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	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - Current)	64.6%
Cumulative Gain	**486%**
Av. annual gain (13 yrs)	**20.3%**

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Bioshares

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

Imugene Acquires Biolife
Takes Aim at the US$6 Billion Her2+ Cancer Market

Imugene (IMU: $0.019) has acquired Biolife Science Qld Ltd, a company which earlier absorbed an immunotherapeutic technology from the Medical University of Vienna. The principal asset of Biolife is HER-Vaxx, a therapeutic vaccine for the treatment of Her2+ breast, gastric and other cancers. About 20% of people with stomach (gastric) cancer test positive for Her2 and 25% of people with breast cancer test positive for Her2. HER-Vaxx has successfully completed a Phase I study.

The vaccine represents a novel approach to treating Her2+ cancers because it is designed to use B-cells to produce antibodies to neutralise Her2 expressing cancer cells. B cells are the cells used by the body to create antibodies. The appeal of the approach is that a patient uses their own B cells as a factory to produce antibodies to attack the cancer. This approach potentially delivers a challenge to the current manufacturing paradigm, shifting the dominant approach in the industry away from the expensive manufacture of monoclonal antibody therapies to a possibly cheaper peptide vaccine approach.

This cost of goods (COGS) feature is becomes important when examining the investment merits of new therapies. Roche dominates the Her2+ therapy space, leading with Herceptin, which generated sales of US$6.3 billion in 2012. It recently launched Perjeta and Kadcyla. These three therapies sell on an annual cost of treatment basis for US$54,000, US$72,000 and US$117,600 respectively. This means that while the Her2+ space is commercially validated, tensions exist in the market regarding the cost of current and emerging therapies. As an aside, the patents covering Herceptin expire in Europe in 2014 and in the US in 2019, which presupposes Roche would be keen to evaluate emerging therapies.

Another driver in the Her2+ market is the development of drugs which are safer than Herceptin, Tykerb and Perjeta, which all come with black box warnings.

A new therapy with the potential to be more profitable because of a lower COGS may be of great commercial interest to Roche, and GlaxoSmithKline (which has achieved modest sales success with its small molecule drug Tykerb, which blocks EGFR and Her2).

Mechanism of Action

HER-Vaxx is made up of a virosome (an inert virus shell) to which are attached three peptides, termed P4, P6 and P7, originating from the larger Her2 protein. These peptides are the antigens that stimulate the production of the antibodies required to bind to the Her2 receptors over expressed on cancer cells. The use of a virosome is an important feature in the design of the therapy because the virosome is recognized very quickly by the immune system, which is alert to viruses because of their size (of about 150 nm).

The three peptides incorporated in HER-Vaxx aim to mimic the method of action of both Herceptin and Perjeta, blocking Her2 signalling (the Herceptin mechanism of action) and

– Imugene cont'd

blocking Her2 from dimerizing (joining) with other receptors (Her1, Her3 and Her4) (the Perjeta mechanism of action). The sum of these effects in the form of HER-Vaxx is a more comprehensive attack on Her2 signalling.

The Acquisition and Capital Raising

Imugene has acquired Biolife Science Qld Ltd through the issue of 300 million shares. In conjunction with the acquisition, $2.5 million has been raised by Forrest Capital, through the issue of 250 million shares at 1 cent. These funds will provide for working capital, the manufacture of clinical trial materials, an Investigational New Drug (IND) submission and for Linguet development. However, more funds will need to be raised to cover the cost of the planned Phase II program.

Phase I Trial Completed

A 10 patient Phase I trial of HER-Vaxx in metastatic breast cancer patients has been completed. The trial showed the drug was safe and tolerable and that HER-Vaxx could generate both an antibody (humoral) response and cellular response.

Phase II Gastric Cancer Trial

A plan for Phase II trial of HER-Vaxx in gastric cancer has been drafted. This trial in 68 subjects will commence in either late 2014 or early 2015 and will take 12 months to complete.

The primary endpoint will be overall survival. Patients will be randomised into the treatment arm which will include HER-Vaxx with cisplatin and 5-FU, and cisplatin and 5-FU alone.

Risks

A nearer term risk to note with Imugene is that the company has to successfully navigate the IND application process with the FDA. This is not trivial because the FDA process could be delayed if the company is asked to provide more information, for example, about drug manufacturing or trial design, which require the company to gather more data for its application.

The initiation of the Phase II clinical trial is dependent on the completion of a second capital raising, which is likely range from $2.5 million to $3 million.

Clinical trial completion times are also another important risk. Although the company plans to run its Phase II trial in Eastern European countries, which should make recruitment easier as well as ethically easier to deal with because of an absence of Herceptin as a first in class therapy, some local risk factors, such as differing clinical practises could impact the trial.

The company has selected gastric cancer which is more common in Eastern Europe and should therefore make patient recruitment easier.

Competition does exist in the area of immunotherapies targeting Her2+ cancers (see table on page 3). The most advanced of these is Galena Pharmaceuticals' NeuVax vaccine (in Phase III). The vaccine aims to stimulate the production of CD8+ cytotoxic T lymphocytes (CTLs). This vaccine is also being studied alongside Roche's Herceptin. A drawback with this approach is that it is selective to certain human leukocyte antigens (HLA-A2/A3), which limit the ethnic (genetic) potential for the therapy.

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Marketed Her2+ Therapeutics

Company	Brand Name	Drug Name	Chemistry	Date Approved	Indications	Black Box Warnings	Treatment Cost USA / Year $US	Sales
Roche/Genentech	Herceptin	trastuzumab	anti-Her2 monoclonal antibody	1998	HER2-positive metastatic breast cancer	Cardiomyopathy (sub-clinical and clinical cardiac failure) AND Infusion Reactions AND Pulmonary Toxicity	$54,000	CY2012: US$6,272 M; CY2013 Nine Months CHF 4,954 M
				2006	HER2-positive adjuvant breast cancer *(in combination with docetaxel and carboplatin) or (in combination with doxorubicin, cycophosphamide and docetaxel)*	as above		
				2010	HER2-positive metastatic gastric cancer (*in combination with cisplatin and capecitabine or 5-FU)*	as above		
GlaxoSmithKline	Tykerb	lapatinib	(oral) small molecule kinase inhibitor - EGFR [ErbB1] and HER2 [ErbB2]	2007	HER2-positive metastatic breast cancer, *in combination with capecitabine and letrozole*	Hepatoxicity	$40,000	CY2012 - US$380 M / H1 CY2013 - US$163 M
Roche/Genentech	Perjeta	pertzumab		2012	HER2-positive metastatic breast cancer	Embryo-Fetal Toxicity	$72,000	2013 Nine Months: CHF 186 M
Roche/Genentech	Kadcyla	trastuzumab emtansine		2013 (March)	HER2-positive metastatic breast cancer		$117,600	2013 Nine Months: CHF 156 M

Selected Her2+ Therapies in Development

Company	Therapeutic Candidate	Chemistry	Target
Phase III			
Galena Biopharma	NeuVaxx (Nelipepimunt-S)	Immunotherapy	T-Cell vaccine; E75 peptide + GMSCF(adj.)
Novartis	Bupralsib (BKM120)	Small mol.	Pan-PI3K
Pfizer	Palbociclib	Small mol.	CDK4/6
Puma Biotechnology	Neratinib (PB272)	Small mol.	EGFR, HER2, HER4
Phase II			
Aslan Pharmaceuticals	ASLAN001(ARRY-543)	Small mol.	Her2, EGFR
Boehringer Ingelheim	Afatinib**	Small mol.	ErbB-4 (HER4)
Macrogenics	Margetuximab	mAb	Fc optimised anti-Her2 antibody
Merrimack Pharmaceuticals	MM-111	mAb	bi-specfic mAb; ErbB3 & ErbB2(Her2)
Novartis	Dovitinib	Small mol.	FGFR
Novartis	LEE011	Small mol.	CDK4/6
Synta Pharmaceuticals	ganetespib (STA-9090)	Small mol.	Hsp90
U of Washington/NCI	Her-2/neu peptide vaccine	Immunotherapy	T-Cell vaccine; p369–377 peptide + GM-CSF(adj.)
Phase I (Selected Immunotherapies)			
Dendreon	DN24-02	Immunotherapy	Autologous Dendritic Cell vaccine
Duke University	AVX-901 (HER2 VRP)	Immunotherapy	B Cell vaccine; Alphavirus (Venezuelan equine encephalitis) vector expressing HER2 ECTM (Extracellular Domain And Transmembrane Region)
NIH/NCI	AdHER2/neu DC Vaccine	Immunotherapy	Autologous Dendritic Cell vaccine; adenovirus vector expressing human HER2 ECTM
Ohio State University	HER-2 vaccine	Immunotherapy	B Cell vaccine; MVF-HER-2(597-626) and MVF-HER-2 (266-296) and ISA720 (adj.) and norMDP (adj.) **

* Brand name GILOTRIF: Approved for first-line treatment for metastatic non-small cell lung cancer with common EGFR mutations
** MVF: Measles Virus epitope

– Imugene cont'd

Several other B-cell vaccines, similar to HER-Vaxx, are in clinical trials, which may become of interest if they also progress into Phase II stages of development. Interestingly, these also have a university origin similar to HER-Vaxx's at the Medical University of Vienna.

Status of the Linguet Programs

Imugene will continue with the development of its Linguet technology, with funding now at hand. Imugene expects to license Linguet for vitamin and supplement applications by 2013 Q4.

Summary

Forrest Capital has resurrected an earlier attempt to backdoor Biolife into the Acuvax shell (see *Bioshares* 495). It has achieved this by splitting the original capital raising into two more manageable parts, so that the second round of funding is more clearly linked to IND and manufacturing progress.

Imugene's HER-Vaxx asset is a very attractive investment proposition because its (biologic) targets are commercially validated, and potential lower manufacturing costs mean that pricing pressures in oncology markets increase the desirability for safer, less expensive and more efficacious drugs.

With a Phase II readout due in 2016, a modest amount of additional capital required to get there, and a sale to a large pharmaceutical company in mind, Imugene is a stock that suits an investor with some medium term patience but an interest in a clear and simple investment proposition.

Imugene also now has additional investment appeal because GlaxoSmithKline's VP of Oncology R&D, Dr Axel Hoos, is likely to join the board of Imugene. The implication here is that GSK would be in a better position to evaluate the vaccine than would its rival Roche.

Including shares issued through the acquisition and capital raising, Imugene is capitalised at $17.8 million and following the capital raising holds near to $3 million in cash.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Additional Note – 18% Royalty to Scientific Founders

Documentation from the earlier attempt to list Biolife through the shell of Acuvax, showed that the scientific founders of the company holding the HER-Vaxx IP, Bio Life Science Forschungs-Und Entwicklungsges M.B.H, were entitled to receive an 18% royalty from any income that Biolife receives from the drug, which we now assume applies toImugene. We assume the 18% royalty agreement still stands.

Cogstate Positions its Diagnostic for the Coming Alzheimer's Disease Therapies

Cogstate (CGS: $0.53) delivered a 31% increase in sales in the September quarter over the previous corresponding period (pcp), recording $2.7 million of sales. The September quarter in the northern hemisphere is always a difficult one because of the July-August holiday period. Receipts from customers were strong, at $3.7 million, up 72% over the pcp.

Although Cogstate is now achieving annual sales of around $12 million, the timing of those sales contracts can be inconsistent. In the September quarter, sales recorded were largely from existing contracts. At the end of September the company had $7.7 million in future expected sales from existing contracts, which was down $4 million from the same time last year.

Cogstate achieves most of its revenue (about 95%) from providing its cognitive test in the clinical trials of new and existing pharmaceuticals and from the service involved in providing that product. This is a profitable business with the cash flow used to fund larger market opportunities for the same or similar cognitive tests, as well as a sports training technology that the company access a few years back. The clinical trials business is expected to contribute to the majority of revenue for the next two years.

At this year's AGM, Chairman Martyn Myer said that the company is now achieving what it set out to do 14 years ago when the company was founded, that being to deliver a test (into the community) that can detect the first signs of dementia. Earlier this year the company's dementia screening tool Cognigram was launched into the Canadian GP market by the company's licensing partner Merck. Myer believes that the company has the best technology in the world in the cognitive assessment field.

For Cogstate, Canada is a pilot market for the company, where it can learn how to best commercialise the product. However Myer said that Canada is also a very important market in its own right, with five million people over the age of 65 and that population group is growing at twice the rate of the overall Canadian population.

This week the Guardian reported on a round table discussion it co-ordinated with dementia experts and conducted in association with the UK Alzheimer's association and Lilly UK. It is estimated that up to 800,000 people are living with dementia in the UK, yet less than half are officially diagnosed. The number of people with dementia is expected to double over the next 30 years.

While some GPs still question the benefit of diagnosing dementia when there is no treatment, the UK is taking a more proactive approach with GPs now offered a financial incentive to identify early stage dementia.

Arguably, the benefit for patients and their families is that correct diagnosis of dementia early on allows planning for future care needs and financial structuring as well as early access to professional support. Exploring other options such as lifestyle changes, pharmaceutical and nutraceutical options (there is no current therapy available that treats the underlying cause of Alzheimer's disease) and investigations of other reasons for dementia are considerations.

For Cogstate, it has arguably the leading tool available to facilitate early dementia testing. Having now launched its product in Canada, Cogstate is exploring the best way to expand into other regions, such as Europe and the largest single market for its test, the USA.

In Canada, only minimal sales have been recorded to date. Over 450 doctors have registered to use the test in Canada, with 20 testing centres now operational, including one specialty memory clinic. The aim is to increase that number to between 50-70 sites over the next 12 months. The test sells for $125. CEO of Cogstate, Brad O'Connor, believes that Merck remains committed to product, with the company having publicly expressed its commitment to the Alzheimer's disease field. Merck has a five year license to market and sell the test in Canada.

Merck's Phase II/III Alzheimer's trial in 1,700 patients

In July this year, Merck presented results from a Phase Ib Alzheimer's disease trial in 32 patients with mild-moderate disease with its BACE1 inhibitor (Beta-site Amyloid precursor protein Cleaving Enzyme), called MK-8931. In measuring AB40, which is a marker of BACE1 activity, the drug candidate was shown to reduce AB40 levels by 57% in the lowest dose from baseline over the seven day treatment, and by 84% in the highest dose from baseline over seven days, showing dose dependency.

In December last year, Merck started a 1,700 patient trial with MK-9431 in Alzheimer's disease. The first 200 patients will be assessed for safety of the drug, with those results expected to be reported this year. Merck will also have side arms to the trial, one being a beta amyloid imaging assessment in the brain of patients using the amyloid tracer 18F. The other will look the impact on beta amyloid levels in cerebral spinal fluid.

Officially the trial is due to conclude by April 2017, and the compound could reach the market in 2018 or 2019. The CEO of Merck is cautious about the likely outcome from this trial, highlighting that the company is assessing the chemical effectiveness of a compound, but also seeking to prove a 'fundamental hypothesis', that being that if you reduce beta amyloid levels in the body, which are found in the plaques in the brains of patients with Alzheimer's disease, that the drug will then impede the process of disease progression. However Merck's CEO earlier this year was quoted as saying '…this could be the kind of compound that changes the world…'.

O'Connor said Merck is building a franchise in the Alzheimer's disease space. He believes Cogstate's Cognigram test fits into the structure by helping to identify the future patient population that will potentially benefit from Merck's MK-9431 drug candidate. Merck not only has compounds in development to treat the underlying Alzheimer's disease but also drug candidates to improve symptom control.

Cont'd over

Bioshares Model Portfolio (25 October 2013)

Company	Price (current)	Price added to portfolio	Date added
Oncosil Medical	$0.140	$0.155	September 13
Calzada	$0.078	$0.073	September 13
Invion	$0.092	$0.060	August 13
IDT Australia	$0.380	$0.260	August 13
Viralytics	$0.350	$0.300	August 13
Circadian Technologies	$0.225	$0.270	March 2013
Tissue Therapies	$0.260	$0.255	March 2013
Benitec Biopharma	$0.555	$0.40	November 2012
Somnomed	$1.27	$0.94	January 2011
Cogstate	$0.530	$0.13	November 2007
Universal Biosensors	$0.59	$1.23	June 2007

Portfolio Changes – 25 October 2013

IN:
No changes.

OUT:
No changes.

Expansion into Other Regions

One of the items on Cogstate's agenda is to expand the Cognigram product into other regions. At this year's AGM, the company voted to increase its capital raising limit in any year by 10% (up to 25%). Although the company has not committed to any capital raising in the year ahead, it does want to keep that option open, should it seek to fund expansion of Cognigram into other markets.

The USA is a 'huge opportunity' said O'Connor, but it will take some time to enter that market. Cogstate may complete the initial work itself in priming the US market, which would improve its negotiating position with a partner. O'Connor said the global Alzheimer's disease testing market is worth $500 million a year.

Cogstate maintains full ownership of the Cognigram product and the test is processed by Cogstate.

Clinical Trials Revenue Outlook

Cogstate expects to record a net loss in 1H FY2014. Although the signing of new contracts has been slow in Q3, the number of proposals the company has submitted is very high. The lower Australian dollar against the US dollar will also assist the company's top and bottom line result this year.

Summary

Alzheimer's disease is one of the few diseases where the pharmaceutical industry has failed to deliver a product that treats the underlying disease. The FDA appears to have become acutely aware of the massive need to deliver a solution to treat an illness where the burden on healthcare has started to accelerate due to an aging population. This is evident by changes and concessions the FDA has made, effectively lowering the bar for Alzheimer's disease drug developers.

Whether there is an effective Alzheimer's therapy available or not, there is a very good argument that dementia awareness should be encouraged to facility timely and effective management of patients. As Merck is showing, there is also a very good reason to ready the market for forthcoming Alzheimer's therapies. This suggests there is an existing market for Cogstate's Cognigram product, and a market with the potential to become very large should we see an effective Alzheimer's disease therapy in the next three to five years.

Cogstate is capitalised at $41 million. It had $3.1 million in cash at the end of September.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Somnomed Returns to 25% Growth in September

In the month of September, Somnomed (SOM: $1.27) got its business back to where it wants it, and that is delivering 25% growth. While Europe has been a very strong region of performance for the company, due to a string of strategic acquisitions of distributors in various countries, its US market needed some fixing over the last 18 months. The measures adopted in the US market now appear to be paying off for Somnomed.

For the September quarter, global unit sales increased by 13.1%, with sales up by 36% to $5.66 million. The difference between revenue growth and unit sales growth was due to foreign exchange movements and the acquisition of its French distributor, which increases sales but not unit sales as the devices which were previously sold to the distributor are now being sold directly by Somnomed.

In the September quarter, the company sold 9,309 devices. These devices are used to prevent snoring and sleep apnea. The December quarter is generally better than the September quarter for Somnomed because of the holiday period in July and August. Last year, December unit sales were 8.7% higher than the September quarter. Given the very positive momentum the company is building, this potentially sets up a strong December quarter, which should see the stock continue to perform well.

In the US, the company has rebuilt and strengthened its management team and improved customer support and turnaround times for its products. The company has also restructured its dental sales team and built a medical sales team to market and sell the product to sleep physicians, as well as building awareness with the assistance of its Chief Medical Officer.

Sales in the US were bolstered in the quarter by the launch of a less expensive Somnodent Herbst product. The company expects to launch two other products in the US in this quarter, those being the Somnodent Herbst Advance and the DentiTrac to be used for measuring compliance.

The company had a poor cash flow quarter, with net cash outflows of $1.07 million. This was as a result of seasonal payments made in the September quarter and the increased receivables as a result of increased unit sales.

Somnomed is capitalised at $55 million with $3.3 million in cash.

Bioshares recommendation: **Buy**

Bioshares

pSivida Knocked Back for Third Time by FDA

pSivida's (PVA: $2.68) licensee Alimera Sciences has received its third knock back from the FDA with respect to its new drug application for Iluvien for the treatment of diabetic macular edema (DME).

In its first NDA, the FDA asked to see three year data from the Phase III trials. However, in its second assessment, the regulator was not satisfied with the drug's risk-benefit ratio. Alimera then re-filed the drug for approval for a third time after discussion with the FDA, seeking a narrower indication, that being for those with chronic DME, where it was seen that the drug had a more beneficial effect. However the FDA has knocked the drug application back once again, citing safety concerns (relating to the incidence of cataracts in recipients).

Iluvien is approved for use in Europe, being currently sold into Germany and the UK. First commercial use occurred on 7 May this year with sales of US$179,000 recorded by Alimera for the June quarter. Alimera expects to launch the drug in France in early 2014. The drug is also approved in Austria, Portugal and Spain. pSivida is entitled to 20% of net profits from sales, which works out to approximately a net 15% royalty stream.

It's going to be an uphill battle to get the drug onto the market in the US. Alimera will meet with an FDA Advisory Panel in January to discuss how to get the drug approved in the US.

In July, pSivida initiated one of two Phase III trials in the US with the same therapy (as Iluvien) for the treatment of posterior uveitis, which is a depot injection of the steroid fluocinalone acetonide which lasts for three years. Although pSivida licensed to Alimera the rights to the therapy for the treatment of DME, pSivida is allowed to commercialise other indications of the therapy and can reference all of the data received from the Iluvien trials.

The market for posterior uveitis is smaller than DME. However, Iluvien has shown to have a much better safety profile that the product Retisert, which is approved for the treatment of posterior uveitis. Both therapies release the same active however Retisert is more difficult to implant and releases the steroid faster which explains the worse side effect profile.

pSivida is capitalised at US$72 million, more than Alimera, which has a market value of $64 million. pSivida had $10.3 million in cash at the end of June and raised US$10.8 million in July.

Whilst pSivida's share price has fallen by 30%, investors may want to wait for further information to emerge from pSivida and its licensee Alimera on the commercial path forward for this potential therapy in the US and wait to see sales traction in Europe.

Bioshares recommendation: **Speculative Hold Class B**

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. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

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: Starpharma Holdings, Cogstate, Bionomics, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Tissue Therapies, Viralytics, Phylogica, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Calzada, Atcor Medical, Invion, Circadian Technologies