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In this edition...
What is the attraction of biotech investing? If it takes so long to get products to market, to see profits made, why bother? If the hurdles seem too numerous and ever changing, why bother? Without doubt, a return on investment is a leading goal, the fact that biotech companies can create and deliver life changing and life saving medical products to a global customer base is also a compelling reason. We are now seeing a number of companies generate sales of life changing medical products, with others, such as Tissue Therapies moving closer to the final stages of clinical development. We comment on the Tissue Therapaies AGM held this week. We also take an indepth look at Phosphagenics' development of its transdermal drug TPM-Oxycodone, one of several emerging from it alpha-tocopheryl platform.
The Editors
Companies Covered: ACL, POH, TIS

	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 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - Current)	2.5%
Cumulative Gain	**197%**
Av Annual Gain (9 yrs)	**18.5%**

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Bioshares

15 October 2010
Edition 381

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

As the AGM Season Begins – A Pause for Reflection

Annual reporting season has just finished and it's time to read through the progress that Australian biotech companies are making. It's also the start of the Annual General Meeting season and *Bioshares* will seek to cover many of these meetings for readers and report on key issues or points raised.

On reading through the annual reports, it is striking to note the progress that many companies in the sector are making and to observe the cutting edge of technology commercialisation at which many companies operate. **Clinuvel Pharmaceuticals**' annual report is well worth the read, perhaps the most comprehensive and informative reports that the company has prepared. Scenesse, a drug developed to provide photo-protection, is on the market in Italy and the product is approaching completion of its Phase III studies for EPP, with a filing for European registration expected in early 2011. The proximity to market and a better understanding of its market and commercialisation strategy has obviously made the company comfortable in detailing very specific information about its target markets and entry process.

Bionomics has once again prepared in its Annual Report an excellent snapshot of the progress that company is making and the key milestones ahead in a format that is very accessible to investors.

Investors are attracted to the biotech sector for a number of reasons. Biotech is about seeking to make a real difference to the standard of living of the world's population. Australian biotech companies are arguably punching well above their weight in this regard with the novel technologies and new therapeutics that in many cases are seeking to deliver critical medicines to address many unmet medical needs, and novel diagnostic products and procedures as the world creeps into more of preventative medicine approach.

It is a time for reflection when many of these medicines and products are now reaching market and it is also a time when Australian investors can be proud of their support for these medical advances. Clinuvel Pharmaceuticals' product Scenesse is now being used by Italian patients with an intolerable exposure to direct sunlight that offers demonstrable relief to a chronic affliction. The product is also being made available to 45 patients on a compassionate use basis at no cost (82% of patients from the Phase III trial in countries where compassionate use is allowed are continuing treatment) while the company waits on broader approval of its product.

Pharmaxis is due to hear back from regulators by year's end about its new therapy for people living with cystic fibrosis. The average life span for people with cystic fibrosis is just under 40 years. Pharmaxis' Bronchitol compound can alter the progression of this condition and should extend the life of people living with cystic fibrosis. That drug is also

– Cont'd over

being made available to people on compassionate grounds at no charge to patients.

Chemgenex has shown how difficult it can be to bring a new cancer drug to market. Its drug candidate Omapro is in development to treat chronic myeloid leukemia in people who have failed all other options. The company submitted its drug candidate with the FDA last year however will need to resubmit its marketing application in early 2011 with a slightly different patient group.

The **Sirtex Medical** Annual Report is another report that is worth taking the time to read. The Sir-Spheres liver cancer treatment product was approved for use in 2002. To date the product has been used to treat over 15,000 people with liver cancer. Associate Professor Peter Gibbs at the Royal Melbourne Hospital said that in his experience, 5% of patients with Sir-Spheres treatment see their tumours disappear, and in most other patients it is progressing patients' lives. There are now 480 hospitals and treatment centers around the world using treatment.

Tissue Therapies' novel wound healing product is nearing the market. Its first application will be for patients with venous leg ulcers that do not heal. Professor Keith Harding, from Cardiff University in Wales, was in Brisbane earlier this month and will be the principal investigator for the forthcoming Australian/European trial. According to the company, Harding is acknowledged as the foremost international researcher/clinician in wound healing. In an interview with the company Harding said that what was impressive about the company's VitroGro wounding healing therapy candidate was its high level of consistency in response, compared to other biological products that he has been worked with.

Bionomics may have world's leading vascular disrupting agent (VDA) drug in development. As the name suggests, vascular disrupting agents destroy tumours from the inside breaking apart tumour blood vessels. Interim results from the company's Phase II renal cancer study and Phase II mesothelioma trial are due in the first half of 2011.

Mesoblast is forging ahead with its new-age regenerative medicine approach. Using the body's own regenerative capabilities, Mesoblast has found multiple potential applications for its adult stem cell therapy and has become the leading global stem cell company. Its autologous stem cell therapy is now available in Australia for the treatment of fractures, including non-healing bone fractures. Its allogeneic stem cell therapy is being investigated the treatment of heart disease, for use in bone marrow transplantation, spinal fusion and cartilage repair.

In the diagnostic space, several Australian companies are seeking to change the way healthcare is practised. Impedimed is selling its product to aid in the detection of sub-clinical lymphedema - that is before obvious symptoms have appeared and the condition is reversible or progression preventable. It is a common additional issue for women who have undergone breast cancer surgery and one that should be completely preventable.

Atcor Medical is seeking to gain wider use of central blood pressure measurement as an early predictor of heart disease (or more specifically arterial stiffness). Standard cuff pressure provides only a limited perspective of the health of a person's vasculature system. Combined with the measurement of central blood pressure, a significantly more insightful assessment can be made non-invasively and quickly about the health of a person's arteries.

Resonance Health has developed a product, called FerriScan, that allows iron levels in the liver to be measured non-invasively, with MRI scans, a technique that also is arguably more accurate that the traditional method of using a 16 gauge needle to take a liver biopsy. The test has been used in over 8,000 people now. In some children's hospitals it has now completely replaced the painful biopsy procedures used in children.

This is not an exhaustive list but merely a snapshot, and companies such as CSL, Biota Holdings and Cellestis also having made important and highly significant contributions to medicine.

The second reason people invest in this sector is because of the interest they have in assessing novel and sometimes cutting-edge technologies. We argue that biotech is a sector that can be far more interesting for investors to study than mining, banks or toll road companies.

The third and most important factor that attracts people's interest to the sector is that very strong returns can in fact be achieved from investing in listed biotech companies. By way of example, the *Bioshares* Model Portfolio has generated an average annual gain over the last nine years of 18.5%. However, volatility remains and is one factor that investors must continue to acknowledge.

The Australian biotech sector is now delivering real products that are being sold into global markets that are changing and improving global healthcare. It can no longer be painted as a sector wantonly proposing 'pie-in-the-sky' development programs. Real businesses have been formed that are profitable, delivering dividends to shareholders and making a tangible difference to people's lives.

A disappointing aspect is that the sector still has not achieved broader investment support, particularly from Australia's superannuation funds. Also disappointing is the crucial lapse of support of the current Federal Government with the cessation of the Commercial Ready grant facility coming at the worst possible time, in the midst of the Global Financial Crisis. While many of the leading/advanced companies have been able to continue to source investment funding, the outlook for smaller and less advanced biotechs in Australia has become very challenging.

Over the last decade Australia has clearly built the expertise to commercialise medical and agricultural technologies that have been pioneered at Australia's world class research facilities. However the longer-term risk is that the wave of commercial medical breakthroughs that is now occurring, and should be celebrated, will not be repeated for another 10 to 15 years, at least not at the level that has been achieved as a result of the last decade of investment into the sector.

Bioshares

Tissue Therapies Builds Momentum All Round

Tissue Therapies (TIS: 41.5 cents) has enjoyed a spectacular run in its share price in the last week on very strong volumes. The combination of continued stunning clinical results from its wound healing therapeutic in development, granting of patents, an interview with one of the world's leading authorities on wound healing about the company's VitroGro therapy, and the holding of Tissue Therapies' AGM this week have all contributed to the rise.

Patents Granted

Just this month, Tissue Therapies announced that its third patent has been granted in the US, its third patent has been also granted in Australia and its first patent has been allowed in Europe. A summary of the company's US granted patents are as follows:

- Dated August 2010, 'Methods of producing growth factor complexes, patent number 7,785,835, expires 2027
- Dated February 2010, "Growth factor complexes and modulation of cell migration and growth", patent number 7,659,367, expires 2024
- Dated April 2009, "Growth factor complex", patent number 7,514,398, expires 2021

The second patent appears to be the core patent for the company, with the patent also listing the uses of the growth factor complexes, which includes for "stimulating or inducing cell migration, and/or proliferation, which may have use in wound healing, tissue engineering, (and) cosmetic and therapeutic applications such as skin replacement, and skin replenishment and treatment of burns".

The granting of these patents has contributed critical value to allow a licensing agreement of the technology, which the company is currently aiming to secure.

Interview with Professor Keith Harding

This week the company released the transcript of an interview it conducted with Professor Keith Harding, from Cardiff University. Harding is a scientific advisor to the company and also is principal investigator of the company's forthcoming trial in Australia and Europe.

The forthcoming trial is targeted for completion by year's end and will seek to enroll 40 patients with venous ulcers. The aim is to report data from the trial by the end of March next year, a goal Harding is confident of meeting.

Further Clinical Data

The company has continued to release further clinical data in recent weeks from its Australian wound healing trial. In the 30 patients recruited, the average patient had been receiving the best standard of care with compression therapy but without full closure of wounds. Using the VitroGro therapy, those wounds were reduced by an average 43% in wound area in just 24 days, with five of the 30 patients achieving complete wound closure in that period.

2010 AGM

In the company's AGM presentation slides this week, Tissue Therapies indicated that licensing discussions for VitroGro were now in the due diligence phase with a number of groups. The company indicated that the global market for its diabetic and venous ulcer dressings was worth $4 billion a year. According to Harding, "the potential for VitroGro, if the evidence that emerges supports the data that is already there, is enormous."

The company will be seeking regulatory approval for VitroGro in the first half of 2011. Its scale up process for its new manufacturing process has been completed. If it can hit all of its planned milestones, including a global licensing deal, then the interest seen in the stock over the last week should almost certainly continue.

Tissue Therapies is now capitalised at $57 million.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

Phosphagenics to Move TPM-Oxycodone Forward into Phase II/III

Phosphagenics (POH: $0.10) is a platform technology company that is developing a range of pharmaceutical and cosmetic products that uses alpha-tocopheryl (a form of Vitamin E) to aid and enhance the transport of other active ingredients across the skin. Alpha-tocopheryl changes the structure of the skin to enable compounds to pass through.

The company is based in Clayton, Melbourne, employing a staff of approximately 25.

Its lead pharmaceutical product in development is TPM-Oxycodone, an extended release drug delivered transdermally for managing breakthrough pain in situations where chronic pain is an issue, such as that experienced by cancer patients, arthritis sufferers, people experiencing back pain and for post-herpetic neuralgia (pain associated with shingles).

Transdermally delivered pain medicines offer the advantage of maintaining constant levels of drug in the blood stream, and therefore can address the problem of breakthough pain that can occur in the peak and trough cycles that stem from administration of oral forms of pain drugs.

Other pharmaceutical products in development include TPM-Lidocaine and TPM- Diclofenac (also for pain), and TPM-Insulin for the management of diabetes.

Oxycodone Market

Oxycodone is a synthetic opioid drug that was first synthesized in 1916 in Germany and then developed as Oxycontin by **Purdue Pharma,** a privately held company based in Connecticut. Oxycontin was approved in 1995 by the FDA. Oxycodone has been a very successful yet controversial drug as it has become a target of abuse and improper use. Sales of Oxycontin in the US totalled US$3 billion in 2009. Oxycodone in immediate release or extended release formulations, alone or in combination with other drugs, accounted for I in 5 opioid prescriptions in the US in 2009.

Oxycodone is between 1.5 and 2 times more powerful than morphine.

Extended release opioid products accounted for 8.9% (22.9 million) of all opioid prescriptions in the US in 2009, in contrast to immediate release opioids with 234 million scripts (91.1%). Within the extended release category, oxycodone scripts totaled 7.7 million (33.7%), morphine 5.2 million scripts (22.5%), fentanyl 5 million scripts (22%), and methadone 4.4 million scripts (19.3%).

Extended release oral formulations of oxycodone are sold by **Mallinckrodt** and **Purdue Pharma**.

The First Oxycodone Patch?

Phosphagenics TPM-Oxycodone could be the first oxycodone patch to reach the market. The transdermal pain patch market was dominated for several years by Duragesic, marketed by **Johnson & Johnson.** This drug saw sales rapidly increase from US$200 million in 2000 to peak at around US$2 billion in 2004, with patents expiring in January 2005 in the US. However, safety issues, including several deaths and the introduction of generic fentanyl patches by **Actavis**, **Lavipharm Labs**, **Mylan Technologies**, **Noven**, **Teva Pharmaceuticals** and **Watson Labs**, have caused sales of Duragesic to decline. Sales of Duragesic in the US in 2005 were US$582 million and globally $1.585 billion. In 2009 Duragesic sales in the US were $216 million and $888 million globally.

However, US prescriptions for extended release formulations of fentanyl increased from 4.3 million in 2005 to 5 million in 2009, a growth of 16%, just slightly below the growth in total opioid prescription of 18% for the same period.

The sustained demand for fentanyl transdermal systems provides some evidence of the opportunity that exists for the development of an oxycodone transdermal system. To date it has been to difficult deliver oxycodone across the skin. Phosphagenics has found it is easier to use the base form (not salt form) of oxycodone to effect transdermal delivery. It has now shown that oxycodone can be delivered using its matrix patch system.

A second potential advantage of Phosphagenics' TPM-Oxycodone is that an inherent property of alpha-tocopheryl has is that it is anti-inflammatory which may mean much less skin irritation occurs while a patch adheres to the skin.

Relatively few transdermal drugs (in patch rather than gel form) have been approved.Those that have include buprenorphine, clonidine, fentanyl, estradiol, granisteron, methylpenidate, nitroglycerin, oxybutinin, rivastigmine, scopolamine, selegiline, testosterone and nicotine.

Competition

Phosphagenics' objective of developing a patch for breakthrough pain is not without competition. This year **Purdue Pharma**'s Butrans (buprenorphine), a semi-synthetic opioid, was approved by the FDA for the management of moderate-to-severe chronic pain in patients requiring a continuous, around the clock opioid analgesic for an extended period of time. Butrans is designed for a seven day application.

Durect has completed a Phase II study of its Transdur-Sufentanil (fentanyl) transdermal seven day pain patch in 74 chronic pain patients and a Phase II study of Transdur- Bupivacaine transdermal three day pain patch in 60 post-herpetic neuralgia patients.

Development History

About four years ago, Phosphagenics began development of a TPM-morphine gel product, which was also going to be developed as a patch product. However, in late 2007 the company met with **Purdue Pharma** and also conducted market research. Results of these discussions and the market research led to the development of an oxycodone transdermal patch product.

Phosphagenics first developed a reservoir style patch, before switching to a matrix polymer film back product. It explored two versions of the matrix patch, one incorporating the hydrochloride oxycodone (the 'salt' form), with the other oxycodone in the base form.

– Phosphagenics cont'd

Risk management issues have driven development down the matrix patch path, which should be more difficult to tamper by persons wanting to extract drug from the matrix.

Phosphagenics has now completed three Phase I trials of TPM-Oxycodone. Its first Phase I trial was a repeat insult test in 50 subjects which showed that a TPM-Oxycodone patch did not cause any opioid based erythema or sensitisation. In its second Phase I trial completed in Q4 2009, it showed that therapeutic levels of oxycodone were delivered in a constant manner. The company evaluated both a reservoir and a matrix patch in 20 subjects, with the patches changed daily for 10 days.

The company announced this week the results of its third Phase I study in 40 subjects, which showed that a weekly patch could deliver enough oxycodone to manage moderate pain but not severe pain. However, the company said it was confident that delivering sufficient drug to treat severe pain could be achieved as it works to scale up the manufacture of the patch.

The company announced this week that it set to move from lab-scale patch manufacturing to commercial manufacturing and would be aiming to commence a Phase II/III trial in 2011.

TPM-Oxycodone – Phase III Program Planned

Phosphagenics intends to conduct a Phase II/III trial of TPM-Oxycodone. According to the company, it believes that for a Phase III program it could conduct a 300 patient Phase II study, and take 60 of the best responders into a Phase III program.

However, we note that Purdue Pharma's Butrans was evaluated in one 12 week study that enrolled 1,024 opioid-naive patients with chronic low back pain and in another 12 week study that enrolled 1,160 opioid-experienced patients with chronic low back pain.

It could well be that Phosphagenics would need to conduct several trials of a similar size. Such a program may cost anywhere between $30 and $40 million to complete. However, Australian investors have been willing to fund advanced development programs with a decreased molecule risk profile, such as Acrux's **Axiron** product ($22.5 million) and **QRxPharma**'s MoxDuo ($21.7 million - FY2010; $51.7 million - IPO).

REMS and Transdermal Drug Guidance

Risk Evaluation and Mitigation Strategies (REMS) and transdermal drug guidance (see side bar) have been progressively brought to bear on drug developers in general and opioid drug developers specifically. They impose new costs at all stages of drug development and this will apply (if indeed it hasn't already) to Phosphagenics and any development partner it enlists.

However, to some degree, Phosphagenics is benefiting from being in the right place at the right time, as it can respond to recent guidance as it finalises and plans for the later stage development of TPM-Oxycodone.

– Cont'd over

FDA Guidance on Transdermal and Related Drug Delivery Systems

In August of this year, the FDA issued draft guidance on *'Residual Drug in Transdermal and Related Drug Delivery Systems'*. The purpose of the guidance is to ensure that the amount of drug remaining in the transdermal device after use is at a minimum. According to the document, residual drug ranges from 10%-90% in existing devices, which means that safety is a concern.

The FDA has recommended that quality by design approach be adopted, which includes continuous product improvement throughout a product's life.

The guidance asks developers to minimise residual drug by optimising penetration enhancers, self-depleting solvent systems, adhesives, the type and concentration of excipients, adhesives thickness, drug load, and thickness of backing layers.

REMS

The FDA can enforce drug developers to design and adopt Risk Evaluation and Mitigation Strategies (REMS) for drugs that it deems warrant additional risk management beyond what is provided in a product label, including black-box warnings.

Approximately 90 FDA approved drugs are subject to REMS management plans, with the FDA paying close attention to opioid-based drugs.

REMS requirements are an expensive additional cost for drug developers and marketers. A REMS plan must include a medication guide, a communication plan, an 'elements to ensure safe use' component, accompanied by an implementation plan and a time table for the submission of assessments.

A REMS plan for example, may require that prescribers have special training, that pharmacists or nurses have special training, or that procedures and systems are in place for the disposal of unused drug.

The FDA has more recently targeted opioid drug manufactures and developers, seeking REMS on a class basis for long acting and extended release and long-acting opioid drugs. One of the drivers for this has been abuse stemming by improper use and prescription of OxyContin (oxycodone). Oxycontin was approved in 1995. Prescriptions of OxyContin increased from 821,000 in 1997 to 6.2 million in 2002, with 85% of prescriptions not related to cancer pain management.

The rate of admissions to hospital emergency department from non-medical used of extended release oxycodone was on average 35 in 10,000, for the years 2004-2006 compared to an average seven per 10,000 for immediate release formulations.

Bioshares Model Portfolio (15 Oct 2010)

Company	Price (current)	Price added to portfolio	Date added
Phylogica	$0.047	$0.053	September 2010
Sunshine Heart	$0.030	$0.036	June 2010
Biota Holdings	$0.96	$1.09	May 2010
Tissue Therapies	$0.42	$0.21	January 2010
QRxPharma	$0.89	$0.25	December 2008
Hexima	$0.30	$0.60	October 2008
Atcor Medical	$0.12	$0.10	October 2008
Impedimed	$0.80	$0.70	August 2008
Mesoblast	$2.54	$1.25	August 2008
Circadian Technologies	$0.62	$1.03	February 2008
Patrys	$0.09	$0.50	December 2007
Bionomics	$0.27	$0.42	December 2007
Cogstate	$0.26	$0.13	November 2007
Sirtex Medical	$5.35	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.19	$0.66	September 2007
Starpharma Holdings	$0.56	$0.37	August 2007
Pharmaxis	$2.70	$3.15	August 2007
Universal Biosensors	$1.44	$1.23	June 2007
Acrux	$2.36	$0.83	November 2004
Alchemia	$0.53	$0.67	May 2004

Portfolio Changes – 15 October 2010

IN:
No changes.

OUT:
No changes.

– Phosphagenics cont'd

Recent Board Changes

On August 24, 2010, the company announced a major change to its board, with Dr John Mills and Michael Ashton stepping down. Stuart James, Don Clarke and Dr Sandra Webb were appointed to the board, joining Jonathan Addison (Chair), Harry Rosen and Dr Esra Ogru (Executive directors).

Stuart James was formerly CEO of Mayne Pharma, Dr Sandra Webb was previously with Quintiles Australia and was a CEO of Amrad and Don Clarke a partner with law firm Minter Ellison.

The objective of the board changes was to add members with stronger pharmaceutical industry experience.

Summary

There is a clear and potentially large market opportunity for TPM-Oxycodone, despite the added development hurdles imposed by the regulator of the US prescription drug market. The market for pain drugs is well established and although subject to generic competition, the demand exists for improved approaches based on proprietary technologies, which is what Phosphagenics offers.

A challenge for Phosphagenics is to marshall financial resources to advance the Phase III development of TPM-Oxycodone.

Phosphagenics is capitalised at $74 million and held cash assets of $8.4 million at June 30, 2010.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Alchemia Edging Closer

Alchemia (ACL: 53 cents) is awaiting approval for the ANDA of its generic fondaparinux drug by the FDA. The FDA has indicated that it will inspect the syringe filling facility of its partner, Dr Reddy's in India, in November. Alchemia believes that FDA manufacturing facility inspections generally occur prior to approval of products. That should place the approval time, if all goes well, around that of Acrux's Axiron product, towards the end of November this year.

Alchemia is capitalised at $101 million.

Bioshares recommendation: **Speculative Buy Class A**

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: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, BioMD, Tissue Therapies, Viralytics, Phosphagenics

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