termsheet

PharmaVentures
Experts in deals and alliances

October 2014 Issue 12

Heads of Terms

Seven steps to successful deal making

Although it occurs among only a minority of our deals, one of the most serious issues we face when assisting our clients is lack of preparation by the client. For either out-licensing activities or a sale process the issue can cause huge problems and, if not resolved, can result in a complete breakdown of negotiations.

So what does being prepared mean?

There is a school of thought that the preparation process starts several years before any deal is contemplated – when the business model is being developed. In our industry, where science dominates, companies can be distracted by the 'sexiness' of the technology and not the true realistic commercial potential. It is necessary, therefore, to have a real commercial case for the products and the business. Assuming the business or the products satisfy these criteria and they are very licensable or sellable, can lack of preparedness truly result in no deal being done? Well yes!!

So what do we recommend?

First, ensure that all the stakeholders, i.e. the shareholders, board and executive management, are fully aligned. This is true even when licensing where licensors are biotech

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industry insight

Convergence of Healthcare with ICT accelerates

Ping Shek

The sale in June of Medical Insight, a Danish enterprise imaging software company, to Karos Health, a Canadian healthcare IT solutions provider, where PharmaVentures advised Medical Insight, is an example of the continuing consolidation trend.

The healthcare market today is driven by the overriding need to deliver better patient care at lower cost whilst being able to serve ever increasing numbers (from an aging population). Technology and innovation are playing a key role in this. The convergence of medical technology with information and communications technology (ICT) enhances the delivery of patient service whilst enabling more effective clinician workflow and healthcare provider administration.

The 'electronic medical platform' ('EMP'), typically provided by ICT groups, is becoming the workflow and administration backbone for healthcare providers. Medical equipment and devices, patient care venues (eg. operating room, radiology centre etc.), Accident and Emergency, ambulances, remote healthcare infrastructure are all integrated into the platform. This architecture enables mobility, 'seamless' interconnection and much improved activity coordination. The EMP plays a crucial role in the delivery of mobile health (mHealth), remote healthcare and home patient care, all of which play significant roles in helping achieve better patient care at lower cost. Importantly, these electronic platforms can be provided using a Software-as-a-Service (SaaS) model which has distinct commercial advantages for ICT firms.

It is, therefore, not surprising that many ICT companies are starting to invest in technologies and/or partner with companies that enable them to better compete in this huge market. For example, Google has struck up a strategic partnership with Alcon (Novartis) to develop its glucose eye monitoring contact lens; it also has an interest in DNAnexus, a bioinformatics company. Cerner (a healthcare IT company) has teamed up with Siemens to jointly develop solutions in laboratory automation and cardiology information systems. Dell acquired InsiteOne, a cloud-based medical data management systems. Moreover, ICT groups are actively evaluating opportunities to gain access to the healthcare ICT market where the cloud SaaS segment is expected to grow at over 20% per year.

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guest contributor

Changing the game for drug development

Steve Bates, CEO, BIA

The BioIndustry Association (BIA) has been working with regulators, at both a European and a UK level, on two schemes which are changing the rules of the game for drug development. The European Medicines Agency's (EMA) Adaptive Licensing (AL) pilot project was launched in March this year, whilst in the UK we witnessed the launch of the complimentary Early Access to Medicines Scheme (EAMS), coordinated by the Medicines and Healthcare products Regulatory Agency (MHRA).

The UK government has long been in support of introducing some form of adaptive licensing as another step towards providing timely access to innovative medicines in order to address unmet medical needs. The adaptive licensing approach allows experimental medicines in the early stages of development to be authorised for use within a restricted patient population. Evidence collected during its use in this 'real world' setting is then used to adapt the marketing authorisation and gradually expand access to broader patient populations.

The UK's Early Access scheme also aims to introduce a more practical and adaptive approach. After a number of years in the pipeline, following a resolute campaign from the BIA to keep it on the government's agenda, the scheme launched at the beginning of April. EAMS is a three-step voluntary evaluation process aimed at allowing access to unlicensed therapies that have completed Phase III trials, but may be applied to those that have completed Phase II trials in exceptional circumstances. Applicants must first apply for a Promising Innovative Medicine (PIM) designation, which is awarded by the MHRA. This is similar to the FDA's 'Breakthrough Therapies Designation'. Once a positive PIM designation is obtained, applicants can then proceed to step two, the EAMS Scientific Opinion, which will describe the benefits and risks of the medicine based on information submitted to the MHRA by the applicant. The final step is commissioning by the NHS.

As with the AL pilot project, the UK's Early Access scheme will utilise data collected during the earlier stages of drug development. It is hoped that the collection of additional data by specialist clinicians during these earlier stages, combined with the comprehensive assessment by the MHRA, will result in a faster and more efficient commissioning process. This, in turn, should lead to a faster route to market for promising new treatments, thus delivering improved therapies for patients across the UK.

It is clear that both the UK and Europe are steadily embarking on a new regulatory era, and one which holds great promise for patients and new opportunities for developers of innovative medicines. The BIA has been an active proponent of this new shift, through our work with the Office for Life Sciences, input into the government's Life Science's strategy and most significantly on an Expert Group on Innovation in the Regulation of Healthcare which recommended both of these approaches. Although we recognise that there are still some uncertainties to overcome with these new pathways, we do nevertheless urge industry to consider these options where appropriate, as we believe there is much to be gained by embracing this new regulatory landscape.

Further information:
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Heads of Terms

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companies with VC investors who often have a major say in the licensing activities of their investee companies. Non-alignment can lead to stalling during negotiations by your side resulting in the other side walking away.

Second, be clear on the process to be employed for doing the deal and who should be involved. This includes ensuring that an appropriate reach to interested parties is attained and that several parties will end up bidding for the assets.

Third, make sure all your financials, including projections, are robust and defendable. This is often the most difficult process and is where misalignment among stakeholders is most likely to happen! Furthermore, being unable to defend ones financial projections will lead to further chipping away of the terms later on.

Fourth, make sure all stakeholders are agreed on what the terms of the deal should be in advance and how sign off will occur.

Fifth, make sure the dataroom is due diligence ready. This means it is properly populated with all the information required by interested parties. These files should be accessible, properly filed and readable.

Sixth, make sure you have a clear strategic path for negotiation. Who are the negotiators and what are the roles of others?

Seventh, be clear on your walk away strategy. Should this need to be implemented everyone needs to be onboard.

Working with an experienced team, like PharmaVentures, can truly help with making sure that all the above are in place so that a smooth and professional approach can be achieved and you get the best outcome.

Dr Fintan Walton
Chief Executive,
PharmaVentures Ltd.

"Looks like these biotech negotiators are starting to play hardball!"

Life science mergers and acquisitions: an introduction

PharmaVentures is pleased to announce the next instalment of our workshop series. ***Life science mergers and acquisitions: an introduction***, will look at both sides of the M&A process. This workshop will take place in the UK in early December.

The workshop will be comprised of a series of seminars and interactive sessions. By attending this one-day workshop, you will benefit from PharmaVentures' corporate advisory team's extensive knowledge of the M&A process.

Topics covered will include:

- Target searching and qualification
- Due diligence
- Negotiation and bidding
- Navigating the legal and regulatory considerations
- Deal structuring
- Managing the M&A process
- Post-merger integration

Attendees will be given the opportunity to fully immerse themselves in the progression of a deal by taking part in a role-play session. Participants will assume roles on buy and sell side and be guided by our course tutors to submit bids. After a Q&A session, the group will be encouraged to reassess and resubmit their bids.

With case studies from PharmaVentures' projects and our team's experience, the life science mergers and acquisitions workshop will provide a thorough introduction to the M&A process.

For more information or to book a place, please email: ali@pharmaventures.com.

A personal view: We're all multichannellers now

Paul Simms, Chairman, eyeforpharma

You may have noticed that marketing has changed dramatically over the past few years. It started a while back when marketing departments were brought closer to existing sales teams – which was bearable, but then came e-marketing (or digital marketing), then multichannel marketing – and now it's all about value-add and 'MCLM' (multichannel closed loop marketing). Why should we, in the pharmaceutical industry, care?

The biggest recent shift in marketing came with the internet. It was a well-timed arrival, given the onset of a global recession, and it allowed the industry to cut down heavily on expensive sales reps that the industry employed.

The internet is the first medium in a hundred years that wasn't invented to make advertisers happy. The connection between running ads and making money is broken, probably forever. As soon as you break that connection, everything changes. This might sound like a problem for marketers, but in fact it's quite the opposite, and here is why.

The holy grail of personalised medicine is still, despite our best efforts, some way off. However, that's only true if you look at it from our clinical point of view. These days, the incredible technology of the smartphone provides an opportunity for a new type of personalisation, almost as useful as the medicine itself. A new type that puts the personalisation in the user's hands, where it should be. We are really only at the very beginning of this revolution, but already there are some big bets being placed (Apple's has declared that Health was where the company is going to focus for its imminent range of product launches). You're about to see an explosion of cheap sensors, software and analysis of patent health data while they undergo treatment. Pharma is miles behind the curve.

The next thing that differentiates the pharma company from its closest competitor is not necessarily down to the creation or acquisition of the next wonder-drug. It's down to their ability to innovate in a different zone, at the patient level. That means providing a useable interface for patients and helping them to understand their medicines better and help them to get healthier soon. It's a move from business development to patient development. It's not just about the pill anymore.

eyeforpharma is a hub for senior-level pharma executives, patient advocacy groups and other health experts to exchange ideas and stay up to date with shifting trends and practices within the pharmaceutical industry. They provide industry-focused commentary, events, reports, and other valuable expert-driven content.

Further information:
enquiries@pharmaventures.com

Convergence of Healthcare with ICT accelerates

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Going forward, we would expect ICT companies to increasingly partner with healthcare IT companies and medical device/equipment makers as part of process of developing the electronic medical platform and integrating technologies to ensure these platforms work effectively across the whole healthcare enterprise. Additionally, we will see further consolidation in healthcare IT software companies as firms team up to provide more comprehensive IT solutions to healthcare providers that maximise the benefits of being connected to the EMP.

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Big Pharma Deal Making – The Beginning of a New Dawn?

Dr Hanna Schutz

It's useful to review deal trends periodically to gain insight in how deal making behaviours are changing from the perspective of numbers and value as well as how emphasis shifts from one therapeutic area to another. The majority of small and mid-size development companies still seek a deal with one of the major pharmaceutical companies in order to commercialise their assets. In recent times, we have seen the economic downturn, patent expiries and expensive late stage drug development failures making life difficult for small and large companies alike. Is there the possibility that things are turning around and should we expect an upturn in deal numbers and values? In this context we have reviewed publically declared and reported deals for Big Pharma going back 10 years, to 2004, to see what it tells us.

10 Year Deal Snapshot

Licensing and M&A are the lifeblood of the pharmaceutical industry. This has increasingly become the case with externalisation of R&D by the big players, making them more reliant upon 3rd parties to innovate and develop new therapeutics. Looking across a 10 year time period it would be reasonable to expect deals done in 2004 to be contributing to revenues around 2008 and beyond. Similarly, those done in 2008 should begin to contribute in 2013. At a high level, one would expect those who do the most deals to benefit the most in revenue terms.

Figure 1 gives a snapshot of revenues versus deal numbers with a lag built in for the deals to start contributing revenues to the company. Holistically, it appears that most of the big pharmaceutical companies' revenues have not grown significantly despite increasing the number of deals they have done. Only Sanofi, Novartis, Merck and Amgen have shown good positive revenue growth coupled with increasing deal numbers. Whilst this is an interesting observation, it does not take into account a myriad of other influencing factors such as drugs going off patent, divestment of business segments etc. This interesting observation is worthy of further analysis. We have therefore drilled down into some specific therapeutic areas to look at the deal trends over a similar time period. For this, more detailed analysis, please download the white paper from our website.

In Figure 2, we can see deal numbers broken down by therapeutic area and their expansion leading up to 2008 and 2009. There then follows a significant decline in all therapeutic areas except oncology from 2009 to date. The global economic crisis in 2008-2010 was undoubtedly a key influencing factor. Of interest is the appearance of deals in autoimmune diseases since 2007 and the decimation of CNS, cardiovascular and metabolic therapeutic areas. Is the trend poised to change? The data presented here is full year apart from 2014 which only shows from January to June. We saw a tentative rise in deal numbers from 2012 to 2013 and, if the second half of 2014 is similar to the first half, we should see the upward trend continue.

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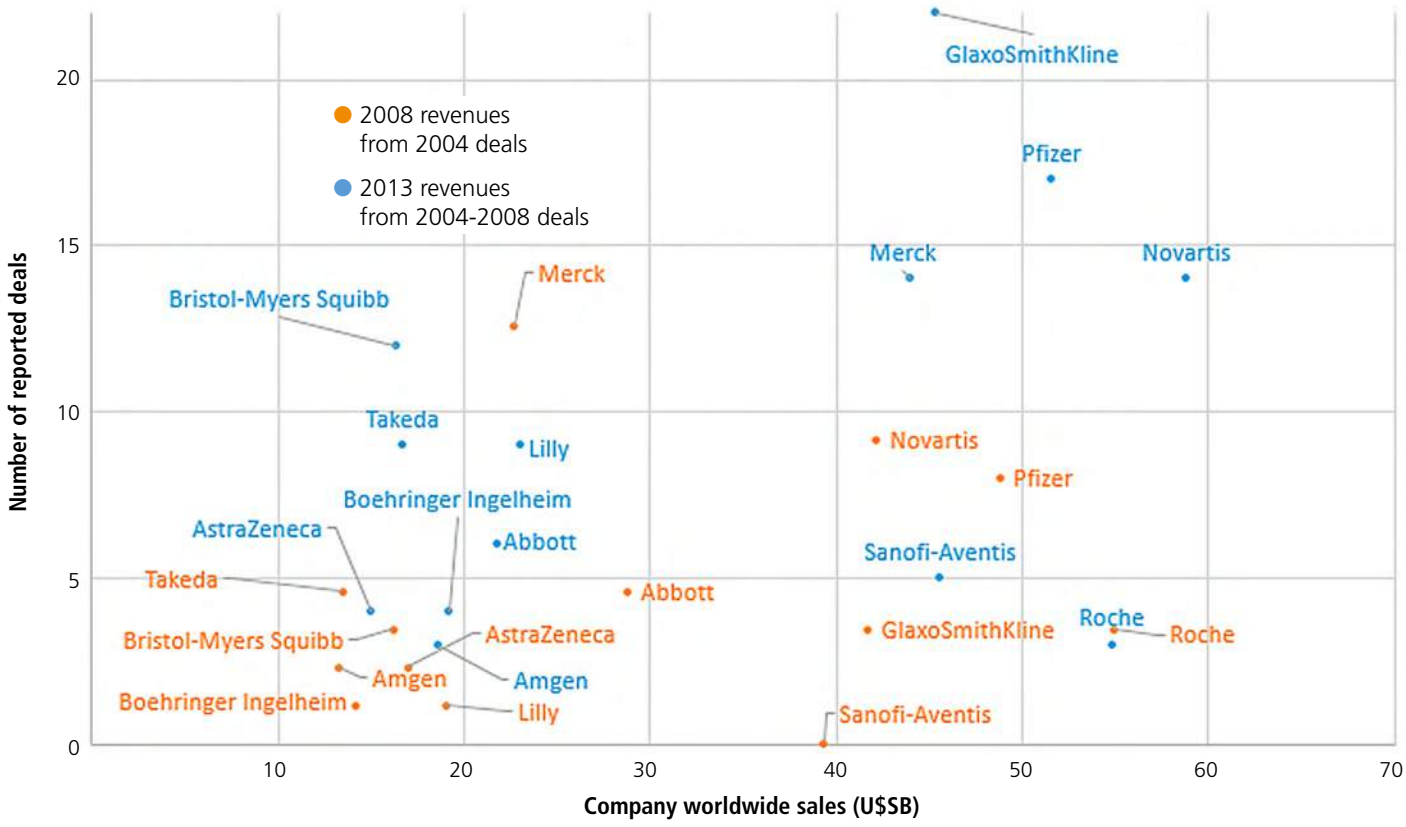

Figure 1: Revenues vs deal numbers 2008 and 2013

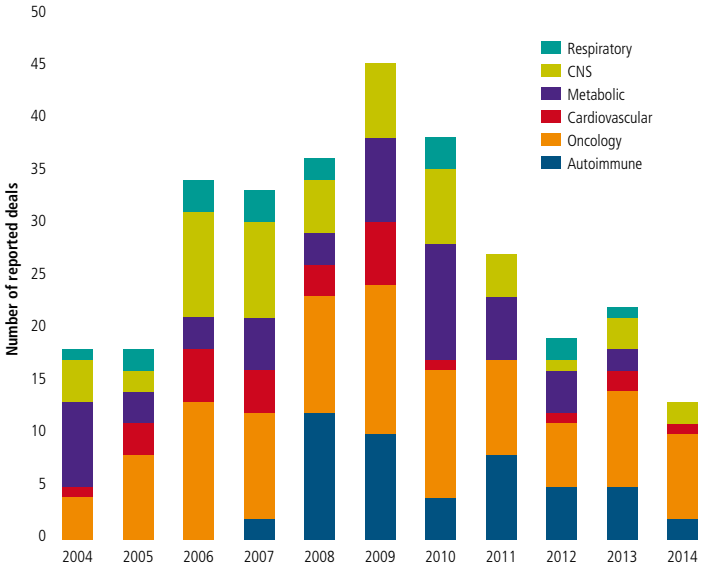

Figure 2*: Acquisition and licensing deals of Big Pharma (2004 – 2014)*

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Oncology Deals

Oncology has perennially been the area of greatest deal making activity and remains so amongst all companies (*Figure 2*). From 2004 to 2013, where financial terms were disclosed, there were 30 oncology M&A transactions worth a total value of $22.4 billion and 31 licensing deals worth a total of $5.7 billion. The difference between deal values by phases, is noteworthy and looked at in greater detail in our white paper available on our website.

For major pharma we can see that there is more spending on early stage oncology assets. This is consistent with increased competition for early stage assets and exemplified by recent deals in the checkpoint inhibitor blocker sector. 72% of oncology drugs fail in Phase II development and Big Pharma has typically waited until Phase II proof of concept data has de-risked an asset. However, market dynamics dictate earlier deal making and greater risk taking. The rewards for successful oncology drugs makes this risk worthwhile although as pressure increases from payers on very expensive oncology drugs that are only used as late or last line treatments, one might speculate that this market dynamic may change in the not too distant future.

CNS Deals

CNS is one of the sectors that has suffered most in recent times. 2006 to 2009 were the halcyon days driven by huge unmet need for new therapies for major diseases such as Alzheimer's, where only symptomatic treatments existed and the potential rewards were huge. The economic events of 2008-2010, coupled with the huge costs of running late stage clinical trials saw a lot of costly late stage failures. Some mid to large pharmaceutical companies now admit they don't have the budgets to run such trials on their own. It is no surprise that we see fewer deals than oncology and no late stage deals from Big Pharma in the last 3 years. The unmet medical need has not gone away and some Big Pharma players remain more active in the sector. When newer therapies emerge, these players will be the big beneficiaries.

Summary

Acquisitions and strategic collaborations have been around for a very long time, and the typical deal structures are well known. However, the scarcity of money supply from 2008/2009 has, until recently, led to fewer deals and increased deal complexity in order to mitigate risk. Parties with money recognise the leverage they have and the opportunity this presented to maintain value whilst limiting exposure. Whilst oncology has remained cushioned from other influences and deal numbers and values remain high, other therapeutic areas have not fared so well. This situation now appears to be changing as the IPO window has opened and biotech companies have a liquidity alternative to licensing in order to continue development. The VC environment is also improving and presents another alternative to being forced to seek a licensing partner earlier than perhaps the optimal point in development. These improvements in the economic environment, should they be sustainable, could see biotechs progressing assets to later stages of development to increase their value. We could consequently see more later stage deals between biotechs and Big Pharma. This should also present Big Pharma with opportunities to replenish pipelines decimated by patent expiries and drug development failures. There will continue to be downward pressure from regulators and payers so, whilst we might see deal numbers recovering, we may well see deal values being either supressed or the continued use of creative deal structures with back ended value.

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PharmaVentures strengthens its expertise in early stage deal making

Dr Christopher Berry

PharmaVentures is pleased to announce the appointment of Dr Christopher Berry, formerly of Sanofi's R&D Transactions Group, as an Associate in the corporate advisory team. Dr Berry has negotiated 56 signed deals since 2010. Partners included universities, biotechnology companies and large pharmaceutical companies. Dr Berry was responsible for building research collaborations in the areas of anti-infectives, biologics, and regenerative medicine, as well as for the Asia-Pacific Therapeutic Unit. He was previously Head of Thrombosis and Haematology in Synthélabo Recherche, one of Sanofi's predecessor companies. He holds a PhD in Pharmacology from King's College, London and an MBA from the Open Business School.

Dr Fintan Walton, CEO, PharmaVentures said *"We are delighted to have Dr Berry join the team. His vast experience in early stage deal making will complement our existing team and enable us to continue to offer our clients expert help throughout their deal making processes"*. Dr Christopher Berry commented *"Early stage deal making is essential as pharmaceutical companies strive to build competitive pipelines"*.

forthcoming conferences

PharmaVentures and PharmaTelevision are delighted to be sponsors and supporters of the **UK Bioscience Forum** and **AusBotech 2014**:

UK Bioscience Forum

October 7, The Royal College of Surgeons, 35 - 43 Lincoln's Inn Fields, London

The UK Bioscience Forum is an ideal place to hear the latest thinking in a number of key areas in the bioscience industry. With parallel tracks based on all the areas of interest to bioscience companies today, the UK Bioscience Forum is topped and tailed by inspiring keynote presentations, exhibition and networking areas and provide a perfect place to make new contacts, build relationships and develop your business.

This is a chance to hear from industry-leading speakers in the global life sciences community – across academia, research charities, pharma, biotech companies and funders at this one-day exciting award-winning conference.

Delegates have the opportunity to meet with a variety of business professionals during the speed partnering sessions which will take place throughout the day.

To arrange a meeting with one of the PharmaVentures Team at this event please contact Maria Seal, maria@pharmaventures.com

conference update

Nordic Life Science Days and ECCP 2014

September 7-9, 2014
Stockholm Waterfront Congress Center, Nils Ericsons Plan, Stockholm

In 2014, the Nordic Life Science Days, in close cooperation with Oslo Cancer Cluster and Toulouse Cancer-Bio-Santé Cluster, will integrate the European Cancer Cluster Partnering conference (ECCP 2014) as its Special Oncology track.

Set in the idyllic city of Stockholm, the largest Nordic partnering conference for the global Life Science industry, brings together some of the best talents in Life Science.

The conference offers conference sessions, panel discussions, company presentations, exhibition, face-to-face meetings and unique receptions offering excellent networking and partnering opportunities.

2nd Annual Value-Added Services 2014 and 4th Annual Multichannel Marketing Summit 2014

September 17-18, Park Plaza Victoria, London

In an uncertain climate, Big Pharma must understand its customers and deliver what they really need: value beyond the pill. In 2013, eyeforpharma ran their first Value Added Services Summit in London to great critical success; in 2014, it's their mission to offer you actual solutions for the implementation of connected health and demonstrate, along with a brand new roster of expert speakers and stakeholders, how the industry can drive change and establish a true integrated strategy.

The 2014 Multichannel Marketing EU Summit will provide the perfect platform for the industry's greatest marketing and digital minds.

At the 2014 Summit there will be over 200 senior executives coming together to discuss topics that will form the pillars of where the industry is at the moment but more importantly – where it is heading and how we can prepare and adapt to the immense changes in the evolving Pharma industry.

AusBiotech 2014 National Conference

AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

The brightest brains in biotechnology and innovation will gather on the Gold Coast for the AusBiotech 2014 national conference, the largest annual gathering of biotechnology experts in Australia and the Asia Pacific region.

The conference will be held from Wednesday 29 to Friday 31 October 2014 at the Gold Coast Convention & Exhibition Centre in Queensland, Australia.

Proudly hosted by AusBiotech together with state host partner, the Queensland Government, AusBiotech 2014 will feature Australian and international speakers from the biotechnology, biopharmaceutical, life science, business, investment, research and health industries.

We live in a time where technological innovation, knowledge and networking are the drivers of our productivity, and technology based on the life sciences is an area where Australia has great expertise. The AusBiotech national conference has proved its relevance to the Australian and international biotechnology industries, annually attracting around 1000 participants, including over 150 international participants.

In addition to the program of quality speakers, the conference will provide valuable networking activities, a highlight being the gala conference dinner on the Thursday evening. There will also be a BioIndustry exhibition hall. AusBiotech's Business Matching Program will facilitate meeting requests between conference delegates.

AusBiotech 2014 is expected to attract a strong contingent from throughout the Asia-Pacific region, the USA and Europe.

For further information and to register visit www.ausbiotechnc.org

Date: 29-31 October 2014
Venue: Gold Coast Convention & Exhibition Centre, Queensland, Australia
Website: www.ausbiotechnc.org

PharmaVentures increases its Asia-Pacific presence

Aki von Roy

PharmaVentures are delighted to announce that Aki von Roy has joined as an Associate, based in Auckland, New Zealand. He has over 30 years experience in Big Pharma and 16 years in biotech. He has been involved in over 18 start-up or merger ventures as director or investor.

His experience includes being Founder CEO of Proacta and CoDa Therapeutics and Founding Director of Corra Life Sciences (USA), Biomatters (NZ) and White Biotech (AUS). He is a former chairman of both private and publicly traded companies including Genesis R&D (NZ), Phylogica (AUS), Vital Foods (NZ) and Phytomedics (USA).

Aki von Roy is currently a Venture Partner at Biopacific Ventures and an advisor to Direct Capital. He was previously a partner of Inventages (US$1.5 billion life science fund).

Dr Fintan Walton, CEO PharmaVentures, said *"Aki has a unique insight into innovative healthcare in the Asia-Pacific region and he will be a great benefit to both PharmaVentures and its clients"*.

Aki von Roy added *"I am delighted to join PharmaVentures, a firm with a proven track record in deal making"*.

Aki is the former European president of Bristol-Myers Squibb, where he was responsible for US$2.2 billion in sales, more than 7,500 employees and some 40 subsidiaries. In 1997, he retired from BMS to establish RvR Associates, a private investment firm specialising in health and related matters.

Top PA joins team

Beverley White

Beverley joins the PharmaVentures team to support its founder and CEO Dr Fintan Walton. Before joining the team Beverley had spent a considerable time working from the Family Office of a HNW Entrepreneur, focusing on the acquisition of high technology medical companies. In that role, she supported a Head Office Team in day to day business operations, strategy, sales, planning, business turnaround, mergers, acquisitions and start-ups. Latterly, she gained experience in the group sale process from early stage exit strategy, planning and preparation, to assisting the Executive completing the deal itself. She has travelled extensively and this has equipped her with a broad range of skills, which, in addition to her previous career experience, make her ideally placed to support our CEO.

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