

Chemgenex Pharmaceuticals CXS (\$0.62) S&P/ASX 300 = 4274.0

SPECULATIVE BUY

Creating Value with Compounds

Analyst: Matthijs Smith



Investment Summary

- ▲ CXS provides an attractive speculative investment opportunity with an extensive portfolio of intellectual property (IP) that includes two anti-cancer compounds currently in Phase-II clinical development for a number of different cancer types.
- ▲ The company has recently licensed a third anti-cancer compound currently in preclinical development that is active against tumours which have a wild type p53 gene and often demonstrate resistance to existing therapies.
- ▲ CXS is leveraging its expertise in pharmacogenomics in the development of these compounds as treatments for cancers that respond poorly to existing therapies. In doing so, the company is at the cutting edge of developing personalised medicines which use genomic information to tailor therapies to specific individual requirements.
- ▲ The company has established research partnerships with two international companies, Merck Santé (Europe) and Vernalis (UK) for its discovery programs in diabetes/obesity and anxiety/depression respectively.
- ▲ The revenue from these partnerships provide the company with over \$4m revenue per annum through research and milestone payments which cover a significant proportion of the company's internal R&D expenditure.
- ▲ In addition, CXS retains a carried interest in IP that is further developed by its partners and also has the opportunity to develop that IP for applications in other therapeutic areas.
- ▲ CXS is in the process of listing on the NASDAQ through the Level 2 ADR program. As there has been considerable interest from several US-based investors, this will provide the company with access to the US market for future capital raising to support the clinical development programs.
- ▲ With results from a number of different clinical programs anticipated over the next 12 months, there are several opportunities for CXS to be significantly re-rated in the near future.

Company Statistics & Performance

Shares on Issues: 86.8m
Market Cap.: \$55.6m
52 Week Range: \$0.43-\$0.72

Daily Volume: 84,000
Net cash: \$8.5m
NTA/ps: na



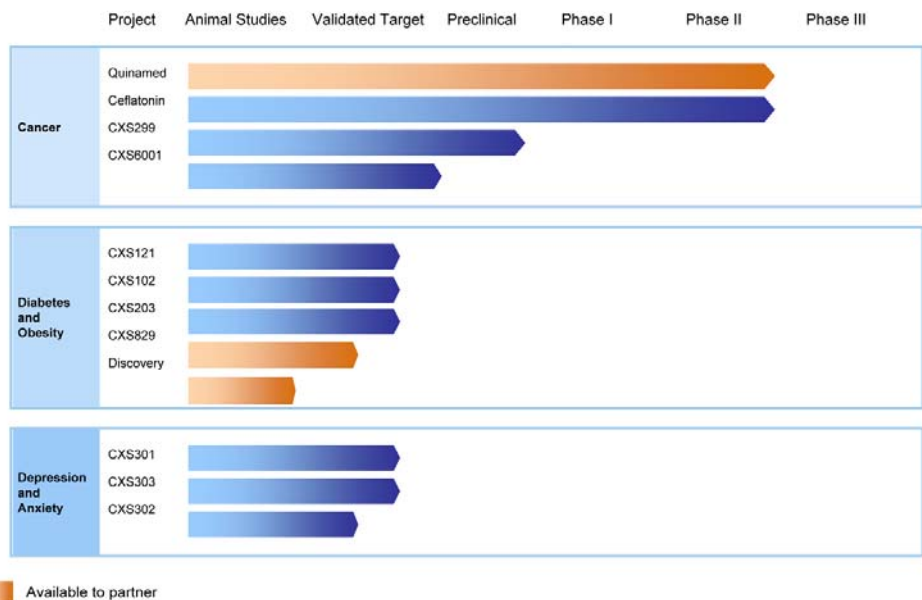
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Company History

- ▲ Chemgenex Pharmaceuticals was established in 2004 through the scrip-based merger of AGT Biosciences (Melbourne) and Chemgenex Therapeutics in Menlo Park, California USA.
- ▲ AGT Biosciences had established an extensive genomics-based discovery and development platform focussed on the identification of new targets and therapeutics for diabetes, obesity, depression and anxiety.
- ▲ The merger with Chemgenex Therapeutics provided the company with a pipeline of advanced products in clinical development and the opportunity to leverage its technology platform for pharmacogenomic applications.
- ▲ Following the merger, CXS has three main discovery and development programs:
 - Cancer therapeutics (Ceflatonin®, Quinamed®, CXS299)
 - Diabetes & Obesity (Merck Santé and internal)
 - Depression & Anxiety (Vernalis)
- ▲ CXS's current pipeline of product in development following the merger with Chemgenex Therapeutics is shown below:

Figure 1: Chemgenex's Product Pipeline



SOURCE: Company information

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Ceflatonin®

- ▲ Ceflatonin® (homoharringtonine or HHT) is a small molecule that was identified from the National Cancer Institute (USA) natural product screening program which kills cancer cells through the induction of apoptosis (programmed cell death).
- ▲ Ceflatonin® has also been shown to be a potent inhibitor of angiogenesis, the formation of new blood vessels which are required to supply tumours as they grow.
- ▲ CXS is initially developing Ceflatonin® to treat specific cancers of the blood namely chronic myeloid leukemia (CML), myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML). Later development may include utilising the compound's anti-angiogenic properties for the treatment of solid tumours.
- ▲ CML is a rare form of leukaemia (5,000 new cases per year in the US) that is caused, in 70-80% of cases, by a chromosomal translocation that results in the generation of a new "hybrid" gene called bcr-abl which causes the unregulated proliferation of myeloid cells.
- ▲ The current treatment for CML is a compound called imatinib mesylate (Gleevec®) which targets the bcr-abl gene product found in these patients.
- ▲ Patients with CML that is not caused by the chromosomal translocation (20-30% of patients) fail to respond to Gleevec®. Furthermore, approximately 20% of patients who initially respond develop resistance and require other lines of therapy.
- ▲ Ceflatonin® has shown promising results in treating CML patients both as a single agent and in combination with Gleevec®. In a previous single agent Phase-II study, Ceflatonin® generated a 98% haematological response rate in CML.
- ▲ The current Phase-II trials are aimed at testing Ceflatonin® as a single agent and in combination with Gleevec in Gleevec resistant CML. This study is expected to be completed in early 2006.
- ▲ While the incidence of CML is low, Gleevec® currently generates annual sales of \$500m for the treatment of CML and total sales in excess of US\$1.6 billion which includes off-label use. As 20-30% of CML patients do not respond to Gleevec® and a further 20% develop resistance, a second line therapy for this disease could be expected to generate annual sales of US\$150m-250m as well as further sales from off label use.
- ▲ Given the limited number of specialist clinics for CML and the relatively small numbers of patients that will be required for Phase-III clinical trials, the company is likely to support the development of the Ceflatonin® into late stage clinical testing. As a result, the company will be in a position to secure significant royalties on sales with future licensees.
- ▲ CXS intends to apply for Ophan Drug Status of Ceflatonin® for the treatment of CML. This would provide the company with a number of benefits including seven year market exclusivity and an accelerated FDA review process.
- ▲ CXS also has an ongoing Phase-II open label study to evaluate the efficacy and safety of Ceflatonin® in the treatment of patients with myelodysplastic syndrome (MDS).
- ▲ MDS is a disease of the bone marrow which often affects patients over 60 years of age and can result in death from infection or bleeding.
- ▲ Results from the current Phase-II trial are expected in early 2006.

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Quinamed®

- ▲ Quinamed® (amonafile dihydrochloride) is a small molecule inhibitor of topoisomerase being developed for the treatment of solid tumours. The compound also affects ADP-ribosylation and the EGFR pathway.
- ▲ In initial clinical trials undertaken by the NCI in the early 1990's, Quinamed® demonstrated anti-tumour activity with response rates up to 25% in patients with advanced breast cancer and 12% in patients with advanced prostate cancer. However, the drug caused unpredictable side-effects and consequently its development was put on hold.
- ▲ Since this initial testing, it has been shown that the side-effects are a result of a metabolite generated from the drug. DNA sequences encoded by the N-acetyltransferase gene (NAT2) determine if a patient is a fast or slow metaboliser of Quinamed® and thus can be used to establish the appropriate dose for treatment.
- ▲ In June 2004, CXS reported the results of a Phase-I/II clinical trial which used patients genotype to determine the appropriate dose of Quinamed® to be used in treatment. In this trial, the drug was well tolerated with reduced side-effects and significant responses were seen in patients suffering from advanced prostate, ovarian and gastrointestinal cancers who had failed multiple prior regimens of chemotherapy including:
 - 40% reduction in tumour volume in a prostate cancer patient
 - stabilization of tumour growth in two ovarian cancer patients
 - response in gastrointestinal cancer patient who had failed previous treatment and surgery
- ▲ Preclinical testing in animal models have shown that Quinamed® is able to chemopotentiate or enhance the effects of standard therapeutic agents such as 5-FU, cisplatin and camptothecin.
- ▲ CXS is currently undertaking a Phase-II trial Quinamed® for the treatment of prostate cancer patients who do not respond to hormone therapy or docetaxel. This study may be expanded to include ovarian cancer patients later this year.
- ▲ The results from the prostate trial will be available in early 2006 and results from testing in patients with other solid tumour types are expected later that year.
- ▲ The results from these trials could result in approval for a salvage therapy indication for the treatment of prostate, colon, stomach and breast cancers. These represent significant markets for which there are currently very limited treatment options.

Table 1: Incidence and Market Size of Target Indication for Quinamed

| Indication | US Annual Incidence | Market Size (\$US billion) |
|------------|---------------------|----------------------------|
| Prostate | 230,110 | 2.1 |
| Breast | 217,440 | 3.3 |
| Colorectal | 146,940 | 2.2 |

SOURCE: American Cancer Society 2004, Company estimates.

- ▲ The company is likely to seek potential licensing partners for Quinamed® on the basis of the results of the Phase-II clinical trials. Such a licensing deal would typically include a royalty stream of 10-20% on sales as well as multi-million dollar upfront and milestone payments.

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CXS299

- ▲ In February 2005, CXS licensed in a novel platinum (IV) compound from the M. D. Anderson Cancer Centre in Houston, Texas, one of the leading cancer research facilities in the US.
- ▲ This compound has activity against cancer cells that have a wild type (non-mutated) p53 gene. Mutation of this gene is one of the common events during carcinogenic progress. However, in many disease types, such as ovarian, breast, testicular and non-small cell cancer, 45-90% of patients who have failed chemotherapy have a wild type p53 in their tumour cells.
- ▲ Thus, in combination with testing for p53 status, CXS299 offers a new approach for treating patients who do not respond to existing platinum (II) therapies such as cisplatin, carboplatin and oxaliplatin.
- ▲ CXS is currently in late preclinical development and is currently scheduled to enter Phase-I clinical testing in 12-18 months.

Diabetes & Obesity

- ▲ CXS's diabetes and obesity program has been supported by a long term partnership arrangement with Merck Santé, the French division of the pharmaceutical company Merck (Market cap €3.2 billion. To date, this partnership has provided the company with over A\$36m from research payments, milestone payments and equity investments.
- ▲ The current research contract continues until early 2006 and provides committed revenue of AU\$2.4 per annum plus additional payments to cover variations to the research program. In addition, CXS will receive \$5m for any target that progresses into Phase-II clinical trial and a 5-7% royalty on net sales.
- ▲ Discussions are in progress regarding the continuation of this partnership beyond 2006. Given Merck Santé participated in the AU\$8.2m capital raising in January 2005 and Merck Santé's CEO, Elmar Schnee, accepted a position on CXS's Board in January 2004, we believe there are good grounds for expecting the partnership to continue.
- ▲ CXS's diabetes and obesity program is based on the company's eXpress technology platform which provides an integrated approach to identify and validate new drug targets.
- ▲ The company has access to 44,000 human DNA samples and proprietary animal disease models as well as state-of-the-art statistical genetics through its facility at the Southwest Foundation for Biomedical Research, San Antonio, Texas.
- ▲ Over 65 novel diabetes and obesity genes have been identified and patented from the program and Merck Santé have taken out licenses to commercialise four of these genes: Beacon and SGIPI for obesity, and SelS and PSARL for diabetes.
- ▲ Both SGIPI and Beacon appear to regulate feeding rates and thus provide potential targets for weight reduction. Merck Santé have designated SGIPI for fast track development with the aim of progressing a lead compound into clinical trials in the next 12 months.
- ▲ Elevation of the SelS gene in animal models leads to diabetes symptoms while PSARL appears to be involved in pathways that are associated with insulin resistance. Merck Santé is in the process of evaluating these targets with a view to identifying lead compounds in the next 12-24 months.
- ▲ CXS retains the right to develop any intellectual property from this program for indications other than diabetes and obesity. Other potential disease applications of these genes currently include cancer and inflammatory disorders.

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Depression & Anxiety

- ▲ CXS's depression and anxiety program was partnered in August 2004 with the leading UK biotechnology company Vernalis (market cap £131m) in an initial deal worth up to A\$2m in the first year.
- ▲ Vernalis is a UK-based biotechnology company with a marketed product, Frovatriptan, to treat migraine and a development pipeline focused on CNS disease and oncology. The company has expertise in the preclinical and clinical development of new therapeutics making it a good partner for developing targets identified from CXS's depression and anxiety program.
- ▲ In February 2005, CXS received a \$720,000 payment from Vernalis for the achievement of a research milestone in its depression target discovery program.
- ▲ We believe discussions with Vernalis to continue and expand the partnership are progressing well and are likely to provide a source of ongoing research revenue as well as an opportunity to retain an interest in IP that is commercially developed by Vernalis.
- ▲ To date, CXS has identified and filed patents for ten novel genes that provide potential targets for the development of depression and anxiety therapeutics.

Management & Board

- ▲ Chemgenex has one of Australia's leading biotechnology teams that has demonstrated its ability to lead and grow the company and secure partnerships and deals in the international arena.
- ▲ Dr Greg Collier (CEO) has been part of the executive management team since 2000 and has led the company since 2002. Dr Collier was instrumental in securing the commercial alliances with Merck Santé and Vernalis and was critical in executing the merger opportunity with Chemgenex Therapeutics which transformed CXS from a discovery company to therapeutics focussed company.
- ▲ Dr James Campbell (VP Operations) has a unique combination of extensive scientific expertise and industry and start-up experience including managing companies from the commercial arm of Melbourne University and management consulting with the international company Booz Allen Hamilton.
- ▲ Dr Dennis Brown (President) heads the company's US operations and has extensive experience in cancer research and product development. Before establishing Chemgenex Therapeutics in 1999, Dr Brown was co-founder of Matrix Pharmaceuticals which was acquired by Chiron Corporation in 2002.
- ▲ Mr Harry Pedersen (VP Business Development) has 15 years experience in the pharmaceutical and biotechnology industry. Based in Menlo Park in the US, Mr Pedersen is well positioned to identify and develop licensing and partnering opportunities for the company's intellectual property.
- ▲ CXS's Board is chaired by Mr Brett Heading who is an experienced corporate lawyer specializing in capital raising and merger and acquisitions. Mr Heading has extensive experience in emerging companies in both the biotechnology and agribusiness sectors.
- ▲ In addition to Dr Collier and Dr Brown, CXS's Board also includes Mr Kevin Dart, representing Charter Pacific who currently holds 19.2% of CXS's ordinary shares, Mr Roger Byrne, former partner of Clayton Utz and Mr Elmar Schnee, Chairman and CEO of Merck Santé which holds an 8.5% interest in CXS.
- ▲ CXS also has a high quality Scientific Advisory Board that includes Dr John Blangero, a leading international statistical geneticist, and Professor Hagop Kantarjian, a leading specialist in leukemia.

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Operations

- ▲ Chemgenex has facilities in three sites:
 - Deakin University in Geelong where the company employs 40 research scientists for its gene and protein discovery programs under a research contract with the University
 - Menlo Park, California which manages the company's clinical development programs
 - San Antonio, Texas which provides access to state-of-the-art statistical genetics
- ▲ The R&D operations at Geelong are supported through the research partnerships with Merck Santé and Vernalis. Furthermore, the company has rolling 1 year research contracts with the University which provides the company with flexibility to adjust its discovery expenditure.
- ▲ During the last reporting period 1H05, CXS generated revenues of \$1.653 and cash expenses (R&D, employees and administration) of \$4.485 providing an EBITDA of (\$2.803m). The net cash flow from operations was (\$3.419m) and closing cash balance was \$3.613m.
- ▲ Since 1 January 2005, the company raised A\$8.2m at an issue price of \$0.55 and has received a milestone payment of \$720K from Vernalis. We would expect that the company would also be able to recognize up to a further \$1.2m revenue from the Merck Santé contract for the 6 months to 30 June 2005. Based on a pre merger cash burn rate of A\$3.4m/HY and an additional \$1m to support the US operations for 6 months and \$300K for clinical trial recruitment, we would anticipate CXS to have a closing cash balance of approximately \$8.5m on 30 June 2005.
- ▲ Assuming the Merck Santé and Vernalis contracts are continued at their current levels, the company will receive up to \$4.4m pa to support its R&D activities. Assuming a base cash burn of \$8.8m pa this will result in a base net burn of \$4.4m pa or a cash runway of approximately 1.9 years.
- ▲ During the next 12 months, the company will be completing Phase-II clinical trials for Ceflatonin® (77 patients for CML and 30 patients for MDS) and Quinamed (30 patients for prostate cancer). Assuming clinical trial costs of A\$15-25K per patient, this will result in additional expenditure of A\$2.0-3.3m reducing the cash runway to 1.2-1.5 years.
- ▲ It is likely that the company will need to raise additional capital within the next 12-18 months. However, with the results from three clinical trials becoming available within the next 9 months and access to the US capital market through the Level 2 NASDAQ listing, we do not anticipate the company will have difficulty in securing additional investment to support further clinical development of its compounds.

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Capital Structure

- ▲ CXS shares are currently quite tightly held with the top four shareholders holding 54.7% of the traded stock and the top 20 shareholders with 69.1%.

Table 2: Significant Shareholders of Chemgenex Pharmaceuticals

| Shareholder | Current Holding | % Traded Stock | % Post Escrow |
|-----------------------------|-----------------|----------------|---------------|
| Charter Pacific | 22,060,087 | 25.4% | 19.2% |
| Queensland Investment Corp. | 11,004,855 | 12.7% | 9.6% |
| Merck Santé | 9,793,750 | 11.3% | 8.5% |
| TOIBB Investment | 4,628,766 | 5.3% | 4.0% |

SOURCE: ASX Perpetual

- ▲ An additional 28m shares that were issued in consideration of the merger with Chemgenex Therapeutics will come out of escrow on 22 June 2005 increasing the number of shares quoted on the ASX to 114.8m. Dr Dennis Brown, the founder of Chemgenex Therapeutics owns 68% of the shares currently in escrow and will hold 16.6% of traded stock.
- ▲ As with many small cap biotechnology stocks, CXS is currently thinly traded with an average daily volume of 84,000 shares. This has resulted in a high degree of share price volatility on relatively small trading volumes.
- ▲ We believe that despite this volatility, the anticipated news-flow over the coming 12 months is likely to have a significant impact on CXS's share price and establish a substantially higher median trading price.

Events Calendar

- ▲ Over the next 12 months, we are anticipating significant news flow that is expected to have substantial impact on CXS's share price and result in an upward re-rating.
 - June 2005: Level 2 listing on NASDAQ
 - September 2005: Extension and expansion of Vernalis partnership
 - December 2005: Update on preclinical data from CXS299
 - Q1 2006: Results from Ceflatonin® Phase-II clinical trial for CML
 - Q2 2006: Results from Ceflatonin® Phase-II clinical trial for MDS
 - Q3 2006: Results from Quinamed Phase-II clinical trial for prostate cancer

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Valuation

- ▲ CXS is one of the few Australian biotechnology companies with multiple products in advanced (Phase-II or later) clinical testing. However, the company is currently trading at a significant discount compared with other biotechnology companies with clinically advanced compounds.

Table 3: Comparison of Australian Biotechnology Companies

| Company | Enterprise Value (\$A) | Compound in Clinical Testing | Stage | Indications |
|-----------|------------------------|------------------------------|----------------------|--|
| Novogen | \$480m | Phenoxodiol | Phase-II | Prostate Cancer Ovarian Cancer Cervical Cancer |
| Metabolic | \$129m | AOD9604 | Phase-II | Obesity |
| Pharmaxis | \$111m | Bronchitol | Phase-II/III | Bronchiectasis Cystic Fibrosis Bronchitis |
| Progen | \$64m | PI-88 | Phase-II | Melanoma NSCLC Myeloma |
| Chemgenex | \$63m* | Ceflatonin Quinamed | Phase-II Phase-II | CML MDS Prostate Cancer Ovarian Cancer |

* Including 28m shares released from escrow on 22 June 2005

SOURCE: Company websites

- ▲ It should be noted that Progen recently released results from its initial trials of PI-88 as a mono-therapy where it demonstrated limited efficacy which has had a significant impact on the company's share price.
- ▲ Our risk-adjusted DCF analysis of the compounds in clinical development and the diabetes/obesity and depression/anxiety programs support a stock price of \$1.15 compared with the current share price of \$0.62. Our model used a 40% discount rate and used conservative industry standard probability adjustments for progression through each stage of clinical development. As the risk will be significantly reduced once the results from one or more of the current Phase-II clinical trials become available, we would expect a significant further re-rating of CXS during H1 2006.

Outlook & Recommendation

- ▲ We believe that the current portfolio of products and the anticipated news flow from the company is likely to result in a significant re-rating of CXS over the next 12 months.
- ▲ As the company has two products in Phase-II clinical trials that have already shown promising data for a number of different indications, we believe that this provides sufficient diversification to significantly reduce the overall development risk across the portfolio.
- ▲ The company has a relatively sound cash position however the costs associated with the upcoming clinical trials will put additional pressure on this.
- ▲ As the company is generating revenues, has demonstrated a track record of securing additional investment from both new and existing investors (A\$6.2m in July 2004 and A\$8.2 in January 2005), and will have access to the US capital market through its NASDAQ listing in June 2005, we are confident that the cash risk is relatively low.
- ▲ Our comparison with other Australian companies with products in advanced clinical trials and our risk adjusted DCF analysis of future revenue streams from current products support our view that CXS is currently undervalued.
- ▲ Given the current thin trading volumes and the resulting share price volatility, CXS will provide an ideal speculative investment opportunity for investors with a 12-24 month investment horizon.

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