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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 - May '14)	26.6%
Year 14 (May '14 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - current)	2.6%
Cumulative Gain	656%
Av. Annual gain (14 yrs)	17.7%

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Bioshares

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

Volpara Adopts Subscription Model For Its Breast Density Assessment Tool

Wellington, New Zealand-based Volpara Health Technologies (VHT:\$0.43) listed in April, issuing 20 million shares at 50 cents to raise \$10 million. The offer was fully underwritten by Morgans Corporate.

Volpara has developed and is marketing a breast density assessment tool, VolparaDensity, and several related products, for use with X-ray breast cancer screening systems, and in conjunction with ultrasound.

VolparaDensity is an 'add-on' software tool which can be downloaded and installed on most common and currently available X-ray systems.

The Clinical Problem

Breast cancers more often develop in glandular tissue in the breast, and less so in fatty or fibrous tissue. Higher levels of glandular tissue represent an increased risk of breast cancer occurring.

According to Volpara's prospectus, breast density is defined as the ratio of the volume of fibrous and glandular tissue to overall breast volume. In general terms, a breast classified as low density has more fat, whereas a breast classified as high density has more fibrous and glandular tissue.

X-rays perform poorly in distinguishing between fibrous and glandular tissue. Evidence of the problem has been shown by a study which reported that 85% of cancers in fatty breasts were detected using X-rays, compared to 59% in dense breasts.

The clinical problem is exacerbated by the fact that the assessment of X-ray images for breast density has been subject to wide variation in human interpretation. (Breast density is typically scored on a four point scale.)

The challenge of screening dense breasts has been met in part, but not satisfactorily, by the application of digital breast tomosynthesis, whole breast ultrasound and breast MRI. Digital breast tomosynthesis is still at an early stage of take-up and Volpara's VolparaDensity is even used alongside this approach. Ultrasound can result in higher rates of false negatives. MRI, which is currently used for imaging women with high risk of breast cancer requires the use of contrast media, more radiation and is more expensive.

Consistent Measurement

What VolparaDensity contributes to the breast cancer screening process is automation of the assessment of density and the delivery of consistent assessment in a timely manner i.e. within two minutes.

Cont'd over

How Does It Work?

VolparaDensity works by breaking images down to the pixel (or voxel) level, and then calculating X-ray attenuation (reduction of intensity) from each pixel to the X-ray source. The approach also exploits images taken from different angles (breast X-rays, or mammograms, are usually taken from four angles.) For every pixel, a ratio of fat-to-fibro-glandular tissue can be derived, which are then aggregated.

The technology also depends on finding a pure fat reference point, which it is able to do using the physics of phase congruency. The approach means that breast tissue composition can be presented numerically as a percentage of composition, which is more accurate than the four 'crude' gradings of density which suffer from inconsistency when made by human operators.

VolparaDoseRT

A second product marketed by Volpara, VolparaDoseRT, takes a volumetric breast density score which then can be used to generate a patient-specific radiation dose, in addition to a breast compression calculation function. This last function has benefits both in terms of patient comfort and optimising radiation dosing.

VolparaAnalytics

Volpara Analytics is a software package which allows operators to collate information across a site containing multiple X-ray systems and conduct in-depth analysis.

Competition

Volpara has identified three main commercial competitors for VolparaDensity. These are Hologic's Quantra software product, which is available only to Hologic's X-ray systems, Philips spectral density solution, which requires special hardware, and iCAD's iReveal which according to Volpara, offers only a visual assessment unlike Volpara's numerically quantified approach.

Market Opportunity & Drivers

Volpara stated in its prospectus that it estimates that globally 75 million women are screened for breast cancer at 10,500 breast centres, of which 39 million screenings are calculated by Volpara to take place in the US across 8,700 centres this year.

In the USA, breast cancer screening is supported by policies from the American Cancer Society, the American College of Obstetricians and Gynaecologists and the US Preventive Services Task Force. Screening policies are backed by data which indicate that women who undergo screening reduce their risk of breast cancer as a cause of death by 40%. However, between 20%-30% of cancers are missed during screening with many being missed because of a high breast density.

Litigation for medical malpractice is an important driver in the US market, where improved diagnostic methods and tools such as Volpara's are able to reduce medical errors.

Another driver in the US market is that 27 states have passed laws making it mandatory that breast density is reported for women undergoing mammography.

Also favouring Volpara is the expectation that the number of women expected to be screened for breast cancer over the next ten years will double.

Sales to Date

Volpara made its first sales in 2011. For the financial year ending March 31, 2016, the company recorded sales of NZ\$2.5 million, up from NZ\$1.9 million in the previous year.

Change to Revenue Model

Volpara currently charges a licence fee and annual maintenance fees for VolparaDensity, which delivers between US\$30,000 and US\$150,000 of sales per customer, depending on the number of X-ray machines the customer has installed. Volpara charges 15% of the original access fee as an annual maintenance charge.

In July 2016, the company will be rolling out VolparaEnterprise, a cloud-based subscription offering, which will allow the company to capture revenues on a recurring basis, as well as being based on the number of mammograms that are taken with each X-ray machine. VolparaEnterprise is also designed to help managers of breast imaging clinics assess productivity across their site or sites and assist with quality assurance.

The company raised its IPO funds in order to launch VolparaEnterprise and to expand the company's sales efforts in the USA, where the company now employs eight people.

Summary

Volpara Health Technologies is a company worth watching, especially as it introduces a subscription revenue model with VolparaEnterprise into a very large breast cancer screening market represented by the previously mentioned 39 million breast cancer screenings that will take place in the USA this year.

Under this new revenue model, the company has the potential to generate high gross margins from a clinically relevant product, with cash flow positive status, in our view, an achievable medium-term objective.

Volpara is capitalised at \$52 million.

Bioshares recommendation: **Speculative Buy Class A**

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Changes in Shareholdings in Selected Companies 2016

Below are tabulated changes in shareholdings in a selection of companies monitored by Bioshares.

Share Sales

With several companies performing particularly well in the sector, long standing directors in some of these companies have elected to take some profits. Leading the list are Nanosonics directors, Maurie and Bernard Stang, who have sold \$11.75 million in stock this year. However they continue to hold a combined interest in the company of 15% which represents a current market value of \$105 million.

David Williams, chairman at Medical Developments International, sold a stake in that company for \$4.6 million although he retains a 30% stake.

Share Purchases

Peter Neustadt, Executive Chairman at Somnomed, is very confident of the company's more aggressive strategy in the US, of opening up sleep treatment centres into which to sell its sleep treatment products. Neustadt invested \$700,000 through the recent capital raising at \$2.50 a share.

Rhinomed's chairman Ron Dewhurst shares a similar confidence in his company, investing \$500,000 through that company's recent placement. Garth Sutherland, founder and CEO of E-Health company Adherium, has invested \$260,000 into that company through an employee share plan loan. There has been some buying by Innate Immunotherapeutics' directors as that company neared the completion of recruitment into its Phase IIb trial.

GI Dynamics appears as though it may be a turnaround story. Director Anne Keating has acquired \$24,000 of shares and major shareholder Hunter Hall Investment, which had a major win with Sirtex Medical, has increased its stake from 15.9% to 17.1% as the share price plummeted.

Investment funds FIL Ltd and Lagoda Investment Managers appear to be behind the majority of the on-market buying of Clinuvel Pharmaceuticals which has seen that stock increase by 73% this year. FID has also been increasing its stake in Impedimed over the year.

New Substantial Shareholders

Regal Funds Management has taken substantial positions in two biotech companies this year, Oncosil Medical and Adherium. More recently, US investment group Sprott Asset Management has taken a substantial position in Rhinomed.

Ceasing Substantial Positions

Kinetic Investment Partners has taken some profits as well in Nanosonics and ceased to be a substantial shareholder in that stock. Hunter Hall has followed the chairman and reduced its position in Medical Developments International. And longstanding shareholders in Cogstate, Asia Union Investment and investment vehicles associated with Charles Goode (former chairman of the ANZ bank), have taken advantage of that stock's run to take some profits. And Kim Hogan's JK Nominees has ceased to be a substantial shareholder in Oncosil Medical.

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Sale of Shares

Company	Entity	Details
Nanosonics	Allan Gray Australia	\$10.8 million, from 8.6% to 6.5% holding
Nanosonics	Bernard Stang (Director)	\$7.9 million, retains 7.3% interest
Nanosonics	Maurie Stang (Chairman)	\$4.75 million, retains 7.6% interest
Medical Developments	David Williams (Chairman)	\$4.6 million, retains 30.66% company ownership
ResApp	Brian Leedman (Director)	\$152,271, retains 30M shares and 23M performance shares
Starpharma Holdings	FIL Ltd	Decreased stake from 8% to 6.9%
Bionomics	Laurance Freedman (LINK)	Decreased stake from 9.75% to 7.8%

Purchase of Shares

Company	Entity	Details
Somnomed	Peter Neustadt (Executive Chairman)	\$0.7 million through entitlement offer
Rhinomed	Ron Dewhurst (Chairman)	\$500,000 through placement
Adherium	Garth Sutherland (CEO)	\$260,000 (via employee share plan loan)
Innate Immunotherapeutics	Andrew Sneddon (Director)	\$47,450 of shares acquired
Innate Immunotherapeutics	Michael Quinn	\$45,000 of shares acquired
Neuren Pharmaceuticals	Richard Treagus (Executive Chairman)	\$35,000 of shares (at 7 cents)
GI Dynamics	Anne Keating (Director)	\$24,225 at \$0.02
Impedimed	FIL Ltd	Increased stake from 7.2% to 8.3%
Clinuvel Pharmaceuticals	FIL Ltd	Increased stake from 6.6% to 9.6%
Clinuvel Pharmaceuticals	Lagoda Investment Managers (and FD&RB)	Increased stake from 7% to 9.8%
GI Dynamics	Hunter Hall Investment	Increased stake from 15.9% to 17.1%

Imugene Set To Commence Phase Ib/II Gastric Cancer Trial

Imugene (IMU: \$0.010) has completed submissions to a number of hospital Ethics Committees for the first part of its Phase Ib/II trial which should start next quarter. The trial will be conducted in Hong Kong, Taiwan and Thailand and will seek to recruit 18 patients with gastric cancer.

Imugene's platform technology is relatively easy to understand. It aims to harness the body's ability to develop antibodies against diseases, achieving a similar or better effect than making those antibodies through recombinant engineering and regularly injecting those antibodies into patients.

In 2015, monoclonal antibody drugs generated sales of US\$72 billion. One of the leading antibody drugs on the market is the cancer antibody therapy Herceptin (and Perjeta) which both target the HER2 cancer antigen. These two drugs generated sales of US\$8.2 billion for Roche in 2015.

Imugene's lead program is a vaccine, HER-Vaxx, which will seek to stimulate patient's bodies' to generate their own antibodies against the HER2 cancer antigen target.

Why Gastric Cancer?

HER2 is common not only on breast cancer cells but also in other cancers, including 20% of all gastric cancers. Imugene is conducting a trial in gastric cancer, rather than in breast cancer, because Herceptin is already the global standard of care in breast cancer and recruitment of patients to stop that therapy would be unethical.

Improvements to HER-Vaxx

Imugene has spent the last two years improving its HER-Vaxx. In April last year the company announced it had improved its potency 10-fold by binding the three peptides in the vaccine together. It then doubled the potency over the last year by changing the carrier in the vaccine (to CRM197, which is a more standard carrier) as well as adding a vaccine adjuvant.

Substantially Higher Incidence of Gastric Cancer in Asia

Imugene had previously planned to conduct its Phase Ib/II trial in Australia and Eastern Europe. However the company has changed trial sites to Hong Kong, Taiwan and Thailand because of the substantially higher incidence of disease in these countries and the greater difficulty in accessing the high priced antibody treatment in those countries (US\$120,000 a year).

The incidence of gastric cancer in Asia is considerably higher than in other regions, which explains why Imugene is conducting its gastric cancer study there. The incidence of gastric cancer in Japan is four times higher than in the UK. In China, the incidence is three times higher than in Australia.

There are a number of factors that are thought to be responsible for this variation. They include the prevalence and virulence of H.pylori and differences in genetic makeup and diet.

Trial Timeline – Start Expected Q3 2016

Imugene's COO, Leslie Chong, said the company's vaccine is now ready for clinical studies. The vaccine has been manufactured by piCHEM in Austria.

The final steps before commencing recruitment is to gain clearance for clinical studies in each of the three countries as well as Ethics Committee approval. As soon as there is clearance in one country the trial will commence. As indicated, recruitment is expected to start in Q3 this year.

The trial will seek to establish the necessary dose, including frequency of dosing of the vaccine. Details of trial progress, including dose selection, will be provided in 1H next year. Results from the Phase Ib part of the trial are expected to be reported in 2H next year.

Endpoints in the trial will firstly be safety and then immunogenicity of the vaccine, which importantly will show how well the vaccine is directing the production of HER2 antibodies in patients.

Aside from efficacy and safety, the trial results will also be used to select the dosage and frequency of treatment (vaccine booster) for the Phase II trial that will follow.

Phase II trial

The Phase II part of the trial is scheduled to start in 2H 2017. That trial will seek to recruit 68 patients in a randomized trial that will compare VER-Vaxx with standard-of-care (SOC) against SOC alone. Results from the Phase II study are expected in 2H 2019.

Imugene has appointed Sydney-based CRO Novotech to coordinate the Phase Ib/II trial.

Earlier Phase I Trial Results

A Phase I trial in 10 patients with end-stage breast cancer had been conducted with an earlier version of the vaccine by the Medical University of Vienna.

In that trial, 50% of patients achieved a stable disease after six months with no systemic toxicity to the vaccine. One patient went into remission following the treatment, which included three injections of the vaccine, and an antibody response was observed in eight of the 10 patients.

With the forthcoming trial involving a vaccine that is 20 times more potent and has a faster onset of action, a higher level of efficacy can be anticipated.

Expansion of Mimotope-Vaccine Platform Collaboration

Imugene's HER-Vaxx technology was originally developed at the Medical University of Vienna. Earlier this year Imugene extended that relationship to acquire and work on new vaccine candidates for other diseases using the same approach.

Other uses for the 'reverse-engineering technology' are to mimic

Cont'd on page 6

A Pre- BIO Q&A With Pharmaxis CEO Gary Phillips

The BIO International Convention is the biotech world's largest meeting in terms of attendance, conference program and business development opportunities. This year BIO is being held in San Francisco from June 6-9.

Almost 16,000 people attended last year's event in Philadelphia.

Many companies use BIO for business development activities, especially for organising meetings between potential licensors and licencees.

For drug discovery and development companies such as Pharmaxis, the event is a valuable opportunity to sound out potential partners about what they might like to see in a drug development program. Partnering meetings have increased by 266% over the ten years to 2015, with 29,000 meetings place in that year, between more than 3,000 companies.

We put several questions to the CEO of Pharmaxis, Gary Phillips, about his plans for attending this year's BIO. We will follow-up with Gary after his return, for a post-event analysis.

What will Pharmaxis be doing at BIO this year?

This year I probably have the most ambitious set of objectives I have had going into the BIO conference:

- I'll be catching up with companies who we have previously discussed our LOXL2 anti fibrotic program for NASH and IPF with to keep them informed of progress and timelines.
- Check on interest in our neuro inflammation SSAO/MAOB program amongst companies that are looking for Alzheimer's drugs. Do they believe that the target has a place in treatment and what pre clinical models would convince them of the potential value? What other neurology indications do they think it might be appropriate for?
- Discussing our oligonucleotide phase 2 respiratory program for interest amongst orphan drug companies. It hits multiple inflammatory targets and has a profound effect on eosinophils so we might find an application there.
- Talking with several smaller companies and universities / research institutes who have interesting anti inflammatory or anti fibrotic programs for potential in licencing.

What is the mindset you have to bring to the business development tasks you have set for yourself at BIO?

The format of BIO restricts most meetings to a maximum of 30 minutes so everything has to be packaged neatly – no time for long scientific debates!

- For companies we are meeting for the first time it is really important to get straight down to business and work out if there is enough interest to make it worthwhile scheduling follow up talks post BIO.

– For companies that we are meeting for the second, third or even fourth time it's about building the relationship, providing enough information to keep their interest and letting them know the timelines for when you will be ready to partner.

– The larger companies have different BD staff for each therapy area so you can also spend time working out with the people you meet how to navigate their internal politics and get to the right person for the asset you are marketing.

What does BIO offer that other events don't e.g is it a superior event for gathering competitive intelligence?

What makes BIO stand out is the sheer quantity of companies and assets that you can assess in a relatively short period of time. The time frame for meetings means that it's more of a triage exercise for opportunities than looking to negotiate and complete transactions.

The other major partnering event of the year is at the annual JP Morgan conference in January. There are less meeting opportunities but the big companies bring larger scientific teams to this conference taking out whole floors in hotels so the meetings are longer and go far deeper.

How many meetings will you conduct?

Well as I write this there are still three days to go before it all kicks off and a lot can happen in that time. My calendar is currently showing that I have 27 meetings scheduled and I have declined more than a 100.

How do you plan to make the most efficient use of your time?

You have to prioritise meetings according to your objectives. It would be very easy to get swamped by accepting meetings that whilst interesting have no immediate value. For example most of the meetings I have accepted are with large Pharma companies that are interested in partnering our assets.

Most of the meetings I have declined are from service providers offering new pre-clinical proof of concept models or companies offering to help with capital raising or business development.

Some of these could be very useful so I make a point of referring them onto appropriate managers in Pharmaxis who might have a use for them in the future and suggest they catch up by teleconference or email after BIO.

How do you avoid 'meeting burn-out'?

I try to have a good set of notes before BIO starts so that I can refresh my mind quickly before each meeting on what I want to achieve with that particular partner. That helps – but so does trying to get some sleep and avoiding the BIO networking events with free alcohol – except the wine tasting at the Australian pavilion of course!

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Bioshares Model Portfolio (3 June 2016)

Company	Price (current)	Price added to portfolio	Recommendation	Cap'n (\$M)	Date added
GI Dynamics	\$0.030	\$0.024	Spec Buy B	\$14	May 2015
Adherium	\$0.385	\$0.495	Spec Buy A	\$58	March 2015
Bionomics	\$0.300	\$0.295	Spec Buy A	\$144	March 2016
Reproductive Health Science	\$0.150	\$0.150	Spec Buy B	\$9	December 2015
Rhinomed	\$0.022	\$0.032	Spec Hold B	\$18	December 2015
AirXpanders	\$0.890	\$0.745	Spec Hold A	\$187	September 2015
Osprey Medical	\$0.230	\$0.695	Spec Buy B	\$35	September 2015
Atcor Medical	\$0.140	\$0.20	Spec Buy A	\$28	June 2015
Clinuvel Pharmaceuticals	\$4.56	\$4.15	Spec Buy A	\$215	December 2014
Innate Immunotherapeutics	\$0.270	\$0.190	Spec Buy A	\$53	November 2014
Opthea	\$0.455	\$0.160	Spec Buy A	\$68	November 2014
pSivida	\$4.850	\$3.800	Spec Buy A	\$165	May 2014
Impedimed	\$1.010	\$0.245	Spec Buy A	\$377	December 2013
IDT Australia	\$0.280	\$0.260	Spec Buy B	\$61	August 2013
Viralytics	\$0.900	\$0.300	Spec Buy B	\$214	August 2013
Somnomed	\$3.23	\$0.94	Buy	\$178	January 2011
Cogstate	\$0.780	\$0.13	Spec Hold A	\$87	November 2007

Portfolio Changes – 3 June 2016

IN:
No changes.

OUT:
No changes

– Imugene cont'd from page 4

the action of other antibody oncology treatments as well as drugs to treat immune-based disorders. (The anti-TNF alpha antibody drug class is an obvious choice with one drug alone in that category, Humira, generating over US\$12 billion in sales last year.)

Professor Ursula Wiedermann from the Medical University of Vienna and who is also Imugene's CSO said the new arrangement will "efficiently transform Imugene into a multi-asset biopharmaceutical company." Other vaccine candidates will be announced at the end of this year.

Management Strengthened

In August last year Imugene appointed Leslie Chong as Chief Operating Officer. Chong has spent 19 years in oncology drug development, first at GlaxoSmithKline, then at Exelixis, after which she moved to Genentech to work on a program that was accessed from Exelixis.

Chong was clinical operations program lead on that MEK inhibitor program with that drug, Cotellic, gaining FDA approval late last year for the treatment of metastatic melanoma in combination with the drug vemurafenib.

Chong has been involved in 300 clinical programs and her extensive experience can be expected to applied effectively to Imugene's clinical program.

Summary

After several years of delays, mostly attributed to vaccine design issues, Imugene is now in a stronger position, with a strengthened management, a re-focused clinical trial plan, an improved vaccine candidate and a broadened technology base in place.

A technology risk with the HER-Vaxx program is that once the immune response has been initiated, it can not be switched off.

Imugene is capitalised at \$17 million. The company had \$2.4 million in cash at March 31, 2015 and is funded through to the end of this year. We expect a capital raising to take place this year.

Bioshares recommendation: Speculative Buy 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

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