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In this edition...
Biodiem received a major endorsement this week by signing an agreement with the US Centers for Disease Control. Is the company vastly under-valued, or is its low cap justified?
We also apply the comparative valuation ruler to Mesoblast and Living Cell Technologies.

Recently, Polynovo, a company in which Xceed Biotechnology holds a 60% stake, established a joint venture with Adelaide burns surgeon Dr John Greenwood.
To get a better understanding of what that JV is all about, and just how Polynovo's polymer technology can actually be applied to treating burns, we have devoted a section for our Q&A with Dr Greenwood.

The editors
Companies covered: BDM, LCT, MSB, XBL

	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 (from 5 May '06)	-13.4%
Cumulative Gain	**141%**
Average Annual Gain	**21.7%**

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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Bioshares

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

Biodiem Partners LAIV with the US Centers for Disease Control (CDC)

Biodiem (BDM: 34.5 cents) co-signed with its manufacturing partner **Nobilon**, an agreement this week with the US **Centers for Disease Control** (CDC). It covers the evaluation and development of a live attenuated intra-nasal flu vaccine (LAIV) suitable for vaccination against the influenza A H5N1 virus, the strain perceived to be the most likely candidate for causing a flu pandemic. An LAIV targeted against the H5N1 virus may give healthcare planners increased flexibility in managing a flu pandemic.

This is a second line of development for the LAIV technology, with first line being the development of a vaccine for seasonal use. A pre-clinical program for seasonal vaccine is underway.

Each year, influenza vaccines are manufactured to cater for what are predicted to be dominant strains of the influenza virus. The majority of vaccines are developed using a 'killed' or inactivated form of the virus. Medimmune has developed, and markets a live attentuated flu vaccine, Flumist, similar to Biodiem's LAIV.

The benefits of the tie-up with the US CDC not only include welcome but unstated funding for the project, but confirm the relevance of Biodiem's LAIV technology by one of the world's most important disease prevention bodies. While LAIV technologies may not be considered worth developing as a potential for flu pandemic preparedness locally, they do appear to have gained the interest of USA authorities.

What has gone unnoticed about the deal is the presence of the third party, Nobilon. This company is developing large scale mammalian cell culture manufacturing capabilities. Such capabilities have been identified by the US Government as a key component of its *National Strategy for Flu Pandemic*.

Biodiem has struggled since it listed to gain acceptance in the market, despite its access to prospective royalties in Europe and shared marketing rights for Japan from a potentially valuable influenza vaccine, and the value yet to recognised from the licensing of marketing rights of the LAIV for North American markets.

Factors mitigating against the stock in the market may be the fact that royalty revenues are still at least three to four years away and that Biodiem must pay 20% of its royalties or out-licensing payments to the **Institute of Experimental Medicine** in Russia.

Biodiem is capitalised at $18 million, including shares to be issued under a proposed underwritten rights issue. The company will hold cash assets in the order of $6.5 million, post rights issue

Bioshares recommendation: **Speculative Buy Class B**

Mesoblast and Living Cell Technologies – Comparative Valuations against US Comparator Companies

The inability of investors to apply traditional investment measures such as price/earning ratios or calculate dividend yields for biotech stocks is a disincentive for many investors. Discounted cash flows valuations are problematic because of the necessity to ascribe probability assumptions that are often subjective and small changes in probabilities can generate significant changes in net present values. Biotech investors are forced to rely on surrogates of value, or potential value, such as the presence of 'recognised' biotech investors on the register, or partnerships and licensing deals signed with larger pharmaceutical firms. Sales of businesses or technology rights are another source of data for use in valuations. Another useful technique, and one that occurs in the valuation of standard industrial stocks is measurement against local or international comparator companies.

The recent listing in the US of **Osiris Therapeutics** has allowed for a comparison to be made with Mesoblast. And Living Cell Technologies has had a comparator company in the form of MicroIslet for some time. We compare and contrast the four companies below.

	Mesoblast		Osiris
	$AU	**$US**	$US
Shares (M)	107.4		27.1
CMP	$1.27	$0.97	$10.9
Capitalisation ($M)	$136	$104	$297
Cash ($M)	$21.2	$16.1	$74.0
Technology Valuation ($M)	$115	$88	$223
Variance (Discount to US comparator)		-61%	

Mesoblast (MSB) and Osiris Therapeutics (OISR)
Osiris listed on August 9, after raising US$38 million in its IPO. It is currently trading at US$10.94 per share, down marginally from its offer price of US$11.00.

How are the two companies alike?
Both companies are aiming to develop cell therapies, based on adult stem cells, called mesenchymal stem cells (MSC). These are the cells that give rise to bone, cartilage, tendon and muscle tissues. Osiris uses mesenchymal stem cells whereas Mesoblast uses mesenchymal *precursor* stem (MPS) cells. On this basis, both companies are very similar, as well as potentially very strong competitors.

How are they different?
A major point of variance between the two companies is that Osiris's intellectual property position is more established, with Osiris possessing five key granted US patents. Osiris also markets Osteocel, which is a bone matrix product that incorporates mesenchymal stem cells. This product generated sales of US$2 million in the nine months to March 2006. Other stem cell products it has in development include Prochymal (for graft versus host disease), Chondragen (for generating growth of the meniscus, a form of cartilage) and Provocel for cardiovascular conditions. Prochymal is entering Phase III for steroid refractory graft versus host disease (GVDH), Phase II for acute GVDH, Phase II for Chrohn's disease. Chondrogen has recently completed enrolment in a Phase I/II trial. Provocel is in Phase I for cardiovascular repair.

In contrast, Mesoblast has two proof-of-concept trials underway for its autologous stem cell therapy in the areas of long bone fracture and heart failure.

Osiris also has effected a research and development collaboration with **Boston Scientific** (March 2003) covering the application of Provocel to treat several cardiovascular disorders. Osiris received a US$10 million investment and access to a US$50 million line of credit from Boston Scientific. Mesoblast has not yet formed any such development partnership.

Osiris has been developing manufacturing capabilities over eight years, whereas Mesoblast's capabilities are perhaps no more than two-to-three years old, through contracting parties.

Another important key difference, as stated earlier, is that where Osiris selects mesenchymal stem cells, Mesoblast selects mesenchymal precursor stem cells. Each company has developed different methods for the isolation and extraction of mesenchymal stem cells (although until Mesoblasts' patents are granted in the US, then the companies freedom to operate in this regards is less certain.)

Mesoblast is also not restricted to sourcing MPS cells from bone marrow as it can access them from other tissues.

Assessment
Osiris is a more mature company than Mesoblast, based on the number and stage of stem cell products it has in clinical development, its partnership with Boston Scientific and the degree to which it has secured patents for its products. For these reasons, Mesoblast should trade at some discount to Osiris. However, the current discount is arguably excessive and advances by Mesoblast in the clinic or on the patent front would justify a re-rating of Mesoblast in line with Osiris' market value. Significant success from Mesoblast's bone repair trial may even form the basis for Mesoblast to warrant a premium to Osiris, but also only if the company's freedom to operate in key markets was made certain.

Bioshares recommendation: **(MSB) Speculative Buy Class A**

Cont'd over

	Living Cell Tech.		MicroIslet
	$AU	**$US**	$US
Shares (M) (LCT- inc.conv note)	135.1		45.5
CMP	$0.21	$0.16	$1.8
Capitalisation ($M)	$28	$21	$80
Cash ($M)	$3.8	$2.9	$1.3
Technology Valuation ($M)	$24	$18	$78
Variance (Discount to US comparator)		-77%	

Living Cell Technologies (LCT) and MicroIslet (MII)

Living Cell Technologies (LCT) and MicroIslet both are focused on the development of cell therapies, in effect transplantation technology, to treat Type I diabetes, which is the form of diabetes that occurs when the bodies insulin producing cells have ceased to function. MicroIslet is developing MicroIslet-PTM and LCT is developing the DiabeCell product.

How are the two companies alike?

Both companies have listed reasonably recently, with MicroIslet listing on the AMEX in October 2003 and Living Cell Technologies listing on the ASX in September 2004. Although MicroIslet is a US based entity, LCT has business development and regulatory operations in the US as well.

Microislet and LCT are both harvesting, preparing and encapsulating porcine islet cells for transplant into humans. Porcine tissue or related products is widely used in human therapeutics because of the constraints in the supply from human sources.

A common uncertainty for both companies, which is reflected in the low market valuations of both companies, is how each company's respective products would be sold and/or reimbursed, and the potential for such products to achieve substantial revenues.

How are they different?

One major point of difference is that LCT possesses a unique herd of biologically certified herd of pigs, that by way of years of geographical isolation are free from the viruses that have infected most of the world's pig herds. MicroIslet holds a two year licence to a less 'pure' herd owned by the **Mayo Clinic**. LCT has made substantial investments in cell processing and manufacturing facilities and virus testing capabilities.

Following several transplants that took place ten years ago in New Zealand, LCT has developed long term safety data that is relevant to its diabetes product. LCT recently submitted an application with New Zealand's regulatory authority for a 12 patient Phase I/II trial.

Living Cell Technologies is a much more broadly-based cell therapy company than MicroIslet, as it also developing products for Huntington's disease (NtCell), using encapsulated choroid plexus cells, and for hemophilia (Fac8Cell), using encapsulated liver cells.

Valuation Assesment

MicroIslet's funding position appears to be no better than LCTs, and the fact that LCT has US operations well in place, only increases the comparability of the two firms. We would argue that with a 77% discount, LCT is significantly undervalued in comparison to MicroIslet, given LCT's product development history, broader product base and ownership of a key 'raw' material resource. Another telling indicator is that US investors now own 12% of LCT.

Bioshares recommendation: **(LCT) Speculative Buy Class B**

The Bioshares 20 Index

Change from June 30, 2006	**-1.1%**
Change - week ago	**-1.1%**
Change - 13 June (Low)	**2.3%**

Bioshares Model Portfolio (1 September 2006)

Company	Price (current)	Price added to portfolio
Acrux	$0.77	$0.83
Agenix	$0.17	$0.22
Alchemia	$0.59	$0.67
Avexa	$0.215	$0.15
Bionomics	$0.15	$0.210
Biosignal	$0.19	$0.22
Cytopia	$0.720	$0.46
Chemgenex Pharma.	$0.46	$0.38
Evogenix	$0.490	$0.47
Optiscan Imaging	$0.500	$0.35
Mesoblast	$1.270	$1.27
Neuren Pharmaceuticals	$0.43	$0.70
Pharmaxis	$2.15	$1.90
Prima Biomed	$0.067	$0.09
Sirtex Medical	$2.30	$1.95

Mesoblast has been added to the portfolio

Polynovo's Novoskin Joint Venture: A Q&A with Dr John Greenwood

In June this year, **Polynovo Biomaterials**, which is 60 % owned by **Xceed Biotechnology** (XBL: 21.5 cents), formed a joint venture with Adelaide burns surgeon, Dr John Greenwood. The joint venture, called **NovoSkin**, is seeking to commercialise the biodegradable polymer technology from Polynovo, called NovoSorb, in an additional application, in the area of wound treatment. At the beginning of this year, Polynovo signed a partnering deal with the major medical device group, **Medtronic**, to apply its **NovoSorb** technology to the improvement of coronary stents. It is also commercialising the same technology in the field of orthopedics.

We invited Dr Greenwood to participate in a Q&A with *Bioshares* to better explain the joint venture and its technical and commercial aims, and he kindly agreed. Below is a transcript of that interview. As well as being the Director of the Adult Burns Unit at the **Royal Adelaide Hospital**, he is also the founder, medical director and supervisor of the Skin Engineering Laboratory in the **Institute of Medical and Veterinary Science** (IMVS) on the Royal Adelaide Hospital campus. Dr Greenwood has withdrawn from his other role in a private practice as a plastic burns surgeon to pursue the NovoSkin JV.

Can you briefly outline the major changes in the ways burns are treated going back over the last 40 years?

Although burn treatments have existed for as long as burn injuries have occurred, most of the major advances in burn care have taken place over the last 70 to 80 years. Surprisingly, most of the advances expected to impact on the mortality rate from burns did not in fact do so. These include the development of penicillins, the establishment of dedicated burns units and teams, improvements in emergency and ICU medicine, understanding of burn pathophysiology and the development of formulae for more accurate fluid resuscitation, enteric feeding and the introduction of topical antimicrobial agents such as silver sulphadiazine. As an example of this, up to the 1970s, a patient who sustained burns to around a third of his body, had a 50% chance of dying and these odds were not improved by the list of advances just mentioned.

Early in the 1970's, Jancekovic, a single-handed burn surgeon in (then) Yugoslavia, reported an improvement in mortality by early removal of the burned tissue which had, up to then, been left on the body and allowed to separate spontaneously over many weeks (providing plenty of time for life threatening infection to become established).

With the change in burn surgery to embrace early burn excision, within a decade the size of a burn expected to kill 50% of patients rose to around two thirds of the body area. Following that single paradigm shift, the advances mentioned previously began to have an impact and today, patients sustaining burns of 80% - 100% of their surface area regularly survive.

Of course, once the burn has been removed, the resulting wounds have to be closed as quickly as possible if life-threatening infection does not take advantage of the loss of the mechanical barrier to bacteria.

Currently, the best available material to repair wounds once the burn has been removed is skin graft taken from uninjured areas of the patient. Whilst this material gives a good rapid repair free from problems of rejection, it is not without its problems. For example, the area from which the skin graft is harvested is itself a wound and so a large burn injury can be transformed into a near total surface area wound by the raising of skin grafts. This does not help the patient in the short-term.

Secondly, in burn wounds exceeding 50% to 60% of the body surface area, even with mechanisms of 'stretching' the available skin graft (such as meshing), there remains an insufficient amount to close all of the burn wounds. A number of skin substitutes have been developed in an attempt to address this problem.

Cont'd over

Globally, the most commonly employed in first world nations, is IntegraTM. This material has two component parts. The underside (which goes against the wound) is made of bovine (cow) collagen and shark chondroitin-6-sulphate. This material allows the ingrowth of blood vessels and the influx of cells responsible for the laying down of the patient's own collagen, in effect becoming a new dermis (the thick, deep part of skin). On its outer surface is a silicone sheet which acts as a barrier while this ingrowth and neo-dermis formation occurs. However, this material also has several drawbacks.

The meticulous development and processing of materials of animal origin plus the high costs of manufacture make the material extremely expensive.

The meticulous development and processing of materials of animal origin plus the high costs of manufacture make the material extremely expensive. An A4-sized sheet costs around $6000, and it is quite easy to spend nearly $200,000 on this material alone on a single major burn patient. The material has no intrinsic antibacterial property and the appearance of a single significant infection can mean loss of all of the material almost overnight. The material is stored wet in cartridges and considerable experience is required for its use. If the material is successful, the silicone portion is removed (usually at about 14 days post application) and a thin skin graft is applied. Again, there may be insufficient graft available to cover the Integra and this process results in the formation of donor site wounds. Most other easily available 'skin substitutes' merely provide a stimulating barrier until donor sites are healed and can be 're-cropped'.

How have these advances in treatment affected the survival rate for patients?

...most modern burn surgeons are more concerned with the re-establishment of function, appearance and the abolition of troublesome symptoms such as itching.

While survival rate is an outcome which can be easily measured, and there is no doubt that the preservation of life is our immediate and short-term goal, most modern burn surgeons are more concerned with the re-establishment of function, appearance and the abolition of troublesome symptoms (such as itching. The restoration of function may allow the patient to return to work (at least in some capacity if returning to their pre-injury employment is impossible), return to recreational activity and home/sexual life. These have an enormous impact of the patient's feelings of self-worth. Striving to improve the cosmetic effect of the scars which result can enable a patient to regain self-confidence, minimising social withdrawal and perhaps lessening post-traumatic depressive disorders. It is because the survival rate in patients sustaining very large burn injuries has increased steadily since the 1970s, that we now have the relative luxury of concentrating on these other aspects.

Can you describe how the first potential product, EASE, will work, who will primarily use the product and in what setting? How long will it take to bring to market?

EASE is an acronym, which stands for 'Easy Application Synthetic Epidermis'. This material is a structural variant of Novosorb which is a liquid at room temperature. The material can be polymerised by the application of a suitable light source. The structure of the polymer can be tailored to absorb from a few percent up to 600% of its weight of water, allowing absorption of wound exudate. It can be occlusive or porous. It has the ability to elute agents such as silver ions and local anaesthetics to control pain and the risk of infection.

The polymer is sprayed over a burn wound and is cured into a solid form by light.

The polymer is sprayed over a burn wound and is cured into a solid form by light. As the polymer cures it has a natural adherence to the surrounding skin . It does not 'roll-up' at the edges and is elastic (allowing the movement of joint of in the burn area without the material cracking). It is transparent, allowing wound monitoring. It can be left to spontaneously detach when healing has occurred or can be removed by peeling if alternative treatment of the wound becomes necessary. Initially, we foresee this having a specialist role in GP practices, hospital emergency departments etc. Eventually, a product will be generated for home 'first-aid' kit use. We are hopeful that the first generation of this product will be ready for mass manufacture in about 18 months.

Cont'd over

What are the limitations with existing treatments for major burn wounds?

The major limitations currently relate to the paucity of available skin graft, the disadvantages conferred by creating donor sites, and the disappointing range of alternative materials

As mentioned earlier, the ideal major burn management involves the very early removal of the burn eschar, timely and appropriate fluid resuscitation and rapid wound closure (the longer wounds remain open, the worse the resultant scarring). The major limitations currently relate to the paucity of available skin graft, the disadvantages conferred by creating donor sites, and the disappointing range of alternative materials (many of which are no more than glorified dressings).

As a result, the bigger the burn, the less skin graft available, the longer wounds remain 'open', the longer the inflammatory phase, the worse the scarring, the worse the functional, cosmetic and symptomatic result, the greater the need for reconstructive surgery, the smaller the likelihood of a return to meaningful function.

The key to all these deficiencies is primarily the loss of dermis. Very few burn practitioners globally feel that cultured epidermal products have much, if anything, to contribute to deep burn management, other than perhaps speeding the rate of donor site healing. Most research groups are looking for ways to create a dermis and most are looking towards collagen.

My philosophy is why struggle along with a biomolecule which cannot be altered, is difficult to manufacture and process and is expensive...

My philosophy is why struggle along with a biomolecule which cannot be altered, is difficult to manufacture and process and is expensive, when materials such as NovoSorb exist; the properties of which can be altered to suit the function required, which can be synthesised cheaply, can be produced in any size, can be designed to absorb exudate, can be porous or occlusive, can be filamentous, woven or electrospun, and can elute a whole range of desirable agents (such as silver irons for antibacterial properties, calcium irons for haemostasis, local anaesthetics for pain relief, growth factors for wound healing and scar modulation etc).

How are full thickness burns treated at the moment and how will your technology be applied to these wounds? How long will it take to bring to market and what will be the anticipated cost?

....there is a general global consensus that early excision of a full thickness burn and repair immediately (or within 48 hours if the patient is not fit for immediate grafting)...yield the best currently achievable result

Although there is the variability in the timing of burn excision and skin grafting between different burn surgeons, there is a general global consensus that early excision of a full thickness burn and repair immediately (or within 48 hours if the patient is not fit for immediate grafting), with split skin graft yield the best currently achievable result. The use of expensive skin replacements (like Integra) is largely confined in most nations to deep burns involving a large percentage of the total body surface area.

The Novosorb platform will enable a generational evolution of products for deep burn injury. The first product in this generation, will be the Biodegradable Temporising Matrix (BTM). Whilst I am unwilling at the current time to reveal much in the way of how the material will be structured, orientated and manufactured, I can say that I expect it to change the timing constraints currently imposed on burn surgeons.

The final product costs for BTM have not been established yet but based on manufacturing costs we believe we will be more price competitive. The final generation for deep burn wounds will be an autologous, bilayer, composite skin. There will be several intervening generations with advanced additional properties. We expect that the pilot clinical trials will start in approximately 15 months and BTM to be ready for mass manufacture within 2-3 years. Further we hope to gain reimbursement by demonstrating high patient efficacy and reduced total cost of treatment.

Cont'd over

How does your technology differ to that being sold by Clinical Cell Culture?

We occupy a different sphere in the direction we have adopted so that we are in no way even in competition with Clinical Cell Culture...

We occupy a different sphere in the direction we have adopted so that we are in no way even in competition with **Clinical Cell Culture** (C3). They are a company whose product portfolio is based on epidermal cells. These are complex products for highly specialized markets, the use of which usually requires a hospital or specialist rooms setting. We are broadly in the space but we are developing non-competing products for different outcomes. The recent stringent **Therapeutic Goods Administration** regulation into the production of cultured epidermal cell products, and even non-cultured products which require manipulation away from the patient, has further complicated this market.

The focus of NovoSkin's BTM is the dermis, the thick portion of the skin which is not predominantly cellular, but made up of huge structural molecules, like collagen and elastin. The dermis, when injured, cannot regenerate to re-establish its pre-injury structure, it can only produce scar tissue. The dermis is flexible and provides the elastic envelope inside which we move, breathe and occasionally expand to accommodate babies; loss of these functions can be devastating. The dermis is the site of scarring and it is here that manoeuvres to alter the way that scars are generated can be performed.

While our long term goal is composite skin, our early product portfolio will not include cellular components and thus regulations governing them are substantially less rigid

NovoSkin's BTM product in its first form is a polymer matrix to support and control patient healing in full thickness skin injuries in burns, plastic surgery and trauma. While our long term goal is composite skin, our early product portfolio will not include cellular components and thus regulations governing them are substantially less rigid. This will facilitate our path to market.

The EASE product is diametrically opposite to the dermal direction. It is a simple, non-cellular technology that we hope will have a broad utility in superficial wounds and eventually the non-specialist home healthcare markets. It is aimed at 'synthetically' replacing the epidermal barrier whist facilitating pain-free healing to occur spontaneously. Both of these products are relatively simple and address poorly serviced areas of wound management. We anticipate the regulatory path to be manageable and adoption to be reasonably straightforward.

Why is the joint-venture a good fit? What skills/technologies do both groups contribute?

The establishment of NovoSkin (the joint-venture) brings together a novel, manipulable, biodegradable polymer generated by highly proactive and ambitious polymer company with a sound financial base and investment future, backed by the CSIRO and Xceed Biotechnology Pty, and an individual with an aggressive approach to burn management and the facilities to fulfil *in-vitro* human cellular, *in-vivo* small and large animal, and pilot *in-vivo* human clinical trials. I also have the experience and standing in the burn field to recognise where the deficiencies in treatment lie and the skin and cellular research experience to realise how they may be remedied.

Thank-you for your time.

Thanks for your interest in our work.

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

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