effect and, potentially, other indications. Positive data and good patent picture. Widely rumored to be an M&A candidate. $5.7 million in revenue in first year of launch (soft numbers). Market cap of $248 million as of November 2011. EMA application recently accepted.

Biofarma - Biofarma for sale via JP Morgan. Reuters (12/6/2010): Citigroup’s (C.N) venture capital arm and two co-investors have begun an auction of Turkish copycat drugmaker Biofarma, three people familiar with the matter said, in what could be Turkey’s biggest healthcare deal.” Update: A number of parties rumored to have looked at this asset but price ask was seen as prohibitive. As of Nov 2011 no sale had taken place.

**UPDATE** Covidien Pharmaceuticals - According to the New York Times on June 7, 2011 “Covidien, the health care company spun out from Tyco four years ago, may seek to sell its pharmaceutical unit...” This division of Covidien (formerly Mallinckrodt) has a major business selling pain products (both branded and generics) and imaging products. Revenues are around $2 billion. Update: As of April 2012 no sale has taken place. Company is rumored to be interested in a sale of the whole business (rather than pieces) for a full price and is now thought to be more likely to be spun out. YE 2011 numbers reported on Nov 15, 2011 and were robust (sales up 9% yoy) with strong performance in generics.

Exelixis - According to Bloomberg on April 12, 2011: “Exelixis Inc. is working with Goldman Sachs Group Inc. to prepare for potential takeover offers after its experimental drug helped prostate-cancer patients in a study.” Company’s XL-184 has reported dramatic data on reducing metastatic prostate lesions at ASCO. Update: company has hired a Chief Commercialization Officer with intention to introduce cabozantinib to the U.S. market and has reported strong data for cabozantinitib in the treatment of medullary thyroid cancer.

**COMPLETED** Gen-Probe - Widely rumored to be for sale with interest from Novartis. Well known diagnostics company. Process well underway but company viewed as expensive. Update: Wall Street journal reports on July 20, 2011 that “Novartis is no longer actively pursuing U.S. medical diagnostic-testing company Gen-Probe, meaning Gen-Probe could end its sales process...” Update: Apr 2012 – Hologic buying Gen-Probe for $3.7bn.

**COMPLETED** GlaxoSmithKline - running a process to divest non-core OTC brands with assistance from Goldman Sachs. The products to be divested, which are primarily sold in Europe and the United States, had sales in 2010 of approximately £500 million, 10% of GSK’s total Consumer Healthcare turnover. They include analgesics: Solpadeine, BC and Goody’s; vitamin and supplement product Abtei; feminine hygiene treatment Lactacyd; and alli
for weight management. Reuters Update on Nov 14, 2011: “GlaxoSmithKline is assessing final bids for a clutch of its non-prescription drugs, keeping the process on track for the selection of a buyer by the end of the year, people familiar with the matter said on Monday.” Transaction completed in a sale of U.S. brands to Prestige Brands in Jan 2012, EU brands to Omega Pharma in March 2012 and other brands to Aspen Pharmacare in April 2012. Total consideration received was £425mm with revenue multiples in the 2-3X range. (Link)

Hi-Tech Pharmacal - Market rumors in April 2011 that company could be purchased. As of April 2012 no transaction had taken place of this manufacturing company of generic liquids and ointments. The company has delivered strong earnings in the last year and has been trading well above its earlier share price.

NEW Human Genome Sciences – Received an unsolicited takeover on April 19, 2012 offer from partner GlaxoSmithKline for $13 per share, or about $2.6 billion in cash. Human Genome, which said the offer did not reflect its “inherent” value, retained Goldman Sachs and Credit Suisse to assist in exploring strategic alternatives, including a potential sale.

Intermune - Bloomberg reports on April 27: “Biotechnology company InterMune Inc known for its drug to treat lung scarring, hired Goldman Sachs (GS.N) to help it weigh a possible sale... Goldman has been conducting an auction of InterMune for more than a month and some potential bidders have been spooked by the biotechnology company’s expectations for a sale price, Bloomberg news reported.” Company commercializing Pirfenidone in Europe.

UPDATE Ipsen – Completed a strategic review in 2011 with the theme of increasing focus and growing the footprint. The implications of this for potential partnerships or asset divestitures are threefold: (1) Ipsen looking for a partner in the French primary care arena, (2) Ipsen looking to find a buyer for its industrial site in Dreux France which makes solid dose and liquid formulations and (3) “Ipsen will explore all options to maximize value (of its short stature franchise) while meeting its obligations to patients and partners. It will be managed directly by regions and countries.” Update: Ipsen sold off the rights to Apokyn in the U.S. for over 1X revenues on Nov 2, 2011. In a February 2012 investor update, the company emphasized goal of partnering French primary care business.

Meda - A Wall Street Journal Report on July 27, 2011 indicated that Valeant had approached Meda about a takeover offer. Meda responded indicating that its board of directors had not received an approach of the kind reported in the WSJ.

COMPLETED Mustafa Nevzat - Turkish generic pharmaceutical maker with revenues of approximately $250mm. According to Bloomberg (Jan 31, 2012), in talks to sell a strategic stake with help from Bank of America Merrill Lynch. Update: Amgen Inc. said it will acquire 95.6% of Mustafa Nevzat Pharmaceuticals A.S. (Istanbul, Turkey) in a cash deal that values the Turkish pharma at $700 million on April 25, 2012.

UPDATE Onyx - rumored to be exploring strategic alternatives. Substantial value potential tied to a recently filed NDA for carfilzomib, a protease inhibitor, for the treatment of liquid tumors including multiple myeloma. Market rumors of an acquisition in April 2012.

Par Pharmaceuticals - Relational Investors filed a 13D showing 8.7% ownership of this company on November 25, 2011. In the 13D Relational indicated: “Despite these opportunities for improvement, the Reporting Persons believe that the Company may continue to trade at discounted prices because of industry challenges and the Company’s sub-optimal size and product scope. If the discount persists, the Reporting Persons believe that, in keeping with sound stewardship principles, the Company’s board will be required to consider broad strategic alternatives. Specifically, the Reporting Persons are confident that substantial cost savings could be achieved in a transaction with a strategic buyer.” Note: there is no evidence that Par Pharmaceuticals has received offers or is open to receiving such offers at present.

COMPLETED Pfizer - has sold its nutritional business to Nestle in April 2012 for $11.5 billion. It is believed that the vet medicines business is most likely to be spun out.
Qualicaps - owned by Carlyle. Maker of gelcaps (like Capsugel) is up for auction. UBS is rumored to be sellside advisor on business with approx. $350mm in EBITDA. As of June 2011 no sale had taken place.

**UPDATE** Riemser - German vertically integrated marketer of generic and branded pharma products with strength in cardiovascular, dental and veterinary medicines. Revenues of this company exceed €100mm and EBITDA around €30mm. Active sale process underway according to Biopharm Insight.

**UPDATE** Rottapharm - for sale according to the Wall Street Journal. Company has two Phase 3 drugs in development and a strong group of branded products in the market. Revenues over $850 million. Sale price could be over $2.5 billion. Company rumored to be using Credit Suisse to find a buyer. According to Bloomberg (3/15/2012) Mylan recently pulled out of a sale process. The article noted that “sources said the selling family has not been able to agree to give up control of the company and was not prepared to compromise enough on price either.”

San Raffaele del Monte Tabor - privately-held Italian pharmaceutical company, is soliciting offers other than the EUR 350m binding offer from Vatican bank IOR and Italian entrepreneur Vittoria Malacalza, according to Il Sole 24 on Dec 2, 2011.

Savient Pharmaceuticals - FDA approved KRYSTEXXA (pegloticase) in Sep 2010, a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Company is seeking a commercial buyer and is using JP Morgan and Lazard in its search for an acquisition partner. Savient is now pursuing a launch of Krystexxa on its own and is building a 50-person plus sales force. ([Link](#))

Sigma-Tau - Reuters (6/2/11): “Italy's Sigma-Tau is eyeing the sale of up to 49 percent in the family-owned drugmaker to private equity, ahead of a possible IPO that could value it at more than $2 billion, people familiar with the situation said.” Company has approximately €1bn revenue with a strong rare disease business and a well established European brand business. It is believed that discussions regarding a stake sale are no longer active but rather the company is focused on restructuring its Italian business.

Stada - Chief executive Hartmut Renttzlaff indicated an openness to takeover offers after the recent sale of Ratiopharm.

**COMPLETED** Thrombogenics – completed Phase 3 studies for Microplasmin in Phase III clinical development for the non-surgical treatment of back of the eye diseases. Good evidence of efficacy with two positive Phase 3 trials reported. Expected to be on market by end of 2012. Would consider a sale. Note: Thrombogenics licensed the rights to this product to Alcon on March 16, 2012 for 75mm EUR upfront plus additional payments and royalties. Thrombogenics has retained the U.S. rights to this program and intends to self-commercialize. ([Link](#))

**NEW** Undisclosed – dermatology player in the U.S. open to a change of control transaction. Revenues > $70mm.

**NEW** Undisclosed player – US cardiovascular specialty pharma company with revenue > $50mm and a hospital sales force is seeking a buyer with assistance from Lazard. Transaction expected soon.

**NEW** Undisclosed player – US hospital / critical care specialty pharmaceutical company is seeking a buyer

**NEW** Undisclosed player – US generics company with strength in injectibles and revenue > $80mm is seeking a buyer.

Undisclosed Player - U.S. generic company with approximately $90mm in gross revenue is searching for a buyer with the assistance of a financial advisor. Company has substantial presence in medicines for cough & cold, womens health and pediatrics.

**COMPLETED** Undisclosed Player - U.S. generic company with more than $100 million in revenues is for sale. Company has a significant branded business and a manufacturing facility. Note: Takeda acquired URL Pharma’s generic and...
branded businesses on April 11, 2012 for $800mm plus contingent payments. The revenues of URL were approximately $550mm.

$ Undisclosed player – US and European player in oncology and hospital products with revenue over $100mm is open to a change of control transaction. Note: EUSA Pharma was acquired by Jazz Pharma for approximately $700mm in April 2012.

Undisclosed player - Division of Indian generic company that is focused on oral solid dose preparations is for sale. Revenues over $300mm. Company has strength in formulation work and manufacturing. Ships product to numerous global locations.

Vivus - Looking to partner Qnexa in Europe and other ROW territories. An approval is possible in the EMA with long-term market exclusivity in mid-2012 (or sooner).

NEW Warner-Chilcott – According to Bloomberg in April 2012, Warner-Chilcott has retained Goldman Sachs to consider potential strategic approaches.

Wockhardt - rumored to be in a process to sell its substantial nutrition business as part of a process to pay down external debt.

BIODEFENSE

Cleveland Biolabs - Looking to partner a radiation antidote (CBLB502) with positive animal data.

Elusys - Has positive animal data for Anthim, a high-affinity humanized monoclonal antibody targeting the anthrax toxin protective antigen. Recently received a U.S. government contract for up to $143 million. In active strategic discussions. (Link)

PharmAthene - Protexia - BCHE functions as a natural bioscavenger, like a sponge, to absorb and degrade organophosphate poisons (e.g. nerve agents) before they cause neurological damage. Phase 1 studies were presented and good news so far. PharmAthene is developing Protexia in collaboration with the U.S. Department of Defense as a broad spectrum prophylaxis for the U.S. military. Company recently indicated that it is open to individual product deals despite not having a company level sale process. (Link)

UPDATE Soligenix - The company is looking to divest biodefense assets including vaccines for ricin toxin botulinum toxin and a product which protects against radiation exposure. Also developing orBec fro the treatment of acute GVHD. Process via HealthPro BioVentures.

Xoma - XOMA 3AB is a biodefense anti-botulism antibody candidate in Phase 1 studies.

BIOSIMILARS

NEW Bolder Biotechnology - BBT-015 is a long-acting G-CSF analog created using site specific PEGylation technology. BBT-015 has a unique structure and PK/PD profile compared to current G-CSF products. Issued patents in the U.S., Europe and Japan. GLP fermentation, purification and release assays in place. Pilot toxicology studies completed. Also developing an EPO and interferon Beta.

NEW Gedeon Richter – looking to outlicense a biosimilar to Neulasta.

Green Cross - In Phase 3 with a pegylated GCSF.

Hanmi Pharma - developing long-acting versions of EPO, GSCF, HGH and an exendin analogue.
ISU Abxis - Biosimilar to ReoPro for adjuvant of PCI (Percutaneous Coronary Intervention) procedure. Clotinab is anti-GPIIb/IIIa monoclonal antibody and Fab Protein which blocks platelet aggregation. On market in 7 countries. Also has biosimilar for Cerezyme.

LG Life Sciences - LGLS rhEPO received CTA approval from EMEA for phase 1 clinical study in EU. Successful pre-IND meeting with US-FDA in May 2011. Also developing a biosimilar of Humira® which is now in Phase 1 studies.

Undisclosed generic player - Looking for a partner for a portfolio generic biologics in development. Wants to retain manufacturing rights.

Undisclosed player – a number of emerging markets players are developing portfolios of generic injectable drugs including cytotoxics and anti-infectives.

Undisclosed player – promising portfolio of oncology biosimilar products in development. Interested parties should contact Lacerta Bio. (Link)

USV - offering a biogeneric PTH. Teriparatide is a recombinant form of N-terminal 1-34 amino acids of human parathyroid hormone which is a 84 AA protein. Approval pending in India. Also partnering a growth hormone and a PDGF product.

Zelos - A better PTH analogue. Strong Phase 2 data. Company also pursuing an intranasal PTH and a potential “biogeneric” PTH. (Link)

BONE AND SPINE / ORTHOBIOLOGICS

Abiogen - Neridronate is an amino-bisphosphonate used in Metabolic Osteopathy and has gone into Phase 3 trials. Also being studies for patients with thalassemias. (Link)

Ablynx - Has positive Phase 1b safety and efficacy data for a “nanobody” targeting RANK-L (compare to Amgen’s Prolia®). Dataset presented at EULAR in May 2011. (Link)

Accelalox - Use of locally delivered proteins to promote fracture healing. Promising osteobiologics company. (Link)

Anika - Introducing MONOVISC™ which is a single injection supplement to the synovial fluid of the osteoarthritic joint in order to provide symptomatic relief of joint pain. Contains sodium hyaluronate. Company also focusing on obtaining FDA clearance for three orthopedic products from FAB which are Hyaloglide, Hyalonect and Hyalofast by the end of Q1 2011. Anika intends to launch its own sales force for the orthopedic market for all of the above products. Note – Anika licensed the U.S. distribution rights to J&J on Dec 21, 2012. (Link)

Bacterin labs – substantial commercial traction of orthopedic product line. (Link)

Bio3 Research - HMGB1 for cartilage repair with promising preclinical results. (Link)

Biomimetic - Rumored acquisition target with injectible bone graft line based upon rhPDGF. PMA application pending and apparently in good shape. Looking for an ex-U.S. partnership. (Link) Ships augment bone graft to Canada. (Link)

BioTime - Using HyStem® hydrogels in the development of therapeutic products for the treatment of osteoarthritis, and plans to develop HyStem®-Rx as a cell delivery medical device to improve outcomes in cell transplant procedures, including reconstructive and cosmetic surgery. (Link)

Chiesi - CHF4227 - SERM for treatment of osteoporosis. Ready for Phase 2 studies.
**COMPLETED** Effrx - Effervescent alendronate. Solves problem of having to sit up for 30 minutes after taking Fosamax. Ex-US partnership via Nycomed. Filed for market approval in Europe. This product was partnered to Mission Pharmacal for U.S. distribution in April 2012.

**COMPLETED** Enobia - Developing **ENB-0040**, a human recombinant tissue non-specific alkaline phosphatase, for the treatment of hyperphosphatasia - a debilitating bone condition. Positive data in man. Update: Company has continued to report positive data and may be looking at a rapid approval with FDA. As a result, has not proceeded with potential M&A deal in light of value inflection ahead. Note: Alexion acquired Enobia for up to $1bn in Q1 2012.

Ferring - Outlicensing a PTH analogue for osteoporosis. Pre-clinical. ([Link](#))

Kaken - KCB-1B is a Trafermin (rh-bFGF) product and under development for Bone Fracture in Japan.

Kuros Biosurgery - KUR-113 has shown strong efficacy in the treatment of open fractures in tibia patients. Study was a Phase 2b trial with 200 patients that reported out in April 2011.

Lexicon Pharmaceuticals - Pursuing **LX1031** for IBS. Could a potent agent for treating osteoporosis. Lexicon completed a Phase 2 clinical trial of LX1031 in patients with non-constipating IBS in November 2009. Company in active discussions on this and two other molecules.

Medi-Post - CARTISTEM® has been developed to treat damaged articular cartilage on knee as a result of acute traumatic injury or more chronic conditions such as osteoarthritis. Phase 3 clinical trial has shown efficacy in cartilage regeneration. KFDA approval pending. U.S. IND filing in process. ([Link](#))

Mesoblast - Preclinical trials showed that a single, low dose of Mesoblast's allogeneic adult stem cells into severely damaged intervertebral discs resulted in dramatic reversal of the degenerative process, regrowth of disc cartilage and sustained normalization of disc pathology, anatomy and function. ([Link](#))

Ono Pharmaceutical - Has completed Phase 2 studies with ONO-5334, a cathepsin K inhibitor for the treatment of osteoporosis. Open to an ex-Japan partnership transaction.

Sanos Bioscience - Promising Phase 2a data for a **GLP-2** for the treatment of osteoporosis.

**UPDATE** Tarsa Therapeutics - has reported positive efficacy and safety results from the Phase III ORACAL trial of its oral calcitonin tablet in the treatment of postmenopausal osteoporosis, and a Phase II osteoporosis prevention trial is underway. NDA filing pending. ([Link](#))

$ Tigenix – Launching ChondroMimetic and ChondroCelect in the EU, a collagen based implant for the treatment of small osteochondral lesions. In studies have seen restoration of the articular surface and integration with the surrounding bone and cartilage at six months in patients treated with ChondroMimetic. U.S. approval by BLA will require an additional study. ([Link](#))

Tokai Pharmaceuticals - **Semparotide**, a PTH, has been in Phase 2. Being developed for increasing osteoblasts in stem cell transplantation.

University of South Carolina - Preclinical binder of PTH1r - promising alternative to use of parathyroid hormone in treatment of bone loss. Supportive pre-clinical data. ([Link](#))

University of Western Ontario - Preclinical peptides which bind collagen and promote bone repair and regeneration in preclinical models. ([Link](#))

USV - offering a biogeneric PTH. Teriparatide is a recombinant form of N-terminal 1-34 amino acids of human parathyroid hormone which is a 84 AA protein. Approval pending in India.
Versalion Pharma - An osteotropic alendronate-b-cyclodextrin conjugate for treatment skeletal diseases, particularly stress fractures. The conjugate shows very strong binding to hydroxyapatite (HA, main component of the skeleton). Its ability in forming molecular inclusion complex with prostaglandin E1 (PGE1), a potent bone anabolic agent) was confirmed by phase solubility experiments and differential scanning calorimetry (DSC). (Link)

Zelos - A better PTH analogue. Strong Phase 2 data. Company also pursuing an intranasal PTH and a potential “biogeneric” PTH. (Link)

**CARDIOLOGY - PRIMARY CARE**

**NEW** Acasti – Pursuing novel Omega-3 Formulation CaPre™. Enrolling patients in a 429-patient 12-week Phase II mixed dyslipidemia study for which patient enrollment commenced in Q4/11 and for which blood lipid data could be available in H2/12.

**NEW** Aegerion - MTP-1 Adjunct therapy to statins for persons with familial hypercholesterolemia. Similar products in development at Japan Tobacco. Recently reported very strong Phase 3 data. High interest. (Link)

**NEW** Alder Bio - ALD306 is a potent, humanized monoclonal antibody that targets PCSK9. This is a late pre-clinical asset. For cardiovascular patients who have trouble reaching target lipid levels with statins, this therapeutic is a promising alternative for lipid control. PCSK9 has been genetically linked to cardiovascular disease. Eliminating this protein in humans has been shown to profoundly alter LDL-C levels in a therapeutically significant way in a number of recent studies. (Link)

**NEW** Alnylam - ALN-PCS is an RNAi Therapeutic Targeting PCSK9 for the Treatment of Severe Hypercholesterolemia. - PCSK9 Synthesis Inhibitor Achieves up to 84% Knockdown of PCSK9 and 50% Lowering of LDL Cholesterol in Single Dose, Statin-Free Phase I Trial in man. Compare to programs at Merck, Regeneron and Alder. (Link)

**UPDATE** Amarin - Developing a pure omega-3 for reduction of triglycerides. Phase 3 data reported out very strong. Company has indicated that is has retained a financial advisor (Lazard) to explore a sale. Amarin is well positioned to be a takeover candidate in 2012 – particularly with recent clarity on its patent position and April 2012 media reports have rumored a pending transaction. (Link)

Amulet Pharmaceuticals - Technology to deliver nitric oxide in conjunction with pharma treatments. Exploring a sale transaction.

**UPDATE** Anthera Pharmaceuticals— Varespladib is an inhibitor of secretory phospholipase in Phase 2 for prevention of arteriosclerosis. Failed to hit endpoint in a Phase 3 trial in March 2012. (Link)

**NEW** Aptalis - Nifedipine ER is a once-daily calcium channel blocker indicated for prophylaxis of chronic and stable angina and treatment of hypertension. Looking for a global marketing partner for this product. (Link)

**NEW** Ardelyx - developing non-absorbed compounds for the control of salt buildup and excess fluid retention. Related compounds in development at Sorbent Therapeutics. The potential market for this class of drugs in persons suffering from salt-related hypertension is very large.

**NEW** BioInvent - BI-204 is a monoclonal antibody targeting oxidised forms of LDL. It is believed to inhibit pro-inflammatory macrophages at the site of the atherosclerotic plaque, reducing inflammation and stabilizing plaque tissue prone to rupture and cause coronary artery disease. In March 2012 it announced that the Phase 2 trial of this drug is fully enrolled. Rights are partnered to Roche in North America but are held by BioInvent elsewhere.

BTG - Angiotensin Therapeutic Vaccine (ATV) for high blood pressure. This therapeutic vaccine (biologic) is in early Phase II clinical development. Large potential market as alternative approach to blood pressure management. (Link)
Carolus Therapeutics - **CT-2008** is a peptide antagonist of the RANTES-PF4 heterodimer which enhances leukocyte recruitment causing inflammation. Preclinical studies have demonstrated that therapeutics targeting the RANTES-PF4 heterodimer can slow the development of plaque in atherosclerosis-susceptible murine models. Also see Novimmune.

Cardax - Heptax, a preclinical compound, reduces cholesterol, triglycerides, blood pressure, liver enzymes, and fasting blood sugar while raising HDL. ([Link](#)) Update: Have been awarded two patents, one including (CDX-085).

**UPDATE** Cerenis Therapeutics - Looking to partner its synthetic apoA-1HDL product and a PPAR-delta (with Phase 1 data). Recently completed a financing to support further studies with the lead program. This company recently restructured moving most of its operations to France.

Cerenis Therapeutics - Would consider partnering a non-flushing niacin that has been through Phase 2 studies. Company recently reported positive data from these studies. ([Link](#))

Essentials - **Diazoxide choline controlled release** tablets for reduction of triglycerides and overall lipid profile. Strong Phase 2 data in reducing triglycerides. Now going into Phase 3 with an SPA for a single study to get to approval.

Furiex Pharmaceuticals - developing a muscle sparing statin, PPD 10558. In a preclinical study comparing PPD 10558 and a commonly prescribed statin, a high dose of the marketed statin caused severe muscle necrosis and increases in liver and kidney function tests and muscle enzyme (CK) levels while PPD 10558 did not demonstrate any such abnormalities. Update: Furiex discontinued development of this product on Dec 8, 2011 after this drug missed its primary endpoint. ([Link](#))

Intekrin - completed Phase 2 trials with **INT131** a PPAR gamma, the PPAR subclass predicted to be less likely to cause the side effects of TZDs. Looking to partner or M&A.

Japan Tobacco - Looking to outlicense JTT-130, an MTP inhibitor for cholesterol management, particularly hypertriglyceridemia. This compound has completed Phase 2 studies and has shown rapid clearance and activity in small intestine. These properties are likely to limit liver toxicity concerns associated with this drug class.

**UPDATE** KaroBio - Eprotirome is a novel, selective, thyroid hormone receptor agonist, developed for treatment of dyslipidemia. Successfully showed reduction in LDL in a recent Phase 2 study. Karo is in a Phase 3 EU trial to demonstrate a reduction on top of statins in familial hypercholesterolemia. Note: On Feb 14, 2012 this program was terminated after observation of cartilage toxicity events in animals. ([Link](#))

**NEW** Miragen – developing innovative microRNA modulators as is Regulus. Impressive preclinical deal in 2011 for ex US rights to a CHF program with Servier. This program has substantial IP protection and additional applications.

Nicox - developing a promising nitric oxide donating statin. High potential to supplement statin therapy.

**UPDATE** Omthera - pursuing Epanova in a Phase 3 study. Epanova is a patent protected, novel, ultra-pure mixture of the free fatty acid forms of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Behind Amarin in development but company claims to have a superior efficacy profile. Update: In Jan 2012 reported that had much higher bioavailability of serum omega-3’s with Epanova versus Lovaza. In April 2012 reported data that did not differentiate highly from Amarin compound. ([Link](#))

Quatrx - Several interesting drugs in dyslipidemia using TSH (thyromimetic) approach. Also see Karo.

**NEW** REGENX BioSciences is developing a therapy for familial hypercholesterolemia. The program uses NAV rAAV8 vectors that express a normal human low-density lipoprotein receptor gene.
Relypsa - positive Phase 2 data achieved for a potassium binder to treat hyperkalemia which is prevalent in persons with end stage renal disease and those with congestive heart failure. Company recently raised $70mm to get through Phase 3 studies of this promising treatment. (Link)

Thorne Research - HEP-40 Cholesterol binder that reduced LDL cholesterol by 17 points over a statin, on average, in a Phase 2 study. (Link)

Undisclosed player - has a promising non-flushing niacin.

$Undisclosed player – company with a marketed but not promoted cardiovascular product with 2011 revenues around $9 million.

UCLA - Selective inhibitor of M-CSF to reduce risk of atherosclerosis (link)

Undisclosed player - Phase 2 data on drug for raising HDL and lowering triglycerides. Novel mechanism and impressive safety profile. Seeking ex-U.S. partnership.

Veloxis - AtorPhen. Phase 2 low dose fenofibrate with atorvastatin. Also looking to partner rights to Fenoglise outside of the U.S.

UPDATE Vitae Pharmaceuticals - VTP-27999 is a novel, potent and selective renin inhibitor offering the potential for superior renal protection in patients suffering from chronic kidney disease. The compound is expected to enter Phase 2b in early 2012 and has shown impressive performance in studies to date. Recent issues with Novartis renin inhibitor are relevant to Vitae's prospects. (Link)

CARDIOLOGY - SPECIALTY CARE

Ablynx - ALX-0081 is a Nanobody targeting von Willebrand Factor (vWF), to reduce the risk of thrombosis in patients with acute coronary syndrome (ACS) and thrombotic thrombocytopenic purpura (TTP). Has been studied through Phase 1b. Phase 2 data are expected.

NEW Acino – has developed a fully registrable film tablet version of clopidogrel. (Link)

Action Pharma - AP214 finished Phase 2, a modified dMSH-peptide analogue, for the treatment of post-surgical kidney injury in the cardiac surgery context. The results demonstrate that AP214 is well tolerated and safe at all three dose levels. At the highest dose level, AP214 prevents the increase in serum creatinine by 50-60%, and in the IL-6 response by 30-40%, compared to placebo (trends based on blinded data). This is consistent with a robust effect to prevent postsurgical acute kidney injury (AKI) and systemic inflammatory response.

UPDATE Acusphere – Imagify is pending EMA filing for this cardiac imaging agent. Highly differentiated from SPECT agents on the market insofar as permits evaluating of myocardial perfusion, an important marker of coronary artery disease (CAD) without radioactive markers. Potential first-to-market drug in $600 million and $2 billion addressable market in E.U. and U.S. respectively. Recent SPA from FDA in US. Will require one further trial for FDA approval. Has recently raised additional capital to complete its approval.

NEW Advanced Accelerator Applications – Cardiogen is a Phase 3 PET tracer for the detection of coronary artery disease in a manner that is safer and less invasive than angiography. (Link)

Adventrx- ANX-188 is a novel, purified, rheologic and antithrombotic compound initially being developed as a first-in-class treatment for pediatric patients with sickle cell disease in acute crisis. Ready for Phase 3 studies and open to partnering deals.

Affimed - Affimed’s fully human antibody predominantly binds to the activated form of a receptor (GPIIb/IIIa) that plays a major role in the formation of blood clots. A better ReoPro. Company looking for a partner.
Aldagen - ALD-401 is a type of adult stem cell called aldehyde dehydrogenase-bright (ALDHbr), stem cells isolated from cord blood. ALD-401 is being developed for the post acute treatment of ischemic stroke and is in a Phase 2 study.

AnGeS MG - Japanese company is looking to partner Collategene, a therapeutic using hepatocyte growth factor (an angiogenic factor) which creates new blood vessels for the treatment of ischemic diseases. Positive Phase 3 data in treating PAD. An SPA has been agreed with the FDA for a Phase 3 trial of Peripheral Arterial Disease.

UPDATE ARCA - Gencaro (Bucindolol) is a nonselective beta-blocker which is being developed for treatment of heart failure on a genetically-targeted basis. Very strong data in preventing death post-MI. Approvable letter from FDA with guidance on a further trial required for approval. Company currently pursuing an AF trial with Gencaro.

ARMGO Pharma - In Phase 2a with a product that stabilizes ryanodine receptor/calcium release channel ("Rycals"). ARMGO hypothesizes that it may be possible to restore the strength of muscle contraction. (Link)

Biolex - BLX-155 is a direct acting thrombolytic (clot dissolver) which was superior to t-PA in a recent preclinical study reported at ISTH. (Link)

$ Canyon Pharmaceuticals - Canyon Pharmaceuticals is seeking to build a strategic alliance preferentially on a worldwide basis to commercialize Desirudin (Iprivask® US-registration / Revasc® EU-registration), a first/best in class anticoagulant drug which is approved by the FDA, the EMA and several of the rest of world authorities. Desirudin is a direct thrombin inhibitor and the only subcutaneous direct thrombin inhibitor (DTI) with approval for venous thromboembolism (VTE) prophylaxis following hip- and knee-replacement surgery.

COMPLETED Cardiokine - Has recently received rights to Lixivaptan for the treatment of hyponatremia. Has finished three Phase 3 studies but has not published the results to date. Two vaptans on the market but potential differentiation of this product. Actively exploring a company sale. Update: this company was acquired by Cornerstone Therapeutics in Jan 2012 for an undisclosed upfront. Cornerstone is now looking for ex-US partners for this product. (Link)

Cardioxyl - CXL-1020 in development for an initial indication of Acute Decompensated Heart Failure, and has completed a Phase I/IIa clinical trial with positive results. Company has recently launched a dose ranging Phase 2 study.

UPDATE Celladon - Developing MYDICAR®, a genetically-targeted enzyme-replacement therapy intended to restore levels of SERCA2a for the treatment of acute and chronic heart failure. The Phase 2 study met its primary safety and efficacy endpoints for high dose MYDICAR versus placebo. The primary efficacy endpoint is a composite endpoint that encompasses the simultaneous assessment of patients’ clinical outcomes, exercise tolerance, heart failure symptoms, biomarkers, and cardiac function. In addition, high dose MYDICAR treated patients had a statistically significant reduction in cardiovascular events as defined by death, the need for left ventricular assist device (LVAD) or cardiac transplant, worsening of heart failure or heart failure related hospitalizations, which at 12 months, translated into a of 88% risk-reduction in favor of high dose MYDICAR vs. Placebo, p = 0.003. Has been granted fast track status by the FDA as of Dec. 2011 for the treatment of advanced heart failure.

Cordex - ATPace™ has an approved SPA to enter a pivotal Phase 2b/3 clinical trial for the treatment of a common heart arrhythmia called paroxysmal supraventricular tachycardia. Cordex believes that ATPace™ is a more reliable and superior product than existing therapies because of its unique ability to recruit the vagus nerve. Cordex has hired WBB Securities to explore strategic options for this product and, potentially, the company. (Link)

Corimmon - German company developing COR-1, a peptide drug for the treatment of immune-mediated heart failure due to anti-ß-adrenergic auto-antibodies, entering phase Ila. Also developing Revacept, a biological for the prevention and treatment of atherothrombosis, Key indications coronary heart disease, acute myocardial infarction and transitory ischemic attacks and stroke. Entering phase 2a shortly. (Link)
**UPDATE** Debiopharm - Debio 0614 - This study has been withdrawn prior to enrollment.

Diffusion Pharmaceuticals - Looking to partner trans sodium crocetinate (TSC) for treatment of intermittent claudication and diseases associated with hypoxia. Reported encouraging data from a Phase 1b study for claudication at AHA in Nov 2010.

Endotis - Developing EP-42675, a synthetic glycol-drug as an anticoagulant. Reported positive Phase 1 data at AHA in December 2009. Has now developed an antidote to the same drug and has reported promising data (also see Polymedix and Portola). ([Link](#))

Evolva - In Phase 1 for **EV-077**, an oral thromboxane inhibitor, for managing platelet aggregation and diabetic nephropathy. In December 2010 reported that had carried out further formulation work and had confirmed that it had found a well behaved formulation of this drug in a Phase 1 study. ([Link](#))

FCB-Pharmicell - Cerecellgram is a bone marrow derived stem cell composition, containing mesenchymal stem cells and cells specifically useful for brain regeneration. Cerecellgram is being developed for the treatment of acute ischemic stroke. In Phase 3 randomized clinical trials. ([Link](#))

Kai - **KAI-1455** is a selective epsilon protein kinase C activator designed to reduce ischemic injury during planned surgical procedures, such as coronary artery bypass grafting, vascular surgery and pediatric cardiac surgery. In Phase 2b trials and open to a partnership transaction. ([Link](#))

Lacer - Spanish company looking for partner for LA-419, an oral eNOS regulator in phase II targeted at ischemic cardiovascular disorders. ([Link](#))

Menarini - Would partner Amediplase, a novel thrombolytic agent that has completed Phase 2 testing. ([Link](#))

Milestone Pharmaceuticals - Milestone Pharmaceuticals has a novel and potent short-acting calcium channel antagonist MSP-2017, in preclinical development for the treatment of transient cardiovascular conditions such as angina and atrial arrhythmias. ([Link](#))

Miragen – developing innovative microRNA modulators as is Regulus. Very large preclinical deal in 2011 for ex US rights to a CHF program with Servier. US rights to program where dramatic efficacy is possible. This program has substantial IP protection and additional applications.

NanoCor Therapeutics - Preparing for clinical trials of Carfostin™, an intracellular protein therapeutic for the treatment of Chronic Heart Failure (CHF). Carfostin™ is comprised of the delivery of a therapeutic gene, protein Phosphatase-1 Inhibitor-1 (I-1) with the use of Biological NanoParticles (BNPs™) and the Self-Complementary Vector Technology. ([Link](#))

**UPDATE** Neurocrine - Looking to partner Urocortin 2 program for CHF. Can improve cardiac output without raising heart rate. Will report out Phase 2 data in 2011. Anticipate having the final results of a pilot study in New Zealand in the first quarter of 2012. ([Link](#))

Nile Therapeutics - Would consider outlicensing its chimeric natriuretic peptide in Phase 1b clinical studies for the treatment of acute decompensated heart failure. Data from this trial were encouraging. ([Link](#))

NoNO - seeking a partner with the capability to develop and commercialise NA-1 (a PSD95 inhibitor) for acute ischemic stroke (AIS).

Oxford University - Has identified a novel receptor for anti-platelet drugs, G6B. ([Link](#))

Paion - Looking to outlicense Solulin, an improved recombinant version of thrombomodulin, a blood coagulant. Has completed Phase 1 studies. Also in Phase 2 with flovagatran, a direct thrombin inhibitor. ([Link](#))
Pervasis - In a POC P1b trial to study PVS-10200 to prevent restenosis in patients with peripheral arterial disease (PAD) who undergo an angioplasty and stent procedure in the superficial femoral artery. Very promising indication. Actively exploring options. Update: This company was acquired by Shire for “single digit millions” upfront plus milestones and royalties that are worth up to $200mm.

Polymedix – Finished Phase 1 with a Factor Xa antitode that reverse effect of heparin and associated compounds. Proof of concept achieved. Now in Phase 2a trial for the reversal of anticoagulant activity of enoxaparin. Also, see Portola for a related Factor Xa antitode. (Link)

Regado Biosciences - Developing injectable antithrombetics. Impressive Phase 2b data reported in November 2011 from REG1 Anticoagulation System, a novel two-component system comprised of a Factor IXa inhibitor anticoagulant and its complementary control agent. (Link)

Sembiosys - APOa1 is a injectible protein that leads to atherosclerotic plaque regression. Preclinical version of protein is available with very strong proof of principal data. Update: Company enters into a licensing deal for partial geographic rights with Tasly of China. (Link)

NEW Shionogi – Developing S-0139, an injectable endothelin type-A receptor antagonist for stroke and other cerebrovascular diseases. This program is in Phase 2 studies.

UPDATE Sygnis - Initially developing AX200 for acute ischemic stroke treatment and completed Phase II trials, however, in February 2012, the company announced it would cease development for this indication after a phase II study missed its endpoints. The drug remains in development for amyotrophic lateral sclerosis, spinal cord injury and peripheral arterial occlusive disease, and is under investigation for Parkinson’s disease. Sygnis plans to focus on protecting and expanding its remaining assets and is evaluating potential merger and acquisition options and financing opportunities. Sygnis might start an additional clinical study, aimed to confirm the efficacy of AX200 for the treatment of acute stroke, by itself or together with an appropriate pharma partner or out-license the entire AX200 project. (Link)

Thrombogenics - TB-402 is a novel human antibody which partially blocks Factor VIII, an essential blood clotting factor. Reported positive Phase 2 data. ThromboGenics and its partner BioInvent plan to out-license TB-402 for its later stage development and commercialization. Currently dosing a P2b study. (Link)

Thrombotech – developing a phase 2a drug for ischemic stroke.

NEW Toray – Toraymyxin for the treatment of sepsis. Very promising Phase 1b data. Toraymyxin is an extracorporeal hemoperfusion device which is composed of polymyxin B covalently immobilized polystyrene derived fibers. Toraymyxin has been used in more than 80,000 patients in markets outside of the U.S. and has been tested in more than 90 published studies. Polymyxin B antibiotics, is well known to bind endotoxin selectively and neutralize its toxicity. In a U.S. pivotal trial by Spectrum Diagnostics. (Link)

Trevena - TRV120027, is a β-arrestin biased ligand of the angiotensin receptor (AT1R) in development for acute heart failure. Ten months into a Phase 2a study. (Link)

$ Undisclosed - pharma company is open to divesting a marketed specialty cardiology product with revenues > $30mm per annum.

$ Undisclosed - Pharma company with a product for heart failure and revenues over $20mm would consider a sale.

NEW $ Undisclosed – Marketer of branded hospital cardiology-oriented pharmaceutical products outside the U.S. with revenues over $50mm is open to a company sale or a strategic investment. Interested parties should contact tim.opler@torreyapartners.com.
UPDATE Via Pharmaceuticals - VIA-2291 is a reversible inhibitor of 5-LO, a key enzyme in the biosynthesis of leukotrienes that impact inflammation and atherosclerosis. Positive Phase 2 data in a recent ACS trial. Also in Phase 1 studies of VIA-3196, a THR beta agonist for management of dyslipidemia. After Madrigal acquired Via's assets in the fall of 2011, no further development had been reported for VIA-2291.

Viron Therapeutics - Developing VT-111, a serine protease inhibitor. Reduces restenosis and increases plaque stability in animal models. Has recently finished a Phase 2a study in PCI patients. (Link). Viron has been granted U.S patents for organ transplant and arthritis drug candidates.

UPDATE Xention – Xention is developing two voltage-gated potassium channel Kv1.5 antagonists: XEN-D0101, and its follow-on XEN-D0103, a chemically distinct compound, for the potential treatment and prophylaxis of atrial fibrillation (AF). A phase I trial began in July 2011 with results expected in early 2012 and phase Ila efficacy trials were also expected to start in 2012. In November 2011, the company was seeking to outlicense the drug. XEN-D0103 is more potent and more selective than XEN-D0101 and has recently completed pre-clinical development. (Link)

Zensun - Phase 2 studies for treatment of CHF via remodeling of cardiac muscle cell sarcomeric and cytoskeleton structure or cell-cell adhesion using rhNRG-1 protein.

CNS - NEUROLOGY

Acadia Pharmaceuticals - In Phase 3 studies of pimavanserin for the treatment of Parkinson’s disease psychosis. This program had been partnered to Biovail but was returned after the merger with Valeant. (Link)

UPDATE Acceleron - Latest stage unpartnered product is ACE-031 which works by inhibiting myostatin and other negative regulators of muscle mass thereby freeing the body to rebuild muscle tissue. Phase 2 trials underway in DMD. Partnered with Shire outside the U.S. Acceleron will retain all commercial rights in North America. They intend to resume studies of ACE 031 in DMD as soon as possible pending further analysis of safety data and following discussions with regulatory agencies. (Link)

$ Accera – Axona, a medical food for treatment of Alzheimers. Related medical food treatments for Alzheimers in development by Adeona, Bellus Health and Groupe Danone. In October 2010, a new CEO appointed. Company remains open to a partnering or change of control transaction.

$ Acorda – FDA approved AMPYRA® (dalfampridine) on Jan. 2010, which is indicated as a treatment to improve walking in patients with MS. Launch of this product is now underway. Recent studies show increased improvement in walking with use of AMPYRA. Partnered Europe rights to Biogen Idec. Company considered a top acquisition candidate. (Link)

NEW Acumen Pharmaceuticals – anti-ADDL antibody for Alzheimer’s Disease that had been co-developed with Merck. This program has entered clinical studies. (Link)

Adamas Pharmaceuticals – In Phase 2/3 with ADS-5102, a proprietary extended release (ER) formulation of amantadine indicated for Levodopa-induced dyskinesia in Parkinson’s disease. (Link)

UPDATE Addex - In Phase 2a for Diplaglurant, an mGLUR5 NAM for the treatment of Parkinson’s Dyskinesia and dystonia. This program is regarded as a very promising approach for PD. Reported P2a data in March 2012. On exploratory efficacy endpoints, diplaglurant-IR significantly reduced peak modified Abnormal Involuntary Movement Scale (mAIMS) scores on day one and day 14 vs. placebo (p=0.042 and p=0.038, respectively). An ER formulation is entering Phase I this year. (Link)

UPDATE Aeoulus Pharmaceuticals – AEOL 10150 is a catalytic antioxidant that mimics and thereby amplifies the body's natural enzymatic systems for eliminating reactive oxygen species. Product has completed Phase 1 and is
Company recently received a $118 million research and development contract from BARDA. Company reported significant survival advantage in non-human primate study of AEOL 10150 as a treatment against lung damage from radiation exposure.

**NEW** Affectis - AFC-5128 is a potent CNS-penetrant oral P2X7 antagonist being developed for the treatment of neuropathic pain and multiple sclerosis. P2X7 is an ATP-gated ion channel which is essential for the maturation and release of the pro-inflammatory cytokines, including interleukin-1beta (IL-1β). A Phase 1 study is planned for 2012. ([Link](#))

**NEW** Afraxis - developing proprietary PAK inhibitors to demonstrate clinical proof-of-concept in Fragile X, and is evaluating PAK inhibitors in a number of CNS disorders including schizophrenia and Alzheimer’s disease. ([Link](#))

**NEW** Alder Bio - ALD403 is a potent, humanized monoclonal antibody that inhibits calcitonin gene-related peptide (CGRP), a molecule shown to trigger migraine attacks. Previous therapeutic approaches targeting CGRP have centered on traditional pharmacology to alleviate migraine symptoms but were halted due to safety issues. Alder is pioneering a new treatment strategy with ALD403, which will be given to chronic sufferers on a monthly basis via a subcutaneous injection. The medicine will be present at the time of migraine onset—by far the most successful treatment point for treating migraines. A Phase I clinical study evaluating ALD403 in healthy volunteers will launch in early Q2 2012. ([Link](#))

Allon Therapeutics - Allon Therapeutics is testing davenutide in a variety of CNS indications including Progressive Supranuclear Palsy (PSP). Positive Phase 2 data in amnestic mild cognitive impairment (aMCI), a precursor to Alzheimer’s disease (AD). Allon is currently a Phase 2/3 clinical trial in progressive supranuclear palsy (PSP), a type of frontotemporal dementia (FTD). Phase 3 is underway. Allon intends to commercialize in and outside of North America. ([Link](#))

Allozyne - Long acting interferon beta for MS. Phase 2 data are upcoming. Update: Allozyne recently merged with Poniard but remains interested in partnering its interferon beta program.

Andalusian Initiative for Advanced Therapies - A research group from the Andalusian Public Health System (SSPA) has developed a NEW composition for the treatment of cognitive disorders associated with Fragile X Syndrome. Phase 1b trial results have shown that the NEW composition counteracts the production of free radicals by reducing oxidative stress, while improving behavior and learning in individuals affected with the Fragile X Syndrome. ([Link](#))

**UPDATE** Ariel Pharmaceuticals, Inc. - AP-1531 is an proprietary EP4 antagonist with potential applications in inflammation, pain and CNS (including MS). Clinical data is available from several studies, currently in Phase 2a.

Avineuro Pharmaceuticals - Has reported positive Phase 1 data on AVN-322, a 5-HT6 antagonist for Alzheimer’s Disease. Is preparing to commence Phase 2 studies. ([Link](#))

Bluebird Bio - Positive Phase 1b type data for LentiGlobin® for gene therapy treatment in a young adult with severe beta-thalassemia, a blood disorder that is one of the most frequent inherited diseases. Also has positive data for a treatment for Adrenoleukodystrophy (ALD) which is a rare, inherited neurological disorder.

Bial - Opicapone (BIA 9-1067) is currently being developed by BIAL to be used in addition to L-DOPA/carbidopa or L-DOPA/ benzerazide preparations in PD patients. Currently in Phase 3 studies. Promising results have been obtained for BIA 9-1067 in previous studies. ([Link](#))

**COMPLETED** Bionomics - BNC210 is a novel anti-anxiolytic which has completed Phase 1 studies and displays good drug-like properties. Two parallel Phase 1b trials of BNC210 were initiated in France in October 2010 and results exceeded expectations. Note: This program was partnered to Ironwood in January 2012.
Bioprojet - In Phase 3 studies of pitolisant for the treatment of excessive daytime sleepiness in Parkinson’s disease. Being tested as an add-on to Modafinil. Supportive Phase 2 data. (Link)

BTG plc - “The development of BGC20-0134 (Pleneva), a potential licensing candidate, was halted following a Phase II study in which it did not meet the primary or secondary endpoints in a study in multiple sclerosis patients.”


NEW BTG - Amyloid aggregation inhibitors. Compound from a novel series of small molecules which display robust in vitro and in vivo profiles in protecting against the toxic effect of β-amyloid assemblies. Potential drug candidate for the treatment of Alzheimer’s disease and other toxic protein accumulation / aggregation diseases. (Link)

NEW Catalyst Pharmaceutical Partners – is in Phase 1 studies with a GABA aminotransferase inhibitor candidate, CPP-115, for the treatment of infantile spasms. The Phase I(a) study is a randomized, double-blind, single ascending dose study in six cohorts of eight normal healthy volunteers, totaling 48 healthy subjects. The study is designed to evaluate the basic human safety characteristics of CPP-115, including CNS side effects, and respiratory and cardiovascular safety. (Link)

Celtic Pharma - Has hired an investment bank to divest Xerecept, a novel agent in late Phase 3 studies for peritumoral brain edema. See a related program at Eustralis Pharma.

CeNeRx BioPharma - Pivagabine (CXB722) has potential as a novel anxiolytic, demonstrating a significant effect on both endocrine and cardiovascular biomarkers associated with stress. CXB722 has been studied in approximately 800 patients, demonstrating safety and efficacy in a range of mood and anxiety disorders. In Phase II and seeking to outlicense after completion. (Link)

NEW Ceregene – In a Phase 2b trial for CERE-120 uses AAV-based gene therapy to deliver the neurotrophic factor, neurturin, to Parkinson’s disease patients in order to restore the function and protect degenerating nigrostriatal neurons. A previous trial failed to show a clinical benefit but a subset analysis of that trial found a patient group that benefitted from therapy. (Link)

UPDATE Chelsea Therapeutics - NORTHERA™ (droxidopa), is an orally active synthetic precursor of norepinephrine initially being developed for the treatment of neurogenic orthostatic hypotension. Large potential in the Parkinson’s market where there has been a reported 60% reductions in falls in PD patients with NOH - also could work in fibromyalgia. On market already through Dainippon Pharma in four Asian countries. On March 28, 2012 Chelsea Therapeutics (CHTP) received a complete response letter (CRL) from the Food and Drug Administration (FDA) for the company’s new drug application (NDA) for Northera (droxidopa) to treat people suffering from symptomatic neurogenic orthostatic hypotension (NOH). In the CRL the FDA asked Chelsea to conduct another study which can demonstrate the drug continues to work for patients over a two to three month period.

Chiesi - CHF1512, an oral, soluble form of carbidopa/L-dopa for Parkinson’s disease. SPA issued by FDA for Phase III study. Ready to start Phase III trials under protocols agreed with the FDA through the SPA process. Note: the rights to this product were returned to Chiesi from Vernalis in 2010 after failing to find a partner. (Link)

NEW Civitas Therapeutics - Positive Results from Phase 1 Study of CVT-301, an Inhaled L-dopa for Parkinson’s Disease

UPDATE $ CNS Therapeutics - has introduced Gablofen, an AP rated intrathecal version of baclofen for control of severe spasticity among patients with movement disorders. This product has significant advantages over the existing marketed product and is likely to have significant revenue traction over the next several years. This
product is promoted and the company is a suitable acquisition candidate for either a branded or generic company. Rumored to be in active sale discussions. (Link)

NEW Cognosci - COG112 is the lead product for MS from Cognosci’s proprietary apolipoprotein E-based drug development platform. This compound acts by modulating the inflammatory response and by promoting regrowth and remyelination of damaged nerves. (Link)

Colucid Pharmaceuticals - Lasmitidan, a novel drug for migraine, selectively targets 5HT1F receptors expressed in the trigeminal nerve pathway is entering Phase 3 trials. Company open to partnering or sale transaction. (Link)

NEW Compugen - CGEN-15001 is a B7/CD28-like based fusion protein for the treatment of autoimmune disease. Using an EAE model, administration of CGEN-15001 to mice with established MS displayed robust inhibition of MS symptoms and abolishment of further relapses. In preparation for clinical studies. Interested parties should contact Tsipi Karen-Lehrer (tsipikl@compugen.co.il). (Link)

UPDATE Cynapsus Therapeutics - APL-130277 is an apomorphine thin film strip formulation for the rescue of patients experiencing “OFF” periods in Parkinson’s disease. Has reported successful human volunteer pilot proof-of-concept results for APL-130277. (Link)

Cytokinetics - According to a recent press release, Cytokinetiсs, Inc. announced opening of next phase II clinical trial of CK-2017357, a fast skeletal muscle activator, in patients with amyotrophic lateral sclerosis. CK-2017357 selectively activates the fast skeletal troponin complex by increasing its sensitivity to calcium, leading to an increase in skeletal muscle force. Saw activity in a recent Phase 2a trial. Actively seeking partnerships. (Link)

$ Daval International - Aimspro has orphan Status Designations have been awarded by the Therapeutic Goods Administration (TGA) for the treatment of Krabbe Leukodystrophy and Amyotrophic Lateral Sclerosis. In June 2011 completed Phase 2 trial study of AIMSPRO for treatment of bladder dysfunction in patients with secondary Progressive MS. In October 2011, Daval announced positive Phase II results for AIMSPRO® as a monotherapy in Established Diffuse Cutaneous Systemic Sclerosis (Scleroderma). Sold on a named patient basis.

EnVivo Pharmaceuticals - EVP-6124, a gamma secretase inhibitor, for Alzheimer’s disease showed signs of cognitive improvement in a Phase 2a study. Currently in Phase 2b studies. Recent issues with Lilly Semagacestat have raised questions about gamma secretase inhibitors as a class. Looking for a partnership. EnVivo currently has partnered with Mitsubishi Tanabe Pharma Corporation (MTPC) for the further research, development, and commercialization of its lead product, EVP-6124, in several Asian countries (most notably, in Japan). (Link)

ExonHit - Looking to partner EHT-0202, which has completed Phase 2a studies in Alzheimer’s disease.

Galantos Pharma - Developing Memogain, which is made up of galantamine, a nicotinic acetylcholine receptor sensitizer marketed as Razadyne by J&J. In pre-clinical studies.

NEW Gedeon Richter – Developing RGH-790, an orally active D3/D2 partial agonist with proven safety profile in Ph1 study and extensive preclinical data in ADHD. Ready to proceed to Phase 2 studies. Other possible indications are cognition, Parkinsonism and autism.

Green Cross - Open to international outlicensure of GCC1290K which is a prodrug of 3-hydroxymorphinan. This has progressed through Phase 1 studies in Korea. (Link)

Green Cross - Developing Intravenous Immune Globulin (IVIG). In Phase 3 in Korea. Recently went forward with an IND in the United States. Extensive evidence supports use of this product to treat Alzheimers disease. (Link)

UPDATE Impax Laboratories – Impax is looking to partner the ex-US rights to IPX056 - a controlled release baclofen for spasticity in multiple sclerosis. However, as of July 2011, the second phase III trial had been put on hold, and the company is seeking to outlicense the drug. (Link)
Innate Therapeutics - Going into Phase 2a studies with MIS416, an immune system modulator, in multiple sclerosis. Patent issued for MS in New Zealand in January 2011 and pending in international markets. Began recruiting patients for Phase II clinical trials in September 2010 and initiated trials in October 2010. (Link)

Intec Pharma - Intec Pharma is developing AP-09004, a gastric retentive Accordion pill formulation of carbidopa/levodopa for the potential treatment of Parkinson’s disease. In July 2011, interim data from the second group were reported from the randomized, safety, efficacy, 17-patient phase IIb trial, boding well for further IIb results later in the year. The Accordion Pill Carbidopa/Levodopa (AP-CD/LD) technology significantly improved its efficacy and enabled a significant reduction in the number of Levodopa doses per day in comparison to the currently marketed Levodopa products. (Link)

Intellect Neurosciences - OX1 is a Phase 1b copper binding molecule that stabilizes non-toxic soluble forms of amyloid and protects brain cells by blocking redox-mediated neurotoxicity. It has been tested for safety in healthy elderly people in Phase 1 clinical trials. Licensed to ViroPharma. (Link)

KemPharm - KP106 is a novel prodrug for the treatment of attention-deficit hyperactivity disorder (ADHD). KP106, a new chemical entity (NCE), is composed of the active pharmaceutical d-amphetamine and a ligand and was created through application of KemPharm’s proprietary Ligand Activated Therapy (LAT) approach. Positive Phase 1 data. (Link)

Kyowa Hakko Kirin - looking to partner a Phase 3 Parkinson’s drug, KW-6002. Istradefyline is an adenosine A2a receptor antagonist. (Link)

NEW H. Lundbeck A/S is seeking to engage with an external partner, the opportunity to develop a phase II ready D1/D2 agonist prodrugs (Lu 02-750 and Lu AE04621) for Parkinson’s disease.

Manhattan Pharmaceuticals - reported positive Phase 1b data for AST-915 for the treatment of essential tremor. Compound associated with reductions in the severity of tremor. (Link)

MarcoPolo Pharmaceuticals - VLB-01 is a ML2 (MT3/Quinone oxidoreductase 2 (QR2)) receptor agonist with a unique receptor profile implying first-in-class anti-epileptic activity. VLB-01 is being developed for treatment of epilepsy. Phase 2a results are pending. (Link)

Marinus Pharma - Positive phase 2a data for Ganalexone, a novel epilepsy neurosteroid, in which statistics showed significant reductions in seizure frequency. The compound is also beginning trials for its affect on PTSD patients and UCD neurologists have been awarded a grant to study the compound in treatment of Fragile-X syndrome starting in the first half of 2012. (Link)

UPDATE Medesis Pharma announced the successful completion of a Phase I clinical trial of NP03 (lithium citrate), a disease modifying treatment for Huntington’s disease. Phase II trials for NP03 in treating both Huntington’s disease and bipolar disorder are set to begin in 2012. (Link)

MediciNova - Running a partnership process for MN-166, indicated for the treatment of relapsing multiple sclerosis. MediciNova is collaborating with Kyorin Pharmaceutical Co., Ltd. in the global development of MN-166. (Link)

MemenPharma Levamfetamine is SN-522 is a cognition enhancer. Memen was in Phase 2 developing a levo-amphetamine sulfate which showed improvement in memory. Company looking for a partner to conduct further Phase 2 work. Phase 2 data show improvement in memory from levo-amphetamine sulfate. Company looking for a partner to conduct further Phase 2 work.

Mithridion - MCD-386, a muscarinic agonist, has completed phase I studies and seeks to halt or slow down the progression of Alzheimer’s disease and improve memory and cognitive function. (Link)
Nelson Pharmaceuticals - Developing MagneVal, a reformulated, patented version of Valproate for epilepsy that is less subject to carnitine deficiency. (Link)

Neuraltus Pharmaceuticals - In Q1 2011, started a Phase II randomized, double-blind, placebo-controlled, multicenter study of NP001 in subjects with amyotrophic lateral sclerosis (ALS). Works by regulating macrophages. (Link)

Neuren Pharma - Developing NNZ-2566, a synthetic analogue of the n-terminal tripeptide of IGF-1, a naturally occurring molecule that has neuroprotective effects in animal models of stroke and head injury. The company is planning to start a Phase 2 trial in Rett Syndrome, an autism disorder in late 2012.

Neurocrine - In Phase 1b with a VMAT2 inhibitor designed to slow the transport of monamines such as dopamine. Intended for Phase 2 studies in tardive dyskinesia associated with Parkinson’s. In second quarter 2011, approached the FDA regarding filing of IND in the US and have meeting schedule with the FDA for June 2011. Enrolling second Phase 2b trial. Looking for ex-U.S. partners. (Link)

UPDATE Neuroderm - In a Phase 2a study for ADHD with patch containing nicotine and other agents. ND0801 in phase II for ADHD and in preclinical trials for other indications. (Link)

UPDATE Neuroderm - Developing ND0611, a carbidopa patch for treating Parkinson’s disease that would largely improve the bioavailability of orally administered levodopa. Reported positive Phase 2 data in November 2011. (Link)

NeuroHealing Pharmaceuticals - Dosing patients in a Phase II/III study to test the efficacy of NH001 (apomorphine) in accelerating the recovery and improving the outcome of patients in a vegetative state following a severe traumatic brain injury (TBI). (Link)

Neurologyx - In Phase 2 with a gene therapy program (NLX-P101) for Parkinson’s Disease with positive data for a non-dopamnergic approach. Has hired MTS Partners to seek “strategic collaborations.” (Link)

Neurotherapeutics Pharma - NTP-2014 has been evaluated in multiple animal models of epilepsy, neuropathic and nociceptive pain, and migraine. In every one of these models, the compound exhibited a dramatic level of efficacy, outperforming positive controls represented by some of the industry’s most commercially successful therapies. An IND is being filed to go forward in man with this compound.

Neurosearch - In Phase 1b with Ordopidine for Parkinson’s dyskinesia. (Link)

UPDATE Neuronova – (sNN0031) - In Dec 2011, NeuroNova concluded a first-in-human study with the drug product sNN0031 in patients with Parkinson’s disease. In June 2011, they had completed a Phase I/II, randomized, double-blind, placebo controlled, safety and tolerability study of intracerebroventricular administration to patients with idiopathic Parkinson’s Disease of moderate severity, using an implanted catheter and a synchromed pump. Also in Phase 1b for ALS therapy. Commercial partners sought for development and marketing outside the EU. (Link)

UPDATE NeuroNova – (sNN0029) - In phase 1b of development with sNN0029, a drug with indications for ALS. While keeping the rights to the drug within the EU, NeuroNova is seeking partner to develop and market the drug abroad.

COMPLETED Newron - has failed with ralfinamide in Phase III for lower back pain. Market cap around $45mm. Has a solid pipeline of CNS candidates. Open to an M&A deal. Update: Had announced a merger with BioTie which was terminated on Oct 28, 2011. Company looking for alternatives. Update: As of April 2012 has signed a license for Asia rights with Meiji and rumored to continue in search for a partner or buyer elsewhere. In April 2012 Newron concluded a licensing deal for ralfinamide with Zambon for approximately $26mm.
UPDATE Noscira - Nypta® (tideglusib) is a GSK-3 enzyme inhibitor that has shown positive effects in experimental models against the main lesions that arise in Alzheimer’s disease: tau protein hyperphosphorylation, amyloid plaques, and neuron loss. In a Phase 2b trial. Also in a trial for the treatment of progressive supranuclear palsy. An active outlicensing program is underway. [Link]

NEW Osmotica – OS-320 for Parkinsons. Done with Phase 2. [Link]

Oxford Biomedica - In a Phase I/II trial of ProSavin for the treatment of Parkinson's disease (PD). This gene therapy has been associated with improvements in patient symptoms. [Link]

PharmaNeuroBoost - Looking to start a Phase 3 program for a fixed dose combination of citalopram and pipamperone. [Link]

Prana - Actively partnering PTB2 for Alzheimers. Good Phase 2a data for novel aggregation inhibitor of amyloid beta plaque. Prana has planned a Phase IIb study to determine the impact of PBT2 on progression of cognitive and functional decline in patients suffering from mild to moderate Alzheimer’s Disease and is going forward with next trial.

Proximagen - 5-HT1a agonist for refractive epilepsy. Safe and well tolerated in >500 patients. In a Phase 2 trial.

NEW Psyadon - Ecopipam is a selective antagonist of the dopamine D1 receptor subtype. There is a large preclinical database supporting its mechanism of action and activity. In addition, its clinical safety profile has been documented in over 2000 patients some of whom have been treated for over a year. Following an end-of-Phase 2 meeting with the FDA, ecopipam is entering a Phase 3 clinical trial for an orphan indication called Lesch-Nyhan Disease. Psyadon has exclusive worldwide rights to ecopipam for all indications.

Psychogenics - Pursuing eltoprazine in Phase 2 studies for ADHD. Supportive Phase 2a data. [Link]

Raqualia - RQ-00000009 is a preclinical 5Ht-4 partial agonist. Compound penetrated into brain effectively and significantly improved memory and cognitive deficit in rodent models. In addition, RQ-00000009 decreased brain cortex β-amyloid proteins in Tg2576 mice.

UPDATE Receptos - in a Phase 1 study for an S1P1 agonost for the treatment of multiple sclerosis. Pharmacology studies in a mouse model of MS demonstrate dose proportional pharmacodynamic effects (lymphopenia) and significant reduction in EAE disease severity scores. Expect to enter Phase 2 studies in mid-2012.

Repligen - Open to partnering RG3039 and RG2833. 3039 is a Phase 1 drug for spinal muscular atrophy and 2833 is a Phase 1 ready drug for the treatment of Friedreich’s Ataxia.

NEW Satori Pharma – going into Phase 1 studies with a novel treatment for Alzheimer’s disease.

NEW Shionogi – in Phase 2 with S-139, an oral thyrotropin-releasing hormone (TRH) mimetic which is in Spinocerebellar ataxia (SCA) or Parkinson’s disease (PD). Open to licensing non-Japan rights.

Siena Biotech - Selisistat is a first-in-class selective SirT1 inhibitor, a potentially disease-modifying mechanism for Huntington’s disease. The compound is currently in Phase 2a clinical trials.

UPDATE SK Biopharmaceuticals - YKP3089 is a novel compound with broad-spectrum anticonvulsant activity under clinical development. Through recent a Phase Ila photosensitivity study, the potential for efficacy in humans was confirmed. Open to discussion for joint development. [Link]

UPDATE SK Pharmaceuticals - YKP509 is carisbamate, an NCE, that has been in 2000 patients for epilepsy and neuropathic pain. Looking for a partner. Phase 2/3 data available, open INDs in anxiety, epilepsy, and pain.
Sonexa - ST101 is a small, orally active molecule that is well absorbed and efficiently penetrates the blood-brain-barrier. In development for Alzheimer’s disease with positive animal data. ST101 has completed Phase I studies and is being evaluated in Phase II Proof-of-Concept trials. (Link)


StemCells - HuCNS-SC is well-characterized, normal human CNS stem cells (HuCNS-SC) from brain tissue, isolated and purified using monoclonal antibodies against cell surface antigens. HuCNS-SC is being developed as intracerebral injection for the treatment of myelin disorders such as Pelizaeus-Merzbacher Disease. Phase 1 data upcoming in 2012. (Link)

UPDATE Supernus - NDA filed for Epliga for Refractory Partial Onset Epileptic Seizures. Once a day CR version of oxcarbazepine. Company has a royalty that has been partially monetized. No active M&A process underway but the company is ventured owned implying an exit is possible. Company has an S-1 on file. (Link)

NEW Supernus – has a Phase 2b program in IA in the setting of ADHD, and a Phase 3 program for the treatment of ADHD. Supernus is seeking ex-US partners for its two filed NDA’s and US partners for its ADHD portfolio.

Suven Life Sciences - SUVN-502 is a potent, highly selective and active antagonist at 5-HT6 serotonin receptor. SUVN-502 is being developed as once daily oral formulation for the treatment of memory and cognitive disorders. Entering Phase 2a studies. (Link)

UPDATE Syngis AG - Was in Phase 2 with AX200 for stroke but after a Phase II trial missed its endpoints, research for that indication has been discontinued. Seeking to partner or outlicense.

UPDATE Synthetic Biologics (formerly Adeona) - Recently missed primary endpoint in trial for zinc therapy for the treatment of Alzheimer’s disease. Company reported a retrospective subgroup analysis in June 2011 where the treatment was associated with an improvement in symptoms; reported top-line results from its pilot Phase I/I open label, three month safety study of oral high dose zinc therapy in ALS. (Link)

UPDATE Synthetic Biologics (formerly Adeona) - In Mid-Phase 2 of a trial for oral estriol (Trimesta) for MS. (Link).

H TauRx Therapeutics - Planning to initiate two Phase III trials testing a NEW reformulated version of its tau inhibitor Rember for the treatment of Alzheimer’s disease. Very promising data obtained with this program. Company open to a partnership transaction.

NEW Theravance - In December 2011, Theravance announced the initiation of an Attention-Deficit/Hyperactivity Disorder (ADHD) Phase 2 proof-of-concept study with TD-9855. TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor (NSRI) discovered by Theravance for the treatment of central nervous system (CNS) conditions such as ADHD and chronic pain.

Transition Therapeutics - Has finished a Phase 1 study for TT-301 for traumatic brain injury.

UPDATE Trophos - Olesoxime was in phase III of clinical trials for treatment of ALSm, though missed endpoints have halted development for this indication. In pivotal efficacy and safety study for SMA, and planning a phase II study for MS. No POC yet in man. Following report of missed endpoints in a phase III study with indications for ALS, Actelion has informed Trophos of its decision to not exercise its exclusive option under the July 2010 Acquisition Option Agreement between Trophos and Actelion. Trophos will continue to develop Olesoxime for other indications, and is financed through 2013. (Link)

Undisclosed party - Developing orphan neurology products based upon a compound designed to correct certain mitochondrial defects.
NEW $ Undisclosed player – bundle of several marketed mature pharma products in the neurology and pain areas. Revenue around $10mm.

NEW Undisclosed - Migraine asset – Phase 1b drug candidate in prophylactic migraine.

NEW Undisclosed party - Positive Phase 2 data for a compound for the treatment of Fragile X syndrome. Company is seeking a buyer or global partnership with assistance of a financial advisor.

NEW $ Undisclosed party - Sale of marketed neurology product with U.S. rights, growing revenues and orphan protection. Interested parties should contact Benj Garrett (benj.garrett@torreyapartners.com).

UPDATE Vectura Group - Positive data from a Phase 2b clinical study for its inhalation product, VR040 (apomorphine hcl), for the treatment of "off" episodes in patients with fluctuating Parkinson's disease. Looking to out-license VR-040 for Parkinson's disease and is in discussions.

Xenoport - XP19986 is a prodrug of the R-isomer of baclofen. Positive Phase 2 data for spasticity. XenoPort reached agreement with the FDA on a Special Protocol Assessment (SPA) for a pivotal Phase 3 clinical trial of arbaclofen placarbil (AP), previously known as XP19986, as a potential treatment of spasticity in multiple sclerosis (MS) patients.

CNS - PSYCHIATRY

Abiogen – ABIO 08/01 is an isoxazoline derivative which is being developed as an oral formulation for the treatment of generalized anxiety disorders. (Link)

UPDATE Acadia Pharmaceuticals – Has just entered Phase I with AM-831 after IND approval, a small molecule product candidate for the improvement of cognition in persons with schizophrenia. This product is partnered with Meiji Seika Kaishia in Asia. Also see Bioline. (Link)

UPDATE Alexza – Developing ADASUVE (Loxapine) which recently met the primary endpoint in a Phase 3 Bipolar Disorder trial. On February 13, 2012, Alexza received preliminary feedback, the Day 80 Assessment Report, from the EMA regarding its MAA, which contained major objections to various aspects of extrapolating phase III of clinical trials in addition to practical concerns. An FDA approval decision is expected in early May 2012. Alexza announced in Dec 2011 that it had hired Lazard to explore strategic options.

NEW Alkermes – ALKS-9070, once monthly prodrug of Aricept® for the treatment of schizophrenia. Going into phase 3 trials.

NEW Alkermes ALKS 5461 is the combination of ALKS 33 and buprenorphine and is designed to be a non-addictive opioid modulator for the treatment of depression. In Jan 2012 Alkermes reported 7 day onset of response (unusually rapid) with this promising product.

Auspex Pharma - SD-254 is a deuterated venlafaxine helps avoid multiple dose levels. Has completed Phase 2a studies and shown superior PK. (Link)

$ Avanir - Launched Neudexta for the treatment of pseudobulbar effect and, potentially, other indications. Positive data and good patent picture. Widely rumored to be an M&A candidate. $5.7 million in revenue in first year of launch (soft numbers). Market cap of $248 million as of November 2011. EMA application recently accepted.

Avineuro Pharmaceuticals - Positive topline results from a Phase 2a clinical proof of concept trial to assess AVN-211 as an augmentation therapy to improve cognition in schizophrenia patients. In a double blind trial in 50 patients stabilized on an atypical antipsychotic therapy, AVN-211 met the protocol criteria for positive results on the primary efficacy outcome measures. (Link)
Azevan Pharma - SRX246 and SRX251 are being developed as novel therapeutics for stress-related CNS disorders, including depression and Intermittent Explosive Disorder. Both are ready for Phase 2 studies. (Link)

**UPDATE** BiolineRx - Recently was returned rights to BL-1020, a late stage drug for cognitive improvement in patients with schizophrenia – positive Phase II data. While seeking to outlicense 1020, they are developing BL-1021 for the treatment of neuropathic pain.

**UPDATE** Biotie (formerly Synosia) - Rufinamide (SYN-111) is no longer in Phase II of development for GAD. Eisai, under license from Novartis, has developed and launched rufinamide. The product is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in adults and children aged 4 years and older. Currently in Phase III of development in Japan for LGS.

Braincells - BCI224 contains sabcomeline, a direct-acting cholinergic muscarinic receptor agonist. BCI224 is being developed as a parenteral formulation for the treatment of major depressive disorders. In Phase 2 studies. (Link)

**UPDATE** Braincells - Also developing BCI-540. Results from the Phase 2a trial suggest BCI-540 has the potential to treat a difficult-to-treat population, people with MDD who have failed previous treatments, and have a co-morbid anxiety disorder. Seeking to outlicense. (Link) (Press release)

CeneRx - TriRima (CX-157) a reversible MAO-A inhibitor in Phase 2 for the treatment of depression. After phase II is completed, CeneRx will look for a partner. (Link)

**COMPLETED** Cortex - Developing AMPAKINE compounds for depression and schizophrenia. Recently returned to company from Merck for repartnering. Also received rights pack from Biovail in May 2011. Partnered on product, CX1632 via an option deal to Servier in June 2011. On October 6, 2011, Servier exercised its option to obtain all the remaining rights to the jointly discovered high impact Ampakine® compound, CX1632 (S47445). In connection with the option exercise, Servier will pay Cortex an additional $2,000,000, as well as certain royalties and milestone payments. (Link)

Cyrenaic Pharmaceuticals - CYR-101 is a small molecule antipsychotic with a unique mechanism of action. It has high affinity for sigma-2 and 5-HT2A receptors and has been shown to be potentially effective in modulating dopamine pathways without the negative dopamine-related side-effects that are associated with all current antipsychotics. Promising Phase 2a data. (Link)

EnVivo Pharmaceuticals - EVP-6124 is a potent, orally bioavailable and selective alpha-7 agonist, for patients with schizophrenia. Recent Phase 2b data showed that EVP-6124 had a clinically meaningful and statistically significant impact on patients’ overall cognition - the trial’s pre-specified primary endpoint - when taken in combination with second-generation antipsychotics and as measured by the full CogState overall cognitive index, or “OCI” (p=0.05 for all patients treated with EVP-6124 versus placebo). Also see Bioline.

Euthymics Bioscience - Developing amitifadine for major depressive disorder. In a 318 patient Phase 2b/3 trial at present. (Link)

Inmedix - Owns use patents for outlicensing to use Pramexipole (Phase 2 completed) and ropinorole’s phase I is completed. (Requip) for fibromyalgia.

**COMPLETED** Intelect - CPI-300 is a novel, high strength of Bupropion HCl, the active ingredient in Wellbutrin XL(R). Indicated for depression. This product was approved in November 2011. In February 2012, Edgemont acquired exclusive US marketing rights.

Intracellular Therapeutics - Pursuing ITI-007 for schizophrenia and other compounds which are unencumbered. This atypical antipsychotic is in Phase 2 and has a differentiated profile from drugs on the market and promises higher efficacy with a better side effect profile. Has partnered its PDE1 inhibitors (ITI-002) for schizophrenia with Takeda. (Link)
UPDATE KemPharm - Developing a thin film strip with a controlled release of Adderal. Less abuse potential than Vyvanse. Looking to partner this drug which has completed Phase 1 studies. Has partnered with MonoSol Rx to develop and commercialize KP-106. KemPharm projects the filing of a NDA for KP106 in 1H2013. (Link)

MarcoPolo Pharmaceuticals - BC-19 is an eburnamine derivative, previously investigated for the indications of cerebral insufficiency and cognitive deficits. As an antidepressant, BC-19 had shown beneficial properties when administered to patients suffering from treatment resistant depression. (Link)

Medicure - In Phase 2 for the treatment of tardive dyskenesia (Tardoxal) as a side effect of schizophrenia treatments. (Link)

UPDATE Naurex – A depression drug based upon Glycine-site Functional Partial Agonists (GFPAs), peptides which are designed to achieve the strong efficacy of classic NMDA modulators without their limiting CNS side effects. Has completed Phase 1 studies with no safety issues. Recently completed an $18mm financing and is in Phase 2a studies for this novel approach. Phase 2a data will report out soon with potentially striking results. Interested parties should contact Chuck Dimmler of Torreya Parters (chuck@torreya.com). (Link)

UPDATE NoNO, Inc. - NA-1 is currently in a multicenter, placebo-controlled randomized Phase 2 trial testing its efficacy in reducing damage produced by strokes incurred following neurointerventional procedures. By January 2012, the drug had been granted Fast Track designation by the FDA, for the reduction of procedurally induced strokes and cognitive impairment in patients undergoing endovascular repair of brain aneurysms. Very positive Phase 2 data reported in March 2012.

UPDATE RepliGen - Would consider a partnership for Uridine which is in Phase 2b for bipolar depression. This compound recently failed its primary endpoint, and appears to have suspended development as it is no longer listed in the company pipeline and there have been no news updates since March 2011. (Link)

UPDATE Reviva Pharma - RP-5063 (formerly RP-5000) is a potent, selective NCE being developed for the treatment of schizophrenia and is available as an oral formulation. Has finished Phase 1b studies with positive results. Currently in Phase II trials and expected to conclude in October 2012. Expected to file NDA in October 2014. This schizophrenia compound went from concept to clinical trials in 30 months. (Link)

NEW Somaxon – marketer of Silenor®, a sleep drug with a favorable label has hired Stifel to explore strategic alternatives. On March 8, 2012 Somaxon reported: “We will also continue to work with our strategic advisor, StifelNicolaus Weisel, to evaluate strategic alternatives with the goal of fully leveraging Silenor for the benefit of our stockholders.” Net product sales of Silenor in 2011 were $16.2 million. (Link)

Spectrum Pharmaceuticals - Looking for a licensee for SPI-376, a novel preclinical molecule for the treatment of schizophrenia. (Link)

Transcet Pharma - Pursuing ultra low dose ondansetron (TO-2061) as an adjunctive treatment of obsessive compulsive disorder. Phase 2 study coming up. (Link)

$ Undisclosed - ADHD marketed drug with revenues > $50 million from a pharma. Would consider a sale.

$ Undisclosed player - sale of company with over $10mm in revenue with largely genericized specialty products in CNS and renal disease.

Undisclosed - U.S. rights to a marketed drug for depression are available.

University of Florida - Halogenated amino acids as a partial agonist of the glutamate-binding site of NMDA receptors for schizophrenia. Research stage.
University of South Carolina - Researchers are working on a homologue of Ritalin for ADHD, or Isopropylyphenidate. Preclinical stage. (link)

**CNS - SLEEP**

Alliance Pharmaceuticals - Looking to outlicense Posidorm, a surge formulation of melatonin. Alliance is seeking a co-development and co-marketing partnership deal with a partner company to progress Posidorm through late stage development to product registration and subsequent marketing. (Link)

**UPDATE** Aptalis - AdvaTab® Temazepam is the first ODT formulation of a highly prescribed benzodiazepine. Currently listed as being in Phase 2 development. Looking for commercialization partner for this product.

**NEW** Aptalis – looking for an ex-US partner for Unisom, an OTC sleep aid that is sold by Sanofi in the U.S. Unisom contains diphenhydramine HCl (50 mg/dose) and acetaminophen.

Bioprojet (in collaboration with Ferrer) - In Phase 3 studies of pitolisant for the treatment of excessive daytime sleepiness in Parkinson’s disease. Being tested as an add-on to modafinil. Supportive Phase 2 data. (Link)

**UPDATE** Evotec AG - Would like to outlicense EVT-201, a GABA Receptor Positive Allosteric Modulator for Insomnia. The results from Phase II have shown positive data. Recently licensed China rights to Zhejiang Jingxin Pharma and filed an IND in China in November 2011.

**UPDATE** Intec Pharma - Intec Pharma announced the Phase 2 clinical data with Accordion Pill Zaleplon. The analysis of the intermediate results of the trial showed that taking the Zaleplon medication with the Accordion Pill resulted in statistically significant improvement in its effectiveness versus placebo. On November 22, 2011, Intec Pharma reported very positive Phase II results of the Accordion-Zaleplon product. (Link)

**UPDATE** Neurim Pharma - Circadin® 2 mg prolonged-release melatonin formulation, approved for use (up to 13 weeks) in treatment of primary insomnia characterized by poor quality of sleep in patients aged 55 years or over. Though launched to treat primary insomnia, further research in other indications is being investigated e.g. broader insomnia disorders and AD. (Link)

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Somnus Therapeutics - dDveloping SKP-1041, a delayed release formulation of Zaleplon for sleep. Key indication is to prevent middle of the night wakening. Positive Phase 2 data. Company interested in finding a partner before starting Phase 3 studies.

Transccept Pharmaceuticals - Looking for an ex U.S. partner for middle of night insomnia drug, Intermezzo. Transccept has formed a U.S. partnership with Purdue Pharma for Intermezzo. Drug was approved by FDA in December 2011.

**UPDATE** Vanda - Tasimelteon is a Melatonin agonist for sleep wake disorders, in phase III. Has orphan designation. The tasimelteon Non-24-Hour Disorder program continues to advance towards a projected mid-2013 NDA filing with the FDA. Vanda is in continuing discussions with the FDA to confirm the path and requirements for this regulatory submission.

**CRITICAL CARE PRODUCTS**
UPDATE Action Pharma - AP214 finished Phase 2, a modified dMSH-peptide analogue, for the treatment of post-surgical kidney injury in the cardiac surgery context. The results demonstrate that AP214 is well tolerated and safe at all three dose levels. At the highest dose level, AP214 prevents the increase in serum creatinine by 50-60%, and in the IL-6 response by 30-40%, compared to placebo (trends based on blinded data). This is consistent with a robust effect to prevent postsurgical acute kidney injury (AKI) and systemic inflammatory response. In June 2011, the company planned for NDA filing in early 2014. At that time, the company had discussed the development plan for registration in lead indication in a Type C meeting with the FDA. (Link)

AM-Pharma - Has achieved highly positive Phase 2 results in the treatment of acute kidney failure with *alkaline phosphotase*. Company advancing a backup program with stronger patent protection. (Link)

UPDATE Asklepion - L-Citruline for the 20 percent of children who have heart surgery with use of the bypass pump develop pulmonary hypertension, or high blood pressure in the lungs. In early studies this product appears to prevent pulmonary hypertension from developing. Now in Phase 3 studies. *Last news of progression was in 2008 – no more recent news on this product, potentially suspended in development and seeking a partner? (Link)*


NEW Cornerstone Therapeutics – Applying for approval of Lixivaptan for the treatment of hyponatremia. Has finished three Phase 3 studies but has not published the results to date. Two vaptans on the market but potential differentiation of this product. Cornerstone is now looking for ex-US partners for this late stage product. (Link)

UPDATE Diffusion Pharmaceuticals - Looking to partner trans sodium crocetinate (TSC) for treatment of intermittent claudication and diseases associated with hypoxia. Positive Phase 1b/2a data reported at AHA in 2010. As of February 2012, Diffusion had begun enrolling participants in a phase I/II study for GBM and expects to complete enrollment by 2013. Development in other indications ongoing. Has Orphan status for GBM as of July 2011.

UPDATE Discovery Labs - Reportedly engaged in partnership discussions with respect to licensing its neonatal franchise, which includes Surfaxin, Sufaxin LS and Aerosurf. Want a partner to collaborate on clinical development for Surfaxin LS and Aerosurf, and to play a central role in commercialization for all three products. Surfaxin is a synthetic KL4 Surfactant for treatment of neonatal RDS. Has granted development and marketing rights for Discovery Labs’ SRT products to Esteve in the key southern Europe markets of Spain, Italy, Portugal, Greece, and Andorra. The FDA has approved SURFAXIN (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants at high risk for RDS. Has recently entered into an agreement with Lacey to manufacture and supply product for the commercial introduction of AFECTAIR®.

DSX Therapeutics - Developing a *Mab* (aSeptiMab) that targets inducible nitric oxide synthase, which is involved in sepsis pathology. Pre-clinical program.

Focus Care Pharmaceuticals - Looking for partners in Europe and other geographical locations for its line of rapid oral rehydration salts.

NEW Galleon Pharmaceuticals - GAL-021 is an IV small molecule designed to support respiratory drive in surgical and critical care patients. The use of anesthetic, analgesic and sedative drugs can produce a well-known respiratory depression. For example, in patients receiving opioids such as morphine GAL-021 could "decouple" the analgesic and respiratory depression effects enabling physicians to better alleviate pain without the well-known fear of respiratory collapse. This NCE is in Phase 1 testing. (Link)

InfaCare - Developing Stannsoporfin (Stanate) for Neonatal Hyperbilirubinemia, which is in a Phase 2b trial. Company expects to report out data soon. (Link)
**NEW** Kyorin – licensing non-Japan rights to KRP-109 which is a highly organ transitional neutrophil elastase inhibitor treatment for acute respiratory distress syndrome and acute lung injury. KRP-109 has the high potency and selectivity to the human neutrophil elastase and the high selectivity to the lung.

**UPDATE** $ Microbix - Owns Urokinase, formerly of Abbott (Abbokinase). Did revenues of $10mm+ recently. Not formally for sale but purchased for a low price due to manufacturing issues which have largely been fixed. As of Jan. 2012, has signed a letter of intent with Zydus Cadila to market Urokinase in the North American markets.  
([Link](#))

**UPDATE** Oxygen Biotherapeutics - In Phase 2b trials for Oxycyte in traumatic brain injury (TBI) in Switzerland and Israel. Company has moved forward to its second cohort in the trial. Recently partnered with Scottish group Aurum Biosciences to develop better treatments for treating acute ischemic stroke.  
([Link](#))

Polymedix - **PMX-60056** is a universal anticoagulant reversing agent, active against both heparin, low molecular weight heparin (LMWH) and pentasaccharide (Arixtra). Phase 1B complete with POC achieved, looking for global and local partners.  
([Link](#))

Serendex APS - Inhaled rfVIIa (recombinant factor VIIa) for blast injury and lung bleeding. Six patient study showed high efficacy. Orphan designation granted.  
([Link](#))

**NEW** Toray – Toraymyxin for the treatment of sepsis. Very promising Phase 1b data. Toraymyxin is an extracorporeal hemoperfusion device which is composed of polymyxin B covalently immobilized polystyrene derived fibers. Toraymyxin has been used in more than 80,000 patients in markets outside of the U.S. and has been tested in more than 90 published studies. Polymyxin B antibiotics, is well known to bind endotoxin selectively and neutralize its toxicity. In a U.S. pivotal trial by Spectrum Diagnostics.  
([Link](#))

**NEW** Undisclosed player – US critical care specialty pharmaceutical company is seeking a buyer.

### DENTAL DRUGS

Array BioPharma - Oral **p38** inhibitor has shown significant analgesic benefit in a recent Phase 2 trial in dental pain.

$ Pierrel Group - Received FDA approval in March 2010 for Articaine - a local dental anaesthetic that contains a thiophene ring. The thiophene ring of Articaine increases its lipophilicity and is highly diffusible allowing an effective tissue penetration.

**UPDATE** Riemser - German vertically integrated marketer of generic and branded pharma products with strength in cardiovascular, dental and veterinary medicines. Revenues of this company exceed €100mm and EBITDA around €30mm. Active sale process underway according to Biopharm Insight.

Sanifit – Has developed ASB 01, an OTC dental health / oral hygiene product inhibits formation of dental calcium deposits (tartar). In NDA filing phase.

**NEW** Toray – Toraymyxin for the treatment of sepsis. Very promising Phase 1b data. Toraymyxin is an extracorporeal hemoperfusion device which is composed of polymyxin B covalently immobilized polystyrene derived fibers. Polymyxin B antibiotics, is well known to bind endotoxin selectively and neutralize its toxicity. In a U.S. pivotal trial by Spectrum Diagnostics.  
([Link](#))

Undisclosed - Marketed dental drug with applications in the treatment of oral mucositis is available. Interested parties should contact tom.babich@torreyapartners.com.

Undisclosed - German vertically integrated marketer of generic and branded pharma products with strength in cardiovascular, dental and veterinary medicines. Revenues of this company exceed €100mm.
$ Anika - Has rights to Elevess®, a hyaluronic acid dermal filler. Open to a partnering deal. The rights were recently returned to Anika and company has been modifying filler to address historical issues with the product.

BiOLab Farmaceutica - Interested in partnering a variety of aesthetic products that are sold in Brazil. (Link)

**UPDATE** BTG - Varisolve, a Phase 3 treatment for the removal of varicose veins. BTG now looking at commercializing this product in the United States. Other regions available. Recently reported positive results from their phase III US clinical trials. (Link)

$ Church & Dwight - Would sell some Del Pharma niche products.

Cosmo Pharma - **CB-03-01** is a NCE anti-androgen for the topical treatment of Acne, Hirsutism and Androgenic Alopecia. Phase II studies showed a POC for acne. Recently showed nice POC in treatment of alopecia. (Link)

Fibrocell Sciences - Laviv (azficel-T) is an autologous cell therapy for the treatment of moderate to severe nasolabial fold wrinkles in adults. Drug has been approved and launched. (Link)

**COMPLETED** $ Lipose - Viafill fat transfer system on the market with applications in aesthetics where traditional volumizers are not well suited - particularly for the face and breasts. Company assisted by Torreya Partners. Update: This company was sold to an aesthetic dermatology player in March 2012.

Lithera - Announced positive results from a Phase IIb clinical study of L IPO-102, its novel injectable combination of salmeterol xinafoate (SX) and fluticasone propionate (FP) for selective, non-ablative fat reduction. In a Phase 2b study L IPO-102 was well-tolerated when administered weekly for 8 weeks into the subcutaneous abdominal fat of healthy subjects and produced dose- and time-related reductions in mean abdominal volume and circumference.

Pharmena - **bundle of dermatology products** that are currently sold in Poland. These products are IP protected and well suited to either an OTC or physician office promotion setting. Looking for an international partner to commercialize. For further discussions contact Tom Bird of Torreya Partners at tom.bird@torreyapartners.com.

$ ScarGuard - Could consider a company sale. Markets ScarGuard MD, a widely used scar remedy used by plastic surgeons. Also has OTC product.

**UPDATE** Sinclair IS Pharma - SPHR913 is designed to restore the quality of the skin by reducing the breakdown of collagen and elastin. Drug may have been suspended in development - no information on the site, very little information about the drug on the internet, last recorded information was a press release from 2009. (Link)

$ Suneva Medical - Marketing Artefill, a long-acting dermal filler with impressive revenue growth. Open to a partnership or even a company sale. In December 2011, the Company reported substantial revenue growth for the year and expects additional growth in 2012. (Link)

**UPDATE** TopoTarget A/S - Avugane contains the HDAC inhibitor VPA for use as a topical treatment of inflammatory skin diseases, including acne vulgaris (common acne), psoriasis and atopic dermatitis. Promising data from a double-blinded placebo controlled Phase 2. Looking to partner. Development within their own pipeline discontinued as of 2009.

$ Undisclosed player - Aesthetic dermatology business has been open to a sale with revenues over $80 million.

Valeant - In a mid-July investor call, the CEO of Valeant indicated that he might consider a sale of the company’s aesthetic assets including the recently acquired Sculptra filler from Dermik. "Well, I think like everything, it
depends what it’s worth to us versus what it’s worth to other people. I don’t think we are at critical mass in the aesthetics area," the CEO said.

**DERMATOLOGY - MEDICAL**

Anacor - Looking for ex-U.S. partnerships for dermatology portfolio including preclinical and clinical compounds for psoriasis, tinea pedis, acne and atopic dermatitis. AN2728 is past POC stage and is in a Phase 2 trial for psoriasis and is expected to report in the first half of 2009. Based on these results, Anacor expects to initiate a Phase 2b dose-ranging trial for AN2728 in mid-2010. Also going into an extensive Phase 3 program for AN2690 for the treatment of onychomycosis. ([Link](#))

**NEW** AndroScience - ASC-J9® represents the first topical agent directed at modulating the effect of androgens (male hormones), through the androgen receptor, a key causative factor in the pathogenesis of acne. The data obtained from this Phase 2 drug candidate have been positive. A large Phase 2b trial is underway. ([Link](#))

Apricus Biosciences - Running a process to outlicense NM100060 (MycoVa) for onychomycosis. Has been in multiple Phase 3 studies. ([Link](#))

**NEW** Basilea Pharmaceutica – Toctino, oral alitretinoin for severe chronic hand eczema (CHE) refractory to potent topical corticosteroids. Strong efficacy reported in its U.S. phase III HANDEL study in March 2012. A candidate for U.S. approval. On the market in Europe with good traction. Basilea intends to self-commercialize this product in Europe but may be open to partnership discussions in other geographies.

**UPDATE** $ Biofrontera – Ameluz (BF-200 ALA) is approved in Europe for the treatment of actinic keratosis. BF-200 ALA combines a nanoemulsion with 5-aminolevulinic acid (ALA). The product is developed in photodynamic therapy of precancerous skin lesions (actinic keratosis). Looking to partner in a variety of EU territories. Plans to meet with FDA to discuss U.S. approval and then partner. ([Link](#))

**NEW** Biotie - BTT-1023 is a fully human VAP-1 monoclonal or plaque psoriasis. The company recently reported what it considered a favorable safety profile of the treatment in a Phase One study. While this early-stage study did not address effectiveness, the company reported that some patients did see their psoriasis improve during the study.

Burke Pharma - Late stage product in development for the treatment of warts (The Wart Eraser/BURKE901). Approved device to accompany pharmaceutical approach.

**NEW** Ceptaris – Formerly Yaupon Therapeutics is filing an NDA for Valchlor, a gel formulation of mechlorethamine for the treatment of mycosis fungoides, a type of CTCL. This orphan disease impacts 80,000 persons in the Western world. Product launch in U.S. anticipated in Q4 2012. Company in active business development dialogue.

**UPDATE** Creabilis - CT327 is a novel topically applied TrkA kinase inhibitor developed using Creabilis’ LSE (Low Systemic Exposure) technology. CT327 contains pegylated K252a, which interacts at a nanomolar level with tyrosine kinase receptor (TrkA), the receptor for nerve growth factor (NGF). It has strong analgesic activity and it acts by blocking NGF activity. Good results in Phase 2a psoriasis study versus placebo. Also positive data in study versus atopic dermatitis. High potential for the treatment of neuropathic pain. Currently enrolling subjects for global phase Ib trials. ([Link](#))

$ DUSA Pharma –Main tool is PDT (Levulan PDT technology platform) coupled with derm drugs. Revenues around $30mm. ([Link](#))

Echo Therapeutics - 505b2 NDA application pending for Durhalieve (triamiconolone) for dermatoses. ([Link](#))

Forward Pharma - Positive Phase 2 data on FP-187 for psoriasis. Would consider a sale. ([Link](#))
UPDATE  Glenmark Pharmaceuticals, Ltd. - Microsphere Adapalene + Clindamycin for acne was compared against Adapalene + Clindamycin in a standard gel formulation and had less irritation. Available for outlicensing. Appears to have been suspended in development - no news after July 2010 press release saying an adapalene gel had received new drug approval.

NEW  HanAll Biopharma - HL009 is a Phase 2 topical gel containing adenosylcobalamine for the treatment of atopic dermatitis. It has comparable efficacy and better safety compared to to topical steroids and immunosuppressants.

Ibsa (Institut Biochimique SA) - Looking to outlicense Betesil, a betametasone valerate patch for treatment of psoriasis. A wide range of markets (EU, USA, South America, Middle and Far East) are still available on exclusive or semi-exclusive basis. Could do a global agreement. (Link)

$  Jina Pharma - Lipid based Amphotericin B Gel (Amfy) is indicated in acute, chronic and recurrent type of skin fungal infection and cutaneous leishmaniasis. Provides specificity to target fungal cells.

Labtec GmbH - LabiPatch adheres to the semi-moist environment of the lip and surrounding skin to deliver acyclovir for herpes sores. Looking for a licensee. Also has a patch for atopic dermatitis.

Laurantis Pharma - Cis-UCA emulsion cream is a phase 2 stage topical dermatology product indicated for the treatment of atopic dermatitis. Preliminary efficacy has been seen in a controlled exploratory phase 2a study in patients with mild to moderate atopic dermatitis. A proof-of-concept phase 2b study with up to 170 patients with moderate to severe atopic dermatitis is ongoing. The study is expected to be completed in Q2/2012.

Mimetica - MTC896 as a topical gel for the treatment of excessive sebum production in subjects with acne and other skin conditions. MTC896 is a highly selective and potent antagonist (<10 nM) of the Melanocortin-5 Receptor (MC5R). The company hired William Blair in October 2010 to seek a company sale. (Link)

NanoBio – NB-002 for onychomycosis is in Phase 2 studies. (Link)

NitricBio – Nitric oxide gas in phase 2 studies for treatment of tinea pedis. Very promising opportunity with applications in the dermatology and podiatry markets. (Link)

NovaBiotics - Novexatin, NP213 is a cyclic arginine heptamer for onychomycosis showed strong positive results in a 48 patient Phase 2 study. NovaBiotics is currently looking to partner the product.

UPDATE  Oxygen Biotherapeutics - has introduced Dermacyte® line in dermatology including an oxygen concentrate pump and an oxygenating eye complex. Enrollment began in January 2012 for a study with new dermatological indications for Dermacyte, initially for pruritis and allergic skin reactions, but with further implications for dermatitis, psoriasis and acne. As of March 2012, the company declared plans to regionalize its sales & marketing strategy in South FL & NC. (Link)

UPDATE  Pergamum AB, DermaGen unit - Antimicrobial peptide DPK-060 to treat and prevent skin infections; lead indication skin infections (atopic dermatitis). Clinical Phase I/II, proof-of-concept study successfully completed. Currently preparations for two additional Phase II studies are ongoing. In January 2012, the company began their Phase II trial for external otitis. Seeking to outlicense the program.

Pharmena - Bundle of dermatology products that are currently sold in Poland. These products are IP protected and well suited to either an OTC or physician office promotion setting. Looking for an international partner to commercialize. For further discussions contact Tom Bird of Torreya Partners at tom.bird@torreyapartners.com.

Piedmont Pharmaceuticals - Have a late stage product for treatment of head lice. Partnered and marketed in Europe. RESULTZ is sold internationally through licensing partners. Looking for other partners.
Provectus - Looking to sell or spin derm business including PH-10 for atopic dermatitis/psoriasis. Phase II completed.

**UPDATE** Rovi (Laboratorios Farmacéuticos ROVI, S.A.) - Nautiol is a Bemiparin-based product for the treatment of Diabetic Foot Ulcer. Recently finished a phase III in Europe with 300 patients and results were less than expected. Update: company announced on Dec 14, 2010 that it would no longer continue development of this product after looking at the Phase III data. ([Link](#))

**COMPLETED** Shunfeng Pharmaceutical, a Chinese topical skin care drug manufacturer is exploring a sale. Revenues around $35mm. As of February 12, 2012, China Resources Sanjiu Medical & Pharmaceutical Co. Ltd was affirmed as the winning bidder of Guangdong ShunFeng Pharmaceutical Co., Ltd.’s equity. ShunFeng Pharmaceutical will become a dermatologic medicine production base of China Resources Sanjiu.

Sinclair IS Pharma - Looking for a U.S. pharma partner to commercialize terbinafine spray for the treatment of Athlete’s foot. Looking at a launch in 2014. ([Link](#))

Third Stream Bioscience - Developing a novel skin antimicrobial based upon a chemical composition developed by Procter & Gamble. Promising data in dermatology (acne) and a variety skin cleansing applications. Hired an investment bank to find a buyer.

**UPDATE** TOPICA - Completed a U.S. Phase II trial of Luliconazole for patients with tinea pedis (athlete’s foot). Should work in onychomycosis as well. Interested in an exit in 18 to 24 months. Phase 2b/3 study starting now. Company has entered into a license agreement for tinea pedis (Sep 2010) but the onychomycosis indication is available. ([Link](#))

**COMPLETED** Undisclosed – dermatology player in the U.S. with strength in brands and generics open to a change of control transaction. Revenues > $70mm. Update: Fougera was acquired by Sandoz for $1.5bn on May 2, 2012.

**COMPLETED** Undisclosed player - dermatology company with more than $40mm in revenue has hired a financial advisor to restructure its debt that likely exceeds intrinsic value of assets. Update: Triax was acquired by PreCision Dermatology on April 30, 2012 for undisclosed consideration.

$ Undisclosed player - seeking buyer for approved product for the treatment of head lice in the United States. Significant commercial traction. Interested parties should contact benj.garrett@torreyapartners.com.

**DIABETES - ORALS**

**UPDATE** Array Biopharma (in collaboration with Amgen) - Reported positive Phase 1b data with ARRY-403, an oral glucokinase inhibitor. As of December 2009, ARRY-403 has been outlicensed to Amgen and is now called AMG-151. It is in ongoing phase II clinical trials. ([Link](#))

BHV Pharma - BHV091009 is a highly selective sodium glucose co-transporter 2 inhibitor ("SGLT2i") being developed for the treatment of diabetes and obesity. Two supportive Phase 2b studies. Also pursuing an obesity indication. ([Link](#))

Genfit - GFT505 PPAR in Phase 2 for diabetes and cardiovascular disease. ([Link](#))

**UPDATE** Generex - Has right to a Metformin gum, may have a better side effect profile than metformin with rapid delivery. There is no news of further development of this product past 2008 - it may have either been withdrawn or suspended in development. Generex is focusing its efforts on a buccal inhalant version of insulin (Oral-lyn).

HanAll Pharmaceutical - Looking to license a 24 hour metformin (GlucoDown OR tab). This would be a 505b(2) approval in the U.S. ([Link](#))
Japan Tobacco - JTT-851. In Phase 1 with this GPR40 agonist. A program at Takeda following a similar mechanism has shown a powerful POC. Works to decrease blood glucose by stimulation of glucose-dependent insulin production. JT interested in partnering the ex-Japan rights to this product after achieving a POC result.

Lexicon Pharmaceuticals - Pursuing LX4211 for Type 2 diabetes. LX4211 is a once-per-day, orally-delivered, small molecule drug candidate that inhibits the sodium-dependent glucose transporter 2 (SGLT2), lowering the accumulation of glucose in the body and reducing caloric load. Very strong Phase 2 data with a 0.76 reduction in HBA1C seen in four weeks. Company in active discussions on this and two other molecules.

Limerick Bio - Developing oral treatment (LIM-0705) to improve glycemic control with a focus on NASH. In Phase 2. (Link)

Poxel SA - Promising phase 2 data in Type 2 diabetes for a novel metformin like treatment. Company open to a change of control transaction.

Rhythm Pharma - RM-493 is a small peptide agonist with high specificity for MC4R. In preclinical studies, RM-493 induced dramatic reductions in food intake, body weight, and insulin resistance. RM-493 is advancing into human clinical trials as a potential new treatment for obesity and diabetes that reduces body fat and insulin resistance and improves cardiovascular function.

Transgeneron Therapeutics - PDX-1 is a transcriptional factor that turns on the body’s beta cell generation process, for Type 1 diabetes. Pre-clinical stage.

UPDATE Verva - VVP808 (002) is a non-thiazolidinedione insulin sensitizer for use in the treatment of type 2 diabetes mellitus (T2DM). Verva reported very phase 2a clinical proof-of-concept data with VVP808 in April 2012. (Link)

**DIABETES - INSULINS / INJECTIBLES**

Adocia - HinsBet is a fast-acting human insulin product comprising of human insulin and one polymer of the BioChaperone platform. This forms molecular complex with human insulin to accelerate insulin blood penetration. Positive data versus Novolog have put this company into Phase 2 trials. (Link)

UPDATE Alkermes - Inhalable insulin which has been discontinued. The market for inhalable insulin tumbled in 2008 when Pfizer pulled similar drug Exubera from the market, leading other pharma groups to cease development.

NEW Amylin – marketer of Byetta® and Bydureon® for the treatment of diabetes has reportedly received an offer from Bristol-Myers Squibb and, according to *Bloomberg* in mid-April 2012 has hired a financial advisor to help find a buyer. Separately, Amylin is interested in finding a partner outside of the U.S. to distribute its products.

UPDATE Aradigm – Inhalable insulin drug no longer appears on their website/pipeline, though is referenced in relation to co-development with Novo Nordisk. Unclear as to most recent development stage of insulin drug, though the AERx technology is being widely used for different indications and with promising results. Has previously completed phase 3 studies, excellent safety and efficacy. Essentially complete preclinical, clinical, and CMC packages. Strong IP generally in the area of inhalable insulins.

BioCon - Looking for partner for its late stage oral insulin project. Program missed endpoint in Indian studies.

UPDATE Biodel - Looking to partner Linjeta®. Completed two important phase 3 studies and has filed for FDA approval. Company received a complete response letter and has indicated that may instead advance other programs forward in clinical development. As of March 14, 2011, Biodel Inc. announced that it has selected two new formulations of recombinant human insulin for clinical testing and is accelerating clinical development plans of these mealtime insulin drug candidates.
**UPDATE** Cebix - Developing C-peptide replacement therapy (Ersatta) for the prevention of complications of diabetes in Type I patients. Company has completed Phase 1 studies and is expecting data from the next study in patients later in 2012. ([Link](#))

Camurus AB - CAM2036 is a convenient once-weekly GLP-1 product for treatment of diabetes type II and obesity. Still in preclinical stage.

**UPDATE** Conjuchem, LLC - After failing to find a buyer and filing for bankruptcy in 2010, the company was resurrected in August 2011 and relocated to Los Angeles. Currently only seeking strategic partnerships to complement their product portfolio. Have three products in the pipeline, one drug in Phase II trials, two platform technologies in preclinical development. Main assets include PC-DAC Insulin Technology, Exendin-4, a GLP-1 agonist in Phase II for the treatment of Type II diabetes and PC-Insulin, a long-acting basal insulin in preclinical testing.

**UPDATE** DiObex, Inc. – Was actively selling its VLD (very low dose) glucagon and glucagon analogue program, for the treatment and prevention of hypoglycemia. As of 2009, exists only as a legal entity. The company was actively looking to market DIO-901 though it is presumed discontinued. Cortendo AB is developing DIO-902 as COR-003 for the treatment of metabolic disorders and type-2 diabetes, in phase Iib studies.

Enject - GlucaPen is an auto-injector pen containing glucagon. Looking to partner or M&A in 2010. ([Link](#))

**UPDATE** Flamel - FT-105 is a basal insulin with a relatively flat PK curve. Appears to be better than Lantus. FT-105 has completed phase 1 studies. ([Link](#))

**UPDATE** Generex - In a Phase 3 trial of an oral insulin, Generex Ora-Lyn, that is already on the market in some countries. Has opened up a Phase 3 trial of this product, aiming for approval in Western countries. ([Link](#))

Halozyme - Has a fast acting insulin technology. Very nice POC shown in a recent Phase 2 trial. ([Link](#))

Hanmi Pharmaceutical - Pursuing HM11260C or LAPS-Exendin, a Phase 1 long-acting exendin-4 analogue. HM11260C is a novel GLP-1 agonist for the treatment of Type II diabetes. HM11260C holds great potential for the world-first, once-monthly administration program among incretin mimetics under development.

**UPDATE** Intarcia Therapeutics - In talks to partner its diabetes program. ITCA 650 uses Duros to deliver Eli Lilly’s Byetta to patients. Very positive Phase 2 data with a presentation at ADA 2011. Company has gone forward into Phase 3 studies with the support and cooperation of Quintiles and is reportedly close to a major partnership or M&A deal.

Mannkind Corporation - Looking to partner AFREZZA, an inhalable insulin, that has an upcoming PDUFA date. Rumored to be in an active M&A mode. Company received an approvable letter on Mar 15, 2010. The FDA asked for more information on data designed to support the clinical utility of Afrezza, as well as information about how comparable the commercial version of the product is to the version used in clinical trials.

Medesis - NP01 (a formulation of vanadium) improves insulin sensitivity leading to insulin sensitisation of peripheral tissues. As a consequence, glucose homeostasis is dramatically improved with better glucose uptake in insulin target tissues such as: skeletal muscle, liver and adipose tissue. Phase 1 trial complete. ([Link](#))

**UPDATE** Nektar Therapeutics - Would relicense EXUBERA - inhaled insulin. Exubera was withdrawn from the U.S. market in 2007 due to lack of consumer demand for the product. No drug safety concerns were cited in this withdrawal, but rather a failure to perform financially. ([Link](#))

**UPDATE** Thermalin Diabetes - Developing a variety of optimized insulin analogues for a variety of purposes. Thermalin Diabetes is targeting an $8 million series B round of investment that would fund the first in-human studies of its insulin analogs...[CEO Rick] Berenson would like to close the investment round by next year’s second...
quarter. Thermalin is targeting the end of 2012 to file an IND application with the U.S. Food and Drug Administration, which would likely enable the company to begin clinical trials in early 2013. (Link)

**NEW** TransPharma Medical - completed a Phase 1b trial of a transdermal GLP1 agonist, which is being developed for the treatment of diabetes mellitus type II.

Versartis - VRS-859, a long-acting exenatide. Positive Phase 1a data recently presented. Open to partnership / M&A. Also developing an IL-1, a glucagon and a HGH using Amunix pegylation technology and is currently in the IND stage. (Link)

**DIAGNOSTICS**

$ Abaxis - Physician office blood diagnostic machines - for sale. (Link)

**UPDATE** Acusphere – Imagify is pending EMA filing for this cardiac imaging agent. Highly differentiated from SPECT agents on the market insofar as permits evaluating of myocardial perfusion, an important marker of coronary artery disease (CAD) without radioactive markers. Potential first-to-market drug in $600 million and $2 billion addressable market in E.U. and U.S. respectively. Recent SPA from FDA in US. Will require one further trial for FDA approval. Has recently raised additional capital to complete its approval.

**NEW** Advanced Accelerator Applications – Cardiogen is a Phase 3 PET tracer for the detection of coronary artery disease in a manner that is safer and less invasive than angiography. (Link)

**NEW** Biotest - In discussions to sell its medical diagnostics business consists of the Biotest Medical Diagnostics GmbH in Dreieich and the Biotest Diagnostics Corporation in Rockaway/ USA. (Link)

**COMPLETED** Gen-Probe - Widely rumored to be for sale with interest from Novartis. Well known diagnostics company. Process well underway but company viewed as expensive. Update: Wall Street journal reports on July 20, 2011 that “Novartis is no longer actively pursuing U.S. medical diagnostic-testing company Gen-Probe, meaning Gen-Probe could end its sales process...” Update: Apr 2012 – Hologic buying Gen-Probe for $3.7bn.

Ikonisys - Marketed oncoFISH Cervical for detection of LSILs, precursor of cervical cancer. Signed a marketing deal with Enzo. (Link)

Ikonisys - Leading automated platform for CTC (circulating tumor cell) detection. (Link)

Norgine - NRL972 is a liver disease detection diagnostic in Phase II clinical development in the US. NRL972 is a liver staging tool, currently in Phase III clinical development in Europe and under an IND in Phase II clinical development in the US.

RedPath Integrated Pathology - Has cancer tests. ExonHit withdrew its public offer, though Company would presumably consider other offers.

**UPDATE** Source MDx - Had prognostic, predictive and early detection molecular diagnostic assays and tests that measure RNA-transcript for cancer and other inflammatory diseases. Its lead test is targeting prostate cancer and is in Phase III trials. Appears to have formally closed, with its intellectual property on auction.

Sienna Cancer Diagnostics - Would consider a sale. Strong diagnostics for bladder cancer and for prostate cancer. (Link)

**DRUG DELIVERY**
Altea Therapeutics - Has agreed to shutter its operations according to a story published in the Atlanta Business Chronicle on Dec 9, 2011 (Link). Atlanta-based Altea Therapeutics Corp. was developing a proprietary, noninvasive method to deliver therapeutic proteins, conventional drugs and vaccines through the skin by creating “micropores” on the skin’s surface.

NEW Aprecia: rapid dispersing tablets that can contain up to 1 gm of active, developed at 3DP / J&J and MIT

UPDATE Bioject Medical Technologies - Needle free delivery technology. Extends supply agreement with Ferring pharma. In Nov 2011, the CEO stepped down as a cost-cutting measure. As of February 2012, the company is reviewing its options with a financial advisor (Ferghana Partners), including a sale of the company. (Link)

SCOLR Pharma - has developed a wide array of controlled release / immediate release products including products including ibuprofen, pseudophedrine, raloxefine, ondansetron, niacin and fenofibrate. Looking for partnerships with assistance from HealthPro Bioadvisors. (Link)

COMPLETED Undisclosed player - player in drug delivery is searching for a merger or sale with assistance of a financial advisor. Company has expertise in both injectibles and controlled release solid dose. Substantial royalties and partnership deals signed. Update: Flamel instead merged with Eclat Pharma and the CEO of this company assumed the CEO role of Flamel and has an intention of building this company.

NEW TransPharma Medical - completed a Phase 1b trial of a transdermal GLP1 agonist, which is being developed for the treatment of diabetes mellitus type II. Also developing a PTH and calcitonin. (Link)

Vyteris - Has indicated that it is interested in disposing of a portfolio of pain products in development. These products include LidoSite®, an FDA approved product for the pretreatment of needle injection and venipuncture sites with Lidocaine (a related product is at Nuvo Research); a Phase 1 zolmitriptan patch and an NSAID patch. (Link)

EMERGING MARKETS - PARTICULARLY BRAZIL, CHINA, INDIA, TURKEY DEALS

UPDATE Abdi Ibrahim Ilac - largest Turkey drug maker with revenues over $800mm. Reported in May 2011 that was in discussions to sell a strategic stake. As of April 2012 it is understood that these discussions have not borne fruit.

Amoun Pharmaceuticals - An Egyptian company that manufactures off-patent branded generic formulations. It is one of the largest pharmaceutical companies in Egypt. It sells over 135 human products in over 275 forms. Of these products, 33 occupy the top 2 positions in their respective therapeutic categories and subcategories. Open to a company sale or strategic stake purchase. Reuters - Dec 6, 2010: “CVC is also preparing to sell Amoun, one of Egypt’s biggest drugmakers, people familiar with the matter told Reuters on Oct. 20. It owns Amoun with two other co-investors.” Bloomberg reported in Feb 2011 that the company has been looking for $1 billion in a sale price but that political upheaval in Egypt has hindered the sale.

UPDATE Biofarma Pharmaceutical Industry Co. - Biofarma for sale via JP Morgan. Reuters (12/6/2010): Citigroup's (C.N) venture capital arm and two co-investors have begun an auction of Turkish copycat drugmaker Biofarma, three people familiar with the matter said, in what could be Turkey's biggest healthcare deal. “A number of parties rumored to have looked at this asset but price ask was seen as prohibitive. A number of parties rumored to have looked at this asset but price ask was seen as prohibitive. As of Nov 15, 2011, it was reported that Biofarma's owners had ended an effort to find a buyer for the company, unable to agree upon a price with prospective bidders, but the owners could resume the sale process at a later stage, according to a source.

UPDATE China Nuokang Bio-Pharmaceutical - Lead products include Baquting for bleeding control, Aiduo, a cardiovascular stress imaging agent, and Aiwen, an anti-arrhythmic agent. The company has a value of $180mm. Biopharm Insight in November reported that this company hired Lazard for a sale process. Nuokang has made new management additions/promotions as of February 27, 2012, in line with their restructuring process, and their lead
product candidate Baquting remains the leader in the hemocoagulase market with 36% market share. In addition to Baquting, revenue from Kaitong has been steadily growing. For 2012, they expect to see revenue contribution from Kaitong and our newly acquired Alpha Lipoic Acid Capsule. Although the recovery process may be gradual, they are confident that 2012 will show sequential revenue and profitability growth compared to 2011.

$ Claris Life Sciences - Indian injectibles company has hired Rothschild to look at strategic options. Company has a rich pipeline of hospital generic injectibles using novel delivery methods. (Link)

COMPLETED Guandong Shunfeng Pharmaceutical, is exploring a sale. Revenues around $35mm. As of February 10, 2012, China Resources Sanjiu Medical and Pharmaceutical Co., Ltd. was affirmed as the winning bidder of the equity of Guandong ShunFeng Pharmaceutical Co., Ltd. a Chinese topical skin care drug manufacturer. China Resources Sanjiu will totally allocate about CNY 600 million to acquire 100% equity of ShunFeng Pharmaceutical. It is said that 0.1688% of ShunFeng Pharmaceutical’s equity are held by its shareholders.

Guangxi Golden Throat (Guang Xi Jin Sang Zi) - This privately held manufacturer of healthcare products is reportedly in sale talks. The company has annual revenues of around $47mm from its throat lozenges, which sell under the ‘Golden Throat’ brandname.

NEW Hailing Chempharma is a Chinese specialty pharma company with net profit of around $40mm. This company has strength in antibiotics and ownership from Mitsubishi UFJ Securities and AIF Capital. They are open to a sale.

Huanghai Pharmaceutical - has been approached by interested bidders according to Biopharm Insight (Nov 15, 2011). It has a well-established products brand and sales network in the local Chinese market, thanks to its star product "Nifedipine" which has 70% market share.

COMPLETED Mustafa Nevzat - Turkish generic pharmaceutical maker with revenues of approximately $250mm. According to Bloomberg (Jan 31, 2012), in talks to sell a strategic stake with help from Bank of America Merrill Lynch. Update: Amgen Inc. said it will acquire 95.6% of Mustafa Nevzat Pharmaceuticals A.S. (Istanbul, Turkey) in a cash deal that values the Turkish pharma at $700 million on April 25, 2012. Price close to 3X revenue.

Undisclosed - Chinese specialty pharmaceutical company with strength in anti-infectives. Good EBITDA and revenue over $70mm in 2011. Torreya Partners assisting in sale of majority stake. For details please contact rodolphe.grepinet@torreyapartners.com.

NEW Undisclosed – Hospital focused company with a strong presence in China is exploring strategic options with assistance of a financial advisor.

Undisclosed player - Division of Indian generic company that is focused on oral solid dose preparations is for sale. Revenues over $300mm. Company has strength in formulation work and manufacturing. Ships product to numerous global locations.

Undisclosed player – A number of emerging markets players are developing portfolios of generic injectable drugs including cytotoxics and anti-infectives.

Undisclosed player - Large domestic generic player in emerging markets has expressed openness to a change of control transaction.

ENDOCRINE

NEW Acino – Has a fully registratable leupreolmin implant system. (Link)

Althea Technologies - has a promising phase 2 extended release version of human growth hormone in development. Previously this compound was at Genentech, and originally at Altus.
Ambrilia Biopharma - Long acting version of ocreotide for acromegaly ready for market introduction in 2010. Large market opportunity. Company in bankruptcy. (Link) Recently agreed to extend licensing option agreement. There are still multiple partnership opportunities available.

Biopartners - In late stage trials with a sustained release version of human growth hormone (sr-rhGH/LB-03002). (Link)

Camurus - CAM2029 (octreotide chloride FluidCrystal® Injection depot) for treatment of acromegaly is in a Phase 2 trial against Sandostatin® LAR from Novartis.

Chiasma - Octreolin™ is an oral form of octracetide for the treatment of acromegaly caused by excessive growth hormone. In Phase 2 studies. (Link)

Critical Pharma - CP016 is a long acting injection of somatropin (recombinant human growth hormone). CP016 is in its phase 1 of studies.

$ IBSA International - Tirosint (L-Thyroxin) in soft gel capsules for treatment of hypothyroidism. Approved in the U.S. but not yet marketed. Company searching for a marketing partner. Looking to outlicense betametasone valerate patch for treatment of psoriasis. A wide range of markets (EU, USA, South America, Middle and Far East) are still available on exclusive or semi-exclusive basis. Possibilities for a global agreement. (Link)

**FIBROSIS**

Angion Biomedica - in Phase 2 studies for BB3, an HGF mimetic for the treatment of hepatic fibrosis and to facilitate better outcomes in renal transplantation. The naturally-occurring cytokine hepatocyte growth factor (HGF), also known as scatter factor, is active in numerous tissues throughout the body, participating in the regulation of angiogenesis, organogenesis, tissue repair and neural induction. (Link)

argEntis Pharmaceuticals - ARG201 in P2 for scleroderma. Some positive data but missed P2 endpoint at 12 months. (Link)

UPDATE Capstone Therapeutics - AZX100 is a novel synthetic 24-amino acid peptide. Based on its demonstrated effects in pre-clinical models and safety in clinical trials it is in Phase 2 development for hypertrophic and keloid scarring with potential for treatment of pulmonary fibrosis and intimal hyperplasia. On January 20, 2012, the company announced that it would cease clinical development of AZX-100 in dermal scarring, though certain pre-clinical, manufacturing and regulatory related projects that are either required form a statutory perspective or are under contract will continue to their completion.

Catena - VPC51299, an orally available pre-clinical molecular, targets LPA GPCRs with high potency (also see Amira). These GPCRs elicit a signaling cascade upon LPA binding the receptor leading to LPA’s biological effects, such as proliferation, migration, angiogenesis and so on. (Link)

UPDATE Conatus Pharmaceuticals - CTS-1027 an oral MMP inhibitor for liver disease with potential to treat liver fibrosis. Phase 2 study on treatment of hepatitis C patients underway. Results from this Phase 2 trial are forthcoming. Note: this trial was terminated in October 2011 due to reports of adverse events in some patients.

$ Daval International - In Oct 2011, announced positive results from a Phase 2 of AIMSPRO in patients with Late Stage Established Diffuse Cutaneous Systemic Sclerosis (diffuse scleroderma). (Link)

FibroGen, Inc. - Would consider outlicensing FG-3019 anti-fibrosis compound. Novel mechanism based on CTGF. Promising Phase 1b data in diabetic nephropathy. (Link)
Fibrotech - Has commenced manufacturing and non clinical toxicology for FT011, an antifibrotic for the treatment of diabetic nephropathy. Clinical trial due to commence in Q1 2012. (Link)

Galectin Therapeutics - Developing drug candidates for the treatment of liver fibrosis based on Galectin modulation. These candidates are currently in preclinical stage. Company planning to file IND. (Link)

**UPDATE** Intercept Pharma - OCA (formerly INT-747), an FXR modulator, for treatment of liver disease including primary biliary cirrhosis and NASH. Phase 2 results were positive. Company in active partnership discussions.

InterMune, Inc. - Bloomberg reports on April 27: “Biotechnology company InterMune known for its drug to treat lung scarring, hired Goldman Sachs (GS.N) to help it weigh a possible sale... Goldman has been conducting an auction of InterMune for more than a month and some potential bidders have been spooked by the biotechnology company’s expectations for a sale price, Bloomberg news reported.” Company commercializing Pirfenidone in Europe. Company market cap over $2bn.

**UPDATE** Phenex Pharma - Undergoing Phase 1 on an FXR agonist for liver fibrosis and NASH (Px-102). See Intercept Pharma for a similar program. Open to a licensing deal. Interested parties should contact Rodolphe.grepinet@torreyapartners.com.

Promedior - Developing recombinant human Serum Amyloid P Component for the prevention and treatment of fibrotic pathology. PRM-151 in Phase 2a trials for prevention of post-surgical scarring in glaucoma patients. Would consider a corporate sale and is currently in active partnership talks after raising an additional $12 million.

**COMPLETED** Stromedix - STX-100 is being developed for the treatment of chronic allograft dysfunction in kidney transplant recipients. Also exploring IFP indication. Humanized monoclonal antibody to integrin αvβ6, going into Phase 2. Note: This company was bought by BiogenIdec in Feb 2012 for $75mm upfront and additional contingent payments of $487.5 million.

Vernalis - V85546 - Phase 2-ready novel selective anti-inflammatory compound that selectively inhibits MMP12 and has in-vivo efficacy in pre-clinical models of Chronic Obstructive Pulmonary Disease (COPD), Multiple Sclerosis (MS) and liver fibrosis. Phase I SAD and MAD studies have been conducted. Substantial safety and tox package would support up to 6 month dosing in Phase II. Worldwide rights available. (Link)

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**GASTROINTESTINAL**

**UPDATE** 4SC AG - 4SC-101 met its primary endpoint in a Phase 2a trials for IBD in 2011. 4SC-101 contains vidofludimus, a novel, selective and orally available small molecule inhibitor of dihydroorotate dehydrogenase (DHODH), which interferes with cell proliferation through blocking the synthesis pathway of pyrimidines, thereby halting the proliferation of rapidly multiplying cells, in particular of lymphocytes which are involved in the pathology of autoimmune disorders. 4SC hoping to partner this program in 2012 and start Phase 2b trials by the end of 2012.

Ajinimoto - AJM300 is an alpha-4 or beta-7 integrin inhibitor, which is being developed for the treatment of Crohn’s disease. This product is in Phase 2 studies.

**UPDATE** Albireo - Positive IBS-c Phase 2 data on A3309 which modulates the enterohepatic circulation of bile acids by inhibiting the Intestinal Bile Acid Transporter (IBAT). Company starting Phase 3 studies. Albireo is rumored to be exploring a company sale with the assistance of a financial advisor. (Link)

Alevium - Long acting PPI. Solves a number of problems with omeprazole and Nexium.

**H** Alvine - Enzymatic treatment for celiac disease. Currently in a Phase 2a clinical trial. (Link)
AM-Pharma - Has achieved early POC results in the treatment of ulcerative colitis with alkaline phosphatase. [Link]

**NEW** Aptalis – very successful player distributing GI / cystic fibrosis medicines in the U.S. and Europe. No known sale process underway but has private equity backing that has been in investment for a number of years.

**NEW** Ardelyx - RDX5791 is a systemic NHE3 (sodium/proton exchanger type 3) inhibitor which increases intestinal sodium leading to enhanced interstitial fluid volume and transit. RDX5791 is being developed as capsule for the treatment of constipation predominant irritable bowel syndrome (IBS-C).

**UPDATE** Aryx Therapeutics - ATI-7505, an improved cisapride like molecule, for reduction of GERD, constipation and dyspepsia. Company retained Cowen to explore strategic options. Dec 15, 2010: “Over the course of the strategic process ARYx initiated earlier this year, the most significant interest, even in the absence of a binding offer, was shown in ARYx's gastrointestinal product candidate, naronapride (ATI-7505), demonstrating the potential value of the asset. Also, interactions with the US Food and Drug Administration ("FDA") in April 2010 substantially clarified the remaining clinical development requirements for the compound. As a result, the lead investors in ARYx encouraged the company to seek substantial additional funding to continue the development of naronapride internally, and such funding has been actively pursued since late summer without final resolution.” In March 2011, the company went into a wind down of its operations. [Link]

**NEW** Atlantic Healthcare Limited - Novel Phase 2 product (Alicaforsen) for treatment of pouchitis. On market in EU on a named patient basis. Open to a U.S. partnership. Interested parties should contact Rodolphe Grepinet at Torreya Partners (Rodolphe.grepinet@torreyapartners.com).

**UPDATE** Bioprojet - Tiorfan/Hidrasec (Racecadotril) is a selective inhibitor of neprilysin (NEP) which exhibits intestinal antisecretory action. Racecadotril is being developed for the treatment of acute diarrhea in children and is in Phase 3 studies. According to their site, Bioprojet's development strategy has brought "one drug up to marketing in France and worldwide (Tiorfan®/Hidrasec®, racecadotril INN, an intestinal antisecretory drug)." Not available in the US, presumably looking for a licensing partner. [Link]

**UPDATE** Cancer Prevention Pharmaceuticals - Seeking a ROW partner for its combo of efornithine and sulindac (CPP-1X/sul). In Phase 3 studies for familial adenomatous polyposis (FAP). As of August 2011 has secured financing to proceed with development, and as of July 2011 CPP had received positive advice from the EMA regarding its Phase III trial.

ChiRhoClin, Inc. - Secretin is a polypeptide hormone having 27 amino acids produced by S cells of the duodenum. Secretin is being developed as intravenous infusion for the treatment of pain due to chronic pancreatitis. [Link]


**NEW** Cosmo Pharmaceuticals S.p.A. - Looking for a partner for low molecular weight heparin derivative (LMW Heparin MMX) that is used to control ulcerative colitis. Impressive Phase 2 dataset supports the story. Interested parties should contact Rodolphe.grepinet@torreyapartners.com.

Cubist - Recently acquired Adolor and open to partnering rights to Adolor products in Asia. Included is ADL5945 for the treatment of opioid induced constipation. This product has completed Phase 2 studies. Interested parties should contact aaron.pelta@cubist.com.

Edusa Pharmaceuticals - In Phase 2 studies with Pumosetrag, a 5-HT3 partial agonist that works locally within the upper GI tract, is being developed to treat GERD symptoms in patients who continue to experience heartburn and regurgitation while on PPIs or H2-antagonists. [Link]

EMBYL Pharmaceutical Company - Would outlicense Kortos cream for hemorrhoids and anal fissures. [Link]
Epiomed Therapeutics - lead product is ETI-385, a novel anti-emetic, non-anxiogenic molecule with multi-receptor pharmacology acting in the CNS at the common final pathway for emesis. ETI-385 blocks all emetic stimuli (i.e. motion, chemical, conditioned) in preclinical models. Epiomed intends to move into human clinical studies in the 3rd QTR of 2012 (ETI-385 is the subject of a pending worldwide patent application).

EryDel SPA - EryDex contains dexamethasone sodium phosphate. Dexamethasone is a glucocorticoid agonist which binds with high affinity to specific cytoplasmic receptors. This results in modification of transcription hence, protein synthesis in order to achieve inhibition of leukocyte infiltration at the site of inflammation. EryDex is being developed as an intravenous infusion using EryDel technology for the treatment of crohn’s disease. In Phase 3 studies. (Link)

Evoke Pharma - EVK-001, an intranasal metoclopramide, is currently in Phase 2b for the treatment of the symptoms associated with diabetic gastroparesis. (Link) Product registration will occur following a pending Phase 3 clinical trial.

Furiex - developing MuDelta which was recently returned by J&J. Company reached an agreement with FDA for a Phase III trial of MuDelta in diarrhea-predominant irritable bowel syndrome (IBS-D) after an End-of-Phase II meeting with the agency. Interested parties should contact Sailash.Patel@furiex.com. (Link)

Galapagos Pharma - GLPG0974 is an orally available small molecule that inhibits GPR43. It plays a key role in inflammation and has shown potent inhibition of neutrophil migration, one of the critical cell types in inflammatory processes. Potential applications in GI and allergy. This product is in Phase 1 studies. (Link)

Genzyme / Sanofi - Outlicensing RDP58 (Delmitide), a clinical-stage D-amino acid decapetide with established anti-inflammatory properties. Proof of concept for this product opportunity has been demonstrated in models of inflammatory bowel disease (IBD).

Hutchison MediPharma - HMPL-004 has completed two global phase II clinical trials in IBD and ulcerative colitis. A 223-patient global Phase IIb trial for the treatment of ulcerative colitis (“UC”) showed a decrease in rectal bleeding and an excellent safety profile. Company initiating Phase 3 studies in 2012. (Link)

Hyperion Therapeutics - Developing Ravicti (formerly GT4P/HPN-100), an ammonium remover, for urea cyclic disorders and hepatic encephalopathy - Positive Phase 3 data and a high likelihood of approval in 2012. As of March 2012, Hyperion acquired the worldwide rights to this compound from Ucyclyd Pharma (of Medicis), though terms were not disclosed. Filed an S-1 IPO registration in April 2012. (Link)

Immune Pharmaceuticals – Has non-opthalmic rights to Bertilimumab, a Phase 2 antibody targeting eotaxin-1 with application to Crohns disease, ulcerative colitis and asthma. (Link)

ImmusanT - Nexvax2 vaccine seeks to reprogram CD4+ T cells to induce gluten tolerance. This Phase 1 program for Celiac disease has high promise.

InDex Pharmaceuticals - Kappaproct®, a nuclear factor NF-kappa-B p65 subunit oligonucleotide has completed its third clinical phase II trial for the treatment of steroid resistant/dependent ulcerative colitis patients and is currently enrolling patients in its phase III COLLECT trial throughout Europe. Has recently brought out a companion diagnostic to complement the drug therapy (March 2012). (Link)

Lexicon Pharmaceuticals - Currently pursuing LX1033, a more potent compound which is near the IND stage and have recently entered phase II trials.

Lipid Therapeutics - Looking for a U.S. partner for LT-02 with strong positive Phase 2b data for Phosphatidylcholine derivative to treat 5-ASA resistant ulcerative colitis. Potential for approval with a single Phase 3 study. Recently entered into a licensing agreement for the European rights to Lipid Therapeutics’ lead product, LT-02, for UC with Dr. Falk Pharma GmbH, which will assume full responsibility for the further development and
commercialization of LT-02 in Europe, with a Phase III induction trial in UC planned to start in the second half of 2012. [March 2012].

Menarini - ibodutant, a tachykinin NK2 receptor antagonist for IBS. In phase I clinical studies in humans, the drug was safe and well tolerated, showing good PK. Now in Phase 2 studies. (Link)

**COMPLETED** Meritage Pharma - Positive Phase 2b data on effect of oral budesonide suspension (OBS) an oral formulation of budesonide for the potential treatment of patients with eosinophilic esophagitis (EoE). As of March 2012, entered into an agreement with ViroPharma that gives them an exclusive option to buy Meritage – have paid $7.5 million upfront and potentially $12.5m more contingent on milestones and further Phase II data from OBS. ViroPharma will have an option to acquire Meritage at ViroPharma’s discretion for $69.9 million plus the potential for additional payments upon the achievement of certain clinical and regulatory milestones.

**UPDATE** Moberg Derma - A-Fizz was in preclinical development for the treatment of chronic anal fissures, but as of October 27, 2011, development was discontinued due to poor preclinical test results.

**UPDATE** NPS Pharma - developing GATTEX for the treatment of short bowel syndrome. Have filed NDA and awaiting feedback from FDA (Sep 2012 PDUFA date). NPS has indicated interest in commercializing this product on its own.

Ocera - Development of a novel carbon sorbent for mild hepatic encephalopathy and IBS. Company to report out Phase 2b data for hepatic encephalopathy compound soon. Active business development discussions underway.

Ocera Therapeutics – Development ongoing for the NCE, OCR-002, for acute liver failure. Also development of a novel carbon sorbent (AST-120) for mild hepatic encephalopathy and IBS. Company to report out Phase 2b data for hepatic encephalopathy compound soon. Active business development discussions underway.

Ono Pharmaceutical - Has completed Phase 1 studies with ONO-2952, a TSPO antagonist for the treatment of IBS. An ex-Japan partnership transaction is possible.

**UPDATE** OxThera AB - Oxazyme is recombinanate oxalate degrading enzyme for the treatment of kidney stones. A related compound is at Altus Pharmaceuticals (ALTU-237), also an oral crystalline formulation of oxalate oxidase, found to be safe and well-tolerated in 2008 Phase I trial data. No more recent trial updates from OxThera, after planning to begin clinical trials in 2007. (Link)

Paion –Looking to outlicense CNS7056 based on the available Phase II data for the drug as a short-acting intravenous anesthetic/sedative for colonoscopy. Positive data were reported out in Nov 2009.

**UPDATE** Palau Pharma - Currently undertaking a Phase 2 clinical trial with Derslazine sodium for mild to moderate ulcerative colitis. Looking for a partner to assist with later stage trials. After an October 2011 sale of their Drug Discovery Unit to Draconis Pharma, the company is focusing exclusively on developing its later stage compounds, and looking for a partner to assist.

Pharmos Corporation - Looking to partner Dextofisopam for diarrhea predominant and alternating diarrhea and constipation irritable bowel syndrome. Positive in Phase 2a and missed endpoint in Phase 2b but activity seen.

RaQualia Pharma, Inc. – Phase II ready with a reversible inhibitor/acid pump antagonist (RQ-00000004, RQ-00000774) of gastric H+/K+-ATPase for GERD. Likely superior to current proton pump inhibitor (PPI) therapies because of rapid onset, long duration and the absence of a food effect. (Link) (Noncon)

Rhythm Pharmaceuticals - RM-131, a novel ghrelin agonist, is effective in restoring normal gastric function in animal models of delayed gastric emptying owing to a direct prokinetic effect. This compound is in Phase 1 trials with a focus on gastroparesis.
Ritter Pharma - RP-G28 for lactose intolerance has completed a Phase 2a study. A multi-center randomized, double-blinded, placebo-controlled parallel group trial using a novel short-chain galacto-oligosaccharide (RP-G28) enrolled 61 proven lactose intolerant maldigesters with the aim of improving lactose digestion and tolerance. Lactose maldigestion (LM) was determined by breath hydrogen. Daily dosing with RP-G28 resulted in a significant reduction in breath hydrogen production (p=0.01), peak hydrogen production (p=0.03) and in symptoms of abdominal pain (p=0.01), flatulence (p=0.05), abdominal cramping (p=0.01) and gurgling (p=0.03) after a 25 g lactose challenge.

Romark - Pursuing Nitazoxanide (NT-675, NT-300) for C diff associated disease, rotavirus and hepatitis C. (link)

Rose Pharma - GLP-1 product ROSE-010 for IBS. Positive data. Compound from Lilly. Company open to a sale transaction.

Salix - looking for a European partner for RELISTOR, an oral/subcutaneous treatment for opioid-induced constipation. This was recently partnered in Asia to Link Healthcare.

S.L.A. Pharma AG - Has developed a formulation of *diltiazem hydrochloride for the treatment of anal fissures. This product is in Phase 3 studies and is licensed to Ventrus Bioscience for the US market. SLA has rest of world rights, seeking partners for various geographic regions and individual countries. (Link)

S.L.A. Pharma AG - Has developed Eicosapentaenoic acid (EPA) is an omega-3 polyunsaturated fatty acid, taken as a gastro-resistant oral capsule, for the treatment of Familial Adenomatous Polyposis (FAP). Phase 3 clinical study data demonstrates a significant reduction in rectal polyp number in subjects with familial adenomatous polyposis who had previously undergone colectomy and ileal-rectal anastomosis. (Link)

Synergy Pharma - Synergy presently has a drug, plecanatide, in clinical development to treat chronic constipation (CC) and constipation-predominant irritable bowel syndrome. Has shown positive Phase 2a data. Compare to Ironwood / Forest compound linaclotide. In Nov. 2011, the company raised $15mm for further trials, and as of April 9, 2012 had achieved halfway mark in enrollment on plecanatide phase II/III trial in chronic idiopathic constipation. (Link)

Theravance - 5-HT₄ receptor agonist compound, Velusetrag (TD-5108), is for the treatment of chronic constipation and other disorders related to reduced gastrointestinal motility. Strong positive Phase 2 data. CEO indicated on Sep 29 the company was “in talks with several companies regarding a partnership, but he is very open to speaking with additional companies.”

Thorne - Arabinex for the prevention of constipation and diarrhea associated with use of antibiotics.
**NEW** Tillotts – looking for a marketing partner for Asacol for ulcerative colitis in the the CEE markets, Latin America and Asia ex-Japan and Korea. ([Link](#))

**NEW** Tillotts – looking for a marketing partner for Colpermin® which contains peppermint oil and is indicated for the symptomatic treatment of bowel spasms and bloating, particularly in irritable bowel syndrome (IBS). Distribution rights for Colpermin® are available for most countries (North America and Europe: except UK, Ireland, Germany, Austria and Switzerland). ([Link](#))

**UPDATE** Tioga - Asimadoline from Merck KGaA. In a Phase 3 trial. Data from the Phase 3 trial (conducted under a SPA) is expected 1H 2013. Asimadoline is an agonist of the kappa opioid receptor with high selectivity over other opioid receptors such that it does not produce classical mu-opioid like effects (such as constipation and dependence). In a 596-subject Phase 2b clinical trial asimadoline demonstrated statistically significant results in the treatment of D-IBS patients with at least moderate pain across multiple parameters including endpoints of pain, urgency, frequency and bloating in both males and females. Rights to certain Asian countries in-licensed by Ono in September 2009. ([Link](#))

**UPDATE** Tranzyme - TZP-102 is an agonist of ghrelin receptors and acts as a GI prokinetic agent in Phase 2a studies. Strong data were seen. Also, TZP-101, is an injectible ghrelin agonist being evaluated in two concurrent Phase IIb data for the treatment of acute indications, severe gastroparesis and post-operative ileus (POI) were not encouraging. Still looking for partners, focusing efforts exclusively on development of TZP-102.

Undisclosed player - Two early stage GI drugs from a large pharma company are available for partnering.

**NEW** Undisclosed player – approved anesthetic that with one additional trial would be appropriate for use as a sedative during a colonoscopy.

**NEW** Undisclosed – product for fecal incontinence that is late stage in clinical development. Interested parties should contact alan.selby@torreyapartners.com.

Undisclosed player - Highly effective product for ulcerative colitis. 80%+ remission rates seen in recent clinical study. Company looking for commercialization partner.

**UPDATE** Ventrus - Have iferanserin ointment (VEN-309) for hemorrhoids with a good data package. The first phase 3 trial began in August 2011 and data are expected by July 2012. In addition, a Phase 3 trial for a separate compound for anal fissures is underway with data expected in June 2012. Company has gone public and raised over $70mm in capital to finance and obtain approval for its top two programs. Product has potential revenues in excess of $1 billion. ([Link](#))

Xenoport - XP19986 is a prodrug of the R-isomer of baclofen. Baclofen is a generic drug that has been shown in investigator-led studies to be effective in the treatment of GERD. Interested in partnering this drug and is in phase 2.

Yuhan Corporation - YH4808 is a Potassium-Competitive Acid Blocker (P-CAB) with characteristics of potent, sustained inhibition of gastric acid secretion with faster onset. Unlike PPIs, YH4808 does not require acid-activation which resulted in rapid increase in stomach pH. Therefore, fast symptom relief in patients expected. Positive Phase 1 data. ([Link](#))

Zealand Pharma - Looking to partner ZP1848 for IBD which is completing Phase I development. ZP1848 is a SIP modified novel GLP-2 peptide analogue with enhanced stability and efficacy. Company has excellent medicinal chem and development capabilities. Would consider an M&A transaction. ([Link](#))

**GENERIC**

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**Actavis** – A number of media reports suggest a likely acquisition of this global pharmaceutical company by Watson for $5-6 billion. Update: Watson announced this acquisition on April 25, 2012.

**Abdi Ibrahim Ilac** - largest Turkey drug maker with revenues over $800mm. Reported in May 2011 that was in discussions to sell a strategic stake. As of April 2012 it is understood that these discussions have not borne fruit.

Amoun Pharmaceutical - An Egyptian company that manufactures off-patent branded generic formulations. It is one of the largest pharmaceutical companies in Egypt. It sells over 135 human products in over 275 forms. Of these products, 33 occupy the top 2 positions in their respective therapeutic categories and subcategories. Open to a company sale or strategic stake purchase. Reuters - Dec 6, 2010: “CVC is also preparing to sell Amoun, one of Egypt’s biggest drugmakers, people familiar with the matter told Reuters on Oct. 20. It owns Amoun with two other co-investors.” Bloomberg reported in Feb 2011 that the company has been looking for $1 billion in a sale price but that political upheaval in Egypt has hindered the sale.

Apoex - looking for ex-Canada licensees / commercial partners for its large portfolio of generic products. ([Link](#))

**Bioton** – Polish manufacturer of insulins and antibiotics open to export and registration of its products in other countries ([Link](#))

**Claris Life Sciences** - Indian injectibles company has hired Rothschild to look at strategic options. Company has a rich pipeline of hospital generic injectibles using novel delivery methods. ([Link](#))

**CNS Therapeutics** - has introduced Gablofen, an AP rated intrathecal version of baclofen for control of severe spasticity among patients with movement disorders. This product has significant advantages over the existing marketed product and is likely to have significant revenue traction over the next several years. This product is promoted and the company is a suitable acquisition candidate for either a branded or generic company. Rumored to be in active sale discussions. ([Link](#))

**Covidien Pharmaceuticals** - According to the *New York Times* on June 7, 2011 “Covidien, the health care company spun out from Tyco four years ago, may seek to sell its pharmaceutical unit...” This division of Covidien (formerly Mallinckrodt) has a major business selling pain products (both branded and generics) and imaging products. Revenues are around $2 billion. Update: As of April 2012 no sale has taken place. Company is rumored to be interested in a sale of the whole business (rather than pieces) for a full price and is now thought to be more likely to be spun out. YE 2011 numbers reported on Nov 15, 2011 and were robust (sales up 9% yoy) with strong performance in generics.

**Daewoong** – has manufactured and patented a process to make generic lopromide, a cardiac contrast agent sold as Ultravist® by Bayer. Available for license. ([Link](#))

**Hi-Tech Pharmacal** - Market rumors in April 2011 that company could be purchased. As of April 2012 no transaction had taken place of this manufacturing company of generic liquids and ointments. The company has delivered strong earnings in the last year and has been trading well above its earlier share price.

**Huanghai Pharmaceutical** - has been approached by interested bidders according to Biopharm Insight (Nov 15, 2011). It has a well-established products brand and sales network in the local Chinese market, thanks to its star product "Nifedipine" has 70% market share.

Ibsa - Tirosint ([L-Thyroxin](#)) in soft gel capsules for treatment of hypothyroidism. Approved in the U.S. but not yet marketed. Company searching for a marketing partner. Ibsa - looking to outlicense betametasone valerate patch for treatment of psoriasis. A wide range of markets (EU, USA, South America, Middle and Far East) are still available on exclusive or semi-exclusive basis. Possibilities for a global agreement. ([Link](#))
Jubilant Pharma - has a list of generic oral solid pharmaceuticals in development that are available for licensing for Europe and the U.S. (Link)

Labormed - Romanian manufacturer of generic drugs is interested in finding global licensing partners for a series of generic products (Link)

Niche Generics - Looking for partners for its long list of generic products that have been developed. Subsidiary of Unichem. (Link)

Par Pharmaceuticals - Relational Investors filed a 13D showing 8.7% ownership of this company on November 25, 2011. In the 13D Relational indicated: “Despite these opportunities for improvement, the Reporting Persons believe that the Company may continue to trade at discounted prices because of industry challenges and the Company’s sub-optimal size and product scope. If the discount persists, the Reporting Persons believe that, in keeping with sound stewardship principles, the Company’s board will be required to consider broad strategic alternatives. Specifically, the Reporting Persons are confident that substantial cost savings could be achieved in a transaction with a strategic buyer.” Note: there is no evidence that Par Pharmaceuticals has received offers or is open to receiving such offers at present.

UPDATE Riemser - German vertically integrated marketer of generic and branded pharma products with strength in cardiovascular, dental and veterinary medicines. Revenues of this company exceed €100mm and EBITDA around €30mm. Active sale process underway according to Biopharm Insight.

UPDATE Rottapharm - for sale according to the Wall Street Journal. Company has two Phase 3 drugs in development and a strong group of branded products in the market. Revenues over $850 million. Sale price could be over $2.5 billion. Company rumored to be using Credit Suisse to find a buyer. According to Bloomberg (3/15/2012) Mylan recently pulled out of a sale process. The article noted that “sources said the selling family has not been able to agree to give up control of the company and was not prepared to compromise enough on price either.”

Stada - Chief executive Hartmut Retzlaff indicated an openness to takeover offers after the sale of Ratiopharm.

COMPLETED Undisclosed Player - U.S. generic company with more than $100 million in revenues is for sale. Company has a significant branded business and a manufacturing facility. Note: Takeda acquired URL Pharma’s generic and branded businesses on April 11, 2012 for $800mm plus contingent payments. The revenues of URL were approximately $550mm.

COMPLETED Undisclosed – dermatology player in the U.S. with strength in brands and generics open to a change of control transaction. Revenues > $70mm. Update: Fougera was acquired by Sandoz for $1.5bn on May 2, 2012.

NEW Undisclosed – UK generic pharmaceutical company with over $50mm in revenues. Expertise in liquids and “specials”. Open to a change of control transaction.

NEW Undisclosed – dermatology player in the U.S. with strength in generics open to a change of control transaction. Revenues > $70mm.

NEW Undisclosed – Indian CRO / drug developer looking for a change of control or new investor. Substantial revenue base.

NEW Undisclosed – UK generic player with strength in oral solid dose looking for an acquirer.

NEW Undisclosed player – US generic player with revenue > $25mm with multiple ANDAs is looking at a potential sale.

NEW Undisclosed player – US generics company with strength in injectibles and revenue > $80mm is seeking a buyer.
Undisclosed generic player - Looking for a partner for a portfolio of generic biologics in development. Wants to retain manufacturing rights.

Undisclosed player - a number of emerging markets players are developing portfolios of generic injectable drugs including cytotoxics and anti-infectives.

Undisclosed player - Large domestic generic player in emerging markets has expressed openness to a change of control transaction.

Undisclosed player - U.S. company with one approved product and a rich pipeline of other high value injectable generic products is looking for either a marketing partner or a company buyer.

Undisclosed - Chinese specialty pharmaceutical company with strength in anti-infectives. Good EBITDA and revenue over $70mm in 2011. Torrey Partners assisting in sale of majority stake. For details please contact rodolphe.grepinet@torreyapartners.com.

Undisclosed player - U.S. generic player with approximately $250mm in net revenues and strength in solid dose manufacturing would consider a company sale.

$ Undisclosed player - sale of company with over $10mm in revenue with largely genericized specialty products in CNS and renal disease.

Undisclosed Player - U.S. generic company with approximately $90mm in gross revenue is searching for a buyer with the assistance of a financial advisor. Company has substantial presence in medicines for cough & cold, womens health and pediatrics.

Undisclosed player - Division of Indian generic company that is selling its oral solid dose preparations business. Revenues over $300mm. Company has strength in formulation work and manufacturing. Ships product to numerous global locations.

Undisclosed Player - U.S. generic company with more than $40 million in revenues is for sale via Torrey Partners. Company has a significant pipeline, high growth and a fully developed operating platform. Interested parties should contact tom.babich@torreyapartners.com.

Undisclosed - German vertically integrated marketer of generic and branded pharma products with strength in cardiovascular, dental and veterinary medicines. Revenues of this company exceed €100mm.

Undisclosed player - U.S. generic company with revenues over $100mm but weak profitability is considering a sale transaction.

Undisclosed player - several portfolios of ANDAs including a group of six solid dose ANDAs on infrequently genericized products (generally through one bio study) and a portfolio of around 20 solid dose/liquid ANDAs on more frequently genericized products.

Undisclosed player - U.S. generic player with approximately $25mm in revenues and an interesting pipeline is running a sale process.

Undisclosed player - U.S. generic player with approximately $30mm in revenues and some manufacturing capacity would consider a company sale deal.

USV - offering a biogeneric PTH. Teriparatide is a recombinant form of N-terminal 1-34 amino acids of human parathyroid hormone which is a 84 AA protein. Approval pending in India.
Ardea Biosciences – lenisurad for the control of gout. Has shown high efficacy in reduction of hyperuricemia in Phase 2 studies and is now in a fully funded 2000 patient Phase 3 registrational program involving four separate ongoing clinical trials. These studies are expected to report out sometime in 2013. Update: On April 23, 2012 – AstraZeneca announced an acquisition of Ardea for $1.3 billion.

**UPDATE** Biocryst - BCX4208 is a next generation purine nucleoside phosphorylase (PNP) inhibitor with the potential for once-a-day dosing suitable for chronic administration. With its novel mechanism of action, BCX4208 has the potential to address unmet medical needs across a broad spectrum of inflammatory diseases, including gout with positive Phase 2 data. In January 2012, BioCryst announced positive long-term results from the extension phase of its randomized Phase 2b study of BCX4208 added to allopurinol in patients with gout who had failed to reach the serum uric acid (sUA) therapeutic goal of < 6 mg/dL on allopurinol alone.

3SBIO / EnzymeRx - Developing Uricase-PEG 20 to treat gout (see Savient). In a Phase 1 study. Company in a sellside process. Update: Company sold global rights to 3SBIO of China for $6.25 million in November 2010. Note that 3SBIO is planning to find a development partner for this product outside of China. ([Link](#))

Metabolex, Inc., a biopharmaceutical company focused on the discovery and development of proprietary NEW medicines for the treatment of metabolic diseases, announced in May 2011 that it has initiated a Phase 2 clinical trial of arhalofenate (MBX-102), its product candidate for the management of hyperuricemia in patients with gout.

Nuon Therapeutics - Developing tranilast for gout with strong positive Phase 2 data reported at EULAR 2010. ([Link](#))

**NEW** Odan Labs - Colchicine is an oral drug (0.6mg and 1mg) for treating Gout and Familial Mediterranean Fever (FMF). This product is on the market in Canada and can be introduced to other markets quickly.

Pharmos - Data from Phase I studies in healthy volunteers using S-Tofisopam showed lowering of uric acid. Company open to a change of control transaction. Also developing a Phase 2 product for GI disorders.

Savient Pharmaceuticals - FDA approved KRUSTEXXA (pegloticase) in Sep 2010, a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Company is seeking a commercial buyer and is using JP Morgan and Lazard in its search for an acquisition partner. Savient is now pursuing a launch of Krystexxa on its own and is building a 50-person plus sales force. ([Link](#))

Topotarget - Inflammasome Inhibitor is a protein scaffold and an interleukin 1 (IL-1) inhibitors are being developed for the treatment of gout.

Undisclosed - Private company has a number of promising NCEs in development for the management of hyperuricemia.

**HAIR / SCALP**

Advagen - Marketing OTC products that stimulate hair growth by inhibiting FGF-5 on the scalp. Based on research from Australian company Cellmid, Ltd. ([Link](#))

Cosmo Pharma - CB-03-01, NCE for the topical treatment of Acne, Hirsutism and Androgenic Alopecia, is in phase II studies. Recently showed nice Phase 2 POC in treatment of alopecia. Open to a partnership. ([Link](#))

Follica - Company is developing technology that stimulates development of hair follicles. ([Link](#))

Histogen - Histogen, Inc. announced the one year data findings of its Hair Stimulating Complex (HSC) pilot clinical trial. Statistically significant new hair growth was seen in HSC-treated subjects at this follow-up timepoint, one year after their single treatment with HSC.
Jina Pharma - MORR-F solution contains minoxidil and finasteride, which on topical application reduces falling of hair and stimulate hair growth in individuals with alopecia. Efficacy shown. ([Link](#))

**NEW** Proceruts – In a Phase 2 trial for ProDermaCel™, a topically applied pharmaceutical that protects normal hair follicle stem cells to prevent the loss of hair (alopecia) suffered by cancer and bone marrow transplant patients undergoing chemotherapy and/or cranial radiotherapy. ([Link](#))

**UPDATE** TG Therapeutics (formerly Manhattan Pharmaceuticals) – In late stage development of Hedrin, a treatment for head lice. Hedrin is the top selling head lice product in Europe. The JV developing this product was recently restructured to give greater ownership to Nordic Biotech Fund II. The JV is actively looking for U.S. and Canada development partners. ([Link](#))

Moberg Derma - K301 for seborrheic dermatitis has shown benefit in two Phase 3 clinical trials. Recently the clinical studies were completed and now are looking for licensing.

Nidus Laboratories - Developing a short Fas-disabling peptide mimetic for topical therapy of hair loss.

Piedmont Pharmaceuticals - Have a late stage product for treatment of head lice. Partnered and marketed in Europe. **RESULTZ** is sold internationally through licensing partners. Looking for other partners.

R-Tech Ueno - Announced that the Phase Ila clinical study of RK-023 to treat androgenetic alopecia has been completed by January 21, 2011.

**COMPLETED** Topaz Pharma - completed two Phase 3 studies for the treatment of head lice with Ivermectin. Planning to submit NDA to FDA in 2011. This company was bought by Sanofi-Pasteur for an undisclosed amount in December 2011.

$ Undisclosed player - seeking buyer for approved product for the treatment of head lice in the United States. Significant commercial traction. Interested parties should contact benj.garrett@torreyapartners.com.

**HEARING / EAR DISORDERS**

13Therapeutics - Developing P13 as a treatment for Acute Otitis Media (AOM). Many colds in young children are accompanied by ear infections. P13 is an orally available anti-inflammatory 20 amino acid peptide derived from a viral regulatory protein. ([Link](#))

Adherex - In Phase 3 development of sodium thiosulfate for treatment of hearing loss associated with **Cisplatin** use. And is still looking for a partner. ([Link](#))

Auris Medical - AM101 is a small molecule, non-competitive antagonist of NMDA receptors that selectively blocks NMDA receptors in the cochlea. AM101 is being developed as parenteral formulation for the treatment of acute inner ear tinnitus. Phase 3 study planned for 2012 following positive data. ([Link](#))

Desitin - studying Travistal in tinnitus. On market in U.S. but potential for new exclusivity surrounding indication.

Foresight Biotherapeutics - Has recently completed a Phase 3 trial of FST-201 (dexamethasone 0.1%) Otic Suspension vs. the FDA-approved drug Ciprodex (ciprofloxacin 0.3%, dexamethasone 0.1%) Otic Suspension (Alcon Laboratories, Inc.) in the treatment of acute otitis externa. ([Link](#))

Octoplus - developing OP-145, a therapeutic peptide for the treatment of chronic middle ear infection.

**UPDATE** Otonomy - Searching for an ex-U.S. partner for a dexamethasone gel for Meniere’s disease which affects 600,000 people in the U.S. Achieved nice Phase POC in the treatment of tinnitus and vertigo in results announced in Sep 2011. ([Link](#))
Sound Therapeutics - going into Phase 2 studies of a product to reduce hearing loss from chemotherapy. ([Link](#))

**HEMATOLOGY**

Abiogen - Neridronate is an amino-bisphosphonate used in Metabolic Osteopathy and has gone into Phase 3 trials. Also being studies for patients with thalassemias. ([Link](#))

Ablynx - **ALX-0081** is a Nanobody targeting von Willebrand Factor (vWF), to reduce the risk of thrombosis in patients with acute coronary syndrome (ACS) and thrombotic thrombocytopenic purpura (TTP). Through Phase 1b. Phase 2 data are expected.

Adventrx- ANX-188 is a novel, purified, rheologic and antithrombotic compound initially being developed as a first-in-class treatment for pediatric patients with sickle cell disease in acute crisis. Ready for Phase 3 studies and open to partnering deals.

**UPDATE** AesRx - Aes-103, is a small molecule (Da 126) discovered by researchers at Virginia Commonwealth University. Treats sickle cell disease by increasing the affinity of sickle hemoglobin for oxygen. Currently, in a Phase 1 trial. ([Link](#))

**UPDATE** Akebia – Positive Phase 2 with a HIF modulator for the treatment of anemia. Originally developed at P&G Pharma. Company reported positive Phase 2 data in pre-dialysis CKD patients in April 2012. At a recent conference, its spin-out company Aerpio indicated that a change of control transaction is likely in 2012. Interested parties should contact Bill Daly ([wdaly@akebia.com](mailto:wdaly@akebia.com)). ([Link](#))

Alder Biopharmaceuticals - Phase 2 data from ALD518 investigational antibody therapeutic that targets interleukin-6 (IL-6) demonstrate a reversal of anemia in patients with advanced non-small cell lung cancer (NSCLC). After 12 weeks of treatment with the anti-inflammatory therapeutic, 58 percent of patients who received ALD518 experienced hemoglobin level increases from less than 11 g/dL to more than 12 g/dL, while no patients receiving placebo experienced this increase. Also saw improvements in lean body mass and reductions in fatigue. Note: this antibody is partnered to BMS for all indications except cancer. ([Link](#))

Amsterdam Molecular Therapeutics (AMT) – Hemophilia B - very promising results from a gene therapy trial to treat Hemophilia B which is due to a deficiency of Factor IX. Update: In Nov 2011 the company indicated that it will be focusing resources on the development of this product. ([Link](#))

AOP Orphan Pharma - P-1101 contains pegylated interferon alfa-2b (PEG-P-INF alpha-2b), a conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol which shows antiviral and immunomodulatory effects. P-1101 is being developed for the treatment of polycythemia vera. A Phase 1b study is underway.

$ Biotest - a major global player in plasma proteins (IGs, coagulation factors) and antibodies (for inflammation) had revenues in 2009 of 440mm EUR. Company was reported by Barron’s as a takeover target in Feb 2010.

**UPDATE** Bluebird Bio - Positive Phase 1b type data for LentiGlobin® for gene therapy treatment in a young adult with severe betathalassemia, a blood disorder that is one of the most frequent inherited diseases. Also has positive data for a treatment for Adrenoleukodystrophy (CCALD) is a rare, inherited neurological disorder. This company has very high potential value given the positive CCALD data and the size of the market.

Catalyst Biosciences - developing improved proteases for hemophilia and inflammation. A Factor VII program has been partnered to Wyeth but a Factor IX program which is in a preclinical stage is company owned at present.

Cellerant - Developing a novel, cell-based medicine ([Myeloid Progenitors / CLT-008](#)) as a treatment for chemotherapy- and radiation-induced neutropenia as well as for Acute Radiation Syndrome. ([Link](#))
Cleveland Biolabs - Open to partnering a preclinical stem cell mobilizer. Partnered in China. ([Link])

Clinuvel - In Phase 3 for European approval for Afamelanotide, a photoprotectant to be used in Erythropoietic Protoporphyria. Update: Company looking to partner in EU first and then the U.S. In active discussions but thinking of going alone.

Emisphere - has developed a rapid release Vitamin B12 which is on the market. Upcoming studies to show relative efficacy of this product which would likely be marketed as a medical food.

COMPLETED Ferrokin - conducting worldwide Phase 1b clinical trials to evaluate the safety, tolerability, and iron clearing activity of FBS0701, a once daily iron-binding compound, for the treatment of transfusional iron overload. Note: this company was acquired by Shire in March 2012 for more than $100mm.

Green Cross - Developing Intravenous Immune Globulin (IVIG). In Phase 3 in Korea. Recently went forward with an IND in the United States. Extensive evidence supports use of this blood product to treat a variety of conditions including Alzheimers disease. ([Link])

Hemaquest - Like Prometic below, exploring use of fatty acids and derivatives for the treatment of anemia, particularly sickle cell anemia. In Phase 2 studies. Recently appointed a new CEO and moved company to San Diego. ([Link])

Incode BioPharmaceutics - HC3-1496 results in enzymatic depletion of the complement protein C3, the key component for all three pathways of complement activation. Preclinical and applicable for oncology, PNH and RA.

Japan Tobacco - Has Phase 1 HIF inhibitor for the treatment of anemia. Prefers to partner non-Japan rights after achieving proof of concept.

Medgenics - Medgenics has EPODURE with promising Phase 1b data showing efficacy in controlling anemia without the cost of EPO. Open to a partnership transaction.

UPDATE Noxxon - has completed Phase 1b studies of NOX-A12, an inhibitor of SDF-1 or CXCR12 – drug candidate was well tolerated and was associated with a dose dependent mobilization of CD34+ cells. This is a chemokine that is a key regulatory element in the homing and retention of hematopoietic stem cells in the bone marrow. SDF-1 binds with high affinity to the chemokine receptors CXCR4 and CXCR7. The CXCR4/SDF-1 axis has been shown to play a role in stem cell mobilization, vasculogenesis, tumor growth, and metastasis. ([Link])

Polyphor - Phase I CXCR4 antagonist, POL6326 for hematological stem cell mobilization. Outlicensing opportunity. Similar to AnorMed Mozobil now controlled by Genzyme. ([link])

Prometic - Exploring partnership options for PBI-1402 for treatment of anemia.

Shield Therapeutics - ST10-021 is a stable complex of ferric iron in an oral formulation for the treatment of iron deficiency anemia associated with inflammatory bowel disease. IDA affects approximately 73% of patients with ulcerative colitis or Crohn’s disease globally. ([Link])

UPDATE SuppreMol - Developing soluble Fcy-Receptors (sFcyRs) for autoimmune disease. These are recombinant autologous proteins with strong immunosuppressive potential. SM101, SuppreMol’s main product is a recombinant, soluble, non-glycosylated version of the human Fcy receptor FyRIIb which is has completed a Phase 1 trial for ITP and recently reported encouraging Phase 2a results in ITP. Going into further studies for lupus. ([Link])

UPDATE Symphogen - Rozrolimupab (Sym001) is a recombinant polyclonal composition of 25 different Rhesus D specific antibodies for the treatment of primary Immune Thrombocytopenia and for Anti-RhD prophylaxis (ADP) in prevention of Hemolytic Disease of the Newborn. Symphogen reported positive data from this drug at ASH in 2011.
in immune thrombocytopenia patients. This product was returned to Symphogen from Biovitrum Swedish Orphan for strategic reasons on Dec 30, 2010. (Link)

TaiGen - G-0054 is a potent and selective CXCR4 receptor antagonist. This molecule rapidly mobilizes stem cells and progenitor cells from the bone marrow into peripheral circulation. (Link). Related drugs in development at Chemokine Therapeutics and Cleveland Biolabs.

**UPDATE** Tarix Pharmaceuticals - In Phase 2 trials with TXA-127 for treatment of patients with stem cell transplant and the prevention of chemotherapy induced thrombocytopenia. TXA-127 has much broader applications in hematology, respiratory disease and fibrosis. Interested parties may contact Tom Bird at Torreya Partners for a non-confidential information package (tom.bird@torreyapartners.com, 1-212-331-7855).

Therapure - TBI 304 is a monoclonal antibody that mimics the natural ability of hemoglobin to stimulate stem cells to produce red blood cells. TBI 304 is in the preclinical stage. (Link)

Thrombogenics - TB-402 is a novel human antibody which partially blocks Factor VIII, an essential blood clotting factor. Reported positive Phase 2 data. ThromboGenics and its partner BioInvent plan to out-license TB-402 for its later stage development and commercialization. (Link)

**HEPATOLOGY**

Alfact Innovation - ALF-5755 has been shown to promote cell survival after apoptotic or oxidative stress, and liver cell regeneration in primary cultures. ALF-5755 is being developed as slow intravenous infusion for the treatment of acute liver failure. Recently granted orphan designation. (Link)

Alfama - In a preclinical stage of testing CORMs to treat acute liver failure. (Link)

Antipodean Pharma - MitoQ contains mitoquinone mesylate, a synthetic form of coenzyme Q10. It is a mitochondria targeted antioxidant that selectively blocks mitochondrial oxidative damage and prevents cell death. MitoQ is being developed by MitoQ Technology as an oral formulation for the treatment of liver inflammation.

Asklepion - Cholic acid is an orphan drug that is a form of replacement therapy for children with a series of inborn errors of bile acid metabolism manifesting as otherwise fatal cholestatic liver disease. This product is at the Phase 3 stage.

Biolex - Locteron recently finished Phase 2 studies for a long-acting interferon for Hepatitis C. On Mar 15, 2010 reported data indicating that flu-like symptoms were much reduced with this compound versus Peg-INTRON and also showed improved antiviral efficacy. (Link)

**UPDATE** Conatus Pharmaceuticals - CTS-1027 an oral MMP inhibitor for liver disease with potential to treat liver fibrosis. Phase 2 study on treatment of hepatitis C patients underway. Results from this Phase 2 trial are forthcoming. Note: this trial was terminated in October 2011 due to reports of adverse events in some patients.

Genfit - FXR agonist in Phase 2. Proof of efficacy and safety of GFT505 have been obtained in Phase I and Phase IIa trials (400 patients or healthy volunteers treated with GFT505 to date). The absence of safety concern has been confirmed in a full toxicological package up to 2-year carcinogenicity studies.

HAC Biomed - a cell therapy company has very promising data for a treatment for the repair of damaged liver tissue. Commercial stage in Germany with market entry in other territories soon. Assisted by Torreya Partners. Interested parties should contact tom.bird@torreyapartners.com.

**UPDATE** Hyperion Therapeutics - Developing Ravicti (formerly GT4P/HPN-100), an ammonium remover, for urea cyclic disorders and hepatic encephalopathy - Positive Phase 3 data and a high likelihood of approval in 2012. As of
March 2012, Hyperion acquired the worldwide rights to this compound from Ucyclyd Pharma (of Medicis), though terms were not disclosed. Filed an S-1 IPO registration in April 2012. (Link)

Intercept Pharma - INT-747, an FXR modulator, for treatment of liver disease including PBC and NASH. (Link) Phase II results were positive.

NasVax Ltd. - In a Phase 2a clinical trial in 36 subjects with NASH (Nonalcoholic steatohepatitis) or “fatty liver” and the metabolic syndrome, oral aCD3 antibody immunotherapy was generally very safe and induced positive trends in blood levels of two enzymes that are biomarkers for liver inflammation. (Link)

Norgine - NRL972 is a liver disease detection diagnostic in Phase II clinical development in the US. NRL972 is a liver staging tool, currently in Phase III clinical development in Europe and under an IND in Phase II clinical development in the US and are looking for partnering options in US and Japan.

NEW Novimmune - NovImmune’s NI-0801 monoclonal antibody was created in an attempt to reduce inflammation linked to abnormal levels of the CXCL10 protein. NI-0801 antibody was safe and well tolerated. The mAb is currently undergoing a Phase II Proof-of-Concept clinical study in Primary Biliary Cirrhosis patients. (Link)

Ocera - Development of a novel carbon sorbent for mild hepatic encephalopathy and IBS, as well as the NCE, OCR-002, for acute liver failure. Company to report out Phase 2b data for hepatic encephalopathy compound soon. Active business development discussions underway.

Phenex Pharma - completed Phase 1 on an FXR agonist for liver fibrosis and NASH with positive data. Company seeking a partnership deal with assistance from Torreya Partners. Interested parties should contact Rodolphe Grepinet at Torreya Partners for a non-confidential overview of the opportunity (Rodolphe.grepinet@torreyapartners.com).

HOSPITAL PRODUCTS

Acusphere - Imagify, pending EMA filing for this cardiac imaging agent. Highly differentiated from SPECT agents on the market insofar as permits evaluating of myocardial perfusion, an important marker of coronary artery disease (CAD) without radioactive markers. Potential first-to-market drug in $600 million and $2 billion addressable market in E.U. and U.S. respectively. Recent SPA from FDA in US. Will require one further trial for FDA approval.

Adamis Pharmaceuticals - Launching Epinephrine Injection USP 1:1000 (0.3mg Pre-Filled Single Dose Syringe) (i.e.: Epinephrine Injection PFS) to compete as a low cost alternative to the well known brand EpiPen®. Company was recently unsuccessful in a “go public” merger with La Jolla Pharmaceuticals.

$ AMAG - Feraheme IV iron product - Recently approved. Company is commercializing on its own. AMAG’s recent merger attempt with Allos was ended in November 2011. On Nov 17, 2011, AMAG announced that it had hired Jefferies to explore all opportunities to enhance shareholder value. Frank Thomas, interim CEO of AMAG indicated: “We will expeditiously complete this process, which will include a parallel review of a potential sale of the company and other strategic merger and acquisition transactions.”

Asklepion - L-Citruline for the 20 percent of children who have heart surgery with use of the bypass pump develop pulmonary hypertension, or high blood pressure in the lungs. In early studies this product appears to prevent pulmonary hypertension from developing. Now in Phase 3 studies. (Link)


Cara Therapeutics - CR845, a selective kappa opioid agonist, has completed a Phase 1 study. Phase 2 studies were positive. Specifically, CR845 provided evidence of analgesic efficacy when administered as a single intravenous...
dose to women following laparoscopic hysterectomy. In addition to decreases in reported pain levels, patients receiving CR845 required substantially lower amounts of postoperative opioids for 16 hours, and showed a significant reduction in the incidence of postoperative nausea. See a similar molecule in testing by Tioga Pharmaceuticals (GI section). (Link)

$ Claris Life Sciences - Indian injectibles company has hired Rothschild to look at strategic options. Company has a rich pipeline of hospital generic injectibles using novel delivery methods. (Link)

**UPDATE** Cohera Medical - Developing TissueGlu, a deep wound adhesive for use in surgical applications. Cohera Medical recently received CE Mark approval for TissuGlu and began selling product to hospitals and surgeons in Germany in September 2011. The company plans to expand the commercial availability of TissuGlu to additional European markets in early 2012. Cohera Medical is also actively pursuing U.S. FDA approval. Heavily used in aesthetic plastic surgery procedures in EU.

**NEW** Cornerstone Therapeutics – Applying for approval of Lixivaptan for the treatment of hyponatremia. Has finished three Phase 3 studies but has not published the results to date. Two vaptans on the market but potential differentiation of this product. Cornerstone is now looking for ex-US partners for this late stage product. (Link)

DSX Therapeutics - Developing a Mab that targets inducible nitric oxide synthase, which is involved in sepsis pathology. Pre-clinical program.

**UPDATE** FCB-Pharmicell - Cerecellgram is a bone marrow derived stem cell composition, containing mesenchymal stem cells and cells specifically useful for brain regeneration. Cerecellgram is being developed for the treatment of acute ischemic stroke. In a Phase 3 randomized clinical trial. This product was recently approved by the KFDA for use in Korea. (Link)

Focus Care Pharmaceuticals - Looking for partners for its line of rapid oral rehydration salts.

**NEW** Galleon Pharmaceuticals - GAL-021 is an IV small molecule designed to support respiratory drive in surgical and critical care patients. The use of anesthetic, analgesic and sedative drugs can produce a well-known respiratory depression. For example, in patients receiving opioids such as morphine GAL-021 could "decouple" the analgesic and respiratory depression effects enabling physicians to better alleviate pain without the well-known fear of respiratory collapse. This NCE is in Phase 1 testing. (Link)

Genervon Biopharmaceuticals - Recruiting participants for a Phase II double blinded, randomized, placebo controlled dose escalation study to evaluate the efficacy and the safety of GM602 in patients with acute middle cerebral artery ischemic stroke within an 18-hour treatment window. GM602 is an endogenous six amino acid neuropeptide with trophic (regeneration) and tropic (guidance) effects on the nervous system. (Link)

**NEW** Great Lakes Pharma – developing a catheter lock solution called B-Lock with high efficacy in the prevention of MRSA and other infectious disease from catheters.

Maruishi Pharma - MR04A3 is a novel isodindoline hypnotic, binds to the central benzodiazepine (BZD) binding site of the GABA A receptor (gamma-aminobutyric acid) and acts as an agonist. It is a sedative and analgesic which has antinociceptive effect. MR04A3 is being developed as an intravenous formulation to induce anesthesia during surgery and is in a Phase 1b trial.

**NEW** Maruishi Pharma - MR08A3 is a neuromuscular blocking agent that has finished EU phase 2 studies. This would be used as an adjunct to anesthesia during certain operations. This agent has ultrashort action and does not need to be reversed.

NoNO - seeking a partner with the capability to develop and commercialise NA-1 (a PSD95 inhibitor) for acute ischemic stroke (AIS).
**UPDATE** Novabay Pharmaceuticals - Aganocide compounds (broad spectrum antimicrobial activity) for a variety of topical applications like treatment of acne, decolonization of MRSA from the nares, and catheter-associated urinary tract infections. The drug candidate, NVC-422 is in clinical studies to treat chronically catheterized patients with high levels of bacteriuria, or bacteria in the bladder. Last year, the company established proof of concept in part A of a phase II trial of NVC-422, demonstrating 80% effectiveness in preventing urinary catheter blockage and encrustation. NovaBay Pharmaceuticals and Galderma SA tweaked a March development deal for skin condition drugs, defining terms and fees and providing for an additional tolerance study. ([Link](#))

Optimer - Promising Phase 3 data for Prulifloxacin in infectious diarrhea. Favorable comparison versus ViroPharma’s vancomycin. Open to a partnership transaction for this drug following the recent approval of Dificid (fidaxomicin) by the FDA.

$ Pacira Pharmaceuticals - Looking to partner Exprarel, a long acting bupivacaine, outside of the U.S. This product was approved by the FDA on Oct 31, 2011. Interested parties should contact Darren Pincus at DarrenP@pacira.com.

PharmaSurgics I (in Phase II development for a pharmaceutical for anti-adhesion treatment after surgery. Very promising approach. ([Link](#))

Polymedix –Finished Phase 1 with a Factor Xa antitode that reverse effect of heparin and associated compounds. Proof of concept achieved. ([Link](#)) Also, see Portola for a related Factor Xa antitode. ([Link](#))

**UPDATE** ProFibrix - Developing a surgical tissue sealant that stops acute and severe bleeding. FibroCaps are a novel powdered mixture of fibrinogen and thrombin. Phase 2 clinical results reported in Jan 2012 were highly favorable.

$ Salix - looking for a European partner for RELISTOR, a subcutaneous treatment for opioid-induced constipation. This was recently partnered in Asia to Link Healthcare.

NEW Theravance – Has full commercial rights to Vibativ (Televancin), an approved product, for the treatment of skin infections caused by MRSA and MSSA gram positive bacteria. This product was previously marketed by Astellas and was returned to Theravance in January 2012. ([Link](#))

$ Undisclosed - Company with a portfolio of marketed hospital injectibles has been in an M&A sellside process.

NEW $ Undisclosed – Pan-European marketer of hospital pharmaceuticals is exploring strategic alternatives. The company has revenues of approximately $20mm. Interested parties should contact rodolphe.grepinet@torreyapartners.com.

NEW $ Undisclosed – Marketer of branded hospital cardiology-oriented pharmaceutical products outside the U.S. with revenues over $50mm is open to a company sale or a strategic investment. Interested parties should contact tim.opler@torreyapartners.com.

NEW Undisclosed – Hospital focused company with a strong presence in China is exploring strategic options with assistance of a financial advisor.

$ Undisclosed - marketed hospital product available on a co-promotion basis for the prevention of acute allergy.

$ Undisclosed player –approved hospital anesthetic in the United States with differentiation from existing products. Also could be used in physician office setting where sedation required. Open to a product sale or other value creating arrangement. Global rights available.

Undisclosed - Phase 2 hospital product available for licensure for the treatment of acute allergy in the ER setting.

$ Undisclosed - marketed antifungal with revenues > $10mm. Hospital setting is where generally used.
Undisclosed - pharma company is open to divesting a marketed specialty cardiology product with revenues > $30mm per annum.

Undisclosed - Several approved products for oncology supportive care in the hospital setting.

Ventria - has developed a recombinant lactoferrin for the prophylaxis and treatment of infection in prematurely born children. Positive POC dataset for this product.

Zurex - Zuragen. Prevention of catheter related bloodstream infections. FDA approval pending.

**IMMUNOLOGY / INFLAMMATION / AUTOIMMUNE DISEASE**

*4SC – 4SC-101 for autoimmune disease.* This oral IL-17 inhibitor saw positive Phase 2 data in RA. In late 2011 also reported very positive data in IBD. A related compound from Eli Lilly saw positive data in psoriasis in March 2012.

AB Science - In Phase 2 studies for Masitinib in in RA. Promising efficacy data in a single arm study but some challenging side effects. (Link)

**NEW** AbGenomics International – Developing AbGn-168H, a humanized monoclonal antibody against CD-162 which induces apoptosis of late-stage activated T-cells and is being developed for the treatment of psoriasis and other immunological diseases. This program was previously partnered with Boehringer-Ingelheim.

Ablynx - reported on November 5, 2011 that it regained rights ATN-103 a nanobody treatment for rheumatoid arthritis based on TNF-alpha modulation. Ablynx is interested in outpartnering this program. (Link)


**UPDATE** Allostera - Developing oral peptides that block signals replacing certain antibodies. Preparing Phase 1 studies of an allosteramer which targets IL-23R for the treatment of inflammation and psoriasis. Similar mechanism as Ustekinumab. Update: Company’s web site is offline and Allostera appears to be out of business.

Anaphore - ATX3105, blocks the receptor complex engaged by interleukin-23 (IL-23), an immunoregulatory protein that has become a key target in strategies to develop better therapies for autoimmune disorders. This preclinical drug candidate is being prepared for an IND. (Link)

Angelini - Bindarit inhibits mcp-1/CCL2. A Phase II clinical pilot study in lupus nephritis (LN) patients demonstrated that subject treated with bindarit showed a significant reduction of urinary albumin excretion (UAE) and urinary MCP-1/CCL2 levels. Promising data in diabetic nephropathy. Going into Phase 3 studies. (Link)

**UPDATE** Anthera Pharmaceuticals— In Phase 2b for A623, an anti-BLyS compound for treating lupus. Good efficacy seen. Company noted in a March 2012 press release: “Development of blisibimod (A-623) continues to progress according to plan. The PEARL-SC study, which completed enrollment in the fourth quarter of 2011, is examining the therapeutic benefit of monthly and weekly subcutaneous administration of blisibimod in SLE patients. The primary endpoint of the PEARL-SC study is clinical improvement at 24 weeks in an SLE responder index. The study remains on track to produce top-line efficacy data in the second quarter of 2012.” (Link)

**UPDATE** Aquinox Pharma - Aqx-1125 modulates SHIP which controls PI3K for the treatment of cancer and inflammatory disease. Aqx-1125, is a highly active and selective small molecule allosteric activator of SHIP1 suitable for once-daily oral dosing as a pill. Aqx-1125 is currently being investigated in two Phase Ia proof-of-concept studies that complete in 2012. One study is looking at the performance of the compound in asthma; the other is looking at respiratory inflammation.
**UPDATE** Ardea Biosciences – lenisurad for the control of gout. Has shown high efficacy in reduction of hyperuricemia in Phase 2 studies and is now in a fully funded 2000 patient Phase 3 registrational program involving four separate ongoing clinical trials. These studies are expected to report out sometime in 2013.

**COMPLETED** Avila - In mid-Phase 1 for a BTK inhibitor that is highly selective and orally dosed. Btk plays a critical role in the development and activation of B cells, and its inhibition will be of therapeutic significance in the treatment of both of B cell-related hematological cancers (e.g. non-Hodgkin lymphoma (NHL) and B cell chronic lymphocytic leukemia (B-CLL), and autoimmune diseases (e.g. rheumatoid arthritis). Note: Celgene acquired Avila in January 2012 for $350mm plus $575 in additional potential milestones. (Link)

Biocon - Would consider a partnership for its anti-CD6 humanized antibody, T1h. Has completed a Phase 1 study in RA and has two Phase 2 studies underway.

Biotest - looking to partner BT-061 once it has Phase IIb proof of concept (POC) data in the lead rheumatoid arthritis. A 300 patient Phase 2b trial is slated to start shortly. Biotest is interested in retaining EU rights.

Catalyst Biosciences - developing improved proteases for hemophilia and inflammation. A Factor VII program has been partnered to Wyeth but a Factor IX program which is in a preclinical stage is company owned at present.

**NEW** Celtaxys - CTX-4430 reduces inflammation in animal models. LTA4H is a key in the production of the major pro-inflammatory mediator Leukotriene B4 (LTB4). LTA4H and receptors to LTB4 are known to be elevated in a number of human lung diseases including Cystic Fibrosis, Asthma and Chronic Obstructive Pulmonary Disease (COPD).

Chelsea Therapeutics - In talks to partner antifolate drug CH-4051 for RA.

**NEW** Compugen - CGEN-15001 is a B7/CD28-like based fusion protein for the treatment of autoimmune disease. Using an EAE model, administration of CGEN-15001 to mice with established MS displayed robust inhibition of MS symptoms and abolishment of further relapses. In preparation for clinical studies. Interested parties should contact Tsipi Karen-Lehrer (tsipikl@compugen.co.il). (Link)

**NEW** Forward Pharma - Positive Phase 2 data on FP-187 for psoriasis. Would consider a sale. (Link)

**NEW** Funxional Therapeutics - FX125L is an orally available somatotaxin, with completed Phase I clinical trials (single and multiple ascending dose studies) conducted in the US, involving over 100 healthy subjects. Data support advancement of this NCE, first in class compound for further studies in autoimmune conditions. (Link)

**NEW** Galapagos Pharma - GLPG0974 is an orally available small molecule that inhibits GPR43. It plays a key role in inflammation and has shown potent inhibition of neutrophil migration, one of the critical cell types in inflammatory processes. Potential applications in GI and allergy. This product is in Phase 1 studies. (Link)

**NEW** Human Genome Sciences – Received an unsolicited takeover on April 19, 2012 offer from partner GlaxoSmithKline for $13 per share, or about $2.6 billion in cash. Human Genome, which said the offer did not reflect its "inherent" value, retained Goldman Sachs and Credit Suisse to assist in exploring strategic alternatives, including a potential sale.

**NEW** Immune Pharmaceuticals – Has non-opthalmic rights to Bertilimumab, a Phase 2 antibody targeting eotaxin-1 with application to Crohns disease, ulcerative colitis and asthma. (Link)

**UPDATE** ImmuPharma In October 2011, ImmuPharma regained worldwide rights to Lupuzor™ for lupus due to the merger of Cephalon with Teva Pharmaceutical Industries. ImmuPharma intends to advance discussions with pharmaceutical companies for the licensing of Lupuzor™. Lupuzor™ has completed successfully phase I, phase Ila and phase IIb and has recently been granted approval by the FDA to commence phase III and has also been
designated "Fast Track". ImmuPharma noted on March 27 2012 that it is in discussions with a number of companies to license this program. (Link)

**COMPLETED** Isotechnika - Voclosporin, an oral Calcineurin inhibitor, for transplant and psoriasis has achieved good POC. Recently did a China deal. Update: The global rights to this program in renal indications including lupus were licensed to Vifor in Jan 2012. (Link)

Italfarmaco - Givinostat is a Phase 2 HDAC inhibitor for inflammatory diseases and cancer. Has been in Phase 2 for juvenile arthritis, myeloproliferative diseases, Hodgkin’s disease and multiple myeloma.

Kiadis - ATIR is a personalized cell based therapy of donor T-lymphocytes depleted of alloreactive T-cells and is infused after a patient receives a mismatched bone marrow transplantation to reduce Transplant Related Mortality. Has shown effectiveness in a recent Phase 2a study.

**UPDATE** Lexicon Pharmaceuticals - In Phase 2 studies in RA with a LX-2931, a S1P lyase modulator. Strong pre-clinical data package and a desire to partner this compound. Lexicon initiated a dose-ranging study to explore higher doses of LX2931 in rheumatoid arthritis patients, with results anticipated in the second quarter of 2012.

**COMPLETE** Micromet - Willing to outlicense a preclinical IL-2 inhibitor (MT-204). Micromet was acquired by Amgen for $1.2 billion in January 2012.

Morphosys - MOR103 is a fully human HuCAL antibody against GM-CSF that is in Phase 1 studies. Also see a similar antibody in development at Kalobiios. (Link)

**UPDATE** Neovacs - TNFalpha Kinoid in Phase 2a study in RA. TNF-alpha Kinoid is an immunotherapy designed to elicit natural polyclonal antibody responses. Positive data were reported from this study in January 2012.

Novimmune - In Phase 2 with an anti-CD3 antibody for Crohn’s disease. Exploring potential as an immunomodulator in Type 1 diabetes and transplant rejection as well.

**NEW** Novimmune - NovImmune's NI-0101 monoclonal antibody potently suppresses inflammatory reactions by blocking TLR4 signaling driven by NovImmune's NI-0101 monoclonal antibody potently suppresses inflammatory reactions by blocking TLR4 signaling driven by several pro-inflammatory cytokines. A Clinical Trial Application for the NI-0101 mAb will be filed in Q2 2012.

**UPDATE** Nuon Therapeutics - Developing tranilast for gout and RA. In discussions with potential partners after successful completion of Phase 2a studies. (Link)

**UPDATE** Opsona Therapeutics - OPN-305 is a humanized Phase 1 IgG4 monoclonal antibody (MAb) against Toll-Like Receptor 2 (TLR2), a target within the innate immune system, and is under development as a treatment for the prevention of Delayed Graft Function (DGF) following renal transplantation, in addition to other therapeutic indications. (Link)

**UPDATE** Phenex Pharma - in preclinical work for a ROR - gamma - t program for treatment of inflammation. High interest in this program. Open to a licensing deal. Interested parties should contact Rodolphe.grepinet@torreyapartners.com.

**UPDATE** Phenex Pharma - in preclinical studies for a biologic, RSLV-125, that targets the interferon pathway with an indication for treatment of lupus. This molecule acts at the most proximal point in the interferon cascade. Potential to be an efficacious and safer therapy than other products in development. (Link)

Rigel - partnering R348 is a selective, potent inhibitor of Janus Tyrosine Kinase 3 (JAK3). JAK3 is critical to immune system activation and is an attractive target because its expression is limited to key cells in the immune system, particularly T-cells, which mediate these diseases.
Sanofi / Genzyme - Looking to outlicense Genz-29155, a novel, small molecule, orally bioavailable, 1x daily novel inhibitor of TNF-α signaling. Proof of concept has been demonstrated in multiple models of transplantation rejection, multiple sclerosis (MS), sepsis, inflammatory bowel disease (IBD) and lupus. (Link)

Savient Pharmaceuticals - FDA approved KRYSTEXXA (pegloticase) in Sep 2010, a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Company is seeking a commercial buyer and is using JP Morgan and Lazard in its search for an acquisition partner. Savient is now pursuing a launch of Krystexxa on its own and is building a 50-person plus sales force. (Link)

SuppreMol - Developing soluble Fcy-Receptors (sFcyRs) for autoimmune disease. These are recombinant autologous proteins with strong immunosuppressive potential. SM101, SuppreMol’s main product is a recombinant, soluble, non-glycosylated version of the human Fcy receptor FyRIIb which is has completed a Phase 1 trial for ITP and recently reported encouraging Phase 2a results in ITP. Going into further studies for lupus. (Link)

Syntrx Biosystems - As a folate analogue, aminopterin competes for the folate binding site of the enzyme dihydrofolate reductase, thereby blocking tetrahydrofolate synthesis. Aminopterin is being developed as an oral dosage form for the treatment of psoriasis and is in Phase 2 studies.

Taligen - Developing a Factor H (TT30) replacement, part of the complement system, for orphan diseases. Note: Alexion acquired Taligen for $111 million in 2011.

Undisclosed - highly promising early stage JAK3 program.

Veloxis - LCP-Tacro has completed Phase II studies with positive data in kidney transplant recipients. 505b2 with better PK of tacrolimus. Other transplant products available. On March 29, 2012 Veloxis reported that it completed enrollment in LCP-Tacro™ 3002 Pivotal Phase III Trial in Kidney Transplant.

Western States Biopharmaceuticals - Developing novel treatments for autoimmune disease. (Link)

Y’s Therapeutics - YSPSL is fused P-selectin glycoprotein ligand (PSGL) and human IgG1. It acts as an antagonist of P-selectin. This is currently in Phase 2 studies for prevention of delayed graft function and prevention of IRI in transplant patients.

Zalicus - Synavive® low dose glucocorticoid treatment for RA without previously noted side effects of this class. Has shown ACR20 score of 63% in a Phase 2 trial with this oral treatment with data to report out in Q3 2012. Potentially an attractive treatment. (Link)

LATE STAGE ASSETS (PHASE 3 STARTED TO APPROVED)

Access Pharmaceuticals - undertaking a commercial launch of Mugard which was approved in 2010. This product is used for treating oral mucositis. Access is actively looking for a co-promotional partner for this product. June, 2011 received acceptance letter from Chinese SFDA citing all documentation for MuGard, indicated for treatment of oral mucositis a side effect of anti-cancer treatments, has been submitted and accepted. (Link)

Acusphere - Imagify, pending EMA filing for this cardiac imaging agent. Highly differentiated from SPECT agents on the market insofar as permits evaluating of myocardial perfusion, an important marker of coronary artery disease (CAD) without radioactive markers. Potential first-to-market drug in $600 million and $2 billion addressable market in E.U. and U.S. respectively. (Link)

Affymax – has achieved approval for Hematide in the U.S. Has divided rights to this compound with Takeda and company retains significant commercial rights.
Alexza – Developing ADASUVE (Loxapine) which recently met the primary endpoint in a Phase 3 Bipolar Disorder trial. On February 13, 2012, Alexza received preliminary feedback, the Day 80 Assessment Report, from the EMA regarding its MAA, which contained major objections to various aspects of extrapolating phase III of clinical trials in addition to practical concerns. An FDA approval decision is expected in early May 2012. Alexza announced in Dec 2011 that it had hired Lazard to explore strategic options.

Amarin - Developing a pure omega-3 for reduction of triglycerides. Phase 3 data reported out very strong. Company has indicated that is has retained a financial advisor (Lazard) to explore a sale. Amarin is well positioned to be a takeover candidate in 2012 – particularly with recent clarity on its patent position and April 2012 media reports have rumored a pending transaction. (Link)

Amylin – marketer of Byetta® and Bydureon® for the treatment of diabetes has reportedly received an offer from Bristol-Myers Squibb and, according to Bloomberg in mid-April 2012 has hired a financial advisor to help find a buyer. Separately, Amylin is interested in finding a partner outside of the U.S. to distribute its products.

Anthera Pharmaceuticals— Varespladib is an inhibitor of secretory phospholipase in Phase 2 for prevention of arteriosclerosis. Failed to hit endpoint in a Phase 3 trial in March 2012. (Link)

AP Pharma - Would outlicense APF530 in Phase 3 for CINV. Positive Phase 3 data. The FDA has accepted for review the NDA and, based on the Prescription Drug User Fee Act (PDUFA), has issued an action date of March 18, 2010. Update: AP received a complete response letter that required additional studies on bioavailability and metabolism. Company has resubmitted a response to FDA. (Link)

Aradigm - (ARD-1600) an inhaled nicotine product. Product replicates PK of a cigarette and faces positive prospects as either an OTC product or an Rx product. Can be introduced to the market immediately due to recent legal developments in the e-cigarette area in the U.S.

ARCA - Gencaro (Bucindolol) is a nonselective beta-blocker which is being developed for treatment of heart failure on a genetically-targeted basis. Very strong data in preventing death post-MI. Approvable letter from FDA with guidance on a further trial required for approval. Company currently pursuing an AF trial with Gencaro®. (Link)

Archimedes Pharma - Is seeking licensees for North America and Japan for PecFent, a nasally-delivered fentanyl product for breakthrough cancer pain, currently in Phase III development. Archimedes Pharma is seeking licensees outside of Europe for PecFent®. Has gained a positive opinion from the CHMP, and has been filed for regulatory approval in the US. Preparing for a U.S. launch.

Ardea Biosciences – lenisurad for the control of gout. Has shown high efficacy in reduction of hyperuricemia in Phase 2 studies and is now in a fully funded 2000 patient Phase 3 registrational program involving four separate ongoing clinical trials. These studies are expected to report out sometime in 2013.

Azanta – Developing Nimoral for Head and Neck cancer which is sold on a named patient basis in two countries. Nimorazole is a hypoxic radio sensitizer developed to be used in combination with radiation therapy for head and neck cancer patients. This product is expected to be approved in the U.S. and Canada on an orphan basis in the next several years.

Basilea Pharmaceutica – Toctino, oral alitretinoin for severe chronic hand eczema (CHE) refractory to potent topical corticosteroids. Strong efficacy reported in its U.S. phase III HANDEL study in March 2012. A candidate for U.S. approval. On the market in Europe with good traction. Basilea intends to self-commercialize this product in Europe but may be open to partnership discussions in other geographies.

BioAlliance Pharma - searching for a U.S. Partner for Oravig. Oravig is miconazole buccal tablets for the treatment of oropharyngeal candidiasis (OPC), more commonly known as thrush, in adults and children age 16 and older. This drug was returned by Strativa Pharmaceuticals recently to BioAlliance.
BioDelivery Sciences - developing BEMA Buprenorphine for the treatment of moderate to severe chronic pain. In September 2011, BDSI reported that it had missed the primary endpoint of improving mean pain intensity scores vs. placebo in the Phase III BUP-301 trial to treat moderate to severe chronic low back pain but saw clinically significant activity in opioid dependent patients. This observation helped to trigger a deal with ENDO Pharmaceuticals that will develop and commercialize this product (announced Jan 6, 2012). ENDO agreed to $30mm upfront plus $150mm in additional contingent payments and royalties. ENDO plans to conduct a second Phase III trial for the product, which the company said will delay an NDA submission to FDA by about one year. (Link)

Biofrontera – Ameluz (BF-200 ALA) is approved in Europe for the treatment of actinic keratosis. BF-200 ALA combines a nanoemulsion with 5-aminolevulinic acid (ALA). The product is developed in photodynamic therapy of precancerous skin lesions (actinic keratosis). Looking to partner in a variety of EU territories. Plans to meet with FDA to discuss U.S. approval and then partner. (Link)

Biosante - LibiGel (testosterone gel) for female sexual dysfunction is in Phase III, and is designed to be quickly absorbed through the skin after a once-daily application. Biosante recently disclosed that LibiGel did not meet its primary endpoints in this trial.

Biovest International - Company emerged from Chapter 11 bankruptcy. Has several assets including BiovaxID which has recently had positive Phase 3 data in NHL.

Camurus - Episil® (CAM2028) is a protective, bioadhesive intra-oral liquid for treatment of oral mucositis. The product is registered in Europe as a Medical Device, Class I, with an expected market launch in Q2 2010. Note: This product was licensed to IS Pharma in Europe after its recent approval. A 510k registration submission in the US is under way.

Canyon Pharmaceuticals - Canyon Pharmaceuticals is seeking to build a strategic alliance preferentially on a worldwide basis to commercialize Desirudin (Iprivask® US-registration / Revasc® EU-registration), a differentiated anticoagulant drug which is approved by the FDA, the EMA and several of the rest of world authorities. Desirudin is a direct thrombin inhibitor and the only subcutaneous direct thrombin inhibitor (DTI) with approval for venous thromboembolism (VTE) prophylaxis following hip- and knee-replacement surgery.

Ceptaris – Formerly Yaupon Therapeutics is filing an NDA for Valchlor, a gel formulation of mechlorethamine for the treatment of mycosis fungoides, a type of CTCL. This orphan disease impacts 80,000 persons in the Western world. Product launch in U.S. anticipated in Q4 2012. Company in active business development dialogue.

Chelsea Therapeutics - NORTHERA™ (droxidopa), is an orally active synthetic precursor of norepinephrine initially being developed for the treatment of neurogenic orthostatic hypotension. Potential in the Parkinson’s market where there has been a reported 60% reductions in falls in PD patients with NOH - also could work in fibromyalgia. On market already through Dainippon Pharma in four Asian countries. On March 28, 2012 Chelsea Therapeutics (CHTP) received a complete response letter (CRL) from the Food and Drug Administration (FDA) for Northera. In the CRL the FDA asked Chelsea to conduct another study which can demonstrate the drug continues to work for patients over a two to three month period.

Clinuvel - In Phase 3 for European approval for Afamelanotide, a photoprotectant to be used in Erythropoietic Protoporphyria. Company hoping for an EMA approval for this product.

Collegium Pharma - NDA pending COL-003, a tamper resistant, abuse-deterrent, sustained release oxycodone formulation. Seeking a partnership.

Corcept Therapeutics - As an orphan designation for Corlux, in development for Cushing’s Syndrome - a condition of hypercortisolism with approx. 20K persons in US. Positive Phase 3 data released in December 2010. In
June, 2011 FDA accepted NDA submission from Corcept for Corlux. This product was approved by the FDA in Q1 2012.

**UPDATE** Discovery Labs - Surfaxin is a synthetic KL4 Surfactant for treatment of neonatal RDS. The FDA has approved SURFAXIN (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants at high risk for RDS.

Durect - Transdur Sufentanil for the treatment of pain. Longer duration than fentanyl patches and smaller patch size. On May 5, 2011 the company wrote: “We continue discussions with potential partners regarding licensing development and commercialization rights to this program to which we hold worldwide rights.”

**UPDATE** Dynavax - HEPLISAV is an investigational adult hepatitis B vaccine. In Phase 3 trials, HEPLISAV demonstrated higher and earlier protection with fewer doses than currently licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV. HEPLISAV combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist to enhance the immune response. In two Phase 3 trials, HEPLISAV demonstrated increased, rapid protection with fewer doses than current licensed vaccines. Positive data reported on July 20, 2011 and BLA submitted on April 26, 2012. European MAA submission upcoming (Link)

Elite Pharmaceuticals - Phase 3 abuse resistant oxycodone for OA under an SPA. Company exploring strategic options.

Exelixis - According to Bloomberg on April 12, 2011: “Exelixis Inc. is working with Goldman Sachs Group Inc. to prepare for potential takeover offers after its experimental drug helped prostate-cancer patients in a study.” Company’s XL-184 has reported dramatic data on reducing metastatic prostate lesions at ASCO. Update: company has hired a Chief Commercialization Officer with intention to introduce cabozantinib to the U.S. market and has reported strong data for cabozaatinib in the treatment of medullary thyroid cancer.

Endoceutics - developing Femivia for the treatment of issues associated with hormone deficiency in post-menopausal women (e.g., memory loss, diabetes, muscle loss). This product is in Phase 3. (Link)

Fibrocell Sciences - Emerged from Chapter 11 bankruptcy proceedings on Oct 6, 2009 (formerly known as Isolagen). Company received a complete response letter from FDA requesting additional histopathological data from the trial of azficel-T for the treatment of wrinkles. Azficel-T is an autologous cell therapy for the treatment of moderate to severe nasolabial fold wrinkles in adults.

Foresight Biotherapeutics - Has recently completed a Phase 3 trial of FST-201 (dexamethasone 0.1%) Otic Suspension vs. the FDA-approved drug Ciprodex (ciprofloxacin 0.3%, dexamethasone 0.1%) Otic Suspension (Alcon Laboratories, Inc.) in the treatment of acute otitis externa (Swimmer’s ear). (Link)

GeneSignal - GS-101 is a topical antisense oligonucleotide that has nearly completed phase III for the prevention of corneal graft rejection. Aganirsen is also entering phase II clinical trials for additional angiogenesis based diseases, such as wet age-related macular degeneration (AMD), neovascular glaucoma, and dermal indications. (Link)

**UPDATE** Hyperion Therapeutics - Developing Ravicti (formerly GT4P/HPN-100), an ammonium remover, for urea cyclic disorders and hepatic encephalopathy - Positive Phase 3 data and a high likelihood of approval in 2012. As of March 2012, Hyperion acquired the worldwide rights to this compound from Ucyclyd Pharma (of Medicis), though terms were not disclosed. Filed an S-1 IPO registration in April 2012. (Link)

$ Ibsa - Tirosint (L-Thyroxin) in soft gel capsules for treatment of hypothyroidism. Approved in the U.S. but not yet marketed. Company searching for a marketing partner. Ibsa - looking to outlicense betametasone valerate patch for treatment of psoriasis. A wide range of markets (EU, USA, South America, Middle and Far East) are still available on exclusive or semi-exclusive basis. Possibilities for a global agreement. (Link)
Intelgenx - CPI-300 is a novel, high strength of Bupropion HCl, the active ingredient in Wellbutrin XL(R). Indicated for depression. This product was approved in November 2011 and Intelgenx is in active licensing discussions to find a commercial partner.

Intermune - Bloomberg reports on April 27: "InterMune known for its drug to treat lung scarring, hired Goldman Sachs (GS.N) to help it weigh a possible sale... Goldman has been conducting an auction of InterMune for more than a month and some potential bidders have been spooked by the biotechnology company's expectations for a sale price, Bloomberg news reported."

Keryx - In Phase 3 with Zerenex, a ferric citrate for treatment of hyperphosphatemia in ESRD. Expects to file an NDA assuming positive data by mid-2012.

Mannkind - Looking to partner Afrezza, an inhalable insulin, that has an upcoming PDUFA date. Rumored to be in an active M&A mode. Company received an approvable letter on Mar 15, 2010. The FDA asked for more information on data designed to support the clinical utility of Afrezza, as well as information about how comparable the commercial version of the product is to the version used in clinical trials.

MAP Pharma - Would look at partnership for its late stage inhaled migraine drug, Levadex. (Link)

Mayne Pharma - Lozanoc™ (SUBA®-itraconazole) is an improved patent protected formulation of itraconazole to treat fungal infections. The bioavailability of SUBA®-itraconazole is twice that of the originator product (Sporanox®) and shows reduced intra- and inter-subject variation. A Marketing Authorisation Application (MAA) in the EU has been submitted (November 2010) and discussions with the FDA are underway regarding further requirements for 505(b)2 filing and US registration. Interested parties should contact andrew.dunbar@maynepharma.com.

Moberg Derma - K301 for seborrheic dermatitis has shown benefit in two Phase 3 clinical trials.

Molecular Insight Pharmaceuticals - Azedra in Phase 2 for the treatment of metastatic neuroendocrine tumors such as pheochromocytoma, carcinoid and neuroblastoma that are not amenable to treatment with surgery or conventional chemotherapy. Very positive recent data that highlight potential for rapid approval. SPA in place with FDA. Company has emerged well capitalized from a bankruptcy process and NEW board of directors.

UPDATE $ Neurogesx - Qutenza is a patch that delivers synthetic capsaicin for PHN on the market in U.S. Recently approved. Partnered in the EU to Astellas in June 2009. Company looking for partnerships in Asia and Latin America. Announced in April 2012 that it is exploring a range of potential transactions with help from JSB Partners. (Link)

UPDATE NPS Pharma - developing GATTEX for the treatment of short bowel syndrome. Have filed NDA and awaiting feedback from FDA (Sep 2012 PDUFA date). NPS has indicated interest in commercializing this product on its own.

NuPath - Recently went public with Zelrix, a promising late stage candidate for migraine (iontophoretic sumatriptan patch). NDA filing in Oct 2010 with PDUFA date of August 29, 2011. FDA issued a complete response letter requesting additional CMC and early stage clinical work. Company is open to strategic discussions.

Optimer - Promising Phase 3 data for Prulifloxacin in infectious diarrhea. Favorable comparison versus ViroPharma's vancomycin. Open to a partnership transaction for this drug following the recent approval of Dificid (fidaxomicin) by the FDA.

OPKO Health - Will report Phase 3 data for Bevasiranib, a siRNA drug designed to silence VEGF for treatment of AMD.

OxiGene - ZYBRESTAT is currently being evaluated in a pivotal registration study in anaplastic thyroid cancer (ATC) under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration (FDA). In active partnership dialogue. Update: Oxigene merger with Vaxgen was declined by Vaxgen Shareholders on Feb 3, 2010.
Pacira Pharmaceuticals - Looking to partner Exprarel, a long acting bupivacaine, outside of the U.S. This product was approved by the FDA on Oct 31, 2011. Interested parties should contact Darren Pincus at DarrenP@pacira.com.


Piedmont Pharmaceuticals - Have a late stage product for treatment of head lice. Partnered and marketed in Europe. RESULTZ is sold internationally through licensing partners. Looking for other partners.

Protein Sciences - Has FluBlok for treatment of influenza. Pending BLA. Agreement of licensing signed by TM and UMN for Asian rights. Update: thinking of an IPO following approval by FDA of FluBlok in 2012. (Link)

Raptor Pharmaceutical –filed NDA and MAA in Mar/Apr 2012 for DR Cysteamine, which is delayed-release, enteric-coated microbead formulation of cysteamine bitartrate for the treatment of cystinosis. In June 2011, Raptor reported positive data from a pivotal, Phase 3 clinical trial, examining the safety and tolerability of every 12-hour DR Cysteamine compared to immediate-release cysteamine bitartrate (the current standard of care) in nephropathic cystinosis patients. Company intends to self-commercialize this product. (Link)

Rempex - planning to file an NDA in 2012 for an undisclosed antibiotic that shows high efficacy versus a tough to treat hospital infection type. In addition, the company is in Phase 1 with a very promising treatment for gram negative infection. (Link)

SciClone - ZADAXIN in Phase 3 for the treatment of hepatitis C.

Savient Pharmaceuticals - FDA approved KRSTEXXA (peguloticase) in Sep 2010, a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Company is seeking a commercial buyer and is using JP Morgan and Lazard in its search for an acquisition partner. Update: Savient has launched Krystexxa on its own with a 50-person plus sales force. (Link)

Shionogi - Ospemifene is a selective estrogen receptor modulator (SERM) being developed for the treatment of postmenopausal vulvar and vaginal atrophy (VVA). Ospemifene offers a unique and substantial commercial opportunity as a new non-hormonal treatment for post-menopausal women, which can provide many of the benefits of long-term estrogen without the associated risks. Shionogi has licensed the worldwide rights for ospemifene from QuatRx Pharmaceuticals and is looking for ex-U.S. partners. Shionogi plans to submit an NDA in the US in 2Q 2012.

Stallergenes –Stalair® line of allergy products including ones aimed at rhinitis, asthma and mites. Late stage opportunity for a large market. Both specialty and potential primary care call points. Company recently indicated that it intends to pursue U.S. commercialization on its own. Currently looking for a China partner. (Link)

Syndax - Entinostat (SNDX-275), an oral class I–selective HDAC inhibitor with a long half life, for cancers. In registration for breast cancer 2nd line treatment. Company would be most likely to consider either a global partnership deal, an IPO or a change of control transaction. (Link)

Talon Therapeutics - Marqibo (vincristine sulfate liposomes injection) is a novel targeted nanoparticle-encapsulated anti-cancer compound that has a robust safety database (over 600 patients). FDA recently announced a PDUFA date of May 13, 2012 for Talon’s NDA for the indication of (Ph-) acute lymphoblastic leukemia (ALL) after a favorable panel vote.

Tarsa Therapeutics - has reported positive efficacy and safety results from the Phase III ORACAL trial of its oral calcitonin tablet in the treatment of postmenopausal osteoporosis, and a Phase II osteoporosis prevention trial is underway. NDA filing pending. (Link)
UPDATE  TG Therapeutics (formerly Manhattan Pharmaceuticals) – In late stage development of Hedrin, a treatment for head lice. Hedrin is the top selling head lice product in Europe. The JV developing this product was recently restructured to give greater ownership to Nordic Biotech Fund II. The JV is actively looking for U.S. and Canada development partners. (Link)

NEW  Theravance – Has full commercial rights to Vibativ (Televancin), an approved product, for the treatment of skin infections caused by MRSA and MSSA gram positive bacteria. This product was previously marketed by Astellas and was returned to Theravance in January 2012. (Link)

COMPLETED  Thrombogenics – completed Phase 3 studies for Microplasmin in Phase III clinical development for the non-surgical treatment of back of the eye diseases. Good evidence of efficacy with two positive Phase 3 trials reported. Expected to be on market by end of 2012. Would consider a sale. Note: Thrombogenics licensed the rights to this product to Alcon on March 16, 2012 for 75mm EUR upfront plus additional payments and royalties. Thrombogenics has retained the U.S. rights to this program and intends to self-commercialize. (Link)

Titan Pharmaceuticals - Probuphine is a novel, subcutaneous implant formulation of buprenorphine designed to deliver six months of medication following a single treatment. This product has demonstrated strong positive results in a controlled Phase 3 study for the treatment of opioid addiction and an NDA filing is in preparation. (Link)

COMPLETED  Topaz Pharma - completed two Phase 3 studies for the treatment of head lice with Ivermectin. Planning to submit NDA to FDA in 2011. This company was bought by Sanofi-Pasteur for an undisclosed amount in December 2011.

Toyama - T-705, a viral RNA polymerase inhibitor, is in Phase 3 studies in Japan and Phase 2 in the United States as a highly promising anti-viral drug for the treatment of influenza. (Link)

Undisclosed - neurology oriented marketer looking for a primary care marketer to co-promote a rapidly growing and recently approved product for migraine attacks.

UPDATE  Vivus - Would be interested in partnering avanafil, a PDE V inhibitor in development for erectile dysfunction. Recently reported out second Phase 3 program also with strong data. This product was approved in April 2012. Cowen predicts this drug will take 8% market share with $800mm in U.S. revenue. (Link)

Vivus - Looking to partner Qnexa in Europe and other ROW territories. An approval is possible in the EMA with long-term market exclusivity in mid-2012 (or sooner).

Winston Pharmaceuticals - Rheumaderm cream for the treatment of OA. NDA pending. Marketed in Canada by Sanofi. Based on civamide which acts on type-C neurons by specific binding to a membrane receptor, the TRPV-1 receptor. Looking for licensing partners in other parts of the world. (Link)

Winston Pharmaceuticals - Also pursuing Civamide, a TRPV-1 modulator, for the treatment of episodic cluster headaches. Late stage with approval pending in Canada. (Link)

Zogenix - Sumavel, a needlefree transdermal delivery of sumatriptan for migraine. Recent FDA approval with product launch using Astellas as a co-promotion partner. Company could consider an M&A transaction. Note: Raised $30mm from Cowen Healthcare Royalty Partners in July 2011.

NEW  Zogenix - Zohydro (hydrocodone bitartrate) extended-release capsules is a novel, oral, single-entity controlled-release formulation of hydrocodone currently for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. An NDA for this product has been submitted.

Zurex - Zuragen is for prevention of catheter-related bloodstream infections. Hospital application available.
MANUFACTURING FACILITIES

**NEW** Fleming Pharma has hired Douglas & Co to find a buyer for its manufacturing facility in St. Louis. (Link)

**NEW** Undisclosed - Large pharma selling an oral solid dose manufacturing facility in the Northeastern U.S. The facility has substantial revenue and EBITDA.

**NEW** Undisclosed – Biotech company willing to sell a small scale but fully outfitted biologics manufacturing facility in the U.S.

**NEW** Undisclosed - Large pharma selling a large oral solid dose manufacturing facility in the Midwestern U.S.

MATURE BRANDED PRODUCTS

**COMPLETED** $ Undisclosed player - process well underway for sale of company with a marketed but not promoted cardiovascular product with 2011 revenues around $9 million. Note: Santarus acquired rights to Fenoglide from Shore Therapeutics in Dec 2011 for $11mm plus royalties.

$ Undisclosed - large pharma disposing of a marketed antibiotic with global rights. This product is off patent.

$ Undisclosed - large pharma disposing of a marketed oncology drug with revenues of around $5mm. Significant barriers to entry.

$ Undisclosed player - sale of company with over $10mm in revenue with largely genericized specialty products in CNS and renal disease.

**COMPLETED** $ Undisclosed - two marketed antibiotics in U.S. One is facing generic competition. Revenues total around $10mm. On March 7, 2012 Cornerstone Therapeutics announced the divestiture of product rights to Factive® (gemifloxacin mesylate) tablets and the Spectracef® (cefditoren pivoxil) family of products in a series of transactions with Merus Labs International Inc. and Vansen Pharma Inc.

$ Undisclosed – Big pharma selling mature cardiovascular product with sales of around $5mm.

$ Undisclosed player - selling off $20mm revenue+ commercial product for narrow market with pediatric applications.

$ Undisclosed player – Sale of some small U.S. female health branded pharmaceuticals.

**NEW** Undisclosed player – bundle of several marketed mature pharma products in the neurology and pain areas. Revenue around $10mm.

$ Undisclosed player – two small oncology products could be acquired from a global pharm player.

**NEW** $ Undisclosed player - mature oncology drug. Interested parties should contact Benj Garrett (benj.garrett@torreyapartners.com).

$ Undisclosed - pharma company is open to divesting a marketed specialty cardiology product with revenues > $30mm per annum.

**UPDATE** $ Undisclosed player - selling off portfolio of $60mm area specialty pharma products included. Four other products remain available. Interested parties should contact Benj Garrett (benj.garrett@torreyapartners.com).
**NEONATOLOGY**

**NEW** Airway Therapeutics - Surfactant Protein D is a normal component of animal (including human) surfactant. Airway’s product, rhSP-D, would be added to existing surfactant prior to treating the very premature newborn, and is going in for an IND.


**UPDATE** Discovery Labs - Surfaxin is a synthetic KL4 Surfactant for treatment of neonatal RDS. The FDA has approved SURFAXIN (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants at high risk for RDS.

Infacare - Developing Stannsoporfin (Stanate) for Neonatal Hyperbilirubinemia, which is in a Phase 2b trial. Company expects to report out data soon. ([Link](#))

Premacure - Lack of IGF-1 in premature babies can lead to severe complications. A Phase I clinical trial for of IGF-I/IGFBP-3 (Premiplex®) found that levels of IGF-1 were increased to within physiological levels and that administration to preterm infants is safe and well tolerated. A Phase II, safety and efficacy multi-center clinical trial has started in Sweden and is currently recruiting patients.

**UPDATE** Symphogen - Rozrolimupab (Sym001) is a recombinant polyclonal composition of 25 different Rhesus D specific antibodies for the treatment of primary Immune Thrombocytopenia and for Anti-RhD prophylaxis (ADP) in prevention of Hemolytic Disease of the Newborn. Symphogen reported positive data from this drug at ASH in 2011 in immune thrombocytopenia patients. This product was returned to Symphogen from Biovitrum Swedish Orphan for strategic reasons on Dec 30, 2010. ([Link](#))

**UPDATE** Prolacta - company developing special type of milk for the treatment of babies born prematurely. On the market and experiencing rapid revenue growth.

Ventria - has developed a recombinant lactoferrin for the prophylaxis and treatment of infection in prematurely born children. Positive POC dataset for this product.

**NUTRITIONALS AND NATURAL PRODUCTS**


$: Bellus Health - Would consider partnering US rights to Vivimind for Alzheimers. Active partnering discussions ongoing in Europe. In April, 2011 announced that it has signed an exclusive license and distribution agreement with Agahan Ayandeye Pars Inc. for this product in the MidEast.

$: Enzymatic Therapy - A natural product distributor sells 250+ natural products. Considering a sale. ([Link](#))

KV Pharma - Licensing rights to prenatal vitams, PrimaCare, and hematinsics, Repliva, via Robert W. Baird. ([Link](#))

**COMPLETED** Pfizer - has sold its nutritional business to Nestle in April 2012 for $11.5 billion. It is believed that the vet medicines business is most likely to be spun out.

**UPDATE** Rottapharm - for sale according to the *Wall Street Journal*. Company has two Phase 3 drugs in development and a strong group of branded products in the market. Revenues over $850 million. Sale price could be over $2.5 billion. Company rumored to be using Credit Suisse to find a buyer. According to Bloomberg (3/15/2012) Mylan
recently pulled out of a sale process. The article noted that “sources said the selling family has not been able to agree to give up control of the company and was not prepared to compromise enough on price either.”

Wockhardt - rumored to be in a process to sell its substantial nutrition business as part of a process to pay down external debt.

**OBESITY**

7TM –TM38837 is a CB1 which has been shown to be inactive in the CNS. This suggests a promising approach given the history with endocannabinoids. It will be important next to show that such a compound is efficacious. ([Link](#))

BHV Pharma - BHV091009 is a highly selective sodium glucose co-transporter 2 inhibitor (“SGLT2i”) being developed for the treatment of diabetes and obesity. Two supportive Phase 2b studies. Also pursuing an obesity indication. ([Link](#))

Fasgen - Obesity and metabolic disease modification programs have progressed and company is looking for a partnership. Strong IP and set of compounds in the fatty acid synthase area including GPAT and CPT-1 inhibitors. Preclinical program entering the lead generation phase. ([Link](#))

Lithera - Announced positive results from a Phase Ib clinical study of LIPO-102, its novel injectable combination of salmeterol xinafoate (SX) and fluticasone propionate (FP) for selective, non-ablative fat reduction. In a Phase 2b study LIPO-102 was well-tolerated when administered weekly for 8 weeks into the subcutaneous abdominal fat of healthy subjects and produced dose- and time-related reductions in mean abdominal volume and circumference.

Neurosearch - Looking to partner obesity program (Tesofensine) going into Phase 3. July, 2011 signed agreement with Biolin Scientific over sale of company’s 30.1% shareholding in Sophion BioScience and all other owners will sell in Sophion will see ownership share.

**NEW** Torrent – Going into Phase 2 studies wit - diiodothyronine (T2), devoid of thyrotoxic effects, being developed for the treatment of cardiometabolic risk associated with visceral adiposity. In preclinical studies TRC150094 has shown increase in energy expenditure through increase in mitochondrial metabolic activity and attenuates visceral adiposity, atherogenic dyslipidemia, blood pressure and improves insulin sensitivity.

University of Strathclyde - Galegine derivatives as anti-obesity compounds. Similar to metformin and likely work through AMP kinase activation. ([Link](#)).

Vivus - Looking to partner Qnexa in Europe and other ROW territories. An approval is possible in the EMA with long-term market exclusivity in mid-2012 (or sooner).

Yonsei University - Peptides which reduce obesity. Preclinical. ([Link](#))

Zafgen - in Phase 1 studies of a novel treatment for obesity in bariatric patients. This drug potentially circumvents many of the problems that have arisen with recent late stage candidates in obesity, including pursuing a sicker patient population with a product that can’t be widely used. July, 2011 signed a $33 million series C financing with Atlas Venture and Third Rock Ventures. ([Link](#))

**ONCOLOGY - LIQUID TUMORS**

4SC - developing resminostat for Hodgkin’s Lymphoma. Phase 2a data showed a few partial responders and some cases of stable disease. ([Link](#))
Acetylon Pharma - Taking ACY-1215, a next-generation Class II-selective histone deacetylase (HDAC) inhibitor - into Phase I/II clinical testing for patients with relapsed and relapsed/refractory multiple myeloma. No POC data yet. (Link)

UPDATE Affimed - Taking AFM13, with a novel tetravalent bispecific antibody structure, for the treatment of Hodgkin's disease (HD) into Phase I. No approved treatments on market. Partnership discussions underway and a deal possible in 2012.

COMPLETED Allos Therapeutics – Oncology marketer with Folotyn® for liquid tumors. After a recently failed merger attempt with AMAG, Allos is rumored to be continuing to explore strategic alternatives with the assistance of JP Morgan. Update: Apr 5, 2012 – Spectrum to by Allos in a deal valued at $206 million. (Link)

UPDATE Antisoma - Partnering AS1413, formerly Xanafide, is a DNA intercalator in phase III development in secondary AML outside the U.S. Expect to report out data in Q1 2011. Note: did not meet its endpoint and ceased development.

Ariad - AP24534, multitargeted kinase inhibitor in Phase 1 for hematological cancer. Appears to address a form of CML caused by a mutant T315I which is resistant to currently available drugs. M&A not likely.

COMPLETED Avila - In mid-Phase 1 for a BTK inhibitor that is highly selective and orally dosed. Btk plays a critical role in the development and activation of B cells, and its inhibition will be of therapeutic significance in the treatment of both of B cell-related hematological cancers (e.g. non-Hodgkin lymphoma (NHL) and B cell chronic lymphocytic leukemia (B-CLL), and autoimmune diseases (e.g. rheumatoid arthritis). Note: Celgene acquired Avila in January 2012 for $350mm plus $575 in additional potential milestones. (Link)

NEW Array Biopharma - ARRY-61, a Dual p38/Tie2 inhibitor for Myelodysplastic Syndromes (MDS). Array presented positive clinical data for ARRY-614 at December 2011 ASH. ARRY-614 demonstrated activity as measured by hematologic improvement (increased neutrophils, platelets and/or red blood cells) in patients with MDS and was generally well tolerated. Discussion underway for a registrational trial.

NEW Array Biopharma - ARRY-520, a KSP inhibitor for Multiple Myeloma (MM): Array presented Phase 1 and Phase 2 clinical data for ARRY-520 at the December 2011 ASH meeting. These data indicate that ARRY-520 has shown preliminary clinical activity in heavily pre-treated patients with MM and was generally well tolerated. Three Phase 2 readouts for this compound are coming up in 2012.

Benitec Limited - starting a small Phase I/II study using Benitec's DNA-directed RNA interference (ddRNAi) technology in lymphoma patients carrying the HIV virus.

Biocryst – Phase 2 open label study with Forodesine for CLL showed 6 of 23 PRs. In May 2011 presented positive data from its two completed, randomized, double-blind, placebo-controlled Phase 2 studies of BCX4208 in patients with gout at the Annual European Congress of Rheumatology. Partnered with Mundipharma for Europe, Asia, Australia and certain neighboring countries.

Biogen Idec - Looking to outlicense Galiximab, an anti-CD80 antibody, which has shown activity in B-cell lymphomas. Has gone through Phase 3 trials. Biogen looking to outlicense after a recent strategic review. (Link)

BioInvent - In Phase 2 studies in multiple myeloma with BI-505 an anti-CD54 antibody. Encouraging Phase 1 data.

UPDATE Celator Pharmaceuticals – Strong Phase 2 data for CPX-351 for AML shown at ASH in Dec 2010. In June 2011 announced positive results in elderly patients diagnosed with secondary acute myeloid leukemia treated with CPX-351. Observations included high-risk patients with secondary AML showed greater improvements with CPX-351. Going into Phase 3 registrational studies. (Link)

Celleron Therapeutics - Developing CXD101, an HDAC inhibitor from AZ with a novel biomarker strategy. (Link)
UPDATE Chroma Therapeutics - Tesedostat has completed a Phase 2B study in elderly AML patients with encouraging response rates. (Link)

UPDATE Clavis Pharma - Elycatarbine 9/61 CRs in a Phase 2 trial in late stage AML. Large clinical trials undertaken. Recently outlicensed second program for pancreatic cancer to Clovis Oncology. In June, 2011 announces that Clovis Oncology, Inc, its development partner for CP-4126, has expanded the ongoing observational study to determine the patient stratification parameters in the pivotal LEAP clinical trial with CP-4126. Update: March 2012 – Clavis moving forward with a Phase 3 trial called CLAVELA. (Link)

NEW Cornerstone Pharma - Developing CPI-613 for AML with encouraging Phase 1 data reported at ASH 2011.. (Link)

NEW Cyclacel - Recently started a pivotal Phase 3, registration-directed, trial of sapacitabine oral capsules as a front-line treatment of elderly patients with newly diagnosed AML who are not candidates for intensive induction chemotherapy. This trial is being conducted under an SPA agreement with the FDA. (Link)

Cytrx - Looking to partner Bafetinif, a dual Bcr-Abl and Lyn-kinase inhibitor for CML where a mutation exists which creates resistance to imatinib and dasatinib. Has completed a Phase 1b study. A Phase 2 study in relapsed CLL is underway.

UPDATE Deciphera - developing switch inhibitors which control kinase shape. Rebastinib (DCC-2036) is a potent inhibitor of the T315I gatekeeper mutant form of BCR-ABL as well as wild-type and other BCR-ABL variants. DCC-2036 in Phase 1 for CML. (Link)

UPDATE Erytech - Graspa® is an innovative formulation of L-asparaginase. Graspa® demonstrated positive results in Phase II trials in acute lymphoblastic leukaemia (ALL) and excellent safety profile compared to control treatment. Graspa® is currently in Phase II/III clinical trial in relapsed and ALL patients in Europe and will shortly be available on a named patient basis.

NEW Formula Pharma - FPI-01, is a first-in-class, synthetic, multi-peptide immunotherapeutic in Phase 2 development for first-remission acute myeloid leukemia (AML) and mesothelioma. (Link)

Il-Yang Pharmaceuticals - looking to partner radotinib, a novel treatment for leukemia based on bcr-ABL modulation. In Phase 3 studies in Korea. (Link)

COMPLETED Intellikine - Very promising dual Pi3k / m-tor compounds, entering Phase 1 clinical trials. Company in active partnership process across all compounds. A partnership is in place witht Infinity Pharma. Intellikine remains an exciting player in its space and is open to a change of control transaction. Update: Takeda acquired Intellikine in Dec 2011 for $190mm upfront and $120mm in additional potential payments.

Italfarmaco - Givinostat is a Phase 2 HDAC inhibitor for inflammatory diseases and cancer. Has been in Phase 2 for juvenile arthritis, myeloproliferative diseases, Hodgkin’s disease and multiple myeloma.

KAEL-GemVax - Phase 3 results anticipated for GV1001 in pancreatic cancer in May 2012. GV1001 is a therapeutic peptide cancer vaccine targeting telomerase. The vaccine has been tested in clinical trials for pancreatic cancer, lung cancer, liver cancer, melanoma and chronic lymphomytic leukemia (CLL).

Lorus - looking to partner antisense approach to AML. Promising Phase 1b data.

OncoNova - Estybon inhibits the PI-3 Kinase, ERK (growth) and AKT (pro-survival) pathways. Entering a Phase 2 study for the control of MDS. July 2011, announced license agreement with SymBio Pharmaceuticals to collaborate and commercialize Rigosertib in Japan and Korea. Conducting late-stage clinical trials in the US, Europe and India for treatment of MDS and solid tumors. (Link)
**UPDATE** Onyx - rumored to be exploring strategic alternatives. Substantial value potential tied to a recently filed NDA for carfilzomib, a protease inhibitor, for the treatment of liquid tumors including multiple myeloma. Market rumors of an acquisition in April 2012.

*S*Bio - going into Phase 2 with novel HDAC inhibitor. In Dec 2010 reported positive safety and tolerability results from Phase 1.

**COMPLETED** S*Bio - In June, 2011 announced results from multiple Phase I/II clinical studies of JAK2 inhibitor Pacritinib confirming safety and efficacy. S*Bio has received the rights back to this program from Onyx Pharma. Has promising data on a Phase 1 HDAC inhibitor. Update: This compound was licensed on April 18, 2012 for $30mm upfront in cash and stock plus milestones and royalties.

**UPDATE** Stemline Therapeutics - A cancer stem cell targeting agent, SL-401, saw Phase 2 data at ASH which demonstrated efficacy, including two durable complete remissions (CRs), multiple blast reductions and disease stabilizations in relapsed/refractory AML, poor risk elderly AML, and high risk MDS. Has filed to go public (Link)

**UPDATE** Sunesis - Vosaroxin in Phase 2 for AML. Data reported in Nov 2010 indicated meaningful response rates and prolonged survival times. In a Phase 3 study known as VALOR. Compound intercalates DNA and inhibits topoisomerase II, resulting in replication-dependent, site-selective DNA damage. Company would consider partnership and, potentially, a sale. VALOR interim analysis: Sunesis expects the planned interim analysis of the VALOR trial by the DSMB to occur in the third quarter of 2012. Has financed its ongoing trial with a recent royalty monetization. (Link)

**UPDATE** Syndax - Entinostat (SNDX-275), an oral class I-selective HDAC inhibitor with a long half life, for cancers. In registration for breast cancer 2nd line treatment. Has started a Phase 1b trial. Company would be most likely to consider a global partnership deal, an IPO or a change of control transaction. (Link)

**NEW** Talon Therapeutics - Marqibo (vincristine sulfate liposomes injection) is a novel targeted nanoparticle-encapsulated anti-cancer compound that has a robust safety database (over 600 patients). FDA recently announced a PDUFA date of May 13, 2012 for Talon’s NDA for the indication of (Ph-) acute lymphoblastic leukemia (ALL) after a favorable panel vote.

Telik - In June, 2011 announced the initiation of Phase II clinical trial to evaluate oral Telintra in patients with Revlimid refractory or resistant, deletion 5q MDS. Trial will enroll up to 117 patients and employ a sequential design with two interim analyses.

Topotarget - Would out license HDAC product, Belinostat, in larger indications. Recently picked up from Curagen. Company considered a takeover target. Positive Phase 1 data reported at ASH 2010. Recently finished recruitment for Phase I trial of oral belinostat in patients with refractory or relapsed Hodgkin’s or non-Hodgkin’s lymphoma as second part of development program.

Undisclosed - Large Pharma disposing of a promising drug for the treatment of NHL.

**COMPLETED** $ Undisclosed player – US and European player in oncology and hospital products with revenue over $100mm is open to a change of control transaction. Note: EUSA Pharma was acquired by Jazz Pharma for approximately $700mm in April 2012.

Xencor - Developing an anti-CD30 (XmAB 2513) antibody for Hodgkin’s disease and T-cell lymphoma. Has finished Phase 1. (Link)

YM Biosciences - CYT387 in Phase 2 study in myelofibrosis. Recently successful completion of Phase 1 and Phase 2 studies. YM argues that this has the potential to be the best in class JAK inhibitor. (Link)

Ziopharm Oncology - Darinaparsin in Phase 2 for PTCL. Favorable results to date.
ONCOLOGY - SOLID TUMORS


**UPDATE**

AB Science – Positive results Phase 3 studies of Masitinib against imatinib (Gleevec®) in GIST. High excitement around this compound and a recent financing. A recent Phase 2 trial saw prolonged PFS and OS. (Link)

Access Pharmaceuticals - Searching for a partner for a platinum prodrug, ProLindac, similar to Eloxitin. Currently in a Phase 2 study in ovarian cancer. Company is also interested in partnering an anti-proliferative antibody called Angiolix which targets Lactadherin. (Link)

Active Biotech - Successful Phase II study showed tasquimod’s ability to impede disease progression in symptom-free patients with metastatic, castrate-resistant, prostate cancer. Drug works by attacking blood vessels. April, 2011 entered partnership to co-develop TASQ with Ipsen. Phase III trial was recently initiated and patient recruitment is ongoing. Rights are available in North America, South America and Japan. (Link)

Adaptimmune - Has opened a Phase I/II, two cohort, open label clinical trial in metastatic melanoma to investigate the safety, bioactivity and anti-tumor effect of patients’ own T cells that have been genetically modified to express a high affinity T cell receptor (TCR) specific for a type of tumor antigen (protein) known as a cancer testis antigen (CT antigen).

**UPDATE**

Adherex - Eniluracil enhances 5-FU effect. Open to partnership. Phase 1 data positive. Enrolling patients in a Phase 2 trial for breast cancer. Enrollment expected to be done in Q3 2012. Was at GSK before. (Link)

**UPDATE**

Advantagene - Phase 2 positive in prostate cancer for AdV-tk (ProstAtak). Enrolling a Phase 3 trial with SPA. (Link)

Advenchen Laboratories - YN-968D1 contains apatinib, a novel small molecule angiogenesis inhibitor that shows selective protein tyrosine kinase (PTK) inhibition on VEGFr2 and Ret and mild inhibition on c-Kit and c-SRC. In Phase 2 studies in China.

**UPDATE**

Agennix - Open to partnering Talactoferrin which is a recombinant form of human lactoferrin - for the indication of non-small cell lung cancer. It is currently in clinical phase III trials (75% enrolled) and has shown good efficacy in Phase 2 in NSCLC and renal cell carcinoma. Data release is imminent. (Link)

Alchemia - Starting a Phase 3 program of its HA-irinotecan with the intention of partnering after data are in. Plans to seek a 505b(2) approval in the United States.

**NEW**

Alligator Biosciences - ADC-1013 is an antibody-based immunotherapy for cancer. Phase 1 studies are planned. (Link)

Ambrx – very exciting platform technologies which allow engineering of proteins developed in both eukaryotic and prokaryotic cells including an antibody drug conjugate program for oncology. (Link)

AmpliMed - Phase II trial of Amplimexon in 142 patients with advanced metastatic pancreatic cancer will report out soon. Will partner before starting Phase 3 trial.

Anaphore - pioneering Altimers®, a NEW class of protein therapeutics that has a trivalent structure. Better ability to lock on to a target. Working on a number of targets including a TRAIL-R antibody for oncology that is pre-clinical. (Link)

Agenus - Prophage, a personalized cancer vaccine tested in 800+ patients - 8 cancers - in over 15 clinical trials spanning Phase 1, 2, and 3 –market approval in Russia. Update: Results recently announced from Phase 2 clinical
trials testing Prophage Series G-200 vaccine in recurrent brain cancer, primary objective to assess survival rate for 26 weeks. Results showed 93% of patients were alive after 26 weeks and had a median overall survival of 11 months.

Angstrom Pharmaceuticals - completed a placebo-controlled Phase 2 study evaluating A6 in recurrent ovarian cancer. The time to tumor progression was doubled in patients receiving A6 over that of placebo (p<0.01). A6 is a urokinase derived octapeptide, an inhibitor of angiogenesis and inducer of tumor apoptosis. (Link)

Antisense Pharma - Trabedersen is an antisense oligonucleotide that suppresses the neoformation of transforming growth factor beta 2 (TGF-b2) at molecular level. Positive Phase 2b results in refractory anaplastic astrocytoma. Recent pharma round. (Link)

Apeiron Biologics - In Phase 3 for CH14.18, an antibody, for neuroblastoma. (Link)

NEW Apogee Biotechnology Corporation - ABC294640 is the first-in-class small molecule inhibitor of the enzyme sphingosine kinase-2 (SK2) that is critical for cancer growth and inflammation. ABC294640 is orally available and can be combined with a variety of standard oncology drugs and radiation. ABC294640 has been granted Orphan Drug designation by the FDA for the treatment of advanced pancreatic cancer. It is currently in Phase 1/2a testing in patients with advanced solid tumors, with an expected cohort expansion with pancreatic cancer patients.

UPDATE Apogenix - in Phase 2 with APG101, a CD95 antibody, for GBM. In March 2012 reported out highly positive data in a controlled trial. (Link)

Aragon Pharma - In phase 1b /2 trial for ARN-509 for castration-resistant prostate cancer. (Link)

NEW Argos Therapeutics – Phase 2a study of AGS-003 reported in Feb 2012, in combination with sunitinib in patients with unfavorable risk, metastatic renal cell carcinoma (mRCC), had demonstrated prolonged survival. (Link)

Ark Therapeutics - Cerepro for brain cancer. Was turned down for approval at EMEA in Mar 2010. Company reported: “Following the withdrawal of the Cerepro® MAA, Ark has initiated a full review of its substantial portfolio of assets, their potential and alternative strategies and options to optimise shareholder value. The review will also consider strategic alternatives in light of approaches that have already been received.”

ARGO Pharmaceuticals - Crenolanib (CP-868,596), a potent FLT3 and PDGFR inhibitor that is active against mutant PDGFR. Phase 2 trials are on-going for glioma and D842V mutant GIST in the US.

UPDATE Arqule - ARQ 621 inhibits Eg5 and reduces tumors in multiple animal models. Finishing Phase 1 studies with a promising BRAF inhibitor. (Link)

UPDATE Array BioPharma - ARRY-520, a KSP inhibitor reported Phase 1 data at ASH. Array reported 2 partial responses in 30 heavily pretreated multiple myeloma patients. Company looking to partner this product. (Link)

Arno Therapeutics - Reported in June 2011 that its Phase 2 clinical study of AR-67 (third generation camptothesic analogue) has met pre-defined interim goals for patients with glioblastoma multiforme (GBM) who were not previously treated with Avastin and will continue toward completion.

Ascenta Therapeutics - AT-101 is a pan-Bcl-2 inhibitor (including Bcl-2, Bcl-xL, Bcl-w, and Mcl-1), that has been shown to directly induce apoptosis by operating as a BH3 mimetic and indirectly as an upregulator of Noxa and Puma. For adjunct therapy with taxanes in HRPC, currently in Phase 2.

NEW Aslan Biopharma – Developing ASLAN will fund and globally develop ARRY-543 through proof of concept, initially targeting patients with gastric cancer through a development program conducted in Asia. ARRY-543 is a
novel, selective and oral HER2 / EGFR inhibitor. Upon achievement of proof of concept, ASLAN will identify a global partner for phase 3 development and commercialization. (Link)

Astex - AT13387 completed a phase 1 study designed to assess the safety and tolerability of AT13387 in patients with advanced refractory tumors. Based upon the results of this initial phase 1 study, Astex Pharmaceuticals™ has initiated a phase 2 study in patients with refractory gastrointestinal stromal tumors (GIST). Open to a partnership deal.

ATLAB Pharma SAS - developing an antibody drug conjugate (ADC) targeting PSMA for the treatment of prostate cancer. In Phase 2 studies. A similar program is at Progenics.

NEW Aveo Pharma – developing AV-299, an anti-HGF/c-MET antibody currently in Phase 2 development for NSCLC. Open to partnering this product. (Link)

NEW Azanta – Developing Nimoral for Head and Neck cancer which is sold on a named patient basis in two countries. Nimorazole is a hypoxic radio sensitizer developed to be used in combination with radiation therapy for head and neck cancer patients. This product is expected to be approved in the U.S. and Canada on an orphan basis in the next several years.

NEW Bavarian Nordic - Looking to partner Prostvac, a prostate cancer vaccine which has completed Phase 2 trials. In extensive partnership discussions and a deal is targeted in 2011. Compared to Dendreon’s Provenge.

UPDATE Bellicum Pharma - Bellicum plans to initiate a Phase 2 DeCiDe vaccine study in 2012. BPX-101 is a therapeutic cancer vaccine being developed for the treatment of patients with metastatic castrate resistant prostate cancer (mCRPC). Recently raised a new round of financing. (Link)

Biogen Idec - looking to outlicense BIIB021, an HSP90 modulator, targeted for GIST. (Link) (Link2). Also outlicensing BIIB028, an HSP90 modulator that is in Phase 1 studies.

Biogen Idec - looking to outlicense Volociximab, a chimeric monoclonal antibody that inhibits the functional activity of α5β1 integrin, a protein found on activated endothelial cells. Blocking the activity of α5β1 integrin has been found to prevent angiogenesis. This product is jointly owned with Abbott’s Facet Biotechnology. (Link)

Biogen Idec - looking to outlicense BIIB015 which consists of Biogen Idec's Cripto-binding antibody and Immunogen’s DM4 cell-killing agent. BIIB015 advanced into Phase I testing in the summer of 2008. This compound was slated for Phase 2 in 2011 until Biogen Idec decided to exit oncology after a recent strategic review.

Biogen Idec - looking to outlicense an anti IGF1-R antibody for solid tumors. Has progressed into Phase 2 studies. (Link)

UPDATE Bionomics - BNC105, looking to partner a vascular disrupting agent which is in Phase 2 trials in renal cancer. Note: a further trial has been started in ovarian cancer. (Link)

Biotecnol - CAB051, an anti-HER2 antibody which is nearing readiness for clinical testing.

Biothera - Imprime PGG is a novel immunotherapy that works synergistically with anti-tumor monoclonal antibodies to activate a large population of the body’s immune cells (neutrophils) to kill cancer cells. Positive Phase 2 results in combination with Erbitux in colorectal cancer.

Biovest International – Has several assets including BiovaxID which has recently had positive Phase 3 data in NHL. Company recently emerged from bankruptcy.
BTG - OncoGel®, a sustained-release formulation of paclitaxel, a well established chemotherapy agent, for local injection. A Phase IIb study in 124 patients with operable oesophageal cancer is ongoing. Preliminary tumour response and histopathology data are expected to be available towards the end of 2010 or in early 2011, with survival data towards the end of 2011. (Link)

Cancer Prevention Pharmaceuticals - CPP’s lead product has been associated with reduced formation of colon polyps, the sole cause of colon cancer in a first Phase III study. A Phase III trial is planned for familial adenomatous polyposis (FAP), an inherited disease with potential annual sales of up to $500 Million. This company has been assisted by Geller Biopharm. (Link)

UPDATE CDG Therapeutics - Developing p28, a peptide (fragment of azurin) completed Phase 1 studies. This product was well tolerated and has promise in further studies.

UPDATE Celator Pharmaceuticals - In Phase 2 trials for CPX-1 for colorectal cancer. Note: the company has not updated progress on this program for several years.

UPDATE CellDex - Their lead antibody-drug conjugate (ADC), CDX-011, is in Phase 2 development for the treatment of locally advanced or metastatic breast cancer (in Phase 2b) and stage III or IV melanoma and data are expected in Q2 2012. Saw 15% ORR in melanoma Phase 2a study. CDX-011 targets glycoprotein NMB, also known as osteoactivin, a cell surface protein overexpressed in certain cancers. (Link)

NEW CellDex - Rindopepimut is an immunotherapy that targets the tumor specific oncogene called EGFRvIII. Presented median overall survival (OS) data. Phase 2 multi-center ACT III study in patients with newly diagnosed EGFRvIII-positive glioblastoma showed a final median OS of 24.6 months from diagnosis, which is significantly better than 15.2 months for a historical cohort of patients selected to match ACT III eligibility criteria.

Celek Pharmaceuticals - CEL-031, is a Phase 2 drug in development for the treatment of non-muscle invasive bladder cancer. Works by inducing tumor cell apoptosis and inhibiting cell proliferation. (Link)

UPDATE Celsion - ThermoDox® is a proprietary heat-activated liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. In the HEAT Study, ThermoDox® is administered intravenously in combination with RFA. In November 2011 the data monitoring committee for the HEAT study completed a planned interim analysis for safety, efficacy and futility and unanimously recommended that the study continue to its final analysis as planned. On March 15, 2012 the company noted: “A total of 380 progression events are required to reach the planned final analysis of the study which the Company reconfirmed was projected to occur in late 2012.” (Link)

NEW Ceptaris – Formerly Yaupon Therapeutics is filing an NDA for Valchlor, a gel formulation of mechlorethamine for the treatment of mycosis fungoides, a type of CTCL. This orphan disease impacts 80,000 persons in the Western world. Product launch in U.S. anticipated in Q4 2012. Company in active business development dialogue.

UPDATE Cerulean Pharma - CRLX101 with camptothecin is in a Phase 2 trial in lung cancer. CRLX301 with docetaxel has finished preclinical work. Both formulations have much lower side effects than on market versions. Looking for partnerships.

NEW Cleave Bio – in preclinical testing for a novel compound in the area of cancer metabolism.

Cornerstone Pharma - Developing CPI-613 for pancreatic cancer. Currently in a Phase 1b trial. Interim data show safety and some hints of efficacy. (Link)

CureVac - upregulates mRNA to create specific autoantigen responses to disease. Has recently shown a nice proof of principle in man for a therapeutic vaccine aimed at prostate cancer in a Phase 1b study. In June 2011 reported results from final Phase Ib/II clinical trial using RNAVactive vaccine CV9103 to treat patients with advanced
castration-resistant prostate cancer. Final trial results confirm preliminary data previously published demonstrating safety and immunogenicity of the vaccine.

**UPDATE** Curis - **CUDC-101** is the first-in-class compound under development to jointly inhibit HDAC, EGFR and Her2. A recent Phase 1 study demonstrated safety and hints of efficacy. Planning a Phase 2 study in Head and Neck cancer soon. ([Link](#))

**UPDATE** Cyclacel - **Seliciclib**, is a first-in-class, orally available, cyclin dependent kinase (CDK) inhibitor. The compound selectively inhibits multiple enzyme targets - CDK2/E, CDK2/A, CDK7 and CDK9 - involved in the process of cell division. Promising Phase 2 data. In June, 2011 announced interim data results from ongoing, multi-center, Phase I/II clinical trial examining safety and effectiveness of oral sapacitabine administered sequentially with decitabine. Currently, in an investigator initiated Phase 2/3 trial.

**UPDATE** Cylene Pharmaceuticals - Phase 2 data pending in neuroendocrine tumors on **Quarfloxin**, a fluoroquinolone that disrupts G-quadruplex (QPLX) DNA structure underlying tumor growth. In June, 2011 announced positive data from ongoing Phase I trials of CX-4945. Results highlighted safety, pharmacokinetic and exposure-related pharmacodynamic responses observed. Has recently brought a back-up CK inhibitor in the clinic.

Cytrx - In July, 2011 announced that its tumor-targeted doxorubicin conjugate, INNO-206, is delivering doxorubicin safely at doses over 4 times higher than the standard doxorubicin dose in the Company's open-label Phase 1b safety and dose escalation clinical trial.

Deciphera - developing switch inhibitors which control kinase shape. DCC-2157, Inhibitor of BCR-ABL and T315I BCR-ABL gatekeeper mutant, resistant to all marketed kinase inhibitors. Also has c-MET inhibitors. ([Link](#))

**NEW** Del Mar Pharma - VAL-083 is a small-molecule chemotherapeutic and bi-functional alkylating agent for the treatment of glioblastoma multiforme (post-Avastin failure). It is an older chemotherapy agent that is being repurposed and is now in Phase 1b studies. Good evidence of tumor regression noted in GBM.

Diffusion Pharma - animal studies demonstrate a tripling of survival and superior tumor control when trans sodium crocetinate (TSC) is combined with radiation and chemotherapy in animal models of cancer. Based on this work, the Company is initiating a Phase II clinical trial of TSC in primary brain cancer (GBM) patients. This trial will examine the survival of newly diagnosed GBM patients when TSC is combined with the current standard-of-care (radiation plus chemotherapy) with enrollment beginning in late 2011. Data expected in early 2013. ([Link](#))

**NEW** Dynamix Pharma – Pursuing novel kinase inhibitors for cancer. Preclinical programs target PKM2 and JAK3. ([Link](#))

Egen - **EGEN-001** in development for advanced recurrent ovarian cancer, as well as other local or disseminated solid tumors. The product is based on TheraPlas(R) delivery technology. It is composed of an interleukin-12 (IL-12) gene expression plasmid and a biocompatible delivery polymer. ([Link](#))

Endoceutics - developing Acolbifene, an estrogen blocker, now in Phase 3 for the treatment of estrogen dependent breast cancer. ([Link](#))

**COMPLETED** Endocyte - **EC145** targets an alkaloid chemotherapy drug to folate receptors over-expressed on cancer cells. Met primary endpoint in Phase II study demonstrating 85% improvement in median progression-free survival for treatment of platinum resistant ovarian cancer. Update: This program was partnered to Merck in April 2012 for $120mm upfront plus additional milestones and royalties. ([Link](#))

EOS - In Phase 1 with a selective FGF / VEGF kinase inhibitor. This is a promising combination for addressing revascularization issues that have been seen with VEGF inhibitors. ([Link](#))
Essa Pharma – developing an androgen deprivation therapy for prostate cancer that has potential to avoid the resistance profile of abiraterone. The product works by binding the N-terminus domain of the androgen receptor.

Exelixis - According to Bloomberg on April 12, 2011: “Exelixis Inc. is working with Goldman Sachs Group Inc. to prepare for potential takeover offers after its experimental drug helped prostate-cancer patients in a study.” Company’s XL-184 has reported dramatic data on reducing metastatic prostate lesions at ASCO. Update: company has hired a Chief Commercialization Officer with intention to introduce cabozantinib to the U.S. market and has reported strong data for cabozantinib in the treatment of medullary thyroid cancer.

Five Prime Therapeutics - in Phase I with FP-1039, a soluble fusion protein consisting of a portion of FGFR1 that is designed to neutralize the activity of multiple FGFs and FGFRs. Many solid tumors depend on FGF. (Link)

Ganymed Pharmaceuticals – Good Phase 1 data with Claudiximab, an iMAB directed against the GC182 target, a gastric differentiation protein that is expressed at the cell surface of 70% of gastric cancers, 50% of pancreatic cancers, 30% of esophageal cancers, and 25% of NSCLC. Now in Phase 2a studies in gastro-esophageal cancer. (Link)

Genesis Pharma - developing a CD-55 antibody against solid tumors. In Preclinical testing. (Link)

Genyous Biomed - Aneustat for solid tumors - targets multiple ligands including VEGF, EGF and IL-1b. (Link)

Globelimmune - GI-4000, a series of Tarmogen® products engineered to express the seven most common KRAS mutations, was given to patients with stage I-III lung adenocarcinoma having a matching KRAS mutation in their tumor. Showed good tolerability and disease-specific immune responses in this phase 1 trial. (Link)

Harbor Biosciences - Has hired Burrill to help partner Apoptone (HE3235) in Phase I/II trials to treat hormone-refractory prostate cancer. Preclinical studies show Apoptone decreased tumor size by inducing programmed cell death, also shrank established tumors and prevented appearance of new tumors in rodent breast cancer models. Company previously called Hollis-Eden.

Hybrigenics - In Phase 2 studies of Inecalcitol, a vitamin D analogue that is more potential than calcitol. Positive data from a single arm study in prostate cancer. In May, 2011 announced complete positive results of clinical tolerance in Phase IIa study of daily oral inecalcitol in castrate-resistant prostate cancer patients in combination with 3-weekly Taxotere chemotherapy regime. Company now moving to a Phase 2b study.

Idera Pharmaceuticals - On Nov 30, 2011 announced that it has regained global rights to IMO-2055, an agonist of Toll-like Receptor (TLR) 9, as part of an agreed-upon termination of its oncology collaboration with Merck KGaA. During the collaboration, Merck KGaA conducted Phase 1 trials of IMO-2055 in several cancer indications and has an ongoing randomized Phase 2 trial of IMO-2055 in combination with Erbitux® in patients with squamous cell cancer of the head and neck (SCCHN).

Immunocellular Therapeutics – ImmunoCellular is in a Phase 2 trial in GBM for ICT-107, an autologous, dendritic cell-based vaccine that activates a patient's immune system against specific tumor-associated antigens. Open to strategic dialogue when data from this trial are available.

Immunocore - IMCgp100 for the treatment of malignant melanoma in Phase 1. This human-specific soluble protein comprises a high-affinity T cell receptor (TCR) specific to a peptide sequence from the gp100 antigen, which is presented on melanoma tumour cells by HLA-A2, fused to an anti-CD3 single chain antibody fragment. Preliminary results suggest IMCgp100 kills cancer-initiating (stem) cells, the subset of tumour cells putatively responsible for initiating and maintaining the disease, as well as bulk tumour cells. (Link)
Immunogen - Seen as one of the more exciting oncology players in the market. Has an unpartnered antibody drug conjugate that binds to CD56 Lorvotuzumab Mertansine for SCLC, multiple myeloma, MCC, Ovarian Cancer and other CD56+ Solid Tumors. A recent study showed a number of partial responses in the treatment of multiple myeloma. (Link)

Immunomedics - In partnership discussions on the oncology indications for two monoclonal antibodies which are currently in Phase 2 trials (Link)

InNexus - Next generation cancer antibodies at pre-clinical stage. Several highly potent anti-CD20 antibodies in development. Has engaged Dundee Securities to act as financial advisor. (Link)

Institute of Cancer Research (UK) - looking to outlicense checkpoint-1 inhibitors (Chk1). Preclinical. (Link)

KAEL-GemVax - Phase 3 results anticipated for GV1001 in pancreatic cancer in May 2012. GV1001 is a therapeutic peptide cancer vaccine targeting telomerase. The vaccine has been tested in clinical trials for pancreatic cancer, lung cancer, liver cancer, melanoma and chronic lymphomytic leukemia (CLL).

UPDATE Keryx - developing KRX-0401, (Perifosine), a novel, first-in-class, oral anticancer agent that inhibits AKT membrane recruitment and pathway activation. Update: On April 2, 2012 Keryx reported that this compound missed its primary endpoint of improved survival in a Phase 3 trial in colorectal cancer. Keryx does not intend to develop this compound further.

Medigene - EndoTAG1 a proprietary cationic liposomal complex encasing paclitaxel which selectively targets angiogenic endothelial cells. Upcoming data and partnership discussions. Update: CFO recently indicated that a deal was expected by mid-year 2010.

Molecular Insight Pharmaceuticals - Azedra in Phase 2 for the treatment of metastatic neuroendocrine tumors such as pheochromocytoma, carcinoid and neuroblastoma that are not amenable to treatment with surgery or conventional chemotherapy. Very positive recent data that highlight potential for rapid approval. SPA in place with FDA. Company has emerged well capitalized from a bankruptcy process and new board of directors.

MolMed - Novel VTA for vascularised solid tumours. Phase II trials as single agent ongoing in colorectal and liver cancer, and in mesothelioma. Company has reported evidence of activity in a number of tumor types. Looking for a development partner. June, 2011 reports NEW clinical data of investigational anticancer drug NGR-hTNF in lung cancer confirming favorable safety profile. (Link)

Myrexis - positive responses in Avastin® failures in glioblastoma multiforme with Azixa, a novel microtubule destabilizing agent. In non-clinical studies, Azixa has demonstrated the ability to effectively cross the blood-brain barrier and accumulate in the brain at levels as much as 30 times that measured in the plasma. (Link)

UPDATE Nektar - pursuing a pegylated irinotecan (NKTR-102) with superior PK profile. Has shown very positive data in breast and ovarian cancer. Phase 3 study in metastatic breast cancer. High response rates in Phase 1 - 2. In P2 ovarian cancer. P2 colorectal cancer ongoing. All monotherapy but has high combination potential. Less diarrhea and neutropenia. (Link)

NEW Neogenix – In Phase 2 in CRC with Ensituximab, a novel antibody targeting an overexpressed cell surface antigen. Using biomarkers to assist in trial. (Link)

NEW Novelos – developing a phospholipid ether analogue that attaches to cancer cells while carrying a radioactive payload. Preparing to enter Phase 2 studies. Also developing an associated imaging agent.

NEW Oncolytics Biotech - Developing Reolysin® for treatment of head and neck cancer. Promising survival results from a recent Phase 2 study with an active control. Now in a randomized phase pivotal trial of Reolysin + paclitaxel
versus paclitaxel alone in head and neck cancer with data expected shortly. Clinical data showed positive results in patients with non-small cell lung cancer. (Link)

OncoNova - Estybon inhibits the PI-3 Kinase, ERK (growth) and AKT (pro-survival) pathways. Entering a Phase 2 study for the control of MDS. July 2011, announced license agreement with SymBio Pharmaceuticals to collaborate and commercialize Rigosertib in Japan and Korea. Conducting late-stage clinical trials in the US, Europe and India for treatment of MDS and solid tumors. (Link)

OxiGene - ZYBRESTAT, a vascular disrupting agent, is currently being evaluated in a pivotal registration study in anaplastic thyroid cancer (ATC) under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration (FDA). Positive final results reported June, 2011 in Phase 2/3 studies of ZYBRESTAT, with median overall survival time at 5.2 months. Have also seen some improvement in patient response in NSCLC. In active partnership dialogue. (Link)

Pathway Therapeutics - in Phase 3 for an optimized PI3K alpha / mTOR compound. High selective with strong preclinical profile. (Link)

Patrys - developing antibodies for solid tumors. In Phase 1 with PAT-SM6 that binds to GRP78 that is found on the surface of cancer cells but not on the surface of healthy tissues. Also in Phase 1 with PAT-SC1 that binds to CD-55. (also see Genesis Pharma). (Link)

UPDATE Peregrine Pharma - Positive data in a single arm Phase 2a trial evaluating Bavituximab in combination with carboplatin and paclitaxel in advanced breast cancer patients. Is currently in two phase 2b trials in NSCLC. Reported 12.4 month overall survival data from Phase II trial in non-small cell lung cancer in June, 2011. Phase 2 NSCLC data reported out in March 2012 and were disappointing. (Link)

PharmaMar - Promising Phase 2 data on Aplidine in a trial of patients with advanced medullary thyroid carcinoma. Open to partnering compound. Just ended a Phase II trial with compound PM001183 with an endpoint of overall survival at 6 months in patients with metastatic pancreatic cancer. Clinical trial results will be performed in several centers and aims to test PM 001183’s antitumor activity as second line treatment.

Philogen - L19-IL2 is well tolerated in patients and is being clinically developed in two registrational clinical trials in patients with metastatic melanoma. In addition, L19-IL2 is being studied in combination with gemcitabine in patients with pancreatic cancer.

Pierre Fabre - Outlicensing North American rights to Javlor (vinflunine) - a newly approved bi-fluorinated MTI (Microtubule inhibitor) for bladder cancer. Licensing process is well underway. (Link)

S*BIO - Looking to partner mTOR/PI3K compounds which are in pre-clinical development. (Link)

Sareum - looking to outlicense Aurora + FLT3 Kinase program. Preclinical. (Link)

Samyang Pharma - Genexol-PM is undergoing clinical phase III trials in Korea for its use as a chemotherapeutic agent for the treatment of refractory cancer. Also in U.S. Phase 2 trials. This is a version of Paclitaxel that does not include Cremophor EL. (Link)

SciClone Pharmaceuticals - Developing an immunomodulatory dipeptide for cancer. Pre-clinical program. Interested parties should contact Reinhard Oesterle (Roesterle@SCICLONE.com).


Spectrum Pharmaceuticals - Looking for ROW partner for Elsamitrucin. This Phase 1 drug induces single strand breaks in DNA and inhibits topoisomerase I and II, enzymes that play an important role in DNA replication. (Link)
Stemline Therapeutics - In June, 2011 announced that clinical results from a multi-epitope brain cancer vaccine, that Stemline has licensed from the University of Pittsburgh (Pitt) and is further developing as SL-701. Showed positive Phase I/II trial results.

Telik - Partnership talks for its compound Telcyta, for the treatment of advanced cancers. Mixed trial results in selected solid tumor indications.

Telormedix - Developing a promising TLR9 modulator that is in a Phase 1 / 2 trial for the treatment of bladder cancer. There should be a data release on this product in 2012. (Link)

Tetralogic - TetraLogic's lead Smac mimetic drug, TL32711, is entering Phase 2 clinical trials and is being developed for both solid tumors and hematological malignancies as a single agent and in combination with several standard-of-care cancer therapies. In Phase 1 clinical studies as a single agent and in combination with standard-of-care chemotherapies, TL32711 has demonstrated strong correlation between drug exposure, target coverage and apoptosis induction in tumors at well-tolerated doses as well as promising anti-tumor activity in patients. (Link)

To-bbb - Glutathione pegylated liposomal doxorubicin (2B3-101) is in development for multiple brain cancer indications with an initial focus on patients with brain metastases of breast cancer. to-BBB started the first phase I/II clinical trial with 2B3-101 in June 2011. (Link)

Tokai Pharmaceuticals - TOK-001 is a specific androgen receptor modulator/lyase inhibitor (SARM/LI) going into Phase 1b/2a trials for prostate cancer. (Link)

Tracon Pharma - TRC105 is a human chimeric monoclonal antibody that binds CD105 (or endoglin), a target that is essential for angiogenesis. A Phase 1 trial of TRC105 for patients with advanced cancer is nearly complete and a Phase 1/2 trial of TRC105 for patients with prostate cancer is ongoing. (Link)

Tracon Pharma - TRC102 is a small molecule inhibitor of base-excision repair intended to reverse resistance to alkylator and antimetabolite chemotherapy. A Phase 1 study of TRC102 in combination with Alimta® chemotherapy was completed and Phase 2 studies are planned in lung cancer and other indications. (Link)

Tragara Pharma - In Phase 2 of Capoxigem®, a Cox-2 inhibitor, for prostate cancer. Expects data in Q2 2011. (Link)

Tyrogenex - More potent PDGFR inhibitor than Nexavar and less cytotoxic in cells. More selective than Sutent, particularly against AMPK and RETD. (Link)

NEW $ Undisclosed player - mature oncology drug. Interested parties should contact Benj Garrett (benj.garrett@torreyapartners.com).

NEW $ Undisclosed player – two small oncology products could be acquired from a global pharm player.

NEW Wilex - RENCAREX (INN: Girentuximab) is a targeted antibody for the treatment of solid tumours and binds specifically to the protein carbonic anhydrase IX (CA IX) expressed on the tumour cells, thereby triggering an immune reaction called Antibody-Dependent Cellular Cytotoxicity (ADCC). CA IX is expressed in over 90% of all clear cell renal cell carcinomas (ccRCC), but not expressed in normal kidney tissue. RENCAREX is currently in a pivotal Phase III trial with 864 patients in over 140 centres in 14 countries as an adjuvant therapy of patients with non-metastatic clear cell renal cell cancer (ccRCC).

NEW Wilex - VTX-2337 is a small molecule Toll-like receptor 8 (TLR8) agonist that stimulates myeloid dendritic cells, monocytes, and enhances NK cell responses. It is administered subcutaneously on a weekly basis, and successfully completed a Phase I study in oncology. (Link)

NEW Viventia - Vicinium® has VB4-84, a humanized, single-chain antibody fragment specific for the EpCAM antigen. The antibody fragment is recombinantly fused to a truncated form of Pseudomonas exotoxin A, ETA(2S2-608),
engineered to lack the cell binding domain, but to retain the active domains necessary to induce cell death. Has done well in Phase 2a studies in bladder cancer. ([Link])

Xcovery - Partnering a rich set of pre-clinical PI3K kinase inhibitors and also candidates for inhibition of ALK and c-MET. High interest.

Y's Therapeutics - Anti-CD26 Humanized Monoclonal Antibody for solid tumors. Phase 1 ready.

YM Biosciences - Is developing an EGFR antibody targeting HER1, Nimotuzumab, for solid tumors. Late stage and on the market in developing countries. Believes that this drug could be introduced to the U.S. market in the next few years, depending on Cuba policy.

### ONCOLOGY - SUPPORTIVE CARE

7TM - TM30339 is a Phase I/II NPY Y4 selective agonist to be used within gastrointestinal disorders including cancer supportive care (mucositis), malabsorption, Ulcerative Colitis, Crohn's disease and short bowel syndrome.

Access Pharmaceuticals - undertaking a commercial launch of Mugard which was approved in 2010. This product is used for treating oral mucositis. Access is actively looking for a co-promotional partner for this product. June, 2011 received acceptance letter from Chinese SFDA citing all documentation for MuGard, indicated for treatment of oral mucositis a side effect of anti-cancer treatments, has been submitted and accepted. ([Link])

ActoGeniX - completed Phase 1b study of topically applied AG013 in 21 subjects receiving induction chemotherapy for the treatment of cancers of the head and neck. AG013 was proven safe and well tolerated. Analysis of initial efficacy showed a 35% reduction of the percentage of days with ulcerative oral mucositis in the AG013-treated patients versus the placebo-treated patients. Looking for a partner. ([Link])

Archimedes Pharma - Is seeking licensees for North America and Japan for PecFent, a nasally-delivered fentanyl product for breakthrough cancer pain, currently in Phase III development. Archimedes Pharma is seeking licensees outside of Europe for PecFent®. Has gained a positive opinion from the CHMP, and has been filed for regulatory approval in the US. Preparing for a U.S. launch.

AGI Therapeutics - Positive results in a Phase II proof of concept study of AGI-004 in the control of chemotherapy-induced diarrhea (CID). AGI004 contains a proprietary form of a known ganglion-blocking drug mecamylamine, which is specifically formulated in a low dose controlled release form to optimize its gastrointestinal effects. ([Link])

AP Pharma - Would outlicense APF530 in Phase 3 for CINV. Positive Phase 3 data. The FDA has accepted for review the NDA and, based on the Prescription Drug User Fee Act (PDUFA), has issued an action date of March 18, 2010. Update: AP received a complete response letter that required additional studies on bioavailability and metabolism. Meetings with FDA to discuss issues raised in complete response letter, and anticipates resubmission of the APF530 NDA during the first half of 2012. ([Link])

Calabar - Would outlicense physostigmine, a phase 2 product for dry mouth (Xerostomia).

Camurus - Episil® (CAM2028) is a protective, bioadhesive intra-oral liquid for treatment of oral mucositis. The product is registered in Europe as a Medical Device, Class I, with an expected market launch in Q2 2010. Note: This product was licensed to IS Pharma in Europe after its recent approval. A 510k registration submission in the US is under way.

Epicept - NP-1 cream for neuropathic pain (4% amitriptyline and 2% ketamine) in Phase 2 development. Company report: “A Phase II trial in chemotherapy-induced peripheral neuropathy (CPN) is being conducted by the National Cancer Institute (NCI)-funded Community Clinical Oncology Program. The double-blind, randomized placebo-controlled study includes approximately 400 patients suffering from painful CPN for at least 28 days following the...
The primary endpoint of the 6-week trial is change in average daily pain intensity scores from baseline to the endpoint. This trial is currently enrolling patients.”

The GI Company - The GI Company recently achieved POC in a Phase II clinical study that evaluated ITF as a treatment for oral mucositis which are lesions that can form in the mouth as a result of chemotherapy and radiation therapy. Currently for sale via Burrill & Company.

ImmuPharma - treatment for cancer pain is based on met-enkephalin, the body's internal analgesic. IPP-102199 is being developed to have major advantages over morphine such as longer pain relief duration and reduced side effects.

Mogam - has developed a GCSF with an alternative pegylation structure. In Phase 2/3 studies in Korea. Available for global licensing.

Lipocine - LPCN 1035, Phase 2 development of benzonatate for opioid resistant cough in advanced cancer patients.

Merrion Pharmaceuticals - Orazol is a once weekly tablet form of zoledronic acid, which is only available as an intravenous infusion (Zometa® and other trademarks, Novartis). Zoledronic acid is a very potent and thoroughly investigated bisphosphonate compound, which has been used to treat over 3 million patients worldwide for bone metastases. Update: Novartis reported in Dec 2010 that Zometa did not meet endpoint for use in breast cancer, an indication that has been targeted by Merrion.


Ohr Pharmaceuticals - In Phase 2b studies with an broad spectrum anti-inflammatory agent for treating cancer cachexia.

Procertus – In a Phase 2 trial for ProDermaCel™, a topically applied pharmaceutical that protects normal hair follicle stem cells to prevent the loss of hair (alopecia) suffered by cancer and bone marrow transplant patients undergoing chemotherapy and/or cranial radiotherapy.

PsiOxus - MT-102 for cancer cachexia. This drug is an anabolic catabolic transforming agent. Ongoing Phase 2 study underway with completion targeted for 2012.

Salient Pharma - developing CASAD for chemotherapy induced diahrrea (CTID). Phase 2 studies underway. Tolerability of CASAD was reported positive for second in-study interim analyses.


Tarix Pharmaceuticals - In Phase 2 trials with TXA-127 for treatment of patients with stem cell transplant and the prevention of chemotherapy induced thrombocytopenia. TXA-127 has much broader applications in hematology, respiratory disease and fibrosis. Interested parties may contact Tom Bird at Torreya Partners for a non-confidential information package (tom.bird@torreyapartners.com, 1-212-331-7855).

Tranzyme - TZP-201 is a potent motilin antagonist for chemotherapy-induced diarrhea, diarrhea associated with infection, and diarrhea associated with irritable bowel syndrome. Tranzyme expects to file an IND for TZP-201 in the next several months.

$ Undisclosed - Marketed supportive care oncology product portfolio available.
Xenome - **Xen2174** is a peptide that binds to norepinephrine transporter (NET), blocking its ability to remove NE from the synapse. Positive Phase 2 data in severe cancer pain.

**OPHTALMOLOGY**

Aerie Pharmaceutical - The company’s lead candidate, AR-12286, is a Rho-kinase inhibitor, which is in Phase 3 trials. ([Link](#))

Alimera Sciences - Positive data from Phase 3 trials of Fluocinolone Acetonide in Diabetic Macular Edema (Iluvien).

Update: Company has gone public and CEO recently indicated to Pharmawire that had received offers prior to IPO but decided they were too low. Company received a complete response letter that requires further analysis of Phase 3 data and questions about relative risk/benefit of Iluvien. Resubmitted NDA for Iluvien in May, 2011 addressing the questions in the complete response letter. Update: In November 2011 FDA indicated that at least two additional studies would be required for approval.

Altheos - developing a Rho-kinase inhibitor for glaucoma (like Aerie Pharma). Has recently raised funds to go forward with clinical studies. ([Link](#))

Clermont Pharma - Looking for a partner for a non-preserved formulation of latanaoprost for glaucoma. NDA filing is pending and FDA decision expected in second half of 2012. The non-preserved latanoprost demonstrated the primary efficacy endpoint of non-inferiority to Xalatan and was better tolerated than Xalatan (less stinging).

Comentis - **ATG-3** is an antagonist of the nACh receptor pathway in the vasculature. A 330 patient Phase 2 dose-ranging study in patients with neovascular or wet AMD is underway.

**COMPLETED** Cutanea - Strong data for Ionic Contra Viral Therapy product **CLS003**. Actively shopping the company. Update: This company was acquired by Maruho in February 2012.

Danube Pharmaceuticals - **DNB-001** has achieved POC for a Phase 2a small molecule for reducing IOP associated with glaucoma.

**NEW** Dong-A Pharma – testing DA-6034 a secretagogue for the treatment of dry eye. Strong animal / human POC data. Going into Phase 3 studies. ([Link](#))

Eyegate Pharma - Just started Phase 3 trials of EGP-437 for treatment of dry eye. The Phase 2 study showed significant improvements in the signs and symptoms of dry eye. Also see Aciont. January, 2011 secured $5.9 million series D venture funding which will be use to further development of EGP-437 indicated for treatment of Dry Eye Syndrome. First company to complete Phase II studies using iontophoresis technology to deliver active compound to the eye under IND application.

**NEW** GeneSignal - GS-101 is a topical antisense oligonucleotide that has nearly completed phase III for the prevention of corneal graft rejection. Aganirsen is also entering phase II clinical trials for additional angiogenesis based diseases, such as wet age-related macular degeneration (AMD), neovascular glaucoma, and dermal indications. ([Link](#))

Hermo Pharma - In Phase 2a for HER-801 for amblyopia (lazy eye). ([Link](#))

**NEW** HanAll Biopharma - HL036 is a preclinical eyedrop formulation of small fragment of TNF-alpha receptor targeting local inflammatory diseases caused by TNF-alpha such as autoimmune uveitis and dry eye.

High Point Pharmaceuticals - HPP851, sterile eye drops for the treatment of primary open angle glaucoma (POAG). Preclinical Inhibitor of 11BHSD1. ([Link](#))
**NEW** Inotek – Developing INO-8875 for the treatment of glaucoma. This product is in mid-Phase 2 trials with encouraging data. Open to partnering global rights or Japan rights.  ([Link](#))

Insite Vision - **ISV-502** (AzaSite Plus) is a topical combination antibiotic/corticosteroid product for blepharitis and blepharconjunctivitis and currently is Phase 3 studies. Has just entered Phase 2 studies for ISV-303 for the treatment of pain and inflammation in cataract surgery.  ([Link](#))


**COMPLETED** $Ista – Strength in ophthalmologic and respiratory disease products. Company received an acquisition offer from Valeant and was ultimately acquired by Bausch and Lomb in March 2012.

Kowa - **K-115** is a small molecule, NCE that selectively inhibits Rho kinase. Kowa is developing K-115 in Japan as an ophthalmic solution for the treatment of glaucoma. In Phase 1 and looking for a US / EU partner.

Macusight - Sirolimus for AMD. Solid Phase 1 data. Partnered in Asia to Santen.  ([Link](#))

Mimetogen – **Positive Phase 2 data for the treatment of dry eye with MIM-D3, a small molecule nerve growth factor peptidomimetic that can stimulate goblet cell differentiation. Interested parties should contact John Cullity at Torreya Partners (john.cullity@torreyapartners.com).**

Neurotech - **NT-501** is being developed for geographic atrophy, a serious sight-threatening condition associated with dry age-related macular degeneration (AMD) and retinitis pigmentosa. Recent Phase 2 data (April, 2011) results showed that NT-501 slowed progression of vision loss in patients with geographic atrophy associated with wet AMD and also demonstrated significant cone photoreceptor preservation in patients with retinitis pigmentosa.

**NEW** Ocularis – night vision product with good Phase 2b data. Open to transaction.

**NEW** Omeros - OMS302 is added to standard irrigation solution used in patients undergoing intraocular lens replacement surgery. OMS302 met its primary endpoint by demonstrating statistically significant (p<0.00001) maintenance of intraoperative mydriasis (pupil dilation). OMS302 also demonstrated statistical superiority (p<0.00001) over placebo in reduction of pain in the early postoperative period.  ([Link](#))

**NEW** On Demand Therapeutics – novel delivery technology to the back of the eye. Working of delivery of “super Avastin” using their technology.  ([Link](#))

Optherion - Has a promising treatment for wet **AMD**. Recombinant ‘protective’ human CFH protein which is in preclinical development. Company has retained an investment bank.  ([Link](#))

Promedior - Developing recombinant human **Serum Amyloid P** Component for the prevention and treatment of fibrotic pathology. PRM-151 in Phase 2a trials for prevention of post-surgical scarring in glaucoma patients. Preclinical data report a demonstration of PRM-151 in the reduction of neovascularization in independent models of AMD and diabetic retinopathy. Would consider a corporate sale and is currently in active partnership talks after raising an additional $12 million.

**NEW** Recopharma – Developing an OTC product for dry eye disease and another OTC product targeting viral conjunctivitis.  ([Link](#))

RegenRx - RGN-259 is a sterile, preservative-free topical eye drop formulation of Tβ4 for ophthalmic indications. Based on recent human clinical data, the company is starting a physician-sponsored Phase 2 trial in dry eye associated with graft versus host disease (GvHD).  ([Link](#))

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**UPDATE** SARcode - developing a novel class of lymphocyte function-associated antigen-1 (LFA-1) antagonists. Company reported positive results of a 230 patient Phase 2 proof-of-concept study evaluating topical SAR 1118 ophthalmic solution in the treatment of aqueous deficient dry eye (keratoconjunctivitis sicca) in May 2010. Reports from Phase II clinical trials show positive results in subjects receiving SAR1118 for the treatment of dry eye, including reduction in corneal staining, increased tear production and improved visual-related function (May, 2011). Currently in a registrational trial for this product. ([Link](#))

Sylentis - focused on topical RNAi therapy with a Phase 1 trial of a therapy for glaucoma and dry eye.

Taejoon Pharma - looking to outlicensing Toravin eye drops (tobramycin). On the market in Japan.

**COMPLETED** Taligen - Developing a Factor H (TT30) replacement, part of the complement system, for orphan diseases. The company will start phase I clinical studies for TT30 shortly. Will likely focus on AMD. Looking for a strategic partner. Bought by Alexion in January 2011 for $111 million.

**COMPLETE** Thrombogenics – completed Phase 3 studies for Microplasmin in Phase III clinical development for the non-surgical treatment of back of the eye diseases. Good evidence of efficacy with two positive Phase 3 trials reported. Expected to be on market by end of 2012. Would consider a sale. Note: Thrombogenics licensed the rights to this product to Alcon on March 16, 2012 for 75mm EUR upfront plus additional payments and royalties. Thrombogenics has retained the U.S. rights to this program and intends to self-commercialize. ([Link](#))

**NEW** Undisclosed – Bundle of ophthalmology assets in Phase 1 – 3 of development.

**ORGAN TRANSPLANT**

ADIENNE Pharma - Begedina is a NEW murine monoclonal antibody directed against CD26 antigens, expressed on a small portion of CD4 T lymphocytes produced by haematopoietic progenitor cells. Begedina is being developed for the treatment of Graft Versus Host Disease. Promising Phase 2 data reported.

Angion Biomedica - in Phase 2 studies for BB3, an HGF mimetic for the treatment of hepatic fibrosis and to facilitate better outcomes in renal transplantation. The naturally-occurring cytokine hepatocyte growth factor (HGF), also known as scatter factor, is active in numerous tissues throughout the body, participating in the regulation of angiogenesis, organogenesis, tissue repair and neural induction. ([Link](#))

Genzyme - Looking to outlicense Genz-29155, a novel, small molecule, orally bioavailable, 1x daily novel inhibitor of TNF-α signaling. Proof of concept has been demonstrated in multiple models of transplantation rejection, multiple sclerosis (MS), sepsis, inflammatory bowel disease (IBD) and lupus. ([Link](#))

Isotechnika - Voclosporin, an oral Calcineurin inhibitor, for transplant and psoriasis has achieved good POC. Recently did a China deal. Plans to start Phase 3 trials in Q3 2012 with a primary endpoint of superiority to tacrolimus in the prevention of biopsy proven acute rejection. ([Link](#))

Limerick BioPharma - developing an adjunct treatment for tacrolimus which is now in Phase 1 clinical testing. The drug restores metabolic control and has been in 120 subjects to date. ([Link](#))

Kiadis - ATIR is a personalized cell based therapy of donor T-lymphocytes depleted of alloreactive T-cells and is infused after a patient receives a mismatched bone marrow transplantation to reduce Transplant Related Mortality. Has shown effectiveness in a recent Phase 2a study.

Novimmune - In Phase 2 with an anti-CD3 antibody for Crohn’s disease. Exploring potential as an immunomodulator in Type 1 diabetes and transplant rejection as well.

**UPDATE** Opsona Therapeutics - OPN-305 is a humanized Phase 1 IgG4 monoclonal antibody (MAb) against Toll-Like Receptor 2 (TLR2), a target within the innate immune system, and is under development as a treatment for the
prevention of Delayed Graft Function (DGF) following renal transplantation, in addition to other therapeutic indications. [Link]

**COMPLETED** Stromedix - **STX-100** is being developed for the treatment of chronic allograft dysfunction in kidney transplant recipients. Also exploring IPF indication. Humanized monoclonal antibody to integrin αvβ6, going into Phase 2. Note: This company was bought by BiogenIdec in Feb 2012 for $75mm upfront and additional contingent payments of $487.5 million.

SuppreMol - Developing soluble Fcy-Receptors (sFcyRs) for autoimmune disease. These are recombinant autologous proteins with strong immunosuppressive potential. SM101, SuppreMol’s main product is a recombinant, soluble, non-glycosylated version of the human Fcy receptor FyRIIb which is has completed a Phase 1 trial for ITP. In Phase 2 studies in ITP and going into further studies for lupus. [Link]

**UPDATE** Veloxis - **LCP-Tacro** has completed Phase II studies with positive data in kidney transplant recipients. 505b2 with better PK of tacrolimus. Other transplant products available. On March 29, 2012 Veloxis reported that it completed enrollment in LCP-Tacro™ 3002 Pivotal Phase III Trial in Kidney Transplant.

Viron Therapeutics - Developing VT-111, a serine protease inhibitor. Reduces restenosis and increases plaque stability in animal models. Has recently finished a Phase 2a study in PCI patients. [Link]. Viron has been granted U.S patents for organ transplant and arthritis drug candidates.

Y’s Therapeutics - **YSPSL** is fused P-selectin glycoprotein ligand (PSGL) and human IgG1. It acts as an antagonist of P-selectin. This is currently in Phase 2 studies for prevention of delayed graft function and prevention of IRI in transplant patients.

**ORPHAN PRODUCTS**

Abiogen - Neridronate is an amino-bisphosphonate used in Metabolic Osteopathy and has gone into Phase 3 trials. Also being studies for patients with thalassemias. [Link]

Adventrx- ANX-188 is a novel, purified, rheologic and antithrombotic compound initially being developed as a first-in-class treatment for pediatric patients with sickle cell disease in acute crisis. Ready for Phase 3 studies and open to partnering deals.

Alvine - Enzymatic treatment for celiac disease. Currently in a Phase 2a clinical trial. Interested parties should contact Jim Watson at jwatson@alvinepharma.com. [Link]

AmpliPhi - Formerly Targeted Genetics. Preparing for a Phase 3 trial of Biophage-PA for the treatment of otitis media. Also effective in cystic fibrosis. BioPhage-PA is a mixture of six bacteriophages that destroy Pseudomonas aeruginosa. Bacteriophage or phages are naturally occurring viruses that consist of an outer protein hull enclosing genetic material. [Link]

**UPDATE** Amsterdam Molecular Therapeutics (AMT) –Glybera for lipoprotein deficiency. This disease is serious, often resulting in death and quite rare (one in a million). This drug could generate annual revenues of more than $300 million. AMT has not yet filed this product with the FDA. Has filed an EMA registration for Glybera to treat lipoprotein lipase deficiency. Update Update: Recently failed to get an EMA approval for this product and will need to run additional trials. AMT has now ceased development of this product. [Link]

Amsterdam Molecular Therapeutics (AMT) –Hemophilia B - very promising results from a gene therapy trial to treat Hemophilia B which is due to a deficiency of Factor IX. Update: In Nov 2011 the company indicated that it will be focusing resources on the development of this product. [Link]
AOP Orphan Pharma - P-1101 contains pegylated interferon alfa-2b (PEG-P-INF alpha-2b), a conjugation of recombinant interferon alfa-2b with monomethoxy polyethylene glycol which shows antiviral and immunomodulatory effects. P-1101 is being developed for the treatment of polycythemia vera. A Phase 1b study is underway.

Arriva Pharmaceuticals - Inhaled protein rAAAT (Respriva) replacement therapy for hereditary emphysema, completed two early Phase II trials and recently completed manufacturing with a more highly purified and higher yield recombinant alpha 1-antitrypsin for upcoming clinical trials. Company is looking at a partnership deal.

UPDATE Atlantic Healthcare Limited - Novel Phase 2 product (Alicaforsen) for treatment of pouchitis. On market in EU on a named patient basis. Open to a U.S. partnership. Interested parties should contact Rodolphe Grepinet at Torreya Partners (Rodolphe.grepinet@torreyapartners.com).

AVI Biopharma - DMD Exon 50 has obtained positive Phase 1 data for Duchenne Muscular Dystrophy. Company is looking to accelerate clinical development with the recent appointment of a NEW CEO. (Link)

Biomarin - In discussions with potential partners to advance its Pompe disease drug candidate, BMN-103.

UPDATE Bluebird Bio - Positive Phase 1b type data for LentiGlobin® for gene therapy treatment in a young adult with severe betathalassemia, a blood disorder that is one of the most frequent inherited diseases. Also has positive data for a treatment for Adrenoleukodystrophy (CCALD) is a rare, inherited neurological disorder. This company has very high potential value given the positive CCALD data and the size of the market.

Cancer Prevention Pharmaceuticals - seeking a ROW partner for its combo of eflornithine and sulindac. In Phase 3 studies for familial adenomatous polyposis (FAP).

Clinuvel - In Phase 3 for European approval for Afamelanotide, a photoprotectant to be used in Erythropoietic Protoporphyria. Company hoping for an EMA approval for this product.

UPDATE Corcept Therapeutics - As an orphan designation for Corlux, in development for Cushing’s Syndrome - a condition of hypercortisolism with approx. 20K persons in US. Positive Phase 3 data released in December 2010. In June, 2011 FDA accepted NDA submission from Corcept for Corlux. This product was approved for the market in Q1 2012.

Cytokinetics - According to a recent press release, Cytokinetics, Inc. announced opening of next phase 2 clinical trial of CK-2017357, a fast skeletal muscle activator, in patients with amyotrophic lateral sclerosis. CK-2017357 selectively activates the fast skeletal troponin complex by increasing its sensitivity to calcium, leading to an increase in skeletal muscle force. Saw activity in a recent Phase 2a trial Actively seeking partnerships. (Link)

$ Daval International - Aimspro, orphan Status Designations have been awarded by the Therapeutic Goods Administration (TGA) for the treatment of Krabbe Leukodystrophy and Amyotrophic Lateral Sclerosis. In June, 2011 completed a Phase 2 trial study of AIMSPro for treatment of bladder dysfunction in patients with secondary Progressive MS. Sold on a named patient basis. In Oct 2011, announced positive results from a Phase 2 in patients with Late Stage Established Diffuse Cutaneous Systemic Sclerosis (diffuse scleroderma).

NEW Discovery Biomed - developing delF508-CFTR correctors and activators of alternative rescue chloride channels in CF human airway epithelial cells as two parallel strategies to control/cure cystic fibrosis. Have several leads and looking for a research partner.

 NEW Dyax - Marketing Kalbitor® (DX-88), for hereditary angioedema. Recently approved. Company going alone at present but could enter either into a partnership or an M&A deal. In May 2011 expanded distribution agreement with Sigma-Tau to include Europe, North Africa, Latin America, Southeast Asia, the Middle East, Russia, Australia and NEW Zealand. (Link)
Edimer Pharma - Developing Edi200, a protein engineered to replace naturally occurring ectodysplasin A that is deficient in patients with XLHED.

Edison Pharma - EPI743 acts by targeting an enzyme NADPH quinone oxidoreductase1 (NQO1) and synchronize energy generation in mitochondria with the need to counter cellular redox stress. EPI743 is in Phase 2 trials for the treatment of inherited mitochondrial respiratory chain diseases. Update: Company completed a financing in Q3 2011.

Edoena - Developing ENB-0040, a human recombinant tissue non-specific alkaline phosphatase, for the treatment of hyperphosphatasia - a debilitating bone condition. Positive data in man. Update: Company has continued to report positive data and may be looking at a rapid approval with FDA. As a result, has not proceeded with potential M&A deal in light of value inflection ahead. Note: Alexion acquired Enobia for up to $1bn in Q1 2012.

EryDel - Phase 2 treatment for cystic fibrosis that is based upon the EryDex system. (Link)

Green Cross - In Phase I/II randomized, single-blind, active-controlled study to evaluate the safety and efficacy of GC1111 (recombinant human iduronate-2-sulfatase) in hunter syndrome (mucopolysaccharidosis ii) patients. This program is drawing high interest. (Link)

Hyperion Therapeutics - Developing Ravicti (formerly GT4P/HPN-100), an ammonium remover, for urea cyclic disorders and hepatic encephalopathy - Positive Phase 3 data and a high likelihood of approval in 2012. As of March 2012, Hyperion acquired the worldwide rights to this compound from Ucyclyd Pharma (of Medicis), though terms were not disclosed. Filed an S-1 IPO registration in April 2012. (Link)

ImmusanT - Nexvax2 vaccine seeks to reprogram CD4+ T cells to induce gluten tolerance. This Phase 1 program for Celiac disease has high promise.

Incode BioPharmaceutics - HC3-1496 results in enzymatic depletion of the complement protein C3, the key component for all three pathways of complement activation. Preclinical and applicable for oncology, PNH and RA. (Link)

Intermune - Filed an NDA for Pirfenidone for IPF in Q4. FDA failed to approve product. Additional trial underway with NDA resubmission planned in 2013. Company is currently commercializing this product in Europe.

Lithera - Announced positive results from a Phase Ib clinical study of LIPO-102, its novel injectable combination of salmeterol xinafoate (SX) and fluticasone propionate (FP) for selective, non-ablative fat reduction. In a Phase 2b study LIPO-102 was well-tolerated when administered weekly for 8 weeks into the subcutaneous abdominal fat of healthy subjects and produced dose- and time-related reductions in mean abdominal volume and circumference.

MondoBIOTECH – In Phase 2 testing of DK-1000-01 for pulmonary arterial hypertension (part of a portfolio of orphan drugs). Peptide is a potent vasodilator and has shown improvement in six minute walk distance in Phase 2a study. (Link)

Neuren Pharma - Developing NNZ-2566, a synthetic analogue of the n-terminal tripeptide of IGF-1, a naturally occurring molecule that has neuroprotective effects in animal models of stroke and head injury. The company is planning to start a Phase 2 trial in Rett Syndrome, an autism disorder in late 2012.

NeuroHealing Pharmaceuticals - dosing patients in a Phase II/III study to test the efficacy of NH001 (apomorphine) in accelerating the recovery and improving the outcome of patients in a vegetative state following a severe traumatic brain injury (TBI). (Link)

Numerate - Ransglutaminase 2 inhibitors for Celiac disease. (Link)
Ocean Therapeutics - Brevenal for the treatment of cystic fibrosis. Requires clinical studies. (Link)

Orphan Drugs NL BV - Developing levamisole for the treatment of steroid resistant nephrotic syndrome in children (a grouping of diseases including FSGS, membraneous nephropathy). Has enrolled 50 patients and this product is available in Europe on a named patient basis. Strong evidence of efficacy in past studies. Not licensed outside of EU. (Link)

Orphazyme – Orph-001, recombinant HSP70 for repair of lysosomal storage diseases. In preclinical testing. (Link)

OxThera - Oxazyme is recombinanate oxalate degrading enzyme for the treatment of kidney stones. No data reported from a pending study in some time. A related compound is at Althea Technologies. (Link)

Oxyrane - developing ERT for Pompe with technology that allows greatly improved uptake of drug. Raised $26mm in November 2011.

Prosensa - has partnered a highly innovative gene therapy program for Duchenne’s Muscular Dystrophy to GSK. Has a further unpartnered program for DMD available.

UPDATE Raptor Pharmaceutical –filed NDA and MAA in Mar/Apr 2012 for DR Cysteamine, which is delayed-release, enteric-coated microbead formulation of cysteamine bitartrate for the treatment of cystinosis. In June 2011, Raptor reported positive data from a pivotal, Phase 3 clinical trial, examining the safety and tolerability of every 12-hour DR Cysteamine compared to immediate-release cysteamine bitartrate (the current standard of care) in nephropathic cystinosis patients. Company intends to self-commercialize this product. (Link)

Serendex - inhaled rFVIIa for blast injury and lung bleeding. Six patient study showed high efficacy. Orphan designation granted. (Link)

Sigma-Tau - Reuters (6/2/11): “Italy’s Sigma-Tau is eyeing the sale of up to 49 percent in the family-owned drugmaker to private equity, ahead of a possible IPO that could value it at more than $2 billion, people familiar with the situation said.” Company has approximately €1bn revenue with a strong rare disease business and a well established European brand business. It is believed that discussions regarding a stake sale are no longer active but rather the company is focused on restructuring its Italian business.

Soligenix - has partnered orBec/BDP with Sigma-Tau in the U.S. Looking to partner in ROW. Indication is GI manifestation of acute GVHD, thereby reducing the need for systemic immunosuppressive drugs to treat GI GVHD. Company is running a confirmatory trial and indicates a partnership is most likely after results are in. (Link)

Stemcells - HuCNS-SC is well-characterized, normal human CNS stem cells (HuCNS-SC) from brain tissue, isolated and purified using monoclonal antibodies against cell surface antigens. HuCNS-SC is being developed as intracerebral injection for the treatment of myelin disorders such as Pelizaeus-Merzbacher Disease. Phase 1 data upcoming in 2012. (Link)

Synageva Pharma - SBC-102 is a recombinant protein and is being developed as a treatment for Lysosomal Acid Lipase Deficiency. This drug candidate is an enzyme replacement therapy (ERT) that would replace the missing enzyme (lysosomal acid lipase) to reduce the build-up of cholesteryl esters and triglycerides throughout the body. Also see Amsterdam Molecular Therapeutics. Note: this company recently merged with Trimeris but may remain interested in partnership. (Link)

Tivorsan - Biglycan induces the expression in the muscle cell membrane (sarcolemma) of utrophin that is typically replaced in adults by dystrophin. Thus, utrophin offers an alternative pathway to maintaining the integrity of the muscle cell membrane in persons with Duchenne’s Muscular Dystrophy. Tivorsan preparing to enter Phase 1 studies in 2011. (Link)
Trevi Therapeutics - Preparing to dose T111 in a Phase 2 trial for chronic uremic pruritis to determine proof of concept for safety and efficacy. (Link)

Undisclosed party - Positive Phase 2 data for a compound for the treatment of Fragile X syndrome. Company is seeking a buyer or global partnership with assistance of a financial advisor.

Undisclosed party - sale of marketed neurology product with U.S. rights, growing revenues and orphan protection. Interested parties should contact Benj Garrett (benj.garrett@torreyapartners.com).

Vanda - Tasimelteon, Melatonin agonist for sleep wake disorders, in phase III. Has orphan designation. This product is on track for a mid 2013 NEW Drug Application (NDA) filing.

Vivendy Therapeutics - Enzyme replacement therapy for N-acetylgalactosamine-6-sulfatase (GALNS) enzyme in MPS IVA by administering a modified recombinant human GALNS enzyme.

Zacharon Pharma - Developing molecule glycan inhibitors for the treatment of MPS and other lysosomal storage diseases. April, 2011 entered into R&D collaboration with Pfizer to develop small molecule drugs targeting carbohydrate polymers. (Link)

Zymenex - Developing Lamazym, for the treatment of the lysosomal disease Alpha-Mannosidosis. This disease is due to a deficiency of the Laman enzyme, affects approximately 500 patients worldwide and the project is in late pre-clinical development. Update: Company headed into first trials in man in 2011.

**OTC PRODUCTS**

**NEW** Aptalis – looking for an ex-US partner for Unisom, an OTC sleep aid that is sold by Sanofi in the U.S. Unisom contains diphenhydramine HCl (50 mg/dose) and acetaminophen.

**NEW** Azanta - Cicatridina (sold as Repadina in the UK) is a hormone free treatment of vaginal dryness on an OTC basis. The active principle of Cicatridina vaginal ovules is hyaluronic acid that guarantees a high level of healing, reducing the risk of bacterial contamination. Cicatridina also contains the natural oils centella asiatica, calendula, aloe vera and tea tree oil added in order to reduce vaginal dryness. Azanta willing to partner this product in markets outside of the UK and Europe.

**NEW** CMP Therapeutics – received a CE-Mark in Jan 2012 in Europe for an OTC microgel of intranasal Chitosan for the prevention of colds and influenza. This product has not yet been licensed. (Link)

**NEW** EctoPharma – KindaPed® is a non-insecticidal product for the treatment of head lice in children. This product is marketed in Europe by Thornton and Ross as an OTC product. EctoPharma seeks a marketer for this product in the U.S. and in China. (Link)

Emisphere - has developed a rapid release Vitamin B12 which is on the market. Upcoming studies to show relative efficacy of this product which would likely be marketed as a medical food.

**COMPLETED** GlaxoSmithKline - running a process to divest non-core OTC brands with assistance from Goldman Sachs. The products to be divested, which are primarily sold in Europe and the United States, had sales in 2010 of approximately £500 million, 10% of GSK’s total Consumer Healthcare turnover. They include analgesics: Solpadeine, BC and Goody’s; vitamin and supplement product Abtei; feminine hygiene treatment Lactacyd; and alli for weight management. Reuters Update on Nov 14, 2011: “GlaxoSmithKline is assessing final bids for a clutch of its non-prescription drugs, keeping the process on track for the selection of a buyer by the end of the year, people familiar with the matter said on Monday.” Transaction completed in a sale of U.S. brands to Prestige Brands in Jan 2012, EU brands to Omega Pharma in March 2012 and other brands to Aspen Pharmacare in April 2012. Total consideration received was £425mm with revenue multiples in the 2-3X range. (Link)
Guangxi Golden Throat (Guang Xi Jin Sang Zi), a privately held manufacturer of healthcare products, is reportedly in sale talks. The company has annual revenues of around $47mm from its throat lozenges, which sell under the 'Golden Throat' brand name.

Izun - Developing Periopatch for treating gingivitis and Synsore for aphthous ulcers. Both destined for OTC market.

Marinomed Biotechnologie - The privately-held Austrian biopharmaceutical company is in talks with pharma players to outlicense its lead compound MAM-05.101, is an antiviral nasal spray for the treatment of the common cold - particularly in children. This product is a GRAS botanical and has shown good efficacy in a Phase 2 type trial. Can likely be introduced to the market now as either an OTC product or medical food. On market in EU. Looking for licensing partner for U.S., Canada and Japan. In Austria the nasal spray has been marketed since 2008, the product was licensed to Boehringer Ingelheim for Europe, Russia and CIS, South America, parts of Asia and Australia in 2010.

Mayne Pharma - Astrix® 100 mg capsules contain aspirin presented as enteric coated extended release pellets. The Astrix® formulation is distinctly different from other aspirin formulations. It is a formulation specifically designed to optimise the cardioprotective effects of aspirin and to reduce the risk of gastrointestinal irritation that can occur with this drug. On market in a number of territories.

NEW NanoBio – NB-001 is a cold sore medicine finishing registrational trials. Partnered in the U.S. and Canada to GSK. Other territories are available.

Pharmena - bundle of dermatology products that are currently sold in Poland. These products are IP protected and well suited to either an OTC or physician office promotion setting. Looking for an international partner to commercialize. For further discussions contact Tom Bird of Torreya Partners at tom.bird@torreyapartners.com.

PLX Pharma - Developing a GI-sparing aspirin product, PL 2200 which is close to market introduction. Phase I human bioequivalence and anti-platelet effects study completed. Update: Company likely to enter into a partnership deal in Q4 2010.

NEW Prestige Brands – major OTC marketer has received an offer from Genomma for acquisition at $834mm in Feb 2012.

NEW Recopharma – Developing an OTC product for dry eye disease and another OTC product targeting viral conjunctivitis. (Link)

$ ScarGuard - Could consider a company sale. Markets ScarGuard a widely used scar remedy as an OTC product.

$ Semprae Laboratories - markets Zestra, an OTC product for female sexual arousal enhancement. This product is backed by clinical studies showing its efficacy. Company is open to promotional or partnership deals.

**PAIN PRODUCTS**

AcelRx - Looking for strategic partners for three pain products including ARX-01 (completed Phase 2), the Sufentanil NanoTab PCA System, for post-operative intravenous patient-controlled analgesia; ARX-02 (completed Phase 2), a sufentanil for breakthrough pain and ARX-03, a sublingual sufentanil / triazolam designed to provide non-invasive mild sedation, anxiety reduction and pain relief in patients prior to a painful procedure in a physician’s office. (Link)

Acino Pharma - markets a fentanyl patch which is in Phase 3 in the U.S. and a diclofenac gel. (Link)
Afferent Pharmaceuticals – Developing P2X3 receptor antagonist for pain. A recent preclinical study indicated that a P2X3 antagonist significantly prevented and reversed bone cancer pain behavior in comparison to vehicle controls. (Link)

Akela Pharma - Pursuing Fentanyl TAIFUN for treatment of cancer pain. This product has been licensed to Teikoku for Japan and to SK Chemicals for Korea. (Link)

Alder Bio - ALD403 is a potent, humanized monoclonal antibody that inhibits calcitonin gene-related peptide (CGRP), a molecule shown to trigger migraine attacks. Previous therapeutic approaches targeting CGRP have centered on traditional pharmacology to alleviate migraine symptoms but were halted due to safety issues. Alder is pioneering a new treatment strategy with ALD403, which will be given to chronic sufferers on a monthly basis via a subcutaneous injection. The medicine will be present at the time of migraine onset—by far the most successful intervention point for treating migraines. A Phase I clinical study evaluating ALD403 in healthy volunteers will launch in early Q2 2012. (Link)

Amarin Tech SA - Offers several pain products ready for licensing including a transdermal device containing diclofenac diethylamine together with permeation enhancers. This product is in Phase 1 studies. HELM AG purchased 30% shareholding of Amarin in December, 2010.

Amarin Tech SA - Offers a transdermal fentanyl patch that is in Phase 1 studies to be shown bioequivalent to Durogesic®. (Link)

Ampio - On July 5, 2011 Ampio Pharmaceuticals, Inc. announced treatment of the first patient in the three-arm, placebo controlled, 60 patient Phase Ib Ampion-In-Knee (AIK) trial for osteoarthritis pain in Australia. (Link)

Aptalis – Amrix is a long acting muscle relaxant (cyclobenzaprine). This product is on the market in the U.S. but rights available in most other global territories.

Archimedes Pharma - Is seeking licensees for North America and Japan for PecFent, a nasally-delivered fentanyl product for breakthrough cancer pain, currently in Phase III development. Archimedes Pharma is seeking licensees outside of Europe for PecFent®. Has gained a positive opinion from the CHMP, and has been filed for regulatory approval in the US. Preparing for a U.S. launch.

Arcion Therapeutics - Topical clonidine (ARC-4558) gel for the treatment of diabetic neuropathy (US Patent 6,534,048). In partnership discussions. Company has shown good response in patients with intact nociceptive function. Presentation on positive results in diabetic nephropathy at ADA in June 2011. In a Phase 2b trial in diabetic neuropathy. (Link)

Array BioPharma - Oral p38 inhibitor has shown significant analgesic benefit in a recent Phase 2 trial in dental pain. A subsequent Phase 2b trial has shown a significant analgesic benefit in surgery patients versus celecoxib. Data from an additional trial are imminent. (Link)

ARTYX Pharma - ART144 is in Phase II/III development. ART144 is is administered by injection into the joint and has proven to be safe and effective in two clinical studies. (Link)

BioDelivery Sciences - developing BEMA Buprenorphine for the treatment of moderate to severe chronic pain. In September 2011, BDSI reported that it had missed the primary endpoint of improving mean pain intensity scores vs. placebo in the Phase III BUP-301 trial to treat moderate to severe chronic low back pain but saw clinically significant activity in opioid dependent patients. This observation helped to trigger a deal with ENDO Pharmaceuticals that will develop and commercialize this product (announced Jan 6, 2012). ENDO agreed to $30mm upfront plus $150mm in additional contingent payments and royalties. ENDO plans to conduct a second Phase III trial for the product, which the company said will delay an NDA submission to FDA by about one year. (Link)
BTG - BTG-1531. This NCE is a proprietary EP4 antagonist with potential applications in inflammation, pain and CNS (including MS). Clinical data is available from several studies. (Link)

Cara Therapeutics - CR845, a selective kappa opioid agonist, has completed a Phase 1 study. Phase 2 studies were positive. Specifically, CR845 provided evidence of analgesic efficacy when administered as a single intravenous dose to women following laparoscopic hysterectomy. In addition to decreases in reported pain levels, patients receiving CR845 required substantially lower amounts of postoperative opioids for 16 hours, and showed a significant reduction in the incidence of postoperative nausea. See a similar molecule in testing by Tioga Pharmaceuticals (GI section). (Link)

Cerimon - a once-daily diclofenac topical patch for musculoskeletal pain that requires a phase 3 trial for FDA approval. This product has been on the market in Japan since 2004, selling over 700 million units. The product has been tested in the US in over 700 patients in seven clinical trials and Cerimon has rights in the U.S. and EU. Company is open to change of control transaction. (Link)

Charleston Laboratories - CL-108 contains hydrocodone, acetaminophen and promethazine being developed as specialized tablet formulation and release technology for the treatment of moderate to severe pain while reducing or eliminating opioid induced nausea and vomiting (OINV). In pivotal study for approval as a 505(b)2. (Link)

Chlorion Pharma - Novel modulator KCC2 (CLP635) for control of neuropathic pain. No clinical data reported as of yet.

Collegium Pharma – COL-003 is a tamper resistant, abuse-deterrent, sustained release oxycodone formulation. Seeking a partnership.

Colucid Pharmaceuticals - Lasmitidan, a novel drug for migraine, selectively targets 5HT1F receptors expressed in the trigeminal nerve pathway is entering Phase 3 trials. Company open to partnering or sale transaction. (Link)

Covidien Pharmaceuticals - According to the New York Times on June 7, 2011 “Covidien, the health care company spun out from Tyco four years ago, may seek to sell its pharmaceutical unit...” This division of Covidien (formerly Mallinckrodt) has a major business selling pain products (both branded and generics) and imaging products. Revenues are around $2 billion. Update: As of December 2011 no sale has taken place. Company is rumored to be interested in a sale of the whole business (rather than pieces) for a full price. YE 2011 numbers reported on Nov 15, 2011 and were robust (sales up 9% yoy) with strong performance in generics.

Creabilis - CT327 is a novel topically applied TrkA kinase inhibitor developed using Creabilis’ LSE (Low Systemic Exposure) technology. CT327 contains pegylated K252a, which interacts at a nanomolar level with tyrosine kinase receptor (TrkA), the receptor for nerve growth factor (NGF). It has strong analgesic activity and it acts by blocking NGF activity. Also positive data in study versus atopic dermatitis. High potential for the treatment of neuropathic pain. Good results in Phase 2a psoriasis study versus placebo. Phase 2b data in psoriasis expected late in 2012. (Link)

Crystal Genomics - CG100649 is a next generation NSAID which inhibits COX-2 in the inflammatory joint, but not in the cardiovascular and gastrointestinal systems. Positive Phase 2a data.

Cytogel - Cyt-1010 is an analogue of endomorphin 1, a naturally occurring pain modulator. Recent Phase 1 trial data found that the drug candidate was well tolerated and effective against pain stimuli. (Link)

Daewoong - DWPO5195 is a Phase 1 oral TRPV1 antagonist (Transient Receptor Potential Vanilloid subtype 1 antagonist). It reduces pain via antagonism of TRPV1 on sensory neurons. Available for global licensure. (Link)

Dara Therapeutics - in Phase 2a studies of KRN5500 for neuropathic pain in cancer patients. KRN5500 is a novel spicamycin derivative produced by Streptomyces alanosinusicus and is available as a solution for intravenous (IV) administration. (Link)
Dharma Therapeutics - Developing a lidocaine patch using iontophoretic technology. Positive Phase 2b data in a recent trial. (Link) (noncon)

Durect - Transdur Sufentanil for the treatment of pain. Longer duration than fentanyl patches and smaller patch size. On May 5, 2011 the company wrote: “We continue discussions with potential partners regarding licensing development and commercialization rights to this program to which we hold worldwide rights.”

**UPDATE** Egalet - Licensing Phase 2 abuse resistant morphine (EG-P066) with strong data. Also has best-in-class abuse resistant hydrocodone product in Phase 2.

Elite Pharmaceuticals - Phase 3 abuse resistant oxycodone for OA under an SPA. Company exploring strategic options. Nov 15, 2010 update: “The company is currently in discussions to license its once daily oxycodone product, ELI-154 to a European marketing partner and is progressing towards scale-up in the development of its abuse-resistant formulation of oxycodone, ELI-216.” (Link)

**NEW** EpiCept Corporation - SunTrust Robinson Humphrey to assist in exploring strategic alternatives to maximize the commercial opportunity of AmiKet™ includes the evaluation of potential transactions involving the sale of the Company. AmiKet™ is the Company’s prescription topical cream intended for the treatment of neuropathic pain. The engagement of SunTrust Robinson Humphrey will focus on the identification and implementation of a strategy designed to optimize AmiKet’s value for the Company’s shareholders. EpiCept recently announced that it has received further encouraging guidance for the Phase III clinical and nonclinical development and subsequent New Drug Application (NDA) filing of AmiKet™ in the treatment of chemotherapy-induced peripheral neuropathy (CIPN). (Link)

**NEW** Esteve – Two innovative Phase 2 pain programs. One is a Selective Sigma-1 Receptor Antagonist, a first-in-class NCE and a new mechanism of action for neuropathic pain. The second project — for moderate to severe pain —is a new dual API-API co-crystal in clinical development.

**NEW** Galleon Pharmaceuticals - GAL-021 is an IV small molecule designed to support respiratory drive in surgical and critical care patients. The use of anesthetic, analgesic and sedative drugs can produce a well-known respiratory depression. For example, in patients receiving opioids such as morphine GAL-021 could “decouple” the analgesic and respiratory depression effects enabling physicians to better alleviate pain without the well-known fear of respiratory collapse. This NCE is in Phase 1 testing. (Link)


$ Horizon Pharma - launching Duexis®, a fixed dose combination of ibuprofen and famotidine for the relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers. This company is preparing to go public and does not have a known process underway to seek a buyer.

**UPDATE** $ Innocoll - Xaracoll Bupivacaine Implant provides pain relief directly at the surgical site. Phase 2 completed.

Inteligex - Has completed a Phase 1b trial of Relivar, a buccal dronabinol (THC) tablet for neuropathic pain. (Link)

Japan Tobacco - JTS653 is a Phase 2 oral TRPV1 antagonist (Transient Receptor Potential Vanilloid subtype 1 antagonist). It reduces pain via antagonism of TRPV1 on sensory neurons. JTS653 is being developed as oral formulation for the treatment of pain.
Kai - **KAI-1678** is an isozyme-selective, small peptide inhibitor of the epsilon protein kinase C pathway. Would look to partner after current Phase 2a trial completes. Note: Kai was purchased by Amgen in Apr 2012 for $325mm.

KemPharm - KemPharm, Inc. announced positive results from a Phase I clinical trial of its most advanced opioid-based drug candidate, KP201, a novel hydrocodone prodrug for treating pain. KP201 is a new chemical entity (NCE) composed of hydrocodone chemically bound to a ligand. (Link)

Labtec - **Sufentanyl** patch for topical pain relief in phase 1 studies.

MAP Pharma - Would look at ex-U.S. partnerships for its late stage inhaled migraine drug, **Levadex**. NDA submitted in May 2011. In January 2011 the company entered into a promotional agreement with Allergan who will promote this product in the U.S. to headache specialists. MAP Pharma retains other physician markets in the U.S. and rights in all other geographies. (Link)

Mika Pharma - Diclofenac spray. Approved in EU. In Phase 3. Note: Giuliani S.p.a. bought a majority stake in Mika in 2010. (Link)

**NEW** Nektar - NKTR-181 is a better oxycodone – slower pharmacokinetic profile which means less euphoria. Good Phase 1 MAD data show safety and control of pain. In a 300 patient Phase 2 study in 2010.

**NEW** Nektar - Nktr-192 is a mu-opiod for acute pain. Less abuse and entry into the CNS. This drug has a steep PK curve which allows rapid resolution of pain. Little abuse potential.

NeurAxon - **NXN-188**, a first-in-class, dual-action drug being developed for the treatment of acute migraine. Oct 31, 2010: “The primary endpoint in this study was Pain Relief at 2 hours: although NXN-188 did not reach significance at this time point (p=0.0801), a statistically significant response was reported from 4 through 24 hours.” (Link)

**UPDATE** $ Neurogesx - **Qutenza** is a patch that delivers synthetic capsaicin for PHN on the market in U.S. Recently approved. Partnered in the EU to Astellas in June 2009. Company looking for partnerships in Asia and Latin America. Announced in April 2012 that it is exploring a range of potential transactions with help from JSB Partners. (Link)

Neurotune - Positive top-line results from its Phase IIa study of dimiracetam (NT-11624) for treatment-induced neuropathic pain in HIV patients receiving anti-retroviral medication. Phase 2b study to start in 2012 under recently granted IND. (Link)

NuPathe - Recently went public with Zelrix, a promising late stage candidate for migraine (iontophoretic sumatriptan patch). NDA filing in Oct 2010 with PDUFA date of August 29, 2011. FDA issued a complete response letter requesting additional CMC and early stage clinical work. Company is open to strategic discussions.

$ Pacira Pharmaceuticals - Looking to partner **Exparel**, a long acting bupivacaine, outside of the U.S. This product was approved by the FDA on Oct 31, 2011. Interested parties should contact Darren Pincus at DarrenP@pacira.com.

Paion - Looking to out license an active potent metabolite of morphine, morphine-6-glucuronide (**M6G**) which may have an equivalent analgesic effect as morphine, but with a reduced tendency to cause nausea, vomiting and respiratory depression. Two Phase 3 trials have been completed. Missed endpoint in one trial. (Link)

Paion –Looking to outlicense Remimazolam based on the available Phase II data for the drug as a short-acting intravenous anesthetic/sedative for endoscopy procedures. Positive data were reported out in Nov 2009. Further positive Phase 2b data in colonoscopy reported in Nov 2010. In 2009 entered into license agreement with Ono Pharmaceutical to develop and commercialize Remimazolam in Japan. Received second milestone payment in
May 2011 through start of Phase 2 clinical trials. Update: In a November 2011 press release, Paion indicated that discussions continue with potential partners for this drug. (Link)

Phoenix Pharmalabs, Inc. - developing novel family of ligands with high binding affinity and balanced activity at all three opioid receptors.

Phosphagenics - in a 65-patient Phase 2 trial to examine the safety and tolerability of its Oxycodone chronic pain management patch.

**COMPLETED**  QRX Pharma - When compared at equianalgesic doses with Percocet, MoxDuo IR demonstrated greater overall tolerability with substantially less side effect. Has finished enrollment of its first Phase 3 study as of Dec 6, 2010 and filed for FDA approval. Open to partnership deals, particularly in China. Update: In Mar 2012, QRX signed a license and option deal for this program with Actavis for a $6mm signing fee. Actavis also acquired an option for Moxduo CR. (Link)

Prophase Labs - Would consider sale of Pharma division. Lead drug is QR-333 in Phase 2 for diabetic neuropathy. Update: Prophase indicated in Q4 earnings release that is not making further investment in this division (known as Quigley Pharma).

Raptor - Looking to divest its pain products that were picked up in an acquisition of Torrey Pines Pharma. Tezampanel, an intravenously administered compound, and NGX426, the oral prodrug of tezampanel, are first-in-class compounds that may represent novel treatments for both pain and non-pain indications. Tezampanel and NGX426 are ionotropic glutamate receptor antagonists that target the AMPA and kainate sub-type receptors. Tezampanel has been through Phase 2b studies. (Link)

RaQualia - Developing EP4 receptor antagonists for the treatment of inflammatory pain. Past POC stage. Update: August 2010 - licensed the Japan and East Asia rights to this treatment to Maruishi Pharma of Japan. Raqualia had a successful IPO in July 2011. (Link)

SantoSolve - Looking to partner 2PX, a topical formulation of strontium, for neuropathic and OA pain control. Statistically and clinically significant Phase 2 improvements in WOMAC scores observed. (noncon). Currently in a large multinational Phase 3 trial for the treatment of OA. (Link)

Spinifex Pharmaceuticals, a private, Australia-based biotech, is developing EMA401, in Phase II for post-herpetic neuralgia (PHN). Data expected in the first half of 2012.

Star Laboratories - Ibuser is being developed as pediatric ibuprofen drops oral suspension (40mg/ml) for the treatment of pain.

**NEW** TTY Biopharm – Developing oral R-Verapamil·HCl useful for the prophylaxis treatment of episodic cluster headache. There is no drug approved for the prophylaxis of episodic cluster headache in the world.

Undisclosed - Active dexamethasone patch with positive Phase 2 data and an associated technology platform.

Undisclosed player - open to a merger or sale of $35mm revenue company with commercial presence in the U.S. pain market. Torreya Partners advising.

$ Undisclosed player - very promising Phase 2 product for treatment for OA using an alternative to Synvisc®. Using a financial advisor to find a buyer or partner.

**NEW** Undisclosed player - Migraine asset – Phase 1b drug candidate in prophylactic migraine.

**NEW** $ Undisclosed player – bundle of several marketed mature pharma products in the neurology and pain areas. Revenue around $10mm.
$ Undisclosed player – approved hospital anesthetic in the United States with differentiation from existing products. Also could be used in physician office setting where sedation required. Open to a product sale or other value creating arrangement. Global rights available.

**NEW** Vapogenix – novel topic product for surgical and other pain due to cuts. In Phase 1 studies.

Vyteris - has indicated that it is interested in disposing of a portfolio of pain products in development. These products include LidoSite®, an FDA approved product for the pretreatment of needle injection and venipuncture sites with Lidocaine (a related product is at Nuvo Research); a Phase 1 zolmitriptan patch and an NSAID patch. ([Link](#))

Winston Pharmaceuticals - Rheumaderm cream for the treatment of OA. NDA pending. Marketed in Canada by Sanofi. Based on civamide which acts on type-C neurons by specific binding to a membrane receptor, the TRPV-1 receptor. Looking for licensing partners in other parts of the world. ([Link](#))

Winston Pharmaceuticals - Also pursuing Civamide, a TRPV-1 modulator, for the treatment of episodic cluster headaches. Late stage with approval pending in Canada. ([Link](#))

Xenome - **Xen2174** is a peptide that binds to norepinephrine transporter (NET), blocking its ability to remove NE from the synapse. Positive Phase 2 data in severe cancer pain.

YM Biosciences - Is currently seeking a partner for **AeroLEF**, a Phase 3 ready inhaled composition of free and liposome-encapsulated fentanyl, for the treatment of moderate to severe acute pain.

Zalicus - Promising **T-Type CCB** program for the treatment of pain, epilepsy and hypertension. Very promising albeit early technology. Going into Phase 1 studies in 2011. ([Link](#))

Zogenix - **Sumavel**, a needlefree transdermal delivery of sumatriptan for migraine. Recent FDA approval with product launch using Astellas as a co-promotion partner. Company could consider an M&A transaction. Note: Raised $30mm from Cowen Healthcare Royalty Partners in July 2011.

**NEW** Zogenix - **Zohydro** (hydrocodone bitartrate) extended-release capsules is a novel, oral, single-entity controlled-release formulation of hydrocodone currently for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. An NDA for this product has been submitted.

**PEDIATRICS**

13Therapeutics - Developing P13 as a treatment for Acute Otitis Media (AOM). Many colds in young children are accompanied by ear infections. P13 is an orally available anti-inflammatory 20 amino acid peptide derived from a viral regulatory protein. Company entering Phase 1 studies. ([Link](#))

Adamas Pharmaceuticals - Launching Epinephrine Injection USP 1:1000 (0.3mg Pre-Filled Single Dose Syringe) (i.e.: Epinephrine Injection PFS) to compete as a low cost alternative to the well known brand EpiPen®.

Althea Technologies - has a promising phase 2 extended release version of human growth hormone in development. Previously this compound was at Genentech.

AmpliPhi - Formerly Targeted Genetics. Preparing for a Phase 3 trial of BioPhage-PA for the treatment of otitis media. Also effective in cystic fibrosis. BioPhage-PA is a mixture of six bacteriophages that destroy Pseudomonas aeruginosa. Bacteriophage or phages are naturally occurring viruses that consist of an outer protein hull enclosing genetic material. ([Link](#))

Ascendis - In Phase 2 studies with a pegylated human growth hormone.
Asklepion - L-Citruline for the 20 percent of children who have heart surgery with use of the bypass pump develop pulmonary hypertension, or high blood pressure in the lungs. In early studies this product appears to prevent pulmonary hypertension from developing. Now in Phase 3 studies. (Link)


Biopartners - In late stage trials with a sustained release version of human growth hormone. (Link)

**UPDATE** Discovery Labs - Surfaxin is a synthetic KL4 Surfactant for treatment of neonatal RDS. The FDA has approved SURFAXIN (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants at high risk for RDS.

**NEW** EctoPharma – KindaPed® is a non-insecticidal product for the treatment of head lice in children. This product is marketed in Europe by Thornton and Ross as an OTC product. EctoPharma seeks a marketer for this product in the U.S. and in China. (Link)

Foresight Biotherapeutics - Has recently completed a Phase 3 trial of FST-201 (dexamethasone 0.1%) Otic Suspension vs. the FDA-approved drug Ciprodex (ciprofloxacin 0.3%, dexamethasone 0.1%) Otic Suspension (Alcon Laboratories, Inc.) in the treatment of acute otitis externa (Swimmer’s ear). Each year, approximately two million children who suffer from persistent ear infection in the U.S are diagnosed with acute otitis media requiring tympanostomy tubes (AOMT). (Link)

KemPharm - KP106 is a novel prodrug for the treatment of attention-deficit hyperactivity disorder (ADHD). KP106, a NEW chemical entity (NCE), is composed of the active pharmaceutical d-amphetamine and a ligand and was created through application of KemPharm’s proprietary Ligand Activated Therapy (LAT) approach. Positive Phase 1 data. (Link)

Marinomed Biotechnologie - The privately-held Austrian biopharmaceutical company is in talks with pharma players to outlicense its lead compound MAM-05.101, is an antiviral nasal spray for the treatment of the common cold - particularly in children. This product is a GRAS botanical and has shown good efficacy in a Phase 2 type trial. Can likely be introduced to the market now as either an OTC product or medical food.

**COMPLETED** Meritage Pharma - Positive Phase 2b data on effect of oral viscous budesonide (OVB) an oral formulation of budesonide for the potential treatment of patients with eosinophilic esophagitis (EoE). ViroPharma will have an option to acquire Meritage at ViroPharma’s discretion for $69.9 million plus the potential for additional payments upon the achievement of certain clinical and regulatory milestones.

$ Nextwave - Novel, sustained release liquid formulations of several Rx and OTC pediatric products in late stage development. Nexiclon XR now on the market and available for treatment of hypertension in kids. (Link)

Orphan Drugs NL BV - Developing levamisole for the treatment of steroid resistant nephrotic syndrome in children (a grouping of diseases including FSGS, membranous nephropathy). Has enrolled 50 patients and this product is available in Europe on a named patient basis. Strong evidence of efficacy in past studies. Not licensed outside of EU. (Link)

Piedmont Pharmaceuticals - Have a late stage product for treatment of head lice. Partnered and marketed in Europe. RESULTZ is sold internationally through licensing partners. Looking for other partners.

Psychogenics - Pursuing eltoprazine in Phase 2 studies for ADHD. Supportive Phase 2a data. (Link)

Star Laboratories - Ibuser is being developed as pediatric ibuprofen drops oral suspension (40mg/ml) for the treatment of pain.
Topaz Pharma - completed two Phase 3 studies for the treatment of head lice with Ivermectin. Planning to submit NDA to FDA in 2011. Note: Sanofi-Pasteur acquired this company without an announcement in Q4 2011. (Link)

Undisclosed player - selling off $20mm revenue+ commercial product for narrow market with pediatric applications.

Undisclosed player - has rights to a Phase 3 ready long acting human growth hormone.

**PROTEIN PLATFORMS**

Ambrx - Very exciting platform technologies with multiple applications which allow engineering of proteins developed in both eukaryotic and prokaryotic cells including an antibody drug conjugate program for oncology. Ambrx interested in a broad strategic alliance that would allow it to expand its platform.

Anaphore - pioneering Altrimers®, a NEW class of protein therapeutics that has a trivalent structure. Better ability to lock on to a target. Working on a number of targets including a TRAIL-R antibody for oncology that is pre-clinical. (Link)

Chiome Bioscience - Can develop antibodies against rare and difficult antigens using its ADLib technology. January, 2011 entered into NEW license agreement for joint invention with RIKEN, which allows Chiome to generate, develop, commercialize, or out license antibodies through preferential use of ADLib system and to license out ADLib for the life of the patent. ADLib system is an innovative technology for preparing antibodies by activating homologous recombination in avian DT40 cells.

Pepscan Therapeutics - Strong platform for the generation of peptides and antibodies that target antigens and proteins. Willing to collaborate on specific targets. (Link) Recently just hired a NEW CEO.

Sembiosys - APOa1 is a injectible protein that leads to atherosclerotic plaque regression. Preclinical version of protein is available with very strong proof of principal data. Company Update: Oct 1, 2010: “SemBioSys Genetics ... announced that it has retained Deloitte & Touche Corporate Finance Canada, Inc. to advise the Company in matters of potential strategic alternatives being considered by the Company and its board of directors.” Update: June 2011 - no sale took place but company raised $4mm in additional capital. (Link)

Symphogen - Novel polyclonal antibody technology platform with a promising antibody in development for RSV (Sym003), still in the pre clinical stage.

**RENNAL / NEPHROLOGY**

Action Pharma - AP214 finished Phase 2, a modified dMSH-peptide analogue, for the treatment of post-surgical kidney injury in the cardiac surgery context. The results demonstrate that AP214 is well tolerated and safe at all three dose levels. At the highest dose level, AP214 prevents the increase in serum creatinine by 50-60%, and in the IL-6 response by 30-40%, compared to placebo (trends based on blinded data). This is consistent with a robust effect to prevent postsurgical acute kidney injury (AKI) and systemic inflammatory response.

Affymax – has achieved approval for Hematide in the U.S. Has divided rights tot his compound with Takeda and company retains significant commercial rights.

Akebia – Positive Phase 2 with a HIF modulator for the treatment of anemia. Originally developed at P&G Pharma. Company reported positive Phase 2 data in pre-dialysis CKD patients in April 2012. At a recent conference, its spin-out company Aerpio indicated that a change ofte f control transaction is likely in 2012. Interested parties should contact Bill Daly (wdaly@akebia.com). (Link)
$ AMAG - Feraheme IV iron product - Recently approved. Company is commercializing on its own. AMAG's recent merger attempt with Allos was ended in November 2011. On Nov 17, 2011, AMAG announced that it had hired Jefferies to explore all opportunities to enhance shareholder value. Frank Thomas, interim CEO of AMAG indicated: "We will expeditiously complete this process, which will include a parallel review of a potential sale of the company and other strategic merger and acquisition transactions."

AM-Pharma - Has achieved highly positive Phase 2 results in the treatment of acute kidney failure with alkaline phosphotase. Company advancing a backup program with stronger patent protection. (Link)

Angelini - Bindarit inhibits mcp-1/CCL2. A Phase II clinical pilot study in lupus nephritis (LN) patients demonstrated that subject treated with bindarit showed a significant reduction of urinary albumin excretion (UAE) and urinary MCP-1/CCL2 levels. Promising data in diabetic nephropathy. Going into Phase 3 studies. (Link)

Angion Biomedica - In a Phase 2a study of BB3 (a hepatocyte growth factor mimetic) to improve renal function in patients with signs and symptoms of significant renal injury after kidney transplantation and at risk for dialysis. (Link)

Concert Pharma - On Nov 14, 2011 announced data from a Phase 1 clinical trial of CTP-499, a novel agent for the potential treatment of diabetic nephropathy. The results demonstrated that a controlled-release formulation of CTP-499 was well-tolerated at single doses up to and including 1800 mg. Concert expects to initiate a Phase 2 clinical trial of CTP-499 in patients with diabetic nephropathy during the first half of 2012. (Link)

Cormedix - CRMD-001 (a proprietary formulation of deferiprone) is in a randomized, double-blind, placebo-controlled Phase 2 clinical trial for the prevention of contrast-induced acute kidney injury in approximately 60 high-risk patients with chronic kidney disease (CKD). Company recently went public.

NEW Cytochroma - CTAP101 Capsules is targeted as a treatment for vitamin D insufficiency in late Phase 2 studies (next generation product) and an injectable CTAP201 an injectable next generation Vitamin D. The company’s CTA018 product has been partnered to Mitsubishi-Tanabe.

Endacea - developing L-97-1, as an oral treatment for renal impairment with HF. This is a preclinical A1 adenosine receptor antagonist. (Link)

Evolva - In Phase 1 for EV-077, an oral thromboxane inhibitor, for diabetic nephropathy. In December 2010 reported that had carried out further formulation work and had confirmed that it had found a well behaved formulation of this drug in a Phase 1 study. (Link)

FibroGen - Would consider outlicensing FG-3019 anti-fibrosis compound. Novel mechanism based on CTGF. Update: FibroGen (like Akebia above) is developing HIF modulators for the treatment of anemia. At November American Society of Nephrology meeting reported strong positive Phase 2b type data for FG-4592. Able to correct anemia reliably in CKD patients without safety problems.

Fibrotech - Has commenced manufacturing and non clinical toxicology for FT011, an antifibrotic for the treatment of diabetic nephropathy. Clinical trial due to commence in Q1 2012. (Link)

NEW Great Lakes Pharma – developing a catheter lock solution called B-Lock with high efficacy in the prevention of MRSA and other infectious disease from catheters.

COMPLETED Kai Pharma - Positive Phase 1b and Phase 2 data for KAI-4169, a novel IV agent being tested for the treatment of secondary hyperparathyroidism, a frequent complication of end stage renal disease. KAI-4169 also is being developed as a transdermal patch product for daily administration in the treatment of Stage 3 and 4 CKD-MBD pre-dialysis patients. In June 2011, announced promising results of KAI-4169 program for treatment of CKD-MBD and presented Phase 2 data in poster at ASN in Nov 2011. Demonstrated a dose-dependent relationship between KAI-4169 exposure and reductions in serum parathyroid hormone (PTH) levels in healthy young males.
following single-dose administration. Company open to partnering this product. In Sep 2011 partnered this product in Japan with ONO. Completed: Kai acquired by Amgen in April 2012 for $325 million. (Link)

**UPDATE** Keryx - In Phase 3 with Zerenex, a ferric citrate for treatment of hyperphosphatemia in ESRD. May, 2011 announced it received positive Scientific Advice from the European Medicines Agency (EMA) for the development of Zerenex for the management and control of serum phosphorus in end-stage renal disease (ESRD) patients undergoing dialysis, and in pre-dialysis chronic kidney disease patients (CKD). The Scientific Advice from the EMA indicates that the Company’s current Phase 3 program in the United States, if successful, in conjunction with safety data generated from other clinical studies with Zerenex, is considered sufficient to support a European marketing authorization application (MAA) to the EMA for the indication in ESRD patients on dialysis. Expects to file an NDA assuming positive data by mid-2012. Positive data on Apr 23 showed non-inferiority to sevelamer This product is partnered in Japan to Japan Tobacco.

**NEW** La Jolla Pharma - GCS-100, which is a potential first-in-class potent and selective inhibitor of galectin-3, a molecular target implicated in organ failure and cancer. GCS-100 has been shown to be well tolerated in multiple clinical trials and is slated to begin studies in renal failure in 2012. The Company anticipates filing an IND for the use of GCS-100 as a treatment for this indication in 2H12/1H13 and anticipates starting a trial in patients with CKD in the first half of 2013.

**UPDATE** NephroGenex - developing Pyridorin for the treatment of diabetic nephropathy. On November 9, 2011 the company announced that it had reached an agreement with the FDA on the design of a new Phase 3 Subpart H program for approval based on serum creatinine. Reported an improvement in a Phase 2b study in creatining in more mild patients.

Noxxon Pharma - Developing NOX-E36, an inhibitor of Monocyte Chemoattractant Protein 1 (MCP-1). Currently completing a Phase 1 study for its indication of treating diabetic nephropathy. Open to a deal. (Link)

**UPDATE** Opsona Therapeutics - OPN-305 is a humanized Phase 1 IgG4 monoclonal antibody (MAb) against Toll-Like Receptor 2 (TLR2), a target within the innate immune system, and is under development as a treatment for the prevention of Delayed Graft Function (DGF) following renal transplantation, in addition to other therapeutic indications. (Link)

Orphan Drugs NL BV - Developing levamisole for the treatment of steroid resistant nephrotic syndrome in children (a grouping of diseases including FSGS, membranous nephropathy). Has enrolled 50 patients and this product is available in Europe on a named patient basis. Strong evidence of efficacy in past studies. Not licensed outside of EU. (Link)

Osprey Pharma - CCL2-LPM, looking for partner to take fusion LPM compound for IgA nephropathy into Phase 2.

**COMPLETED** Pervasis - Developing Vascugel, a cell therapy product, to accelerate vein remodeling for patients receiving an AV fistula (AVF) in end stage renal disease. Compare to Proteon Therapeutics which has optioned a product for the same indication to Novartis. Update: This company was acquired by Shire for “single digit millions” upfront plus milestones and royalties that are worth up to $200mm.

**UPDATE** Raptor Pharmaceutical –filed NDA and MAA in Mar/Apr 2012 for DR Cysteamine, which is delayed-release, enteric-coated microbead formulation of cysteamine bitartrate for the treatment of cystinosis. In June 2011, Raptor reported positive data from a pivotal, Phase 3 clinical trial, examining the safety and tolerability of every 12-hour DR Cysteamine compared to immediate-release cysteamine bitartrate (the current standard of care) in nephropathic cystinosis patients. Company intends to self-commercialize this product. (Link)

**UPDATE** Reata - positive phase 2b data for bardoxolone methyl for diabetic nephropathy. Bardoxolone methyl is an antioxidant inflammation modulator (AIM) that activates Nrf2, thereby inducing the transcription of more than 250 genes that decrease the level of oxidative stress and suppress several inflammatory mediators. Partnered
outside the U.S. to Abbott and to KHK in Japan. Phase 3 pivotal study is well underway and an approval is possible in 2014. Planning to self-commercialize in the U.S. upon approval. (Link)

H Relypsa - positive Phase 2 data achieved for a potassium binder to treat hyperkalemia which is prevalent in persons with end stage renal disease and those with congestive heart failure. Large market potential. Company recently raised $70mm to get through Phase 3 studies of this promising treatment. (Link)

Rockwell Medical Technology - Going into Phase 3 for Soluble Ferric Pyrophosphate (SFP), a novel continuous iron-replacement therapy designed to treat iron deficiency anemia in hemodialysis patients. Recently had a satisfactory end of Phase 2 meeting with FDA. Ongoing Phase III efficacy study. Anticipate SFP commercial launch U.S. (upon FDA market approval est. 2013).

UPDATE Sorbent Therapeutics - Oral, non-absorbed polymer for treatment of diseases with fluid, potassium or sodium imbalance. Has completed Phase 1 and is intended for persons with ESRD. Update: Company completed a financing round in September 2010 which will facilitate going forward into further clinical trials. Update: June 30, 2011, Sorbent Therapeutics completes $36 million Series B Financing for a net raise of $53 million. Has not yet reported out its Phase 2 dataset.

Spectrum Pharmaceuticals - Looking for a ROW partner for RenaZorb™, a preclinical second generation lanthanum-based phosphate binding agent. (Link)

COMPLETED H Stromedix - STX-100 is being developed for the treatment of chronic allograft dysfunction in kidney transplant recipients. Also exploring IPF indication. Humanized monoclonal antibody to integrin αvβ6, going into Phase 2. Note: This company was bought by BiogenIdec in Feb 2012 for $75mm upfront and additional contingent payments of $487.5 million.

Tengion - Leading regenerative medicine company open to partnership deals for the development of both an artificial bladder and an artificial kidney. Tengion has recently gone through a leadership transition and plans an FDA meeting to discuss the kidney program before the end of 2011. (Link)

H Toray Pharma - has recently reacquired rights to a promising Phase 2 compound for the treatment of uremic pruritis from Acologix. On the market in Japan as REMITCH through Japan Tobacco’s Torii subsidiary. U.S. and European rights are available. (Link)

Trevi Therapeutics - Preparing to dose T111 in a Phase 2 trial for chronic uremic pruritis to determine proof of concept for safety and efficacy. (Link)

Veloxis - Positive top-line results from a Phase 2 clinical trial involving 63 patients comparing LCP-Tacro™ tablets administered once daily versus Prograf® (tacrolimus) capsules (Astellas Pharma) administered twice daily in de novo kidney transplant patients. Currently in Phase III clinical trials for treatment of kidney transplant patients with NDA/MAA submission in the US and EU expected in Q1 2013.

UPDATE Vitae Pharmaceuticals - VTP-27999 is a novel, potent and selective renin inhibitor offering the potential for superior renal protection in patients suffering from chronic kidney disease. The compound is expected to enter Phase 2b in early 2012 and has shown impressive performance in studies to date. Recent issues with Novartis renin inhibitor are relevant to Vitae’s prospects. (Link)

Y’s Therapeutics - YSPSL is fused P-selectin glycoprotein ligand (PSGL) and human IgG1. It acts as an antagonist of P-selectin. This is currently in Phase 2 studies for prevention of delayed graft function and prevention of IRI in transplant patients.

H ZS Pharma - Potassium and ammonium binders. In Phase 1 studies after a recent funding round. Related potassium binders at Relypsa and Sorbent Tx in Phase 2.
RESPIRATORY

Actelion – Phase 2 with a novel CRTH2 antagonist with met its primary endpoint in study results reported in May 2011. A Phase II dose-finding study in asthma is currently enrolling and is expected to report results mid-2012. Would prefer to wait for full Phase 2 data prior to partnering this compound.

Adamis Pharma - developing an inhaled nasal steroid for the treatment of allergic rhinitis and a metered dose inhaler for asthma and COPD. Going into Phase 3 studies. (Link)

Aerovance - Exploring partnering / sale options with positive Phase 2b data for AEROVANT, an asthma drug which is an inhibitor of the IL-4 and IL-13 receptors. As of June 7, 2010, Phase IIb clinical trial results showed Aerovance’s Aerocant is effective in patients with Eosinophilic Asthma.

Allergy Therapeutics - Pollinex Quattro in the treatment of seasonal allergic rhino-conjunctivitis (“SAR”) caused by grass pollen has successfully completed a Phase 3 study. Partnered in Canada to Takeda. Company open to partnering rights in the U.S. Negotiating a protocol with FDA and anticipates lift of clinical hold on its program. (Link)

Almirall - Looking to partner LAS100977, once daily long acting beta agonist. Recently shown positive data in a Phase 2 study for asthma and COPD. Partnered in Japan to Kyorin and in the U.S. to Forest. (Link) EU rights available.

AIM Therapeutics - AIM-102 is a non-steroidal, anti-inflammatory drug which acts by modulating inflammatory mediators such as eosinophils, neutrophils and macrophages. In Phase 2 development for asthma and COPD.

UPDATE Anergis - Developing 5-injection/2-month specific immunotherapy therapy with its lead product AllerT for birch pollen. Positive Phase 2 data. Has an earlier stage ragweed allergy program. (Link)

NEW Apeptico - AP301 IH is being developed for the treatment of edematous respiratory failure and pulmonary edema in various lung diseases and critical conditions. AP301 IH is a fully synthetic peptide version of a loop region of a human protein. As indicated by a phase 1 clinical trial, AP301 IH is safe and well tolerated. A Phase Ila clinical trial "proof-of-concept was initiated in mid-2012. (Link)

UPDATE Aquinox Pharma - AQX-1125 modulates SHIP which controls PI3K for the treatment of cancer and inflammatory disease. AQX-1125, is a highly active and selective small molecule allosteric activator of SHIP1 suitable for once-daily oral dosing as a pill. AQX-1125 is currently being investigated in two Phase Ila proof-of-concept studies that complete in 2012. One study is looking at the performance of the compound in asthma; the other is looking at respiratory inflammation.

Argenta Discovery - In Phase 2a for ADC-4022 for COPD.

APT Pharma - Positive Phase 2 results for Pulminiq –an inhaled cyclosporine for preventing lung transplant rejection. Currently in a fully enrolled Phase 3 trial. Data has not been reported out as of December 2011. (Link)

Aradigm - Strong Phase 2b data of once daily inhaled ciprofloxacin in bronchiectasis and cystic fibrosis. Also has a Phase 1 inhaled nicotine program. (Link)

NEW Array Biopharma - ARRY-502 is a CRTh2 antagonist for asthma. Array completed a randomized, double-blind, 14-day multiple ascending dose Phase 1 trial with ARRY-502 in healthy subjects. ARRY-502 was well tolerated at all doses evaluated, and all observed treatment-related adverse events were mild. Array plans to initiate a Phase 2 trial in persistent asthma during the first half of 2012. Array expects top-line results from this trial during the first quarter of calendar 2013 and intends to seek a partner for further development. (Link)
Arriva Pharmaceuticals - Inhaled protein rAAT (Respiva) replacement therapy for hereditary emphysema, completed two early Phase II trials and recently completed manufacturing with a more highly purified and higher yield recombinant alpha 1-antitrypsin for upcoming clinical trials. Company is looking at a partnership deal.

NEW Asmacure – Two Phase 2 studies underway of ASM-024, a first in class nicotinic receptor modulator for bronchodilation and control of inflammation in persons with asthma.

BioMark Pharmaceuticals – In Phase 2 for BIO-11006 an inhibitor of MARCKS protein for oversecretion of mucus in COPD and CF. Recent Phase 2a data showed clinical significant effects on FEV-1. Statistical significance was dependent on the endpoint and population. (Link)

Biomay - developing products for grass and birch allergy. In Phase 2 and 3 studies. (Link)

UPDATE Biota Holdings - Looking to partner a once weekly inhalable long-acting neuraminidase inhibitors for the treatment of flu. Would compete against Relenza from GSK. Currently partnered with Daichi-Sankyo in Japan. One of two Phase 3 studies have reported out with positive data - large market. Update: Biota is merging with Nabi (Apr 2012). (Link)

UPDATE Biota Holdings - Also looking to partner a product to treat the common cold. Specifically, canyon-like clefts on rhinovirus surface attach to the receptor allowing infection. Biota achieved proof of concept in a Phase Ila (challenge study) in 2009. Now in Phase 2b studies for this product. Update: Biota is merging with Nabi (Apr 2012). (Link)

Biotie Therapies - ELB353 is a PDE4 inhibitor for treatment of inflammatory related diseases such as COPD. Has completed Phase 1 studies. Looking for a partner.

NEW Celtaxys - CTX-4430 reduces inflammation in animal models. LTA4H is a key in the production of the major pro-inflammatory mediator Leukotriene B4 (LTB4). LTA4H and receptors to LTB4 are known to be elevated in a number of human lung diseases including Cystic Fibrosis, Asthma and Chronic Obstructive Pulmonary Disease (COPD).

NEW Corridor Pharmaceuticals - C-122 has undergone extensive preclinical pharmacokinetic and toxicology testing. In animal models of Pulmonary Artery Hypersension. The drug candidate prevents the elevation of pulmonary arterial blood pressure and reduces arterial hypertrophy and perivascular fibrosis. Entering human testing.

H Cytos - looking to partner CYT003 for allergic rhinoconjunctivitis. Vaccine has finished Phase 2b studies. Asthma symptoms decreased by 33% under QbG10 treatment despite corticosteroid withdrawal, while they increased by 29% under placebo treatment (p=0.01). Use of relief medication doubled in the placebo group, while it remained stable in the QbG10 group (p=0.01). (Link)

NEW Discovery Biomed - developing delF508-CFTR correctors and activators of alternative rescue chloride channels in CF human airway epithelial cells as two parallel strategies to control/cure cystic fibrosis. Have several leads and looking for a research partner.

UPDATE Discovery Labs - Surfaxin is a synthetic KL4 Surfactant for treatment of neonatal RDS. The FDA has approved SURFAXIN (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants at high risk for RDS.

**NEW** Hunter Immunology – Phase 2b data expected in COPD in Q2/Q3 2012 for a highly innovative anti-bacterial approach to the disease. ([Link](#))

Ligand / CyDex - **CDX-313** (CE-budesonide and azelastine) CyDex is developing CDX-313 as a treatment for seasonal / perennial allergic rhinitis. Recently shown positive data in Phase II EEC study completed in 105 subjects.

**NEW** Marinomed Biotechnologie - Privately-held Austrian biopharmaceutical company, is in talks with pharma players to outlicense its lead compound **MAM-05.101**, an antiviral nasal spray for the treatment of the common cold - particularly in children. This product is a GRAS botanical and has shown good efficacy in a Phase 2 trial. ([Link](#))

**UPDATE** Medicinova - Would consider a partnership for **MN-221**, a selective β2-adrenergic receptor agonist being developed for the treatment of status asthmaticus. Phase 2b study underway. Update: As of March 21, 2012, this trial is fully enrolled. Data release expected imminently.

**NEW** MondoBIOTECH – In Phase 2 testing of **DK-1000-01** for pulmonary arterial hypertension (part of a portfolio of orphan drugs). Peptide is a potent vasodilator and has shown improvement in six minute walk distance in Phase 2a study. ([Link](#))

N30 - N6022, is designed to treat asthma, chronic obstructive pulmonary disease, and inflammatory bowel disease. N6022 is a reversible inhibitor of GSNOR, which increases levels of GSNO, which helps maintain normal respiratory function. Going into Phase 1.

Ono Pharmaceutical - Has completed Phase 1 studies with **ONO-4034**, a PGD2 antagonist for the treatment of allergic rhinitis. An ex-Japan partnership transaction is possible.

**UPDATE** Oxagen - **CRTH2** antagonists for asthma, allergy and respiratory disease. Phase 2a POC data with enrollment of a Phase 2b study completed. Phase 2b data are reportedly positive. Exploring partnership/sale.

Palatin Laboratories - **PL-3994** in phase 2 trial in stable asthmatics to determine if patients achieve a clinically meaningful increase in pulmonary function. Compound is a NPRA agonist. ([Link](#))

Pari - Looking to partner a Phase 3 **Tobramycin** for cystic fibrosis. Also developing a liposomal cyclosporine for lung transplant that is in Phase 2.

Pearl Therapeutics - Developing **PT003**, a fixed dose combination of glycopyrrolate and formoterol delivered via a pressurized hydrofluoroalkane metered dose inhaler (HFA-MDI). Good efficacy and differentiation signals in a Phase 2b clinical trial in patients with moderate to very severe chronic obstructive pulmonary disease (COPD). Results show PT003 provides safe and superior bronchodilation compared to the current market leader, tiotropium bromide (Spiriva® Handihaler®), as well as to formoterol fumarate (Foradil® Aerolizer®), placebo and the individual components of PT003 (p≤0.0002 for all comparisons). ([Link](#))

Pernix / SEEK Joint Venture - Looking to sell the rights to Theobromine for the treatment of cough with assistance of JP Morgan. Manfred Scheske, Chief Executive Officer of the SEEK/Pernix joint venture, commented: “We believe theobromine (BC1036) is a late-stage, low-risk asset and will be the first NEW treatment for cough in over 50 years.” Going into a Phase 3 clinical trial. As of November 2011, Pernix indicated: “Joint venture continues to evaluate opportunities and expects to continue discussions with interested parties to maximize the value of the Theobromine asset.” ([Link](#))

**UPDATE** Pharmaxis - Preparing to launch **Bronchitol®** for the treatment of patients with cystic fibrosis in Q1 2011. Bronchitol launched in Australia and approved in Europe in April 2012.

Pharmaxis - **TPI 1100** is a novel, potent, selective and dual-acting RNA-silencing oligonucleotide against phosphodiesterase isoforms PDE4 and PDE7. For COPD going into Phase 1.
Pharmaxis - **TPI ASM8** for mild to moderate asthma has been shown to be effective at very low doses in a first Phase II, placebo-controlled study that evaluated the effects of a once-daily (QD) inhaled dose of TPI ASM8.

Promedior - Developing recombinant human **Serum Amyloid P Component** for the prevention and treatment of fibrotic pathology including its manifestations in scarring associated with asthma and IPF. Would consider a corporate sale and is currently in active partnership talks after raising an additional $12 million. Company presented encouraging Phase 1b data at the American Thoracic Society meeting in May 2011.

Revotar - **Bimosiamose**, a pan-selectin antagonist, targeted against the selectin family of cell adhesion molecules, for COPD with promising Phase 2 data. Open to partnership or company sale.  

Serendex - inhaled rfVila for blast injury and lung bleeding. Six patient study showed high efficacy. Orphan designation granted.  

SkyePharma - recently received rights to Flutiform® back from Abbott. This product is available for repartnering. FDA approval quite challenging. The inhaled drug, which is being developed for the treatment of asthma and chronic obstructive pulmonary disease, would if approved compete with Advair and Symbicort.  

Stallergenes –Stalair® line of **allergy products** including ones aimed at rhinitis, asthma and mites. Late stage opportunity for a large market. Both specialty and potential primary care call points. Company recently indicated that it intends to pursue U.S. commercialization on its own. Currently looking for a China partner.  

Syntaxin - Interesting albeit early program in COPD. The inhaled delivery of Syntaxin’s novel proteins target respiratory epithelial cells controlling airway mucus hypersecretion in diseases such as COPD and bronchitis.  

$ Undisclosed - company that sells raw materials for allergy shots. Good revenue / profitability and potential for growth into the emerging market for FDA approved products.  

$ Undisclosed - marketed product available on a co-promotion basis into the hospital setting for the prevention of acute allergy.  

VentiRx –In October 2010 reported a positive proof of concept for TLR8 drug VTX-1463 in grass allergy. Data shown at AAAI in 2011 were impressive.  

Vernalis - V85546 - Phase 2-ready novel selective anti-inflammatory compound that selectively inhibits MMP12 and has in-vivo efficacy in pre-clinical models of Chronic Obstructive Pulmonary Disease (COPD), Multiple Sclerosis (MS) and liver fibrosis. Phase I SAD and MAD studies have been conducted. Substantial safety and tox package would support up to 6 month dosing in Phase II. Worldwide rights available.  

Verona Pharma - Willing to partner RPL554, a PDE3/4 inhibitor for asthma and COPD. Positive Phase I/IIa results. Data showed that FEV1 improved relative to placebo by up to 10%.  

### REVERSE MERGER CANDIDATES

**NEW** Columbia Labs – recent issue with approval of its partnered product Prochieve. After FDA indicated that an additional trial is generated, the company indicated that it has hired Cowen to explore strategic alternatives. Columbia has a royalty stream, some cash and is a good candidate for a reverse merger transaction.  

La Jolla Pharmaceuticals - would consider a reverse merger transaction.  

**NEW** Myrexis - good candidate for a reverse merger transaction. Company has substantial negative enterprise value and has hired Stifel to explore strategic alternatives. Feb 15, 2012: “Myrexis, Inc. (Nasdaq: MYRX), a biotechnology company focused on the development of small molecule therapeutics, today announced that its Board of Directors has retained Stifel Nicolaus Weisel, an investment banking firm, to assist it in reviewing and evaluating a full range
of strategic alternatives available to the Company to enhance shareholder value. Myrexis has also suspended development activities on all its pre-clinical and clinical programs. The Company will initiate an alignment of resources consistent with its decision to suspend further development activities.” (Link)

**COMPLETED** Nabi - good candidate for a reverse merger transaction following a recent Phase 3 failure with NicVax. On Nov 7, 2011, the company said: “Nabi Biopharmaceuticals today announced that its Board of Directors has retained Piper Jaffray to assist with its exploration of the strategic alternatives available to the company to enhance shareholder value.” Update: In March 2012 the company indicated that it plans to announce the result of its plans in Q2 2012. Update: Apr 2012 – company announced a merger with Biota.

**RIGHTS IN ASIA**

$ Acrux - rights outside of the U.S. are available for Estradiol MDTS® is a novel Estradiol Metered Dose Transdermal Spray (MDTS®) hormone replacement product for the treatment of moderate to severe symptoms due to menopause. This product was recently approved in Sweden and has pending approvals in a number of other countries.

Active Biotech - Successful Phase II study showed tasquinimod’s ability to impede disease progression in symptom-free patients with metastatic, castrate-resistant, prostate cancer. Drug works by attacking blood vessels. April, 2011 entered partnership to co-develop TASQ with Ipsen. Phase III trial was recently initiated and patient recruitment is ongoing. Rights are available in North America, South America and Japan. (Link)

Amylin - has purchased rights to Byetta® back from Eli Lilly. This GLP-1 inhibitor is expected to have $1 billion or more in revenues and has substantial ex-U.S. revenue. Amylin is searching for a commercialization partner outside of the United States.

Anacor - Looking for ex-U.S. partnerships for dermatology portfolio including preclinical and clinical compounds for psoriasis, tinea pedis, acne and atopic dermatitis. AN2728 is past POC stage and is in a Phase 2 trial for psoriasis and is expected to report in the first half of 2009.

Antares - Anturol: a novel and proprietary transdermal gel system for the delivery of oxybutynin which has successfully completed a pivotal Phase III trial for the management of overactive bladder and has been filed for NDA approval in December 2010. Licensed to Watson for marketing in the U.S. and Canada. Looking for a partner in Asia. (Link)

Antisoma - Partnering AS1413, formerly Xanafide, is a DNA intercalator in phase III development in secondary AML outside the U.S.

NEW Aptalis – Amrix is a long acting muscle relaxant (cyclobenzaprine). This product is on the market in the U.S. but rights available in most other global territories.

Aradigm - (AERX) inhalable insulin is available. Nine complete phase 3 studies, excellent safety and efficacy. Essentially complete preclinical, clinical, and CMC packages. Strong IP generally in the area of inhalable insulins.

Archimedes Pharma - Is seeking licensees for North America and Japan for PecFent, a nasally-delivered fentanyl product for breakthrough cancer pain, currently in Phase III development. Archimedes Pharma is seeking licensees outside of Europe for PecFent®. Has gained a positive opinion from the CHMP, and has been filed for regulatory approval in the US. Preparing for a U.S. launch.

Auxilium – willing to partner rights to Testim, a testosterone product, in Japan.

BioDelivery Sciences - Has recently received approval for Onsolis in the U.S. and has a marketing partner in North America and the EU. Searching outside these regions.

Biofrontera – Ameluz (BF-200 ALA) is approved in Europe for the treatment of actinic keratosis. BF-200 ALA combines a nanoemulsion with 5-aminolevulinic acid (ALA). The product is developed in photodynamic therapy of precancerous skin lesions (actinic keratosis). Looking to partner in a variety of EU territories. Plans to meet with FDA to discuss U.S. approval and then partner. (Link)

Cadence Pharmaceuticals - looking for Chinese partner for their IV acetaminophen product.

Cancer Prevention Pharmaceuticals - seeking a ROW partner for its combo of efllornithine and sulindac. In Phase 3 studies for familial adenomatous polyposis (FAP).

Cempra - preparing CEM-102 (Fusidic Acid or Taksta®) for Phase 3 studies that is designed to show non-inferiority to linezolid in patients with acute bacterial skin and skin structure infections. (Link)

Cornerstone Therapeutics – Applying for approval of Lixivaptan for the treatment of hyponatremia. Has finished three Phase 3 studies but has not published the results to date. Two vaptans on the market but potential differentiation of this product. Cornerstone is now looking for ex-US partners for this late stage product. (Link)

Cosmo Pharmaceuticals - Looking to license Rifamycin SV MMX, a treatment for CDAD in Asia. Recent deal done with Santarus on Budesonide and Rifamycin for the U.S.

Cubist - recently acquired Adolor and open to partnering rights to Adolor products in Asia. Included is ADL5945 for the treatment of opioid induced constipation. This product has completed Phase 2 studies. Interested parties should contact aaron.pelta@cubist.com.

Endocyte - EC145 targets an alkaloid chemotherapy drug to folate receptors over-expressed on cancer cells. Met primary endpoint in Phase II study demonstrating 85% improvement in median progression-free survival for treatment of platinum resistant ovarian cancer. Update: This program was partnered to Merck in April 2012 for $120mm upfront plus additional milestones and royalties. (Link)

Epicept - Ceplene approved for AML in Europe. Active partnership process underway. Jan 11: EpiCept announces commercial licensing agreement for Ceplene(R) with Meda in Europe and Pacific Rim. Receives $3mm upfront and royalties and milestones. U.S. rights available but company received a refusal to file on Aug 23, 2010 from FDA. (Link)

Inotek – Developing INO-8875 for the treatment of glaucoma. This product is in mid-Phase 2 trials with encouraging data. Open to partnering global rights or Japan rights. (Link)

MAP Pharma - Would look at ex-U.S. partnerships for its late stage inhaled migraine drug, Levadex. NDA submitted in May 2011. In January 2011 the company entered into a promotional agreement with Allergan who will promote this product in the U.S. to headache specialists. MAP received $60 million upfront as part of the consideration for this agreement. MAP Pharma retains other physician markets in the U.S. and rights in all other geographies. (Link)

Neurogesx - Qutenza is a patch that delivers synthetic capsaicin for PHN on the market in U.S.. Recently approved. Partnered in the EU to Astellas in June 2009. Company looking for partnerships in Asia and Latin America. (Link)

Optimer - has received approval to market Dificid for CDAD in the U.S. Is looking for a commercial partner for China, Australia, South Korea and Japan. Update: March 30, 2012 – Optimer licenses Japan rights to
Astellas for $20mm upfront plus milestones and royalties. Rights to China, Australia and South Korea are still available.

$ Pacira Pharmaceuticals - Looking to partner Exprarel, a long acting bipuvicaine, outside of the U.S. Interested parties should contact Darren Pincus at DarrenP@pacira.com.

Pearl Therapeutics - Developing PT003, a fixed dose combination of glycopyrrolate and formoterol delivered via a pressurized hydrofluoroalkane metered dose inhaler (HFA-MDI). Good efficacy and differentiation signals in a recent Phase 2 study.

PharmaNova - Gabapentin is a proprietary formulation of gabapentin being developed for hot flashes. In Phase 3 in U.S. (Link)

QRX Pharma - When compared at equianalgesic doses with Percocet, MoxDuo IR demonstrated greater overall tolerability with substantially less side effect. Going into Phase 3. Open to regional partnership deals, particularly in China. (Link)

RaQualia - Has Japan only rights for Geodon and Eraxis. (Link)

Relypsa - positive Phase 2 data achieved for a potassium binder to treat hyperkalemia which is prevalent in persons with end stage renal disease and those with congestive heart failure. Large market potential and high interest. Company recently raised $70mm to get through Phase 3 studies of this promising treatment. Open to a Japan partnership deal. (Link)

Revotar - positive results on a Phase IIa study conducted to evaluate the effect of Bimosiamose on ozone-induced airway inflammation in healthy subjects with a new controlled breathing nebulizer device. Further ongoing trials for this promising clinical candidate for the treatment of COPD. (Link)

Rovi - Bemiparin is currently in the market in 44 countries and in registration process in 18 additional countries. This low molecular weight heparain is for the treatment of thromboembolism. No marketing partner in Southeast Asia and Australia.

Soligenix - has partnered orBec/BDP with Sigma-Tau in the U.S. Looking to partner in ROW. Indication is GI manifestation of acute GVHD, thereby reducing the need for systemic immunosuppressive drugs to treat GI GVHD. Company is running a confirmatory trial and indicates a partnership is most likely after results are in. (Link)

Stallergenes –Stalair® line of allergy products including ones aimed at rhinitis, asthma and mites. Late stage opportunity for a large market. Both specialty and potential primary care call points. Company recently indicated that it intends to pursue U.S. commercialization on its own. Currently looking for a China partner. (Link)

Supernus - a neuroscience focused specialty pharmaceutical company with two filed NDA’s in epilepsy, a Phase 2b program in IA in the setting of ADHD, and a Phase 2 program for the treatment of ADHD. Supernus is seeking ex-US partners for its two filed NDA’s and US partners for its ADHD portfolio.

Tillotts – looking for a marketing partner for Asacol for ulcerative colitis in the the CEE markets, Latin America and Asia ex-Japan and Korea.

Transcept Pharmaceuticals - Looking for an ex U.S. partner for middle of night insomnia drug, Intermezzo. Transcept has formed a U.S. partnership with Purdue Pharma for Intermezzo.

Undisclosed - Chinese specialty pharmaceutical company with strength in anti-infectives. Good EBITDA and revenue over $70mm in 2011. Torreya Partners assisting in sale of majority stake. For details please contact rodolphe.grepinet@torreyapartners.com.
Ventrus - faster treatment for hemorrhoids with a good data package. Enrolling a Phase 3 study which will report out in Q2 2012. Company has gone public and raised over $70mm in capital to finance and obtain approval for its top two programs. Product has potential revenues in excess of $1 billion. (Link)

Vernalis - Frovatriptan rights for migraine available in Asia except South Korea.

Vifor - looking for a Japan partner for Ferinjection, an IV iron.

Zogenix - Sumavel, a needlefree transdermal delivery of sumatriptan for migraine. Recent FDA approval with product launch using Astellas as a co-promotion partner. Company could consider an M&A transaction. Note: Raised $30mm from Cowen Healthcare Royalty Partners in July 2011.

ZS Pharma - Drug for treatment of hepatic encephalopathy. Large Asian market due to prevalence of liver failure.

RIGHTS IN CANADA


Chelsea Therapeutics - In late stage development of Droxidropin for the treatment of orthostatic hypotension. In active talks to partner the drug in in hypotension. Large potential in the Parkinson’s market - also could work in fibromyalgia. On market already through Dainippon Pharma in four Asian countries. Company recently reported that it has potential to file for an NDA based on studies that have already been completed.

Dong-A Pharmaceuticals - Looking to Canadian rights to a U.S. Phase 3 PDE V inhibitor that is on the market in Korea. Licensed in the U.S. to Warner-Chilcott. (Link)

Dyax - Looking to partner DX-88 in EU, for hereditary angioedema. BLA filed with a priority review.

MAP Pharma - Would look at ex-U.S. partnerships for its late stage inhaled migraine drug, Levadex. NDA submitted in May 2011. In January 2011 the company entered into a promotional agreement with Allergan who will promote this product in the U.S. to headache specialists. MAP received $60 million upfront as part of the consideration for this agreement. MAP Pharma retains other physician markets in the U.S. and rights in all other geographies. (Link)

$ Pacira Pharmaceuticals - Looking to partner Exprarel, a long acting bipudicaine, outside of the U.S. Interested parties should contact Darren Pincus at DarrenP@pacira.com.

Rovi - Bemiparin is currently in the market in 44 countries and in registration process in 18 additional countries. This low molecular weight heparin is for the treatment of thromboembolism. No Canada marketing partner.

NEW: Supernus - a neuroscience focused specialty pharmaceutical company with two filed NDA’s in epilepsy, a Phase 2b program in IA in the setting of ADHD, and a Phase 2 program for the treatment of ADHD. Supernus is seeking ex-US partners for its two filed NDA’s and US partners for its ADHD portfolio.

UPDATE: TG Therapeutics (formerly Manhattan Pharmaceuticals) – In late stage development of Hedrin, a treatment for head lice. Hedrin is the top selling head lice product in Europe. The JV developing this product was recently restructured to give greater ownership to Nordic Biotech Fund II. The JV is actively looking for U.S. and Canada development partners. (Link)

RIGHTS IN THE EU

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Acrux - rights outside of the U.S. are available for Estradiol MDTS® is a novel Estradiol Metered Dose Transdermal Spray (MDTS®) hormone replacement product for the treatment of moderate to severe symptoms due to menopause. This product was recently approved in Sweden and has pending approvals in a number of other countries.

Advanced Life Sciences - Looking to partner Restanza, cethromycin, a late stage compound for treatment of community acquired infection. Approvable letter with FDA requesting an additional clinical study. Partnered in Asia with Wyeth. (Link)

Alkermes - ALKS-33, a unique opioid receptor profile with strong efficacy data demonstrating rapid onset and extended activity beyond 24 hours. Broad applicability including treatment for reward/impulse control disorders. Multiple clinical studies conducted including Phase II for alcohol dependence. Interest in partners for rights outside of North America.

Almirall - Looking to partner LAS100977, once daily long acting beta agonist. Recently shown positive data in a Phase 2 study for asthma and COPD. Partnered in U.S. to Forest. (Link) EU rights available.

Amylin - has purchased rights to Byetta® back from Eli Lilly. This GLP-1 inhibitor is expected to have $1 billion or more in revenues and has substantial ex-U.S. revenue. Amylin is searching for a commercialization partner outside of the United States.

Anacor - Looking for ex-U.S. partnerships for dermatology portfolio including preclinical and clinical compounds for psoriasis, tinea pedis, acne and atopic dermatitis. AN2728 is past POC stage and is in a Phase 2 trial for psoriasis and is expected to report in the first half of 2009. Based on these results, Anacor expects to initiate a Phase 2b dose-ranging trial for AN2728 in mid-2010.

Antisoma - Partnering AS1413, formerly Xanafide, is a DNA intercalator in phase III development in secondary AML outside the U.S.

Aptalis – Amrix is a long acting muscle relaxant (cyclobenzaprine). This product is on the market in the U.S. but rights available in most other global territories.

Aptalis – looking for a partner for Unisom, an OTC sleep aid that is sold by Sanofi in the U.S. Unisom contains diphenhydramine HCl (50 mg/dose) and acetaminophen.

Aradigm - Inhalable insulin is available. Nine complete phase 3 studies, excellent safety and efficacy. Essentially complete preclinical, clinical, and CMC packages. Strong IP generally in the area of inhalable insulins.

Ardana - Markets urology products in Europe. Currently in administration. Products include Emselex for OAB and Striant (testosterone). Pipeline of urology products. (Link)

Bellus Health - Would consider partnering US rights to Vivimind for Alzheimers. Active partnering discussions ongoing in Europe. In April, 2011 announced that it has signed an exclusive license and distribution agreement with Agahan Ayandeye Pars Inc. for this product in the MidEast.

BioInvent - BI-204 is a monoclonal antibody targeting oxidised forms of LDL. It is believed to inhibit pro-inflammatory macrophages at the site of the atherosclerotic plaque, reducing inflammation and stabilizing plaque
tissue prone to rupture and cause coronary artery disease. In March 2012 it announced that the Phase 2 trial of this drug is fully enrolled. Rights are partnered to Roche in North America but are held by BioInvent elsewhere.

Cancer Prevention Pharmaceuticals - seeking a ROW partner for its combo of efollornithine and sulindac. In Phase 3 studies for familial adenomatous polyposis (FAP).

**UPDATE** Chelsea Therapeutics - NORThERA™ (droxidopa), is an orally active synthetic precursor of norepinephrine initially being developed for the treatment of neurogenic orthostatic hypotension. Potential in the Parkinson’s market where there has been a reported 60% reductions in falls in PD patients with NOH - also could work in fibromyalgia. On market already through Dainippon Pharma in four Asian countries. On March 28, 2012 Chelsea Therapeutics (CHTP) received a complete response letter (CRL) from the Food and Drug Administration (FDA) for Northera. In the CRL the FDA asked Chelsea to conduct another study which can demonstrate the drug continues to work for patients over a two to three month period. Open to ex-US partnerships.

Clinuvel - In Phase 3 for European approval for Afamelanotide, a photoprotectant to be used in Erythropoietic Protoporphryia. ([Link](#))

**NEW** Cornerstone Therapeutics – Applying for approval of Lixivaptan for the treatment of hyponatremia. Has finished three Phase 3 studies but has not published the results to date. Two vaptans on the market but potential differentiation of this product. Cornerstone is now looking for ex-US partners for this late stage product. ([Link](#))

Cosmo Pharmaceuticals - Looking to license Rifamycin SV MMX, a treatment for CDAD in Asia. Recent deal done with Santarus on Budesonide and Rifamycin for the U.S.

Dyax - Looking to partner DX-88, for hereditary angioedema. Recently approved. No known sale process underway but company appears to be an attractive takeover target.

Epicept - Ceplene approved for AML in Europe. Active partnership process underway. Under the terms of the agreement, EpiCept will grant Meda the right to market Ceplene in Europe and several other countries including Japan, China, and Australia. ([Link](#))

Gentium - Defibrotide for the treatment of severe Hepatic Veno-Occlusive Disease (VOD) have indicated both efficacy and lack of significant toxicity. Rights outside of the U.S. are available. IDS partner for EU

**H** Intermune - Filed an NDA for Pirfenidone for IPF in Q4. FDA failed to approve product. Additional trial likely required.

Ipsen - completed a strategic review in 2011 with the theme of increasing focus and growing the footprint. The implications of this for potential partnerships or asset divestitures are threefold: (1) Ipsen looking for a partner in the French primary care arena, (2) Ipsen looking to find a buyer for its industrial site in Dreux France which makes solid dose and liquid formulations and (3) “Ipsen will explore all options to maximize value (of its short stature franchise) while meeting its obligations to patients and partners. It will be managed directly by regions and countries.”

MAP Pharma - Would look at ex-U.S. partnerships for its late stage inhaled migraine drug, Levadex. NDA submitted in May 2011. In January 2011 the company entered into a promotional agreement with Allergan who will promote this product in the U.S. to headache specialists. MAP received $60 million upfront as part of the consideration for this agreement. MAP Pharma retains other physician markets in the U.S. and rights in all other geographies. ([Link](#))

Mayne Pharma - Lozanoc™ (SUBA®-itraconazole) is an improved patent protected formulation of itraconazole to treat fungal infections. The bioavailability of SUBA®-itraconazole is twice that of the originator product (Sporanox®) and shows reduced intra- and inter-subject variation. A Marketing Authorisation Application (MAA) in the EU has been submitted (November 2010) and discussions with the FDA are underway regarding further requirements for 505(b)2 filing and US registration. Interested parties should contact andrew.dunbar@maynepharma.com.
UPDATE Novabay Pharmaceuticals - Aganocide compounds (broad spectrum antimicrobial activity) for a variety of topical applications like treatment of acne, decolonization of MRSA from the nares, and catheter-associated urinary tract infections. The drug candidate, NVC-422 is in clinical studies to treat chronically catheterized patients with high levels of bacteriuria, or bacteria in the bladder. Last year, the company established proof of concept in part A of a phase II trial of NVC-422, demonstrating 80% effectiveness in preventing urinary catheter blockage and encrustation. NovaBay Pharmaceuticals and Galderma SA tweaked a March development deal for skin condition drugs, defining terms and fees and providing for an additional tolerance study. (Link)

Optimer - Promising Phase 3 data for Prulifloxacin in infectious diarrhea. Favorable comparison versus ViroPharma’s vancomycin. Open to a partnership transaction for this drug following the recent approval of Dificid (fidaxomicin) by the FDA.

$ Pacira Pharmaceuticals - Looking to partner Exprarrel, a long acting bipuvcaine, outside of the U.S. Interested parties should contact Darren Pincus at DarrenP@pacira.com.

PharmaNova - Gabapentin is a proprietary formulation of gabapentin being developed for hot flashes. In Phase 3 in U.S. (Link)

Salix - looking for a European partner for RELISTOR, a subcutaneous treatment for opioid-induced constipation. This was recently partnered in Asia to Link Healthcare.

Santhera - looking to outlicense rights in Europe and Asia to JP-1730/fipemazole for Parkinson’s diskinesia after licensing product in North America to Biovail in Aug 2009 and currently in phase II studies. (Link)

NEW Shionogi - Ospemifene is a selective estrogen receptor modulator (SERM) being developed for the treatment of postmenopausal vulvar and vaginal atrophy (VVA). Ospemifene offers a unique and substantial commercial opportunity as a new non-hormonal treatment for post-menopausal women, which can provide many of the benefits of long-term estrogen without the associated risks. Shionogi has licensed the worldwide rights for ospemifene from QuatRx Pharmaceuticals and is looking for ex-U.S. partners. Shionogi plans to submit an NDA in the US in 2Q 2012.

Soligenix - has partnered orBec/BDP with Sigma-Tau in the U.S. Looking to partner in ROW. Indication is GI manifestation of acute GVHD, thereby reducing the need for systemic immunosuppressive drugs to treat GI GVHD. (Link)

NEW Supernus - a neuroscience focused specialty pharmaceutical company with two filed NDA's in epilepsy, a Phase 2b program in IA in the setting of ADHD, and a Phase 2 program for the treatment of ADHD. Supernus is seeking ex-US partners for its two filed NDA's and US partners for its ADHD portfolio.

Transcept Pharmaceuticals - Looking for an ex U.S. partner for middle of night insomnia drug, Intermezzo. Transcept has formed a U.S. partnership with Purdue Pharma for Intermezzo.

$ Veroscience - Global rights to Cycloset that improves HBA1C and CV health through a CNS mechanism. Approved by the FDA and launched in the U.S. by Santarus. European deal is in the works.

$ Vivus - Looking to partner Onexa in Europe and other ROW territories. An approval is possible in the EMA with long-term market exclusivity in mid-2012 (or sooner).

Zogenix - Sumavel, a needlefree transdermal delivery of sumatriptan for migraine. Recent FDA approval with product launch using Astellas as a co-promotion partner. Company could consider an M&A transaction. Note: Raised $30mm from Cowen Healthcare Royalty Partners in July 2011.

RIGHTS IN LATIN AMERICA
Active Biotech - Successful Phase II study showed tasquinimod’s ability to impede disease progression in symptom-free patients with metastatic, castrate-resistant, prostate cancer. Drug works by attacking blood vessels. April, 2011 entered partnership to co-develop TASQ with Ipsen. Phase III trial was recently initiated and patient recruitment is ongoing. Rights are available in North America, South America and Japan. (Link)

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UPDATE Apricus Bio - has filed for market authorization to sell its erectile dysfunction drug, Vitaros®, in Latin America. Open to a commercial partnership deal. Expects approval in Europe in 2012 and is actively seeking commercial partners in Europe. Warner-Chilcott owns the U.S. marketing rights.

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BioDelivery Sciences - Has recently received approval for Onsolis in the U.S. and has a marketing partner in North America and the EU. Searching outside these regions.

Biocryst - In Phase 2 with Forodesine for CTCL. Data expected in Q4 2010. Trial underway in CLL. Partnered with Mundipharma for Europe, Asia, Australia and certain neighboring countries.

Cadence Pharmaceuticals - looking for Latin American partner for their IV acetaminophen product - OFIRMEV.

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Dong-A Pharmaceuticals - Looking to Canadian rights to a U.S. Phase 3 PDE V inhibitor that is on the market in Korea. Licensed in the U.S. to Warner-Chilcott. (Link)

Kissei - Owns rights to Silodosin for BPH outside of NA, EU and Japan. Approved in U.S. and Japan.

MAP Pharma - Would look at ex-U.S. partnerships for its late stage inhaled migraine drug, Levacap. NDA submitted in May 2011. In January 2011 the company entered into a promotional agreement with Allergan who will promote this product in the U.S. to headache specialists. MAP received $60 million upfront as part of the consideration for this agreement. MAP Pharma retains other physician markets in the U.S. and rights in all other geographies. (Link)
$ Neurogesx - Qutenza is a patch that delivers synthetic capsaicin for PHN on the market in U.S.. Recently approved. Partnered in the EU to Astellas in June 2009. Company looking for partnerships in Asia and Latin America. (Link)

UPDATE Novabay Pharmaceuticals - Aganocide compounds (broad spectrum antimicrobial activity) for a variety of topical applications like treatment of acne, decolonization of MRSA from the nares, and catheter-associated urinary tract infections. The drug candidate, NVC-422 is in clinical studies to treat chronically catheterized patients with high levels of bacteriuria, or bacteria in the bladder. Last year, the company established proof of concept in part A of a phase II trial of NVC-422, demonstrating 80% effectiveness in preventing urinary catheter blockage and encrustation. NovaBay Pharmaceuticals and Galderma SA tweaked a March development deal for skin condition drugs, defining terms and fees and providing for an additional tolerance study. (Link)

$ Optimer - has received approval to market Dificid for CDAD in the U.S. Is looking for a commercial partner for Latin America.

$ Pacira Pharmaceuticals - Looking to partner Exprarel, a long acting bipuvicaine, outside of the U.S. Interested parties should contact Darren Pincus at DarrenP@pacira.com.

PharmaNova - Gabapentin is a proprietary formulation of gabapentin being developed for hot flashes. In Phase 3 in U.S. (Link)

Santhera - Looking to outlicense rights in Europe and Asia to JP-1730/fipemazole for Parkinson’s diskinesia after licensing product in North America to Biovail in Aug 2009 and currently in phase II studies. Company reported revenues of 23mm CHF for 2009. (Link)

Soligenix - has partnered orBec/BDP with Sigma-Tau in the U.S. Looking to partner in ROW. Indication is GI manifestation of acute GVHD, thereby reducing the need for systemic immunosuppressive drugs to treat GI GVHD. (Link)

NEW Supernus - a neuroscience focused specialty pharmaceutical company with two filed NDA's in epilepsy, a Phase 2b program in IA in the setting of ADHD, and a Phase 2 program for the treatment of ADHD. Supernus is seeking ex-US partners for its two filed NDA's and US partners for its ADHD portfolio.

NEW Tillotts – looking for a marketing partner for Asacol for ulcerative colitis in the the CEE markets, Latin America and Asia ex-Japan and Korea.

Transccept Pharmaceuticals - Looking for an ex U.S. partner for middle of night insomnia drug, Intermezzo. Transccept has formed a U.S. partnership with Purdue Pharma for Intermezzo.

Vernalis - Frovatriptan rights for migraine available in Asia except South Korea. (Link)

RIGHTS IN MIDDLE EAST / AFRICA

Amylin - has purchased rights to Byetta® back from Eli Lilly. This GLP-1 inhibitor is expected to have $1 billion or more in revenues and has substantial ex-U.S. revenue. Amylin is searching for a commercialization partner outside of the United States.

NEW Aptalis – Amrix is a long acting muscle relaxant (cyclobenzaprine). This product is on the market in the U.S. but rights available in most other global territories.

NEW Aptalis – looking for a partner for Unisom, an OTC sleep aid that is sold by Sanofi in the U.S. Unisom contains diphenhydramine HCl (50 mg/dose) and acetaminophen.
UPDATE Auxilium - Exploring a partnership process for Xiaflex for Dupuytrens contracture. Injectable collagenase shows high efficacy. Recent partnership with Actelion in some international territories. Still looking in Middle East and Africa.

UPDATE Chelsea Therapeutics - NORHERA™ (droxidopa), is an orally active synthetic precursor of norepinephrine initially being developed for the treatment of neurogenic orthostatic hypotension. Potential in the Parkinson’s market where there has been a reported 60% reductions in falls in PD patients with NOH - also could work in fibromyalgia. On market already through Dainippon Pharma in four Asian countries. On March 28, 2012 Chelsea Therapeutics (CHTP) received a complete response letter (CRL) from the Food and Drug Administration (FDA) for Northera. In the CRL the FDA asked Chelsea to conduct another study which can demonstrate the drug continues to work for patients over a two to three month period. Open to ex-US partnerships.

Kissei - Owns rights to Silodosin for BPH outside of NA, EU and Japan. Approved in U.S. and Japan.

MAP Pharma - Would look at ex-U.S. partnerships for its late stage inhaled migraine drug, Levadex. NDA submitted in May 2011. In January 2011 the company entered into a promotional agreement with Allergan who will promote this product in the U.S. to headache specialists. MAP received $60 million upfront as part of the consideration for this agreement. MAP Pharma retains other physician markets in the U.S. and rights in all other geographies. (Link)

PharmaNova - Gabapentin is a proprietary formulation of gabapentin being developed for hot flashes. In Phase 3 in U.S.

Pacira Pharmaceuticals - Looking to partner Expraral, a long acting bipuvicaine, outside of the U.S. Interested parties should contact Darren Pincus at DarrenP@pacira.com.

Supernus - a neuroscience focused specialty pharmaceutical company with two filed NDA's in epilepsy, a Phase 2b program in IA in the setting of ADHD, and a Phase 2 program for the treatment of ADHD. Supernus is seeking ex-US partners for its two filed NDA’s and US partners for its ADHD portfolio.

Transcept Pharmaceuticals - Looking for an ex U.S. partner for middle of night insomnia drug, Intermezzo. Transcept has formed a U.S. partnership with Purdue Pharma for Intermezzo.

Vernalis - Frovatriptan rights for migraine available in South America. (Link)

Veroscience - Global rights to Cycloset that improves HBA1C and CV health through a CNS mechanism. Approved by the FDA and ready for launch in March 2010. Active discussions underway on a commercialization deal.

Zogenix - Sumavel, a needlefree transdermal delivery of sumatriptan for migraine. Recent FDA approval with product launch using Astellas as a co-promotion partner. Company could consider an M&A transaction. Note: Raised $30mm from Cowen Healthcare Royalty Partners in July 2011.

ROYALTIES

Avanir - Would sell Abreva royalties. Docosanol 10% cream is marketed in North America under the band name Abreva by our marketing partner, GlaxoSmithKline.

Entremed - Has announced that will sell a royalty on Thalomid. (Link)

Enzon - may be open to monetizing remaining PEG-INTRON royalties. Revenues have been declining.

Mountain View Pharmaceuticals - Would consider sale of royalties on Savient’s Puricase.
Undisclosed - Torreya Partners is handling a sale of royalties on three marketed products. Interested parties should contact Biliana.rajevic@torreyapartners.com. This transaction was completed in Dec 2012. A specialty finance player lent $65mm against the portfolio of royalties.

SMOKING CESSATION / SAFE CIGARETTES

22nd Century Limited - developing a very low nicotine cigarette. Showed substantially higher quit rates in a Phase 2 trial than nicotine lozenges The Company is conducting a Phase II-B trial in 2011 and plans to conduct two larger and concurrent Phase III trials in 2012. The FDA-approval process for its X-22 smoking cessation aid is expected to be completed by 22nd Century and upon such approval launch X-22 in the U.S. market in early 2013 (as a prescription), and in other top smoking cessation markets thereafter. (Link)

Acrux - developing a transdermal nicotine replacement therapy.

UPDATE Aradigm - (ARD-1600) an inhaled nicotine product. Product replicates PK of a cigarette and faces positive prospects as either an OTC product or an Rx product. Can be introduced to the market immediately due to recent legal developments in the e-cigarette area in the U.S.

Beech Tree Labs - in Phase 1 for a centrolling acting drug candidate that reduces cravings associated with nicotine and other addictive substances. (Link)

Cary Pharma - Looking to carry out a Phase 2 trial of QuitPak® for smoking cessation. Open to a partnership deal. (Link)

Cypress Bio - Cypress was recently purchased by Ramius and Royalty Pharma. The key value was in the company’s Savella® royalty. However, Cypress has the rights to Stacatto® Nicotine which could be repartnered. Planning a Phase 1 trial in late 2011. (Link)

Embera NeuroTherapeutics is developing EMB-001 which is designed to reduce craving for addictive substances. The product is a combination of oxazepam and metyrapone. In Phase 1 studies. Shown to be more effective in reducing craving than Chantix® in animal studies.

NEW Extab Pharma – developing Tabex®, a pharma grade Cytisine for the treatment of nicotine-addiction in the U.S. market. First marketed in 1980 in Bulgaria, Tabex is now available in many countries in Central and Eastern Europe, where over 8 million people have been treated. An extensive literature documents the efficacy of this approach. (Link)

COMPLETED Ploom - Technology that heats tobacco but does not burn it. Delivers flavor in vapor but not nicotine and other particulates associated with burning of tobacco. Note: Ploom licensed the ex-U.S. rights to their product to Japan Tobacco in late 2011. (Link)

SPECIALTY PHARMA - MARKETED PRODUCTS

COMPLETED Allos Therapeutics –Oncology marketer with Folotyn® for liquid tumors. After a recently failed merger attempt with AMAG, Allos is rumored to be continuing to explore strategic alternatives with the assistance of JP Morgan. Update: Apr 5, 2012 – Spectrum to by Allos in a deal valued at $206 million. (Link)

$ AMAG - Feraheme IV iron product - Recently approved. Company is commercializing on its own. AMAG’s recent merger attempt with Allos was ended in November 2011. On Nov 17, 2011, AMAG announced that it had hired Jefferies to explore all opportunities to enhance shareholder value. Frank Thomas, interim CEO of AMAG indicated: “We will expeditiously complete this process, which will include a parallel review of a potential sale of the company and other strategic merger and acquisition transactions.”
Amoun Pharmaceutical - An Egyptian company that manufactures off-patent branded generic formulations. It is one of the largest pharmaceutical companies in Egypt. It sells over 135 human products in over 275 forms. Of these products, 33 occupy the top 2 positions in their respective therapeutic categories and subcategories. Open to a company sale or strategic stake purchase. Reuters - Dec 6, 2010: “CVCI is also preparing to sell Amoun, one of Egypt's biggest drugmakers, people familiar with the matter told Reuters on Oct. 20. It owns Amoun with two other co-investors.” Bloomberg reported in Feb 2011 that the company has been looking for $1 billion in a sale price but that political upheaval in Egypt has hindered the sale.

NEW Amylin – marketer of Byetta® and Bydureon® for the treatment of diabetes has reportedly received an offer from Bristol-Myers Squibb and, according to Bloomberg in mid-April 2012 has hired a financial advisor to help find a buyer. Separately, Amylin is interested in finding a partner outside of the U.S. to distribute its products.

UPDATE Aradigm - (ARD-1600) completed a phase 1 inhaled nicotine program. Product replicates PK of a cigarette and faces positive prospects as either an OTC product or an Rx product. Can be introduced to the market immediately.

$ Avanir - Launched Neudexta for the treatment of pseudobulbar effect and, potentially, other indications. Positive data and good patent picture. Widely rumored to be an M&A candidate. $5.7 million in revenue in first year of launch (soft numbers). Market cap of $248 million as of November 2011. EMA application recently accepted.

NEW Bacterin labs – substantial commercial traction of orthopedic product line. (Link)

Biofarma - Biofarma for sale via JP Morgan. Reuters (12/6/2010): Citigroup’s (C.N) venture capital arm and two co-investors have begun an auction of Turkish copycat drugmaker Biofarma, three people familiar with the matter said, in what could be Turkey's biggest healthcare deal.” Update: A number of parties rumored to have looked at this asset but price ask was seen as prohibitive.

$ Canyon Pharmaceuticals - Canyon Pharmaceuticals is seeking to build a strategic alliance preferentially on a worldwide basis to commercialize Desirudin (Iprivas® US-registration / Revasc® EU-registration), a differentiated anticoagulant drug which is approved by the FDA, the EMA and several of the rest of world authorities. Desirudin is a direct thrombin inhibitor and the only subcutaneous direct thrombin inhibitor (DTI) with approval for venous thromboembolism (VTE) prophylaxis following hip- and knee-replacement surgery.

UPDATE $ CNS Therapeutics - has introduced Gablofen, an AP rated intrathecal version of baclofen for control of severe spasticity among patients with movement disorders. This product has significant advantages over the existing marketed product and is likely to have significant revenue traction over the next several years. This product is promoted and the company is a suitable acquisition candidate for either a branded or generic company. Rumored to be in active sale discussions. (Link)

UPDATE Covidien Pharmaceuticals - According to the New York Times on June 7, 2011 “Covidien, the health care company spun out from Tyco four years ago, may seek to sell its pharmaceutical unit...” This division of Covidien (formerly Mallinckrodt) has a major business selling pain products (both branded and generics) and imaging products. Revenues are around $2 billion. Update: As of April 2012 no sale has taken place. Company is rumored to be interested in a sale of the whole business (rather than pieces) for a full price and is now thought to be more likely to be spun out. YE 2011 numbers reported on Nov 15, 2011 and were robust (sales up 9% yoy) with strong performance in generics.

Dusa Pharma –Main tool is PDT coupled with derm drugs. Revenues around $30mm. (Link)

COMPLETED $ Ista – Strength in ophthalmologic and respiratory disease products. Company received an acquisition offer from Valeant and was ultimately acquired by Bausch and Lomb in March 2012.
$ Lipose - Viafill fat transfer system on the market with applications in aesthetics where traditional volumizers are not well suited - particularly for the face and breasts. Company assisted by Torreya Partners. Update: This company was sold to an aesthetic dermatology player in March 2012.

$ Pacira Pharmaceuticals - Looking to partner Exprarel, a long acting bipuvicaine, outside of the U.S. Interested parties should contact Darren Pincus at DarrenP@pacira.com.

UPDATE Riemser - German vertically integrated marketer of generic and branded pharma products with strength in cardiovascular, dental and veterinary medicines. Revenues of this company exceed €100mm and EBITDA around €30mm. Active sale process underway according to Biopharm Insight.

UPDATE Rottapharm - for sale according to the Wall Street Journal. Company has two Phase 3 drugs in development and a strong group of branded products in the market. Revenues over $850 million. Sale price could be over $2.5 billion. Company rumored to be using Credit Suisse to find a buyer. According to Bloomberg (3/15/2012) Mylan recently pulled out of a sale process. The article noted that “sources said the selling family has not been able to agree to give up control of the company and was not prepared to compromise enough on price either.”

San Raffaele del Monte Tabor- privately-held Italian pharmaceutical company, is soliciting offers other than the EUR 350m binding offer from Vatican bank IOR and Italian entrepreneur Vittoria Malacalza, according to Il Sole 24 on Dec 2, 2011.

Savient Pharmaceuticals - FDA approved KRYSTEXXA (pegloticase) in Sep 2010, a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Company is seeking a commercial buyer and is using JP Morgan in its search for an acquisition partner. Savient is now pursuing a launch of Krystexxa on its own and is building a 50-person plus sales force. Update: First year sales were $2.6 million. Market Cap of $160mm. (Link)

Sigma-Tau - Reuters (6/2/11): “Italy’s Sigma-Tau is eyeing the sale of up to 49 percent in the family-owned drugmaker to private equity, ahead of a possible IPO that could value it at more than $2 billion, people familiar with the situation said.” Company has approximately €1bn revenue with a strong rare disease business and a well established European brand business. It is believed that discussions regarding a stake sale are no longer active but rather the company is focused on restructuring its Italian business.

$ Suneva Medical - Marketing Artefill, a long-acting dermal filler with impressive revenue growth. Open to a partnership or even a company sale. (Link)

COMPLETED $ Undisclosed player - process well underway for sale of company with a marketed but not promoted cardiovascular product with 2011 revenues around $9 million. Note: Santarus acquired rights to Fenoglide from Shore Therapeutics in Dec 2011 for $11mm plus royalties.

COMPLETED Undisclosed Player - U.S. generic company with more than $100 million in revenues is for sale. Company has a significant branded business and a manufacturing facility. Note: Takeda acquired URL Pharma’s generic and branded businesses on April 11, 2012 for $800mm plus contingent payments. The revenues of URL were approximately $550mm.

NEW $ Undisclosed – Pan-European marketer of hospital pharmaceuticals is exploring strategic alternatives. The company has revenues of approximately $20mm. Interested parties should contact rodolphe.grepinet@torreyapartners.com.

NEW $ Undisclosed – U.S. specialty pharmaceutical company has high growth with revenues over $125mm and around 150 sales reps. Focused on a narrow physician population and looking for a strategic acquirer.

NEW $ Undisclosed player – US hospital / critical care specialty pharmaceutical company is seeking a buyer.
Undisclosed player – US and European player in oncology and hospital products with revenue over $100mm is open to a change of control transaction. Note: EUSA Pharma was acquired by Jazz Pharma for approximately $700mm in April 2012.

Undisclosed player - selling off $20mm revenue+ commercial product for narrow market with pediatric applications.

Undisclosed player - selling off portfolio of $50mm area specialty pharma products with some pediatric products included.

$ Undisclosed player – approved hospital anesthetic in the United States with differentiation from existing products. Also could be used in physician office setting where sedation required. Open to a product sale or other value creating arrangement. Global rights available.

Undisclosed player - open to a merger or sale of $35mm revenue company with commercial presence in the U.S. pain market. Torreya Partners advising.

Undisclosed player - dermatology company with more than $40mm in revenue has hired a financial advisor to restructure its debt that likely exceeds intrinsic value of assets. Process has been underway for a month or two.

$ Undisclosed player - availability of product with psych and primary call point. $12mm product sales run rate.

$ Undisclosed - Pharma company with a product for heart failure and revenues over $20mm would consider a sale.

Undisclosed - U.S. rights to a marketed drug for depression are available.

NEW Warner-Chilcott – According to Bloomberg in April 2012, Warner-Chilcott has retained Goldman Sachs to consider potential strategic approaches.

Zogenix - Needlefree transdermal delivery of sumatriptan for migraine. Has 80 sales reps. Recent FDA approval with upcoming product launch using Astellas as a co-promotion partner. Update: company filed for an IPO in Sep 2010 - had $7mm in revenues in first half of 2010 with a substantial operating loss.

STEM CELLS, RNAI AND CELL THERAPY

Aldagen - ALD-401 is a type of adult stem cells called aldehyde dehydrogenase-bright (ALDHbr) stem cells isolated from cord blood. ALD-401 is being developed for the post acute treatment of ischemic stroke and is in a Phase 2 study.

Calando Pharmaceuticals - Has a promising nanotechnology approach for delivery of RNAi. Looking for a company sale. (Link)

Cardio3 - Developing a stem cell transplant method to address CHF after MI using cardiopoietic cells. (Link) Cardio3 BioSciences SA signs a co-development agreement with Artelis SA for the industrialization of the manufacturing process of C-Cure and inaugurate its NEW premises in Mont-Saint-Guibert. (Link)

Cellerant - Developing a novel, cell-based medicine (Myceloid Progenitors / CLT-008) as a treatment for chemotherapy- and radiation-induced neutropenia as well as for Acute Radiation Syndrome. Update: Sep 1, 2010: received a substantial BARDA grant. On March 22, 2011, Cellerant Therapeutics initiates a Phase I/II clinical trial of CLT-008 for Chemotherapy induced neutropenia in acute Leukemia patients.

UPDATE Geron - has ceased development of its embryonic stem cell development program and is open to partnering this program to a third party. On Jan 11, 2012 Geron reported that it had hired Stifel Nicolas to sell it stem cell business so that it can focus on its cancer programs.
**NEW** Gliamed - has initiated IND-enabling studies of GM1485 for wound healing, including laser skin resurfacing and oral mucositis, and is evaluating strategies for follow-on studies, including treatment of androgenetic alopecia, actinic keratosis and diabetic foot ulcer. ([Link](#))

HAC Biomed - a cell therapy company has very promising data for a treatment for the repair of damaged liver tissue. Commercial stage in Germany. Assisted by Torreya Partners. Interested parties should contact [tom.bird@torreyapartners.com](mailto:tom.bird@torreyapartners.com).

Innovacell - Positive Phase IIb data for ICES13, a personalised cell therapy for SUI. The primary endpoint met on the trial was a reduction in incontinence episode frequency across 32 centres in four EU countries. ([Link](#))

Ipiereian - Working on reprogramming of pluripotent stem cells for various therapeutic applications. ([Link](#))

Kiadis Pharma - **Reviroc** is being developed as a treatment that eliminates blood cancer cells from autologous transplants for patients with end stage blood cancer. Granted orphan by FDA which is in Phase 3. ([Link](#))

MaxCyte - transfection cell platform with ability to program cells to attack a variety of major diseases.

Medi-Post - CARTISTEM® has been developed to treat damaged articular cartilage on knee as a result of acute traumatic injury or more chronic conditions such as osteoarthritis. Phase 3 clinical trial has shown efficacy in cartilage regeneration. KFDA approval pending. U.S. IND filing in process. ([Link](#))

**NEW** Miragen – developing innovative microRNA modulators as is Regulus. Very large preclinical deal in 2011 for ex US rights to a CHF program with Servier. US rights to program where dramatic efficacy is possible. This program has substantial IP protection and additional applications.

Oxford Biomedica - In a Phase I/II trial of ProSavin for the treatment of Parkinson's disease (PD). This gene therapy has been associated with improvements in patient symptoms. ([Link](#))

**NEW** Parcells Labs – Generating revenue from cells that repair cartilage and bone. Very promising technology and company.

**COMPLETED** Pervasis - In a POC P1b trial to study PVS-10200 to prevent restenosis in patients with peripheral arterial disease (PAD) who undergo an angioplasty and stent procedure in the superficial femoral artery. Very promising indication. Actively exploring options. Update: This company was acquired by Shire for “single digit millions” upfront plus milestones and royalties that are worth up to $200mm.

Quintessence Biosciences - RNA degrading **Ribonucleases** being developed for oncology applications.

**NEW** REGENX BioSciences is developing a therapy for familial hypercholesterolemia. The program uses NAV rAAV8 vectors that express a normal human low-density lipoprotein receptor gene. In a study, the use of the NAV rAAV8-mediated gene program to deliver hLDLR lowered LDL-C in a mouse model.

Santaris Pharma - Phase 2a data of miravirsen, a microRNA-targeted drug, shows dose-dependent, prolonged viral reduction of 2-3 logs HCV RNA after four-week treatment in Hepatitis C patients. ([Link](#))

Silence Therapeutics - Disclosed on Sep 6th 2010 that it had received an approach that could lead to an offer. Company is a leader in RNAi delivery and associated therapeutics. Silence has retained a financial advisor and is pursuing its duties as a UK listed company to maximize shareholder value. Dec 21, 2010: “Further to the announcement dated 6th September 2010, Silence confirms that it remains in an offer period. The Company continues to explore a variety of strategic opportunities.” Feb 7, 2011: The Board of Silence received a number of indicative proposals but it is the view of the Board that none of these were sufficiently compelling to pursue further in the context of the continued success of the Company. The Board has therefore terminated these
discussions to allow management to focus all of its efforts on the ongoing business for the purpose of creating long-term shareholder value."

Stemcells - HuCNS-SC is well-characterized, normal human CNS stem cells (HuCNS-SC) from brain tissue, isolated and purified using monoclonal antibodies against cell surface antigens. HuCNS-SC is being developed as intracerebral injection for the treatment of myelin disorders such as Pelizaeus-Merzbacher Disease. Phase 1 data upcoming in 2012. (Link)

Sylentis - focused on topical RNAi therapy with a Phase 1 trial of a therapy for glaucoma and dry eye.

Tengion - Leading regenerative medicine company open to partnership deals for the development of both an artificial bladder and an artificial kidney. Tengion has recently gone through a leadership transition and plans an FDA meeting to discuss the kidney program before the end of 2011. (Link)

UROLOGY AND MEN’S HEALTH

**NEW** Acino – Has a fully registratrable leuprorelin implant system. (Link)

Afferent Pharmaceuticals –Developing P2X3 receptor antagonist for OAB. Supportive preclinical data. (Link)

Ampio - Zertane is a 5-Hydroxytryptamine Inhibitor (5-HT) and mu-opioid receptor agonist (low dose tramadol). Zertane is being developed as fast dissolving oral tablets for the treatment of premature ejaculation in men. Very strong Phase 3 data reported in a recent trial in the prevention of premature ejaculation. (Link)

**UPDATE** Apricus Bio - has filed for market authorization to sell its erectile dysfunction drug, Vitaros®, in Latin America. Open to a commercial partnership deal. Expects approval in Europe in 2012 and is actively seeking commercial partners in Europe. Warner-Chilcott owns the U.S. marketing rights.

Aptys - looking to outlicense transdermal surfactant-free testosterone gel. Phase 3 ready.

**NEW** Altherx - Solabegron, is a highly selective and potent beta3-adrenoceptor agonist in development for the reduction of symptoms of Overactive Bladder and Irritable Bowel Syndrome. Program has a a good look.(Link)

Camurus - Prosenze® Depot (CAM2032) is a ready-to-use LHRH agonist depot designed for easy and painless subcutaneous administration being developed for treatment of prostate cancer and endometriosis. The product has shown positive Phase 2a data.

Celek Pharmaceuticals - CEL-031, is a Phase 2 drug in development for the treatment of non-muscle invasive bladder cancer. Works by inducing tumor cell apoptosis and inhibiting cell proliferation. (Link)

Clarus Therapeutics - OriTex, a proprietary oral testosterone product being developed in Phase 2 for use in men with low testosterone levels.

Conjugon - **(C-1205)** in Phase 1b studies for *e. coli* donor technology to prevent UTI’s in men with a urinary catheter. (Link)

**NEW** Dong-A - DA-8031 is a monoamine transporter that is in Phase 1 studies for the prevention of premature ejaculation in man. Strong animal data. (Link)

GP Pharm - developing long-acting injectibles in the oncology area. Looking for licensors for Leuprorelin 1 month, Leuprorelin 3 months, Triptorelin 1 month, Triptorelin 3 months, Gosorelin 3 months, Octreotide LAR and Octretide MAR. Also has developed desmopressin drops.
Innovacell - Positive Phase IIb data for ICES13, a personalised cell therapy for SUI. The primary endpoint met on the trial was a reduction in incontinence episode frequency across 32 centres in four EU countries.

Intelgenx - INTO007 found to be bioequivalent to a leading branded tablet containing a phosphodiesterase type 5 (PDE-5) inhibitor for the treatment of erectile dysfunction. INTO007 has been developed using IntelGenx' proprietary immediate release "VersaFilm" drug delivery technology. Market ready in 2012 as a 505(b)2. (Link)

Japan Tobacco - TRPV1 antagonist in Phase 1 development. Rights available. (Link)

King's College - Reversible, non-hormonal, oral delivery approach to male contraception. Preclinical. (Link)

Medicnova - MN-246 is a novel, orally bioavailable β3-adrenergic receptor agonist under development for the treatment of urinary incontinence. MN-246 represents a new approach to treating urinary incontinence and may have advantages over existing therapies, including improvements in efficacy through increases in bladder volume with decreases in involuntary bladder contractions and the absence of anti-cholinergic effects such as dry mouth. Has successfully completed a Phase 1 trial. (Link)

Merlion - Developing finafloxacin, a best in class 4th generation fluoroquinolone being targeted against severe, life-threatening infections. Compound has successfully progressed through to mid-stage clinical development. Oral formulation demonstrated in PoC studies compelling efficacy in uncomplicated UTI and the eradication of Helicobacter pylori. IV formulation currently completing Phase I trials and Phase II studies in complicated UTI are planned for late 2011, as are clinical protocols in complicated respiratory tract infections. (Link)

Merrion Pharma - Acyline is an oral GnRH antagonist for treatment of prostate cancer. Today’s products are injectible. (Link)

Novabay Pharmaceuticals - Aganocide compounds (broad spectrum antimicrobial activity) for a variety of topical applications like treatment of acne, decolonization of MRSA from the nares, and catheter-associated urinary tract infections. The drug candidate, NVC-422 is in clinical studies to treat chronically catheterized patients with high levels of bacteriuria, or bacteria in the bladder. Last year, the company established proof of concept in part A of a phase II trial of NVC-422, demonstrating 80% effectiveness in preventing urinary catheter blockage and encrustation. NovaBay Pharmaceuticals and Galderma SA tweaked a March development deal for skin condition drugs, defining terms and fees and providing for an additional tolerance study. (Link)

Novadel - Developing Duromist (a lingual mist version of sildenafil) for introduction to the market after the Viagra® patent expiration in 2012. Can complete pivotal 505b(2) trial when needed. Recently filed an IND to start studies.

OxThera - Oxazyme is recombinantate oxalate degrading enzyme for the treatment of kidney stones. No data reported from a pending study in some time. A related compound is at Althea Technologies. (Link)

Palatin Technologies - Bremelanotide is a melanocortin agonist that has shown positive results in four Phase 2 efficacy for erectile dysfunction studies enrolling more than 1,300 men. Was partnered with King and after a formulation change is intended for further Phase 2/3 studies in the next several years. Also showed positive results in a Phase 2a pilot study for female sexual dysfunction (FSD). Company announced commencement of enrollment in a Phase 2b study for FSD on June 28, 2011. (Link)

Pierre Fabre - Outlicensing North American rights to Javlor (vinflunine) - a newly approved bi-fluorinated MTI (Microtubule inhibitor) for bladder cancer. Licensing process is making substantial progress. (Link)

Protox Therapeutics - PRX302 has completed a promising open-label Phase 2a study in BPH. Topline data pending on Phase 2b study in Q1 2010 and were quite positive. Warburg Pincus recently made a $35 million investment which will facilitate registrational trials for this drug. Rights to this drug in Japan were licensed to Kissei. (Link)
Quatrx - **Fispemifene** similar to GTX. Would partner this drug. ([Link](#)) Fispemifene has completed two Phase I clinical studies in Europe and one Phase II clinical study in the US.

Stellar Pharma - has retained U.S. rights to Uracyst® from Watson. This is an investigational drug/device combination for the treatment of interstitial cystitis. Watson indicated that the product did not meet its endpoint in a double-blinded placebo controlled study. There may be an opportunity to redefine the patient population in a further study with this drug and still achieve approval in the U.S. Note: On June 8, 2011, Stellar announced that it had retained an advisor for its U.S. market products.

Taris Biomedical - Has completed a Phase 1 study showing the ability of an intravesical delivery system to get drug to the bladder for the treatment of interstitial cystitis. Raised $18mm in April 2011. Recently started enrollment of a Phase 2 trial. ([Link](#))

Telormedix - Developing a promising TLR9 modulator that is in a Phase 1 / 2 trial for the treatment of bladder cancer. ([Link](#))

Tengion - Leading regenerative medicine company open to partnership deals for the development of both an artificial bladder and an artificial kidney. Tengion has recently gone through a leadership transition. ([Link](#))

Theravida - Combination of oxybutynin and an agonist to improve tolerability and efficacy of oxybutynin for treatment of overactive bladder (OAB). Will report out Phase 2b data in 2012.

Toray Industries - TRK-130 provides new mechanism of action which relates to CNS, and controls lower urinary tract function. Indicated for OAB. Phase Ila study has been completed and efficacy has been confirmed.

Urigen - In Phase 2 with URG101 for the treatment of acute flares of Interstitial Cystitis (IC/BPS). ([Link](#))

NEW Urogene – Besipirdene is a potential novel first-in-class oral treatment for OAB currently in Phase 2 development, with a mechanism of action clearly different from that of antimuscarinics. ([Link](#))

Vantia - Positive Phase 2a data with VA106483, a vasopressin agonist, for treatment of nocturia, excessive trips to urinate at night. Likely to be effective based on mechanism. VA106483 is currently being investigated as a new treatment for nocturia in a 30 patient trial to find the dose in older men with BPH. Data from this trial are expected shortly. Recently raised $6mm. ([Link](#))

UPDATE Vivus - Would be interested in partnering avanafil, a PDE V inhibitor in development for erectile dysfunction. Recently reported out second Phase 3 program also with strong data. This product was approved in April 2012. Cowen predicts this drug will take 8% market share with $800mm in U.S. revenue. ([Link](#))

### VACCINES

Agenus - Adjuvant QS-21 has consistently stimulated strong cell-mediated and humoral immune responses when combined with a variety of vaccine antigens. Approximately 15 product candidates utilizing QS-21 are currently in clinical development by Agenus’ commercial licensees and collaborators.

Archivel Farma S.L - running a double-blind, randomized, placebo-controlled phase II clinical trial to investigate the safety, tolerability, and immunogenicity of the novel antituberculous vaccine RUTI following one month of isoniazid treatment in subjects with latent tuberculosis infection.

NEW Bavarian Nordic - Seeking external funding to perform clinical development in broader partnership for our tropical vaccines against dengue fever & Japanese encephalitis. These products are pre-clinical.
BioDiem - Working on a cell-based influenza vaccine. In Phase 2 studies. Open to a global partnership deal. Also working on an intranasal Live Attenuated Influenza Vaccine (LAIV). The LAIV is now on market in India and has been licensed for other emerging markets to Merck/WHO. (Link)

BTG - Angiotensin Therapeutic Vaccine (ATV) for high blood pressure. This therapeutic vaccine (biologic) is in early Phase II clinical development. Large potential market as alternative approach to blood pressure management. (Link)

BTG - CoVaccine HT. This is a proprietary vaccine adjuvant platform that generates very powerful antibody responses. It has been used in a number of studies and diseases by groups around the world with impressive performance data available.

CureVac - upregulates mRNA to create specific autoantigen responses to disease. Has recently shown a nice proof of principle in man for a therapeutic vaccine aimed at prostate cancer in a Phase 1b study.

Cytos - looking to partner CYT003 for allergic rhinoconjunctivitis. Vaccine has finished Phase 2b studies. Asthma symptoms decreased by 33% under QbG10 treatment despite corticosteroid withdrawal, while they increased by 29% under placebo treatment (p=0.01). Use of relief medication doubled in the placebo group, while it remained stable in the QbG10 group (p=0.01). Update: Company has been exploring strategic options with aid of a financial advisor. Recent attempt to restructure bonds has not succeeded. (Link)

Cytos - In preclinical development with Qb-Flu. This is a bacterially produced subunit vaccine composed of the globular domain of the Influenza A hemagglutinin surface protein conjugated to Cytos’ virus-like particle Qb. Has shown strong antibody titres achieved with this vaccine. What is important is that this approach avoids the manufacturing issues associated with both cell culture and egg-based flu vaccines. (Link)

Dynavax - HEPLISAV is an investigational adult hepatitis B vaccine. In Phase 3 trials, HEPLISAV demonstrated higher and earlier protection with fewer doses than currently licensed vaccines. Dynavax has worldwide commercial rights to HEPLISAV. HEPLISAV combines hepatitis B surface antigen with a proprietary Toll-like Receptor 9 agonist to enhance the immune response. In two Phase 3 trials, HEPLISAV demonstrated increased, rapid protection with fewer doses than current licensed vaccines. Positive data reported on July 20, 2011 and BLA submitted on April 26, 2012. European MAA submission upcoming (Link)

Eurocine Vaccines - Immunose™ FLU is a nasal inactivated influenza vaccine adjuvanted with Endocine™. The vaccine has been tested in a phase I/II study where it showed good safety results and an immunological response. (Link)

GlycoVaxyn - Strong Phase 1 data for a novel vaccine for Shigella. Open to partnering. (Link)

Inovio - Looking for partnerships based upon its Syncon vaccine platform. Syncon facilitates better vaccines that address changing strains of diseases, including HIV, HCV, HPV, and influenza. Planning to complete a Phase 1 for a universal flu vaccine in 2011. Has shown positive results in recent HIV vaccine Phase 1 study. Starting a Phase 2 study in 2011 in cervical cancer. (Link) (noncon)

InterCell - rumored takeover candidate. Strong Japanese encephalitis vaccine marketed by Novartis and CSL.

Inviragen - DENVax, a promising clinical development candidate for dengue fever and other tropical diseases. Phase 2 data coming up for this candidate which has a substantial commercial market. Interested parties should contact Wilder Fulford of Torreya Partners (wilder.fulford@torreyapartners.com). (Link)

JN International Medical - NmVac4-A/C/Y/W-135 is a lyophilized preparation of purified polysaccharides from Neisseria meningitidis (meningococcus) of groups A, C, W135 and Y. Highly effective in a recent Phase 3 trial. (Link)
LigoCyte - has a Phase 2 vaccine is designed to treat norovirus, the leading worldwide cause of infectious gastroenteritis, or inflammation of the stomach and intestines. Positive Phase 1b data. The company is exploring strategic alternatives with assistance from Montgomery Marhsall (now Sagent). As of Dec 2011, no transaction had taken place.

Okairos - Hepatitis C vaccine in development has shown T-cell response in Phase 1. (Link) A second Phase I study is going to be started soon, in order to evaluate an alternative heterologous prime-boost regimen based on the AdCh3, for the priming, and a Modified Vaccinia Ankara vector encoding NSmut, for the boosting (HCV003).

Update: Company completed a 16mm EUR financing in Sep 2010 led by Versant Ventures.

Pevion Biotech AG - In Nov 2010 reported positive preliminary results from a Phase I study of PEV7, the first vaccine against recurrent vulvovaginal candidiasis (RVVC). Also known as chronic recurrent thrush. Occurs in 3 to 6% of women. (Link)

Protein Sciences - Has FluBlok for treatment of influenza. Pending BLA with an approval likely. Company is exploring an IPO.

Vaxart – highly promising oral vaccine technology with data expected in Q3 2012 in flu. (Link)

VaxInnate - Developing Universal flu vaccines. Strong Phase 2 data. Company is open to a strategic transaction.

Virionics - VLPs for HPV and HCV. Therapy and diagnostics story. MediGene holds exclusive marketing rights to CVLP products in Germany and co-exclusive marketing rights for the rest of Europe. (Link)

Xiamen Innovax Biotech - Has developed a Hepatitis E vaccine that has recently been shown to be completely effective in the prevention of Hepatitis E in a 110,000 patient clinical trial. Approximately 30% of the world’s population has Hepatitis E. Xiamen open to licensing rights to this product outside of China. (Link)

VIROLOGY

Achillion - ACH-1625, a Phase 2 pan-genotypic protease inhibitor, has shown strong activity against HCV genotype 1 and 3. On Apr 23 a Phase Ia trial of ACH-1625 treat chronic HCV genotype 1 infection showed that 100%, 94% and 100% of patients receiving once-daily 200, 400 and 800 mg oral ACH-1625 in combination with peginterferon alfa-2a and ribavirin, respectively, achieved a complete early virologic response (cEVR) at week 12. The shares fell on these data. The company is going into Phase 1 ACH-3102, a second generation NS5A inhibitor. The company’s CEO Michael Kischbach indicated that they are in “advanced discussions” with potential partners and acquirors.

Adamas Pharmaceuticals - Pursuing Triple Combination Therapy for Influenza (ADS-8902). Adamas Pharmaceuticals, Inc., a privately held company, announced today that it has expanded its Phase 2 clinical study of a proprietary investigational triple-combination antiviral drug therapy for influenza to include centers in the United States, Canada and Europe. (Link)

Aicuris - Good Phase 2b data in treatment of human CMV. Looking to outlicense this compound. Recently granted orphan designation by COMP of the EMA. The recent phase 2b data presented “show important results indicating that Letermovir (AIC246) apart from meeting both primary endpoints for efficacy showed also a very good safety profile an thus will allow for a paradigm shift in treating patients at risk for developing HCMV infection or diseases,” according to Helga Rübsamen-Schaeff, CEO of AiCuris. (Link)
Aicurus - Phase 2 data for AIC-316, herpes simplex product. Looking to partner global rights before running Phase 3 trial. Large market with data to be released in early 2011.

Agenus - AG-707 is an investigational vaccine consisting of recombinant human heat shock protein-70 complexed with 32 distinct synthetic antigens from the HSV-2 proteome. Has finished Phase 1 studies.

Avexa - In Phase 3 for apricitabine with positive data, a next generation NRTI for HIV (origin Biochem Pharma / Shire). Announced on July 6, 2011 that it had retained Pharma Ventures to assist in outlicensing this compound.

**COMPLETED** Avila Therapeutics - Developing AVL-181 which silences proteins. Works as a pan-genotype protease inhibitor for Hepatitis C with promising pre-clinical data. Update: Nov 29, 2010 - Avila publishes further work in Nature showing increased selectivity, potency and duration of action of this NS3 inhibitor. Note: Celgene acquired Avila in January 2012 for $350mm plus $575 in additional potential milestones. ([Link](#))

Avir Green Hills Biotechnology - deltaFLU is a live attenuated influenza virus with an optimal balance between attenuation and immunogenicity. Produced in CHO cells. deltaFLU is applied intranasally with a spray device. Positive Phase 1 data. ([Link](#))

Beech Tree Labs - In Phase 2 for an agent to treat herpes simplex. The agent BTL-TML-HSV is a broad antiviral and inhibits viral reassembly after infection and viral uncoating. Update: company recently completed a financing which will facilitate completion of the clinical trial. ([Link](#))

**UPDATE** BioAlliance Pharma - Looking to partner Sitavir (acyclovir Lauriad) for herpes labialis. ([Link](#)) positive results in a pivotal phase III clinical study in immunocompetent patients with recurrent herpes labialis (LIP Study) treated with acyclovir Lauriad. Filing for approval. ([Link](#))

$ BioAlliance Pharma - searching for a U.S. Partner for Oravig. Oravig is miconazole buccal tablets for the treatment of oropharyngeal candidiasis (OPC), more commonly known as thrush, in adults and children age 16 and older. This drug was returned by Strativa Pharmaceuticals recently to BioAlliance.

BioCryst Pharma - developing peramivir, a Phase 3 IV antiviral treatment for influenza. Has substantial promise. ([Link](#))

BioDiem - Working on a cell-based influenza vaccine. In Phase 2 studies. Open to a global partnership deal. ([Link](#))

Biolex - Finishing up Phase 2 for a long-acting interferon for Hepatitis C ([Loctemapron](#)).

Bionor Pharm - ([Vacc-4x](#))HIV vaccine generates a positive immunologic response in Phase 2 trials.

**COMPLETED** Biota - Looking to partner a once weekly inhalable long-acting neuraminidase inhibitors for the treatment of flu. Would compete against Relenza from GSK. Currently partnered with Daichi-Sankyo in Japan. One of two Phase 3 studies have reported out with positive data - large market. Recently received a large BARDA grant and has retained Piper Jaffray as financial advisor to maximize value of existing programs and help to enter the U.S. market on a commercial basis. Update: Biota merged into Nabi in April 2012 which lists the company in the U.S. ([Link](#))

Biota Holdings - Looking to partner a product to treat the common cold. Specifically, canyon-like clefts on rhinovirus surface attach to the receptor allowing infection. Biota achieved proof of concept in a Phase IIa (challenge study) in 2009. Now in Phase 2b studies for this product. ([Link](#))

**NEW** Biotica-based Cyp inhibitor which has demonstrated clinical activity alone and/or in combination for treatment HCV.
**UPDATE** Biotron - BIT225 represents a first-in-class drug for treatment of HCV, targeting the p7 protein of HCV. In a Phase 2a study with data reporting out in September 2011. In January 2012, the company planned for further clinical development of the drug, including an extended 3 month trial in combination with current SOC, a trial against genotypes of HCV other than genotype 1, combination trials with new classes of drugs (anti-HCV), and a trial in difficult to treat populations, especially HIV and HCV co-infected patients. Seeking to outlicense. (Link)

**UPDATE** Chimerix - **CMX001** is a lipid mimic of cidofovir that more easily passes into cells and then targets double viruses including herpes viruses and orthopoxviruses. Current in Phase 2 against CMV and BK virus. A recent trial showed that this drug works better than existing antivirals in persons with impaired renal function. In active partnership talks; also in development for smallpox. On February 6, 2012, announced positive results from Study 201, a Phase 2 study evaluating the prevention of CMV disease in hematopoietic stem cell transplant (HCT) recipients. The CMO commented “We look forward to initiating the Phase 3 CMV program later this year.” (Link)

**UPDATE** Compass Biotechnologies – (formerly Virionics, Cyplasin) – On January 5, 2012, announced it was relocating to Phoenix, AZ from Canada. Recently restructured to form several franchises or business units. Working on the commercialization of certain generic products in addition to patented, proprietary products. Formerly had license to virus-like particles (VLPs) for HPV and HCV. Originator MediGene holds exclusive marketing rights to CVLP products in Germany and co-exclusive marketing rights for the rest of Europe. On April 10, 2012, Medigene presented promising preclinical data at the World Vaccine Congress, alternative to conventional vaccines.

**NEW** Cytheris - Recombinant Interleukin-7 (CYT107) in a Phase 2 trial expands CD4 T-Cells in Gut Mucosa of Chronically HIV Infected Immunological Non- Responder Patients.

**UPDATE** Eiger BioPharmaceuticals - Developing Clemizole as a NS4B-RNA binding inhibitor for the treatment of hepatitis C. Completed Phase 1 trials. In May 2011, received further funding from the National Institute of Allergy and Infectious Disease for the project.

Endeavor Vision - LMV-601 is the first in a new class of drugs known as PC-PLC inhibitors that is being developed with Lumavita. It has outstanding antiviral properties resulting from the inhibition of early viral gene transcription. It is currently in clinical development (Phase I on infected patients) for the treatment of Human Papillomavirus (HPV) infection of the cervix.

**UPDATE** Epiphany Bio – Developing Valomaciclovir (EPB-348), a late-stage, next-generation novel herpes drug with broad-spectrum antiviral activity. Both a Phase 2b clinical study of Valomaciclovir for the treatment of shingles and a Phase 2 study of Valomaciclovir for the treatment of acute infectious mononucleosis have been successfully completed. No partnership announced thus far, and no further progress reports on site past 2009. Licensed from Medivir. (Link)

**UPDATE** Flamel - Looking to license a long-acting IFN-alpha (compare to PEG-INTRON) for Hepatitis C which is currently in phase II. Intermediate analysis of that study was presented in November 2011 at the AASLD’s “Liver Meeting” in San Francisco: improved safety profile of IFN-α XL versus PegIntron during a 3-month course of combined therapy with weight-based ribavirin was confirmed.

**NEW** Geovax – in a clinical trial with an HIV vaccine.

Globelimmune - Strong efficacy in treating Hepatitis C with GI-5005 a viral fusion protein. Phase 2b data show that the HCV vaccine increased sustained virologic response by 12 percent in patients who previously failed therapy with standard of care. (Link)

Idera - looking to partner IMO-2125, its TLR9 agonist for hepatitis C (HCV) after positive Phase 1 data. Mechanistically, this is a DNA-based compound that stimulates an innate immune response, including the induction of high levels of interferon-alpha and other cytokines that work to suppress HCV viral replication. Phase 2 studies have been delayed. (Link)
Inhibitex - Reported Phase II data in December 2010 from a clinical trial of FV-100, its antiviral compound in clinical development for the treatment of herpes zoster (shingles). While the results showed improvements in the reduction in the severity and duration of shingles-associated pain of 3% and 7% for the 200mg and 400mg patient cohorts, it was far from the 25% reduction called for as the primary endpoint, and not statistically significant. Open to partnering this compound. Note: Inhibitex was acquired by BMS in January 2012 for $2.5 billion.

Inhibitex - Pursuing a nucleotide polymerase inhibitor for HCV which has shown high promise in Phase 1b data reported on November 29, 2011. INX-189 with a substantial reduction in HCV RNA. Note: Inhibitex was acquired by BMS in January 2012 for $2.5 billion. (Link)

Innate Pharma – As of February 14, 2012, was acquired by BMS. Looking to partner IPH-1201, a gamma-delta agonist immune modulator, for Hepatitis C. Solid Phase 2a data reported at EASL, though no development has been reported since 2008, and the program is assumed to be discontinued. Its two products in development are partnered with Novo Nordisk and BMS.

Inovio - Looking for partnerships based upon its Syncon vaccine platform. Syncon facilitates better vaccines that address changing strains of diseases, including HIV, HCV, HPV, and influenza. Has shown positive results in recent HIV vaccine Phase 1 study. Began a Phase 2 study in 2011 in cervical cancer; efficacy data expected 2H 2013. On March 26, 2012, the USPTO granted U.S. Patent No. 8,133,723, covering Inovio’s SynCon® universal vaccine related to H1N1 influenza, a formulation expected to generate interim Phase I clinical data in Q2 2012. (Link) (noncon)

Japan Tobacco - looking to partner JTK-853, an RNA polymerase inhibitor for the treatment of Hepatitis C. Has completed POC in a Phase 1 study.

LG Life Sciences - LB80380 - Phase 2 novel nucleotide polymerase inhibitor for chronic HBV infection. An ester prodrug of phosphonate nucleotide analogue of guanosine monophosphate with potent activity against hepatitis B virus (HBV). Designed to overcome problems of currently approved HBV drugs such as resistance and renal tox.

Marinomed Biotechnologie - The privately-held Austrian biopharmaceutical company is in talks with pharma players to outlicense first marketed product MAM-05.101, an anti-viral nasal spray for the prevention and treatment of common cold based on the MAVIREX technology platform. This product is a GRAS botanical and can likely be introduced to the market now as either an OTC product or medical food. Looking for licensing partner for U.S., Canada and Japan. In Austria the nasal spray has been marketed since 2008, and is currently also marketed in Israel, Turkey, UK and was further out-licensed for 54 countries to Boehringer Ingelheim to all of Europe (except UK and Ireland), Russia & CIS, South America and Australia in 2010 as well as for 19 countries to local partners worldwide.

Mymetics - Has hired Lazard to look at its strategic alternatives. Company developing mucosal antibodies to prevent HIV infection. Phase 1 data show safe and well tolerated. Also has a preclinical RSV vaccine. Preparing a combined Phase I/II end 2012. Recently regained its intra-nasal influenza vaccine from Solvay. (Link)

Myrexis - Portfolio includes Vivecon, a Phase 2 maturation inhibitor for HIV. Company also has additional pre-clinical HIV products. Has suspended development of this product and is seeking an external partner. (Link)

NanoViricides – Developing nanoviricides designed to attract and trap viruses, dismantling it without immune system assistance. One of these virus-specific candidates is the clinical stage FluCide, for seasonal influenzas, bird flues, epidemic flu and swine flu, with excellent efficacy shown in H1N1-animals, H5N1 animals. On April 2, 2012, the company announced that a pre-IND meeting was had with the FDA, and were “given a good roadmap for advancing toward an IND application.” (Link)
Neurotune - Positive top-line results from its Phase IIa study of dimiracetam (NT-11624) for treatment-induced neuropathic pain in HIV patients receiving anti-retroviral medication. Phase 2b study to start in 2012 under recently granted IND. (Link)

**UPDATE** Okairos – Hepatitis C vaccine in development in two formulations: developing ProCvax, a prophylaxis HCV drug approaching phase II, and TerCvax, a therapeutic HCV drug in Phase I. Intend to bring core vaccine candidates through to the completion of Phase II proof-of-concept trials, and will seek partnerships to support Phase III trials and market the vaccines worldwide. On 4 March 2012, initiated a 350-subject Phase I/II clinical trial evaluating its vaccine. (Link)

**UPDATE** Presidio Pharmaceuticals - No longer listed on the company’s pipeline website, though listed in the December 2011 Product Pipeline Review. PPI-802 is a nucleoside reverse transcriptase inhibitor (NRTI) with a novel “penultimate chain termination” mechanism of action. PPI-802 shows preclinical efficacy against multi-drug resistant HIV strains, including those harboring the clinically important M184V and K65R substitutions. Currently undergoing IND-enabling studies. The company is open to selective out-licensing and partnership discussions for current programs. (Link)

**UPDATE** Presidio Pharmaceuticals - PPI-461 is a small-molecule NS3A inhibitor for hepatitis C. Has shown favorable data and is well-suited to be a part of an oral combination drug for HCV. On November 4, 2011, announced clinical proof-of-concept data from its Phase 1b trial, and that “the company intends to bring 2 or 3 of its novel HCV NS3A inhibitors through early clinical development (Phase 1b/2a), with subsequent Phase 2-3 clinical evaluation of such NS3A candidates in suitable combination regimens with other HCV antivirals through corporate partnering or intercompany collaborations.”

**UPDATE** Protein Sciences - Has FluBlok for treatment of influenza. Pending BLA with an approval likely. Company is exploring an IPO. On March 29, 2012, the company announced it would open a new Product Realization Lab in its Meriden, CT campus, designed to accomodate and support the manufacture of FluBlok and the development of other novel biologics.

Progenics - looking to outlicense its virology pipeline. Included is PRO-140, a Phase 2 antibody for HIV. Unlike small-molecule CCR5 antagonists, PRO 140 inhibits HIV entry at concentrations that in vitro do not appear to block CCR5’s natural activity of directing the migration of immune cells towards sites of inflammation in the body. (Link)

Quantum Pharmaceuticals - Matrix M1 protein inhibitors for the management of influenza. (Link)

**UPDATE** Redox - Phase 2 trials of Doxovir, a non-nucleoside analogue, for Herpes labialis, have been successful. On September 15, 2011, announced the granting of a new US patent on the use of Doxovir for psoriasis. (Link)

Sanitaris Pharma - Phase 2a data of miravirsen, a microRNA-targeted drug, shows dose-dependent, prolonged viral reduction of 2-3 logs HCV RNA after four-week treatment in Hepatitis C patients. (Link)

**UPDATE** SciClone - ZADAXIN in Phase 3 for the treatment of hepatitis C. Partnered in Europe to Sigma-Tau. ZADAXIN is approved in over 30 countries worldwide for five different clinical indications, and may be used for the treatment of hepatitis B, hepatitis C, as a vaccine adjuvant, and certain cancers, according to the approvals in these countries. From the March 13, 2012 Q4 financial results report: “Our 23% annual ZADAXIN revenue growth, which exceeds the growth rate of the China pharmaceuticals market, and the overall strengthening of our China platform, position SciClone in the top-performing echelon of multi-national companies in this important and growing market.”

Scynexis - SCY-635 targets cyclophilin for treatment of Hepatitis C. Novel mechanism and promising Phase 1 data. Currently in Phase 2 studies. On November 7, 2011, data was presented at the 61st Annual Meeting of the AASLD demonstrating that the drug reactives the body’s natural defense mechanism, making it capable of inhibiting the replication of the virus, and could be an effective replacement for recombinant Interferon.
**UPDATE** Shire – While Shire has a robust human genetic therapies pipeline, a Gene-Activated Human Growth Hormone (GA-IFNα) for Hepatitis C is no longer listed in their development pipeline. Other indications are for DMD, HS, MLD, Sanfilippo A/B syndrome and Santaris collaboration.

**UPDATE** Starpharma – VivaGel® is being developed for the prevention of HIV and HSV-2 (genital herpes). It has also shown very promising activity against the human papillomavirus (HPV). In August, reported positive data from a Phase 2 trial. The study showed that treatment with VivaGel (containing 1% of the active, SPL7013), once daily for seven days, resulted in 74% of patients achieving Clinical Cure of BV 2 to 5 days after completion of therapy compared with just 22% in the placebo group (P=0.0002). On March 26, 2012, the commencement of two concurrent pivotal phase 3 clinical trials of VivaGel for VG, following receipt of ethics approval. The results of the trials are anticipated by the end of 2012.

Symphogen - Novel polyclonal antibody technology platform with a promising antibody in development for RSV (Sym003), still in the pre clinical stage.

**NEW** Theravance - NSSA inhibitor for HCV (TD-2872), part of the Viral NSSA Protein Inhibitor (VIPER) Program. Less potential for resistance. Positive preclinical trials; have initiated IND-enabling studies as of March 2012

Toyama - T-705 (favipiravir), a viral RNA polymerase inhibitor, is in Phase 3 studies in Japan and Phase 2 in the United States as a highly promising anti-viral drug for the treatment of influenza. ([Link](#))

**NEW** TrellisBio - Antibody for CMV that targets gB epitope.

**NEW** Undisclosed – marketed product for stress urinary incontinence in EU. Late stage in U.S. interested parties should contact [alan.selby@torreyapartners.com](mailto:alan.selby@torreyapartners.com).

![VaxInnate](#) VaxInnate - Developing Universal flu vaccines. Strong Phase 2 data. Company is open to a sale. Recently received a major U.S. government contract. As of December 19, 2011, the company granted CJ CheilJedang Corp an exclusive license to manufacture, develop and commercialize their recombinant seasonal and pandemic flu vaccines in South Korea; also includes a non-exclusive license to market the vaccines in certain SE Asian countries (ex. China).

**UPDATE** Xiamen Innovax Biotech - Has developed Hecolin, a Hepatitis E vaccine that has recently been shown to be completely effective in the prevention of Hepatitis E in a 110,000 patient clinical trial. Approximately 30% of the world’s population has Hepatitis E. Xiamen open to licensing rights to this product outside of China. On January 31, 2012 the news about the approval of Hecolin® in China was published by WHO’s Global Immunization News, affirming the vaccine had received a certificate for medicine production in December 2011. ([Link](#))

**WOMEN’S HEALTH**

Acrux - regained rights in May 2011 to Luramist®, a testosterone spray for women to enhance female sexual function. This program has progressed through Phase 2 studies with Vivus. Also has a promising Phase 1 completed progestin solution for birth control. ([Link](#))

$ Acrux - rights outside of the U.S. are available for Estradiol MDTS® is a novel Estradiol Metered Dose Transdermal Spray (MDTS®) hormone replacement product for the treatment of moderate to severe symptoms due to menopause. This product was recently approved in Sweden and has pending approvals in a number of other countries.

Adamis - successful completion of a Phase III contraceptive trial of the company's contraceptive gel product candidate named Savvy (C31G) in Dec 2010. Looking to outlicense this product.
UPDATE Agile Therapeutics - AG20015 is a low-estrogen dose once-weekly contraceptive patch containing levonorgestrel (100-120mcg) and ethinyl estradiol (25-30mcg) as active ingredients. This product has successfully progressed through Phase 2 studies and has high promise. On January 2, 2012, the company announced the database had been locked for the final Phase III clinical trial, and is on track to submit an NDA in Q1 2012. Agile is also in Phase 2 with a contraceptive product that does not use estrogen. (Link)

UPDATE Alliance Pharma - Isprelor contains misoprostol as an active ingredient. It is a synthetic PGE1 analogue and serves on both to ripen the cervix and augment labor as a one-step labor induction agent. Isprelor is being developed as vaginal tablets (25mg) for the induction of labor and has completed Phase 3 studies. Following completion of clinical development, an application for an EMA is planned, and the company is looking to outlicense. (Link)

UPDATE Antares Pharma - Has published successful results from a dose-finding Phase II trial for a novel contraceptive gel containing the progestin Nestorone and estradiol (NES/E2) utilizing the Antares ATD (advanced transdermal delivery) gel system. This program has initiated Phase 3 studies, with an NDA filed. According to Seeking Alpha on Dec 28, 2011: “At this time, the company has no debt, 32 million USD cash on hand, a low cash burn, and excellent management that displays a clear, concise, and disciplined vision for the company’s future. Once the progress on Phase III studies are released, Nestrage’s speculative value will increase tremendously which could result in a run similar to that seen with Dendreon” (Link)

UPDATE Anterion Therapeutics - Has finished Phase 2 studies for Annuelle III, a contraceptive product that lasts for three years. Records as of February 21, 2012 show that the company filed for bankruptcy. (Link)

UPDATE Aoxing Pharmaceutical Company - Has enrolled over 120 patients in its on-going Phase III clinical studies of oral TJSL (Tong Jin Shu Ie) Capsules, a novel investigational drug to treat primary dysmenorrhea (“PD”), or menstrual pain, in adult women. This product is based upon Chinese herbs. According to an operational results report released February 14, 2012, the company has almost completed the analysis of this trial and has been preparing to file an NDA for the indication of menstrual pain. (Link)

Apricus Bio - Femprox contains alprostadil which is a synthetic version of prostaglandin E1 (PGE1), a naturally occurring vasodilating agent which increases blood flow to the female genitalia. Apricus Biosciences has completed one Phase II trial in the United States and one Phase III study in close to 400 women in China, which achieved a 44% positive response rate as compared to a placebo. Looking for a development partner. A Pre-NDS meeting is scheduled in Canada. (Link)

Athena DDS - Has a one shot treatment for bacterial vaginosis. Secnidazole 2gm single dose is comparable to 7 days treatment with Metronidazole tablet. Sachets are well accepted by patients and easy to use. Has been approved in France.

Ausio Pharma - AUS-131 is a first-in-class, nonsteroidal, nonhormonal estrogen receptor β (ERβ) agonist that offers a potentially safer alternative to estrogen for the treatment of menopausal symptoms and is currently in Phase 2a clinical trials. (Link)

UPDATE Bionovo - Looking to partner a SERM with promising Phase 2 data for hot flashes. This is based upon a botanical product. Does not bind to estrogen receptor alpha. The company’s Phase 3 trial of this drug was halted on March 30, 2012 due to a lack of company funding. (Link)

UPDATE Biosante - LibiGel (testosterone gel) for female sexual dysfunction is in Phase III, and is designed to be quickly absorbed through the skin after a once-daily application. Biosante recently disclosed that LibiGel did not meet its primary endpoints in this trial.

UPDATE Bioterm Pharmaceuticals - Developing Preventerm, a drug candidate for the prevention of pre-term birth. Has patented the use of Preventerm globally (approved in Australia), and has been used for indications, in high doses, even in pregnancies, with no adverse effect on baby and mother. BT is currently seeking an equity
investment of $ 7-9 million to complete Phase II clinical trials for Preventerm and its other molecular candidate, to broaden management, and to enhance marketing and business development activities in the U.S. and Europe. (Link)

Burdica - Zestica Fertility™, a personal lubricant using the fertility enhancing properties of HA. The product range was subsequently augmented by the introduction of Zestica Moisture™, designed to alleviate the dryness and discomfort which is experienced after menopause. (Link)

Chiesi - Would outlicense CHF4227 program (SERM) that has completed Phase 1 testing. Available for worldwide licensing since October 2009, appears no further development has occurred.

Concert Pharmaceuticals - CTP-347 for hot flashes in Phase 1 which is completed. Good efficacy story. Company is seeking to outlicense. (Link)

UPDATE Dilafor - Tafopixarin is being developed as a subcutaneous injection for the prevention and treatment of protracted labor (prolonged labor) during child birth. In a randomized, double-blind, placebo-controlled clinical trial on 263 women showed that treatment with tafopixarin provided a statistically and clinically significant reduction in the incidence of protracted labor and caesarean sections. Seeking an arrangement for a single partner who would undertake to develop, gain regulatory approval and ultimately market and sell the drug on a worldwide basis. (Link)

$ Dong-A Pharma - Outlicensing Gonadopin® - a recombinant human follicle stimulating hormone (rec-hFSH) for controlled ovarian hyperstimulation. Launched in Korea. Note: a similar product was recently in-licensed from Itero to Watson Pharmaceuticals. Other similar products available for license from Ibsa and LG.

UPDATE Easton Pharmaceuticals - VIORRA is an over-the-counter aid for the treatment to restore and improve vaginal moisture and elasticity which has a very positive effect on women’s sexual desire and arousal. ViorraTM will be launched in two phases. Regulatory approval in Mexico pending. Recently received two financing proposals, and has begun the process of submitting patent applications for the product. Planning the launch of a clinical safety trials in the US as a precursor to the product launch, and has entered into discussions for distribution agreements in East Asia. (Link)

Embil - Would outlicense Kortos cream for hemorrhoids and anal fissures. (Link)

Endoceutics - Developing Femivia for the treatment of issues associated with hormone deficiency in post-menopausal women (e.g., memory loss, diabetes, muscle loss). This product is in Phase 3 and the company is seeking to outlicense the drug. (Link)

FemmePharma - Running an open-label, multicenter Phase 2a evaluation of the use of topically administered FP1198 (testosterone-agonist danazol) for the treatment of moderate to severe cyclic breast pain (cyclic mastalgia). (Link)

UPDATE GlycoTope - FSH-GEX is a Phase 1 follicle-stimulating hormone produced recombinantly with a fully human glycosylation. FSH-GEX is being developed as subcutaneous formulation based on GlycoExpress technology for the treatment of infertility. Anticipating phase II trials for 2012, and first possible BLA filing anticipated for 2014/15. (Link)

UPDATE Hisamitsu / Noven - Positive Phase 2 data for low dose oral paroxetine mesylate for treatment of hot flashes (Mesafem). As of April 3, 2012, clinical trial records show a phase 3 safety and efficacy study of mesafem capsules for VMS had concluded. May be interested in finding a partner for this product.

HRA Pharma - Two UPA contraceptive products (UPAC-ring and UPAC-IUS) based on the molecule ulipristal acetate, a new chemical entity which modulates the activity of the progesterone receptor. This is in Phase 2 trials. (Link)
**UPDATE** Instead Sciences - **Amphora** is a lubricating vaginal gel that has demonstrated efficacy in preventing conception and STIs in extensive in-vitro studies and human clinical trials. It has been cleared by the FDA as safe for use in humans; received 510k device clearance as a lubricant in 2004 and is currently the only microbicide candidate to date able to be marketed and sold for human use.

Kade - Would outlicense **Cliovelle** - a low dose Estradiol / Progestin combination product for treatment of menopausal disorders.

**NEW** Medicinova - MN-221 is a novel, highly selective β2-adrenergic receptor agonist under (non-core) development for the treatment of preterm labor, in phase Ib. In pre-clinical pharmacology studies in pregnant rats and sheep conducted by Kissei Pharmaceutical, MN-221 reduced the number of spontaneous or drug-induced uterine contractions in those animal models. Has shown positive pharmacokinetic trends in Phase 2 studies in man. Continues to be studied in indications for exacerbations of asthma/COPD. ([Link](#))

Meditrina - Has hired Robert W. Baird to explore strategic options. Company working with aromatase inhibitors, MPI-676 and MPI-674 candidates should soon advance to Phase III clinical trials. ([Link](#))

**UPDATE** Pantec Biosolutions AG - FSH Patch in Phase 2 testing for infertility treatment. Drug patch development for IVF hormones is underway and the Company intends to commercialise their product solution "P.L.E.A.S.E." - device plus drug patches" with a pharma partner company.

**UPDATE** PearTree Women’s Healthcare – Were developing PT-201 and 01 for treatment of urogenital atrophy. PT-100 is a fixed dose combo of estriol and progesterone as a vaginal suppository. PT-101 is a vaginal suppository containing a SERM indicated for prevention of urogenital atrophy associated with menopause. This developing company appears to have gone out of business, and the program is assumed to be discontinued. ([Link](#))

**UPDATE** Pevion Biotech AG – Anticipated as the first vaccine against recurrent vulvovaginal candidiasis (RVVC), also known as chronic recurrent thrush. Occurs in 7% of adult women worldwide. On January 17, 2012, announced positive data from the ongoing phase I clinical study of PEV7, demonstrating the generation of specific and functional B cell memory in 100% of vaccinees. Furthermore, the results confirm the capability of Pevion’s second generation virosomal vaccine platform to induce strong and long-lasting immunity in humans against otherwise weak antigens. Phase I administration is both intramuscular and intravaginal, finalization expected for Q3 2012.

**UPDATE** Repros Therapeutics - **Proellex** off clinical hold in Phase 3 for uterine fibroids. As of January 3, 2012, announced it has completed dosing in its Phase 2 low-dose trial intended for the treatment of symptoms of uterine fibroids and endometriosis. The Company will request a Type B meeting with the FDA on completion of the final clinical study report. Based on the present data and the strong efficacy signal in its previous Phase 2 studies, the Company hopes to re-enter Phase 3 with low dose oral Proellex. The Company believes this meeting can be scheduled with the FDA during the second quarter of 2012. The company also announced its IND for Proellex-V, or vaginally delivered Proellex, has been accepted by the FDA. The indication identified in the new IND is for the use of Proellex-V for the purpose of significant fibroid size reduction and symptom elimination with the goal of avoiding surgery.

$ Semprae Laboratories - Markets Zestra, an OTC product for female sexual arousal enhancement. This product is backed by clinical studies showing its efficacy. Company is open to promotional or partnership deals.

**NEW** Shionogi - Ospemifene is a selective estrogen receptor modulator (SERM) being developed for the treatment of postmenopausal vulvar and vaginal atrophy (VVA). Ospemifene offers a unique and substantial commercial opportunity as a new non-hormonal treatment for post-menopausal women, which can provide many of the benefits of long-term estrogen without the associated risks. Shionogi has licensed the worldwide rights for
ospemifene from QuatRx Pharmaceuticals and is looking for ex-U.S. partners. Shionogi plans to submit an NDA in the US in 2Q 2012.

**UPDATE** Starpharma – VivaGel® is being developed for the prevention of HIV and HSV-2 (genital herpes). It has also shown very promising activity against the human papillomavirus (HPV). In August, reported positive data from a Phase 2 trial. The study showed that treatment with VivaGel (containing 1% of the active, SPL7013), once daily for seven days, resulted in 74% of patients achieving Clinical Cure of BV 2 to 5 days after completion of therapy compared with just 22% in the placebo group (P=0.0002). On March 26, 2012, the commencement of two concurrent pivotal phase 3 clinical trials of VivaGel for VG, following receipt of ethics approval. The results of the trials are anticipated by the end of 2012. ([Link](#))

**UPDATE** Trimel Biopharma - Phase 2 data were positive for an intranasal low-dose gel formulation of testosterone for FSD, Tefina. On February 14, 2012, the results of TBS-2 Phase II Vibrotactile Stimulation study yielded positive outcomes for all Anorgasmia parameters, and the Company will initiate a multinational TBS-2 Phase II Ambulatory clinical program, based on dialogue with the FDA.

Undisclosed player - Partnering a Phase 2 progesterone modulator for uterine fibroids and endometriosis.

Undisclosed player - Partnering a Phase 3 ready drug for bacterial vaginosis. Differentiated from current treatments.

NEW Undisclosed player – Group of reproductive health drugs in development.

NEW $ Undisclosed player – Sale of some small U.S. female health branded pharmaceuticals.

**UPDATE** Vantia - Pursuing VA111913, a vasopressin antagonist for dysmenorrhea, menstrual cramping pain. An exploratory Phase 2 trial of VA111913 showed promising evidence of reduced pain levels in patients receiving the drug candidate. Currently no targeted therapies for dysmenorrhoea; market op estimated to be over $1B/yr. As of July 6, 2011, the company had raised $6.5M in a series B financing round to advance development for this drug and fellow pipeline drug VA106483 for nocturia. ([Link](#))

**UPDATE** Vyteris - Has indicated that it is interested in disposing of a portfolio of products in development. Vyteris’ transdermal drug delivery technology can be utilized for the delivery of many drugs, including a patch that delivers a fertility enhancing hormone: "Agreements are already in place to accelerate entry into significant high-growth markets with unmet medical needs, regarding the licensing and marketing of a product based on Vyteris’ active patch technology delivering a fertility enhancement peptide.” ([site](#)) ([Link](#))

NEW Warner-Chilcott – According to Bloomberg in April 2012, Warner-Chilcott has retained Goldman Sachs to consider potential strategic approaches.

**UPDATE** Zelos (now Azelon Pharmaceuticals) - Spun-out of the National Research Council of Canada, having been exclusively licensed a core platform of PTH analogs. On October 11, 2011, Prospect Venture partners led the $4.5M Series A financing intended to support the phase 2a clinical development of ZT-034, a nasal spray formulation of teriparatide for the treatment of osteoporosis. Exploring its options related to partnerships for further development and commercialization of the lead product candidate. ([Link](#))

**WOUND CARE AND TISSUE SEALANTS**

Adocia – Has completed Phase 2 trial for the treatment of diabetic foot ulcers against Regranex with rhPDGF-BB spray. Interim results show non-inferiority. ([Link](#))

**UPDATE** $ Alliqua - SilverSeal Hydrogel dressings (using AquaMed Technologies' platform Hydress +Plus) received FDA approval for a silver-based wound dressing. The Company said that in 2012 it intends to aggressively pursue
distribution contracts, and expects SilverSeal Hydrogel Dressing to be available in the US at the beginning of Q2 2012. (Link)

**UPDATE** Auxano Biomedical / Emergent Bio - Developing SP-1 for wound repair along with some wound diagnostic tools. Stage of development beyond research unclear at this time. (Link)

**UPDATE** Cohera Medical - Developing TissuGlu, a deep wound adhesive for use in surgical applications. This product is currently approved in Europe and on the market in Germany. On January 24, 2012, Cohera received an IDE from the FDA to begin a prospective, multicenter, randomized clinical trial for TissuGlu in the US.

**UPDATE** Coloplast - Rumored to be considering disposal of wound care product line, including Biatain foam dressings product line.

**NEW** Daewoong – Has introduced Easyef®, a recombinant epidermal growth factor, in Korea for the treatment of diabetic foot ulcers and other wound types. This product is available for licensure and registration in other territories. (Link)

**UPDATE** Derma Sciences - Completed Phase 2 studies in diabetic foot ulcers of DSC127 which appears to stimulate production of dermal adult progenitor cells, including mesenchymal stem cells, following injury. In June 2011, Derma raised $29mm in a private placement financing. As of March 6, 2012, the company announced that discussion of Phase 2 results with the FDA had concluded that the drug’s development program supports initiation of phase 3 studies, which are expected in the second half of 2012. (Link)

**UPDATE** FirstString Research - Bioengineered peptide based on a naturally occurring protein that accelerates wound healing and tissue regeneration with significantly reduced scarring (in topical formulation). Positive Phase 1 data reported in Sep 2010. Granexin™ Gel is currently under evaluation in three Phase II human clinical trials to demonstrate safety and efficacies for scar reduction of acute surgical wounds and the treatment of chronic wounds; Diabetic Foot Ulcers and Venous Leg Ulcers. (Link)

**UPDATE** First Texas Medical - innovative portfolio of marketed wound care and dermatology products. Interested parties should contact John Bradley at Torreya Partners (john.bradley@torreyapartners.com).

Glycotex - GLYC-101 is being developed to stimulate and modulate the natural cascade of wound healing activities of several cell populations (including upregulation of TNF-alpha). The product candidate is a topical gel to be applied directly on the wound surface. In May 2006, Glycotex completed a Phase II clinical trial of GLYC-101 in Australia, in which GLYC-101 produced a statistically significant rate of wound area reduction versus combined placebo and standard care in patients with chronic venous ulcers. In June 2011, positive results of another Phase 2 study were reported. (Link)

**UPDATE** Innocoll - Cogenzia is a biodegradable and fully resorbable Gentamicin-Collagen Sponge formulated and manufactured using Innocoll’s proprietary collagen-based drug delivery technology, CollaRx. Treats wound infections and shown in one Phase 2 trial to be superior to the current standard of care in diabetic wounds. Company beginning Phase 3 trials of this product in 2012.

NB Therapeutics - Nitric oxide gas can be used for wound healing. Has been in a Phase 2 study but no recent updates on clinical development of this product. (Link)

**COMPLETED** Pervasis - Developing Vascugel, a cell therapy product, to accelerate vein remodeling for patients receiving an AV fistula (AVF) in end stage renal disease. Compare to Proteon Therapeutics which has optioned a product for the same indication to Novartis. As of April 12, 2012, Shire plc acquired substantially all the assets of Pervasis; it will provide an upfront payment, plus milestones that are dependent on Shire’s achievement of certain clinical dev., regulatory and sales targets.
PharmaSurgics (under Pergamum) - In Phase 2 development for a pharmaceutical for anti-adhesion treatment after surgery (PXL-01). Very promising approach. The Pergamum Operating unit located in Gothenburg - has received approval from the German Regulatory Authority and the Independent Ethics Committee to begin a Phase 2 clinical trial in Germany. (Link)

**UPDATE** ProFibrix - Developing a surgical tissue sealant that stops acute and severe bleeding. FibroCaps are a novel powdered mixture of fibrinogen and thrombin. Entered into a component supply agreement with CSL Behring in June 2010. Has raised US $11 million in series B financing for Fibrocaps. On Nov 15, 2011, reported that its Dutch Phase 2 trial met its primary endpoint (50% reduction in mean time to hemostatis versus active control). On Jan 4, 2012 the company reported that its US Phase 2 trial confirmed similarly positive results. Company planning to start a Phase 3 trial in H1 2012 and target a BLA filing in 2013.

**UPDATE** Third Stream Bioscience - Developing a novel skin antimicrobial based upon a chemical composition developed by Procter & Gamble. Promising data in dermatology (acne) and a variety skin cleansing applications. TSB is seeking $3-4million in capital to finish development and commence sales; anticipate a European commercial/hospital hand sanitizer in 2012, and further approvals in the next few years for surface disinfectants, cutaneous antiseptics and acne rx.

Undisclosed - Large pharmaceutical company interesting in outlicensing a late stage program in wound care.
**TORREYA PARTNERS LLC** is a leading boutique investment banking firm that provides strategic advice and assistance with Mergers & Acquisitions, Partnering and Financings to life science companies worldwide. Torreya Partners has offices located in London, New York and Philadelphia. Further information is at www.torreya.com.

### TORREYA PARTNERS PERSONNEL

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Specialty Area</th>
<th>Geography</th>
<th>Mobile Phone</th>
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</thead>
<tbody>
<tr>
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### RECENT TRANSACTIONS WHERE TORREYA ACTED AS FINANCIAL ADVISOR

<table>
<thead>
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<th>Client</th>
<th>Closing Date</th>
<th>Value</th>
<th>Completed Assignment</th>
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<tbody>
<tr>
<td>Agvar Chemical</td>
<td>Apr-12</td>
<td>Undisclosed</td>
<td>Financial Advisor to generic pharma / API company</td>
</tr>
<tr>
<td>Lipose</td>
<td>Apr-12</td>
<td>Undisclosed</td>
<td>Sale to a specialty dermatology company</td>
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<tr>
<td>Specialty Pharma</td>
<td>Apr-12</td>
<td>Undisclosed</td>
<td>Sale of mature pharmaceutical product in cardiology</td>
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<tr>
<td>Global Pharma</td>
<td>Mar-12</td>
<td>Undisclosed</td>
<td>Sale of two marketed pharmaceutical products</td>
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<td>Multinational food co.</td>
<td>Jan-12</td>
<td>$300mm</td>
<td>Neutraceutical transaction in Asia</td>
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<td>Fund Group</td>
<td>Jan-12</td>
<td>Undisclosed</td>
<td>Acquisition of pharmaceutical royalty bond</td>
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<tr>
<td>Hedge Fund</td>
<td>Dec-11</td>
<td>$65mm</td>
<td>Placement of collateralized royalty bond</td>
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<td>Fund group</td>
<td>Dec-11</td>
<td>$25mm</td>
<td>Acquisition of royalty-linked securities</td>
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<td>Specialty Pharma</td>
<td>Nov-11</td>
<td>Undisclosed</td>
<td>Acquisition of a dermatology Rx product</td>
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<td>Healthcare IT Company</td>
<td>Nov-11</td>
<td>Undisclosed</td>
<td>Completion of bridge financing</td>
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<td>Specialty Pharma</td>
<td>Oct-11</td>
<td>Undisclosed</td>
<td>Sale of pre-natal vitamin line</td>
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<tr>
<td>Biotech company</td>
<td>Oct-11</td>
<td>Undisclosed</td>
<td>Pain product licensing transaction</td>
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<tr>
<td>Amorcyte</td>
<td>Oct-11</td>
<td>$20mm +</td>
<td>Sale of cardiac cell therapy company to Neostem Inc.</td>
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<td>Ventrus Bio</td>
<td>Jul-11</td>
<td>$52mm</td>
<td>Financial Advisor in a public equity financing</td>
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<td>Predictive Edge</td>
<td>Jul-11</td>
<td>Undisclosed</td>
<td>Equity financing for a novel pharma IT company</td>
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<td>Two fund groups</td>
<td>Jun-11</td>
<td>$110mm</td>
<td>Sale of pharmaceutical product royalty interests</td>
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<td>Specialty Pharma</td>
<td>Jun-11</td>
<td>Undisclosed</td>
<td>Sale of an approved hospital drug with global distribution</td>
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<td>Undisclosed</td>
<td>Co-promotion agreement for a U.S. marketed pain product</td>
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<td>Aegera Therapeutics</td>
<td>May-11</td>
<td>Undisclosed</td>
<td>Sale of the company to Pharmascience</td>
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<td>Thorne Research</td>
<td>May-11</td>
<td>Undisclosed</td>
<td>Strategic alliance in oncology with Helsinn</td>
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<td>Global fund group</td>
<td>Apr-11</td>
<td>$487.5 mm</td>
<td>Sale of Cubicin / Lexiscan royalties to Royalty Pharma.</td>
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<td>Cynapsus Therapeutics</td>
<td>Apr-11</td>
<td>Undisclosed</td>
<td>Fairness opinion in the acquisition of Adagio Pharmaceuticals</td>
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<tr>
<td>Lpath, Inc.</td>
<td>Dec-10</td>
<td>Up to $504mm</td>
<td>Option to License Isonep to Pfizer</td>
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<td>Quinnova Pharma</td>
<td>Dec-10</td>
<td>Undisclosed</td>
<td>Sale of company to Amneal LLC for an undisclosed price.</td>
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<td>Financial Players</td>
<td>Dec-10</td>
<td>Undisclosed</td>
<td>Multiple secondary sales of royalty bonds.</td>
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<td>Three Rivers Pharma</td>
<td>Oct-10</td>
<td>$100mm +</td>
<td>Sale of company to Kadmon, Inc.</td>
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<tr>
<td>Actient Pharma / GTCR</td>
<td>Jul-10</td>
<td>Undisclosed</td>
<td>Purchase of products with $54mm in revenue from UCB</td>
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<tr>
<td>Columbia Laboratories</td>
<td>10-Jul</td>
<td>$108mm +</td>
<td>License of progesterone business to Watson Pharmaceuticals</td>
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<td>Dov Pharma</td>
<td>Jul-10</td>
<td>$2mm</td>
<td>Fairness opinion in sale to Euthymics</td>
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<td>DNP Health</td>
<td>Jun-10</td>
<td>Undisclosed</td>
<td>Merger with Thorne Res., a substantial neutraceutical company</td>
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<tr>
<td>Undisclosed Biotech</td>
<td>Jan-10</td>
<td>$100+mm</td>
<td>License of anti-infective program to global player with profit split</td>
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<td>Athyrium Capital</td>
<td>Dec-09</td>
<td>$15mm</td>
<td>Purchase of royalty on approved cardiovascular drug.</td>
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<tr>
<td>Undisclosed</td>
<td>Dec-09</td>
<td>$400+mm</td>
<td>In-license of an investigational hospital drug.</td>
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<td>Ikonisys</td>
<td>Dec-09</td>
<td>Undisclosed</td>
<td>Partnership of OncoFISH Cervical with Enzo</td>
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<td>Nabi Biopharma</td>
<td>Nov-09</td>
<td>$48mm</td>
<td>Sale of Pentastaph to GlaxoSmithKline (with milestones)</td>
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<td>Athyrium Capital</td>
<td>Sep-09</td>
<td>$10mm</td>
<td>Purchase of Telaprevir Milestone Payments from Vertex</td>
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<td>Introgen Therapeutics</td>
<td>Sep-09</td>
<td>$31mm +</td>
<td>Sale of rights to drug pipeline to asset management company</td>
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<td>Teikoku Pharma</td>
<td>May-09</td>
<td>Undisclosed</td>
<td>Purchase of Travanti Pharma</td>
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<td>Description</td>
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<td>Introgen</td>
<td>Apr-09</td>
<td>Undisclosed</td>
<td>Sale of ITS to Western General and IP Portfolio to Crucell.</td>
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<td>Investor Group</td>
<td>Mar-09</td>
<td>$47,000mm</td>
<td>Advisor to Genentech minority investor group in sale to Roche</td>
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<td>Aradigm</td>
<td>Feb-09</td>
<td>$4.5mm</td>
<td>Financial Advisor in Registered direct financing.</td>
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<td>AGI Dermatics</td>
<td>Sep-08</td>
<td>Undisclosed</td>
<td>Sale to Estee Lauder Companies</td>
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<td>Portola Pharma</td>
<td>Jul-08</td>
<td>$60mm</td>
<td>Financial Advisor in Series D Preferred Financing</td>
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<td>Navitas Pharma</td>
<td>May-08</td>
<td>Undisclosed</td>
<td>Sale to Gilead</td>
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<td>Specialty Pharma</td>
<td>Mar-08</td>
<td>Undisclosed</td>
<td>Fairness opinion in company sale</td>
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<td>ProEthic Pharma</td>
<td>Mar-08</td>
<td>$60mm</td>
<td>Sale to Kowa</td>
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<td>Midlothian Labs</td>
<td>Dec-07</td>
<td>$7mm</td>
<td>Sale to Hi-Tech Pharmacal</td>
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</table>
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