ISSN 1443-850X

In this edition...
Twelve back-to-back company presentations can tire the most ardent student of biotech investment. However, there are rewards for the patient conference attendee. At the Wilson HTM Life Science conference held in Sydney on Monday Oct. 12, attendees may have been impressed to learn, among other things, that within twelve months, Biota is likely to have two drugs in Phase II trials, that Acrux has been actively looking at ways to extend the scope of its transdermal drug delivery technology, and that in the not to distant future Pharmaxis will be on to its fourth Phase III trial.

The editors
Companies covered: ACL, ACR, AVX, BTA, COH, CXS, CXD, HXL, NAN, PXS, SHC, UBI

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (from 4 May '07)	-7.7%
Cumulative Gain	**202%**
Av Annual Gain (6 yrs)	**26.8%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd. The company also provides market and company analysis of the Australian pharmaceutical and biotech industries for local and international funds management institutions, venture capital funds and other related industry groups. For further details contact David Blake (see details below).

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Individual Subscriptions (48 issues/year)
$320 (Inc.GST)
Edition Number 237 (19 October 2007)
ISSN 1443-850X

Bioshares

19 October 2007
Edition 237

Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.

Conference Report

Wilson HTM Conference "Tapping into International Markets"

The 3rd **Wilson HTM Investment Group** Life Sciences Conference was held in Sydney on Monday October 15, 2007. Twelve Australian listed life science firms presented on the topic of "Tapping into International Markets". Edited highlights from a number of company presentations follow.

Alchemia (ACL)

Presenter: Dr Peter Smith, CEO

Alchemia is a developing a generic version of **GlaxoSmithKline**'s anti-coagulant drug, Arixtra (fondaparinux). This was initially developed by **Sanofi**, which took ten years to develop the compound. Arixtra is manufactured using a 62-step process that takes 18 months to complete, with a yield of 1%. Arixtra is a superior anti-coagulant but is a late entry in the market.

Alchemia has developed a novel patent-protected method of synthesis for fondaparinux, which it has licensed to Dr Reddy's. Prior to that, Alchemia had established a manufacturing relationship with Dr Reddy's to decrease the cost of manufacture. Dr Reddy's is the second largest pharmaceutical firm in India, and manufactures active pharmaceutical ingredients for 100 products. Dr Reddy's is close to completing a first manufacturing run of fondaparinux.

Alchemia believes fondaparinux will be entering a market worth around US$250 million, and according to CEO Peter Smith "will be a very profitable drug".

CEO Peter Smith posed the question "why is Arixtra (fondaparinux) interesting as a generic?" He said generic pricing depends on the number of sellers. But in the case of fondaparinux there would be only one other apart from the branded drug. Smith believes its version of fondaparinux could sit at price at levels close to the branded drug.

Smith was asked if it would be possible for a competitor to use Alchemia's manufacturing method. His answer was that it would be very difficult, because Alchemia has patents covering the basic building blocks.

Smith would not disclose when Alchemia/Dr Reddy's would file an ANDA (Abbreviated New Drug Application), because of concerns of GSK launching an authorised generic, although he did not think this is a strategy they would adopt. Smith said Alchemia's strategy was to gain a 40%-50% market share and sell its product at a modest discount to the branded drug.

Sunshine Heart (SHC)

Presenter: Brian Bolton, CFO

Sunshine Heart is developing the C-Pulse heart assist device that can address heart failure. The cost of heart failure is estimated at US$33 billion. There are an estimated 1.8 million Class I (least severe) patients, 1.6 million Class II patients, 1.4 Class III patients and 0.4 million Class IV (most severe). Sunshine Heart estimates of these, about 1 million patients represent unmet need

The C-Pulse device delivers a 60% increase in blood flow to the heart and 30% increase in blood flow to the body. A significant point of difference to other heart assist devices is that the device can be disconnected, with the risk of clotting and stroke non-existent. And all 900 cardiovascular surgery centres in the US would be capable of implanting the device

The company is waiting on the FDA to get the final approval to commence a US trial of the device. CFO Brian Bolton said that the company was optimistic that FDA approval and first patient implant will occur before year-end. A key endpoint of the clinical trial is reduction in hospitalisation.

Bolton was quizzed on the time taken by the FDA to review its US regulatory submission. He said that while the FDA is extremely thorough, the issues (raised by the FDA) are not a showstopper. Bolton said that the trial should last a year and cost about $11 million.

Bolton said that Sunshine Heart share price "had to be due for a re-rating (with the current share price) not reflective of a company on the cusp of a US trial."

Universal Biosensors (UBI)

Presenter: Mark Morrisson CEO

Universal Biosensors has developed a diagnostic platform that allows quantitative point-of-care (POC) diagnostic tests to be manufactured with large cost discounts to existing quantitative systems. The first product is a glucose monitor that the company is likely to form a manufacturing agreement with **Johnson & Johnson**'s Lifescan. Lifescan has about 25% of the global glucose diagnostic market. It has the option to license the technology for the glucose application only from Universal Biosensors.

Universal Biosensors has ramped up its staffing numbers, from 28 when it listed last year to 41 people now. Universal Biosensors' CEO Mark Morrisson was keen to remind investors the real upside for the company was to apply the technology to other diagnostic tests other than glucose and that any deal with Lifescan must make sense for shareholders.

Each of the diagnostic tests will require individual registration. The company could license the tests or take the products to market independently, with a similar distribution model to that planned for Pharmaxis and CathRx.

Universal Biosensors will look to enter the European market first because the barrier to entry is low. The US will take extra time to introduce the products. The company's aim is to have the glucose test registered by the end of next year.

The next diagnostic product will be the prothrombin time test, which is used for regular measurement of people on chronic use of the anticoagulant warfarin, such as people with a mechanical heart valve (see *Bioshares* 234). Another test under development is for the 'C-reactive protein', which provides a measure of inflammation within the body. The global market in 2005 for POC prothrombin tests was $125 million and for C-reactive protein (both laboratory and POC) was US$300 million. Product validation with these tests is expected to occur in 2009.

The company will have its official opening of its new manufacturing facility next month. Universal Biosensors will not rush to bring its products to market at the expense of quality or reliability, a point Morrisson was also clear to make with investors. He referred to these tests as transforming products of the future, and has confirmed the changing landscape in healthcare to point-of-care diagnostics that is now underway. Universal Biosensors has a current cash burn of $400,000 per month.

Nanosonics (NAN)

Presenter: Geoff Marshall CEO

Nanosonics is a developer of products that disinfect and sterilise medical devices, although the technology is applicable beyond that area. The company was spun out six years ago from Novopharm Research. The company's first product is a disinfectant for ultrasound probes. The technology utilises dispersed nano-droplets of hydrogen peroxide. The technology is also designed to generate revenue flows from the sale of consumables (cartridges of biocide solution). The technology allows for rapid cycle times, is environmentally friendly and disinfects at near ambient temperatures.

In addressing the conference theme of "Tapping into International Markets", Nanosonics CEO Geoff Marshall responded with a presentation sub-titled "R&D is only half the challenge". Marshall described the company's planning position from two years ago. This plan included raising 24 months of capital to cover slippage and affirm control, recruiting key personnel and finding and aligning with the right partners. And in an interesting twist, Marshall said the company planned to commence commercialisation prior to the completion of the R&D phase.

Marshall described the drivers in the disinfection market. These include the growing use in minimally invasive surgery which now often incorporate optical and other fragile materials, and an increase in hospital acquired infections (there are 7,000 deaths in Australian hospitals each year from hospital acquired infection). In addition, current disinfection methods are costly, time consuming and inadequate. For example, gas sterilisation is very capital intensive, autoclaves can damage delicate equipment and liquid immersion approaches require the use of toxic chemicals.

In developing the company's commercialisation strategy, Nanosonics' task was to find markets where there were gaps and do detailed sensitivity analysis so they could to understand how members of the value chain could generate returns.

A second challenge was to define the market, although in an overall sense the disinfection market was already defined. However, Nanosonics' research showed customers and medical instrument manufactures wanted change but there was no alternative to many current low cost but sub-standard approaches. Market development strategies for Nanosonics include identifying stakeholders and influencers and engaging them through a systematic campaign.

Marshall was asked how Nanosonics technology differs from comparable **Steris Corp's** technology. The main differences he said is that Steris technology is operated by central sterilising units, which means it doesn't address the POC market. Steris' equipment sells for US$70-US$100,000. In contrast, Nanosonics pricing, which is not yet finalised will be between US$6,000 and US$10,000. The pricing is getting narrower and narrower and will be finalised just before the first product hits the market. The company expects to receive roughly 50% of the list price with the remainder being shared with distributors.

The company has committed to manufacturing its products, essentially to ensure quality control. Nanosonics has developed a facility that can manufacture 3000 units a year on one shift a day. This can increase to 5000 units a year on two shifts a day. However, the company is in discussions with a third party manufacturer to produce up to 10,000 units per annum.

Nanosonics expects first sales to occur in the second half of FY2008.

Biota Holdings (BTA)

Presenter: Damian Lismore CFO

Biota is currently in a legal dispute with **GlaxoSmithKline**. Biota's litigation against GSK will take four years from when the action was commenced to the time it gets to court, which will be July next year, with the resolution anticipated by the end of 2008. Biota has modified its statement of claim, claiming damages of between $564 million - $704 million.

While the focus with many investors for Biota Holdings was the outcome of the litigation action against GlaxoSmithKline, Biota's CFO Damian Lismore was keen to draw attention to the transformation underway at the company. With one drug on the market (Relenza, sold by GSK) which helped the company generate $57 million of revenue last financial year, the company is in the process of building an advanced stage biotech company (after Relenza).

If all goes well, in three years time Biota will be a company with three Phase III programs underway. Lismore said that two of the company's clinical programs will move into Phase II clinical trials in the next twelve months. *More commentary on Biota's pipeline can be found on page 6.*

Avexa (AVX)

Presenter: Dr Julian Chick

Avexa is developing apricitabine (ATC), a small molecule anti-HIV drug. ATC is also classified as a nucleoside reverse transcriptase inhibitor (NRTi). According to the company, ATC could potentially serve as part of the second-line and third-line regimes of drugs that are used to treat HIV that are resistant to current NRTi drugs.

The full marketing rights for ATC were acquired from **Shire Pharmaceuticals** in January 2007. Avexa completed a $US65 million fund raising in April 2007.

Results from a 24 week dosing of ATC were recently released, with up to 85% of patients achieving a reduction in viral load of less than 400 HIV copies/mL. Another positive result from that stage of the trial was that there was a greater increase in CD4 cells in the ATC arm compared to the 3TC arm (another HIV drug). There were also no signs of resistance to ATC emerging in the study. Data from 48 weeks of treatment will be released in March 2008.

Avexa is planning a Phase III study, which is expected to commence by the end of 2007 (assuming discussion with the FDA conclude satisfactorily).

According to Chick ,one of the market drivers for the development of ATC is that eight of the ten major firms that dominate the HIV drug space do not have a nucleoside inhibitor in their portfolio or pipeline. Chick said that a product such as ATC "would sit comfortably with all of them".

Hexima (HXL)

Presenter: Dr Dan O'Brien

Hexima is an ag biotech company that recently listed on the ASX, raising $40 million. The company is developing genetically engineered plant traits that provide insect-resistance and fungal-resistance. The company is not focused on the Australian agricultural sector, but on initially applicating its technology to the high value corn and soy bean crops in the US and Brazil.

Hexima's insect resistance technology is based on a proteinase inhibitor discovered in the stem of a flower. When engineered into crops, insects are unable to digest the plant material. Hexima also has a multi-gene expression vehicle that enables the transfer of multiple genes into a plant in a single event.

Hexima's technologies are in a sweet spot because of the growth in energy prices and the desire to shift to alternative fuel systems such as bio-fuels (eg ethanol). However, increasing land scarcity and increased affluence, with the demand for meat protein increasing in developing countries are also key drivers.

Upcoming milestones for the company include an expansion to the collaboration the company has with **Dow Agrosciences**, and within 12 months, be able to announce one or more collaborations for the fungal resistance applications.

Pharmaxis (PXS)

Presenter: Dr Alan Robertson

Pharmaxis has brought the Aridol lung function test to market in Australia and Sweden, with more European states expected to follow. The company will file an NDA for Aridol with the FDA in Q1 2008. The company is also developing Bronchitol, a product that promotes the clearance of mucous from the lungs of cystic fibrosis, bronchiectatic and COPD patients. Pharmaxis employs 70 staff.

The company is finalising a Phase III cystic fibrosis trial of bronchitol with the FDA, which is expected to commence in the first quarter of 2008 and be completed in H2 2009. Pharmaxis recently successfully completed a Phase III trial of Bronchitol for bronchiectasis in Europe, Australia and New Zealand. Pharmaxis has in the planning stages, commenced or completed four Phase III trials. Alan Robertson said that when he started at Pharmaxis he was told that it was impossible for an Australian company to run Phase III trials.

The company recently raised $50 million to support the construction of new manufacturing facilities. Since 1999, the company has raised $194 million. CEO Robertson said that the reason why the company raised funds "was to make Pharmaxis a profitable and going concern" and that “raising funds on a milestone basis was not the way to build a profitable business". This is something of a minority view in the Australian biotech sector, but nevertheless is a forceful proposition, coming as it does from the CEO of the leading company at the emerging end of the biotech sector.

One important point mentioned by Alan Robertson was that Pharmaxis has been very successful in adjusting (over time) its shareholder register. In June 2005, founders and VC investors held 38% of the company; after the November 2005 raising their respective share was 27% and currently the figure stands at 2%. The implication is that VCs and founders have now made significant returns, which can allow those funds to repatriate earnings to their investors.

Acrux (ACR)

Presenter: Dr Richard Treagus CEO

Acrux is a drug delivery technology company that expects to have its first product, Evamist, on the market by the end of the year. Evamist is a transdermally-delivered formulation of estrogen indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

For the US market, Evamist is now partnered with **KV Pharmaceuticals**. Evamist will be competitive in price with existing hormone replacement therapies. Acrux expects Evamist to sell for approximately $40 per monthly treatment, with the marketing strategy driven by leveraging off patient preference for a low dose drug and convenient transdermal spray delivery.

CEO Richard Treagus described KV Pharmaceuticals, which will be marketing Evamist with its current sales force of 300 people, as "very aggressive" and as "very incentivised" to market Evamist, given that they acquired the rights to Evamist from Vivus for an up-front payment US$140 million.

Acrux raised $23 million in July to support the Phase III development of its male testosterone product. The company's decision to fund this next stage of development came at a time when it had received strong interest from potential licencees. However, the company realised there was meaningful value creation it could manage so long as it had the appropriate funds. It also undertook market research, which endorsed it decision.

Of the $20 million being applied to the male testosterone development, $15 million will support the clinical trial, with $5 million to fund development of the applicator, regulatory matters and commercial scale up. The trial will involve 150 patients at 30 sites, including three in Australia.

The Acrux CEO also revealed that the company had been undertaking research on improving the scope of the company's transdermal technology. The company had found that some compounds thought to be previously intractable to transdermal delivery were now more amenable to TD delivery, using various co-solvents and enhancers. The company has been evaluating the delivery of water-soluble compounds, and different ways of disrupting the stratum corneum.

Currently Acrux's cash position stands at $40 million. According to Treagus, the company "has no intention of coming back to the market for money”.

Cochlear (COH)

Presenter: Dr Chris Roberts CEO

Cochlear now employs 1700 people in 20 countries, and sells its products into 100 countries.

Chris Roberts, Cochlear’s CEO, observed that while the first cochlear implant occurred 25 years ago, the industry is still implanting at less that the annual incidence rate. This is one reason why the market is continuing to grow. At Cochlear the ten-year CAGR for sales is 18%, with a 24% increase recorded for FY2007.

What Cochlear is not sure of is if growth will continue at a high rate boosted by bi-lateral implants, or if growth will revert to the mean. For Cochlear,15% of unit sales are for a second implant, which represents growth off an installed base. However, one of the reasons Cochlear's sales grew so strongly is that the productivity of implant surgeons increased, implanting 25% more than the previous year, due to the efficiency of support the company is providing.

ChemGenex (CXS)

Presenter: Dr Greg Collier

Chemgenex is developing the cancer drug ceflatonin, a semi-synthetic alkaloid. Ceflatonin is covered by five US granted patents, and been administered to more than 500 patients. It has achieved favourable safety and toxicology results.

The drug is being trialed in several chronic myeloid leukemia (CML) niche indications, including the 'T315i mutation' sub-set of patients and the sub-set where two or more tyrosine kinase inhibitors have failed.

CEO Greg Collier explained that CML has become an attractive opportunity for ceflatonin, with patient numbers growing significantly because of the success of Gleevec. However, a problem with Gleevec has been that it doesn't penetrate the bone marrow and kill the cells that cause the disease, which contributes to the development of resistance. In June 2006, BMS's Sprycel was approved to treat Gleevec resistance but not the T315i mutation.

Collier's view is that ChemGenex is "ahead of the pack in terms of competition" with the closest drug in development being **Merck/ Vertex's** IV-delivered drug which has yet to show a hematalogical response.

CathRx (CXD)

Presenter: Neil Anderson

CathRx is developing a range of catheter devices that can be used in the diagnosis and treatment of cardiac arrhythmias (electrical problems of the heart). The company recently raised $25 million to accelerate development of devices to be used in treating atrial fibrillation. The company has cash on hand of $27.8 million and the quarterly burn rate in the September quarter was $1.67 million.

Growth in the catheter market is being driven by an ageing population, with the market growing at 10% CAGR. In 2007, an estimated 1 million diagnostic catheter procedures will be performed compared to 520,000 therapeutic procedures. The estimated value of the diagnostic component is $660 million, while the value of the therapeutic sector is $380 million.

CathRx developing a suite of products. It is initially concentrating its efforts on the European market, which represents 25% of the global market. CathRx is differentiating its products by offering formable stylets and reusable deflectable stylets, that incorporate modular componentry, to gain market share from the 'fixed curve' market. Modularity is also a feature of the 4mm and 8mm range of catheters.

CathRx has received CE Mark approvals for its own diagnostic fixed curve catheter and its diagnostic deflectable catheter. However, it has submitted 'change notes' to cover the incorporation of the formable stylet with the fixed curve catheter, and to cover electrode radio-opacity for the diagnostic deflectable catheter.

Bioshares Model Portfolio (19 October 2007)

Company	Price (current)	Price added to portfolio
Acrux	$1.38	$0.83
Alchemia	$0.79	$0.67
Biota Holdings	$1.62	$1.55
Circadian Technologies	$1.26	$1.45
Clinuvel Pharmaceuticals	$0.52	$0.66
Cytopia	$0.47	$0.46
Chemgenex Pharma.	$1.08	$0.38
Optiscan Imaging	$0.41	$0.35
Peplin	$0.90	$0.83
Peptech	$1.16	$1.31
Pharmaxis	$4.18	$3.15
Phylogica	$0.24	$0.42
Probiotec	$1.20	$1.12
Progen Pharmaceuticals	$3.29	$3.52
Sirtex Medical	$4.15	$3.90
Starpharma Holdings	$0.47	$0.37
Sunshine Heart	$0.18	$0.19
Tissue Therapies	$0.46	$0.58
Universal Biosensors	$1.25	$1.23

Portfolio Changes – 19 Oct 2007

IN:
No changes

OUT:
No changes

Update – Biota's Pipeline

Biota has been progressively builidng its pipeline of drugs in development. The following update is sourced from the company's R&D day with analysts held early in the year and Biota's presentation at the October Wilson HTM Conference.

BTA798 – Rhinovirus

BTA798 is a compound that targets the rhinovirus, a virus responsible for the common cold. BTA798 has completed Phase I safety studies and will move into Phase II trials in the second quarter of next year. This will be a challenge study, where volunteers will be infected with the virus and then treated with BTA798. The target market is asthmatics and people with chronic pulmonary obstructive disease. For most people, the common cold is a minor irritation, however 71% of children in emergency rooms are infected with the rhinovirus.

The drug candidate works by encapsulating the virus thereby preventing it from entering the host cell. BTA798 is designed around the **Schering-Plough** drug Pleconaril, also for the treatment of the common cold. The Biota team have tried to design out the side effects of Pleconaril, for which there have been concerns of pharmacodynamic interactions with oral contraceptives leading to unwanted pregnancies. Preclinical studies have shown BTA798 to be as effective as Pleconaril at a fraction of the concentration. Biota aims to take the drug to the end of Phase IIb studies and then to license the drug to a pharmaceutical partner.

CS8958, Flunet – Influenza

In conjunction with **Daiichi-Sankyo** in Japan, Biota is developing a second generation Relenza product which is a longer acting influenza drug targeting the same protein pocket as Relenza. The compound (CS8958), one generated by Daiichi-Sankyo, is expected to move into Phase II studies next month with a novel inhalation device. The back-up compound for this program and also co-owned by the two companies is called Flunet and has been taken as far as the preclinical stage.

RSV partnership

The company's second collaboration is with **MedImmune**, which has recently been acquired by **AstraZeneca**, for the development of an antiviral drug to treat the respiratory syncytial virus. RSV is an infection that most children under the age of two have experienced. The total deal value with MedImmune was worth US$107 million including an upfront US$5 million. The company recently received a US$3 million milestone payment as the project moved into Phase I studies.

MedImmune already has an antibody RSV drug, Synagis, on the market generating sales of US$1.1 billion. The Biota drug candidate has the opportunity to grow the RSV market for MedImmune significantly. (Synagis is predominantly used prophylactically in premature children. It is dosed once a month by injection during the RSV season and costs around $900 per month.) An oral and cheaper RSV drug would have good synergies with MedImmune's Synagis product.

HCV partnership

Biota's third drug development partnership is with Boehringer Ingelheim for the development of a therapeutic for the treatment of hepatitis C virus. This program is worth up to US$102 million in upfront and milestone payments. Hepatitis C is a difficult therapeutic space for a number of reasons. The virus is difficult to grow, the animal models are complex, the replicon differences (from where the virus replicates), and hepatitis C is a mutable virus.

This program comes from Biota's **Numax** acquisition in the US in 2001 and is based on Numax's nucleoside platform, which goes after the RNA production target of virus. Nucleoside analogue drugs have been ignored by major pharmaceutical companies although biotech companies such as Gilead Sciences have been successful in this area with antiviral drugs such as Emtriva. About 40% of antivirals are nucleoside analogues which work by stopping the elongation of virus chain growth. The are a few companies with hepatitis C nucleoside drug candidates in clinical studies. These include **Isis/Merck**, **Idenix/Novartis** and **Pharmasset/Roche** with each of these nucleoside drug candidates in Phase I clinical trials.

Within three years Biota will have products in three Phase III trials, if clinical development progresses well.

Bioshares

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Phylogica, Pharmaxis, NeuroDiscovery, Biotech Capital, Cygenics, Cytopia, Biodiem, Peptech, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Medical Therapies, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD

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