



Heads of Terms

Dealing with Experience

A successful dealmaker is often considered to be someone who has closed lots of deals. This is clearly true but one should also take into account the number of deals that didn't close. My own experience has been sharpened by the deals that failed. Learning to identify what will be sellable or licensable is an important part of being a good dealmaker.

In my early years as a negotiator I thought that having strong persuasive qualities alone was key to being a good dealmaker, but the painful journey of negotiating many deals made me quickly realise that there are many other qualities required to be successful.

Understanding the technological and commercial value of the asset to be sold or licensed is essential. Without this you can either waste your time finding a non-existent interested party or waste your time sparring with the other side on value only to be 'taken to the cleaners' by them. It is amazing how many people simply do not know enough about the arguments for or against the value of an asset. They think it is all about bargaining!

Understanding the strengths and weaknesses of the team on 'your' side and 'their' side is essential. These individuals can be the potential makers or breakers of a deal. I don't know how many times I have cringed watching people on either side of the table destroy a deal due to poor performance or through a personality disorder. What's more painful is to see a great technology or therapeutic going nowhere because of this incompetence!

In the past I have talked about how important it is to have alignment between shareholders, board and executive management. A failure of alignment is often the biggest disappointment when negotiations fail.

Learning from these mistakes and experiencing a number of deal failures will enhance your chances of being a successful dealmaker!

Dr Fintan Walton

Chief Executive, PharmaVentures Ltd.

industry insight

Is Live Cell Imaging becoming a 'Must Have' Technology for Regenerative Medicine?

Issac Jacob | Senior Director, PharmaVentures Limited



A new age of cell based therapies is dawning and recent developments in immuno-oncology around CAR-T and T cell engager therapies has highlighted both the technical and commercial viability of this approach. More and more diseases will be tackled by harnessing the body's immune system and manipulating it or using stem cells in regenerative medicine to return the individual to health.

This requires the manipulation of cells ex-vivo and then returning them to the patient. The conventional cell imaging technologies employed in research generally utilise reporter species such as fluorescence or radioactivity to detect the cells and understand the intra and extra-cellular processes. Obviously such "tagged" cells cannot be returned to a patient and thus the need for live cell imaging technologies is becoming increasingly important.

The recent transaction between PharmaVentures' client, CM Technologies, a Finnish live cell imaging company, and Yokogawa Electric, a Japanese engineering, measurement and microscopy company, highlights this growing demand.

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deal update

PharmaVentures advises Douglas Pharma in acquiring Vital Foods' Phloe product line

In early September PharmaVentures was pleased to announce that it acted as advisor to Douglas Pharmaceuticals, New Zealand's largest pharmaceutical manufacturer, in acquiring from Auckland-based Vital Foods their Phloe® product line in New Zealand for an undisclosed sum. The deal, completed on 1st September, includes an option for additional territories.

The sale of the Phloe® product line to Douglas Pharmaceuticals allows for the growth of Phloe® in New Zealand and enables Vital Foods to focus more effectively on the international market for Phloe® products.

Phloe® Bowel Health contains Zyactinase®, a proprietary kiwifruit extract with a unique mode of action derived from naturally occurring prebiotics, enzymes and fibre that aids regular and efficient bowel function.

Aki von Roy, Associate Director Asia-Pacific, PharmaVentures, said: "We are delighted to support Douglas Pharmaceuticals in its plans for growth both in New Zealand and globally".

Fintan Walton, Chief Executive, PharmaVentures, added: "This latest deal reflects the growing number of global deals that we have achieved in recent years".



Live Cell Imaging

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A large number of cell imaging techniques have evolved to become routine in laboratories in recent years including flow cytometry, cell isolation and expansion, functional assays for cell viability and proliferation, high content analysis, and labelling chemistry techniques. These technologies have furthered the understanding of cell interactions and intracellular processes and pathway elucidation immeasurably. What they cannot do, because of the requirements for labelled species, is take that next critical step and participate in the generation of actual cellular therapies.

Step forward live-cell label-free imaging technologies developed by CM Technologies. Live cell imaging technology can address questions regarding dynamic processes, cell morphology, cell motility, and intracellular molecular interactions; it is an effective approach for high-resolution and non-invasive imaging of live organisms, making it suitable for clinical applications in regenerative medicine and iPS.

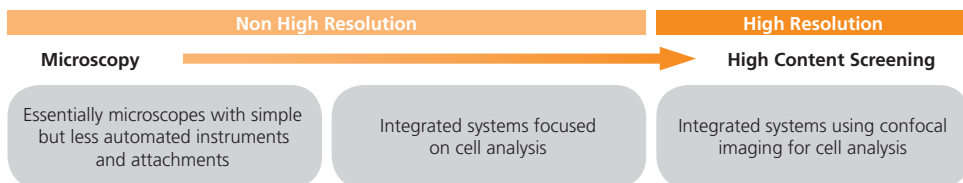


Figure 1 Live-cell imaging

Live cell imaging allows for the investigation of process dynamics of living cells in real time in situ (cellular networks) and in-vivo (whole organisms). Scientists and researchers working in pharmaceutical, biotechnology, academic research, and government and hospital facilities utilise the technology to investigate tissue structure and cell function

on-a-chip microfluidics systems offering novel solutions for the analysis of cells, deoxyribonucleic acid (DNA), ribonucleic acid (RNA), and proteins. In addition, cell research is further aided by the explosive rate of developments in fluorescent protein, quantum dot, and synthetic fluorophore technologies. The combined use of these

by imaging a variety of dynamic events with high spatial and temporal resolution over a wide range of time scales. It is currently the most powerful technique to observe the kinetics of dynamic processes, such as active transport versus diffusion or microtubule turnover, to follow the order of sequential events in real time, and to record sensitive or transient processes in-vivo, such as calcium signalling transients, ion gradients, or membrane potential.

Technological advances in recent years, such as improvement of sensor sensitivity, computer power, brighter and more stable fluorescent proteins, and new fluorescent probes for cellular compartments, have given researchers the tools to study complex biological processes in great detail.

Live-cell imaging techniques involve a broad spectrum of imaging modalities, including wide-field fluorescence, confocal, multiphoton, and total internal reflection, fluorescence resonance energy transfer (FRET), lifetime imaging, super resolution, and transmitted light microscopy. This past decade has heralded the advent of “omics”-technologies and nanotechnologies, which have produced commercially available lab-

systems with microscopic imaging platforms to study biological material, or to view cell morphology has been proven to be very successful. Indeed, driven by the latest innovations in omics-based technologies and personalised medicine approaches, these platforms are beginning to be adopted into mainstream medicine, leading to new opportunities in life sciences and clinical research.

Live-cell imaging is viewed as an important area for a wide variety of research areas, including stem cell research, bioprocessing, regenerative medicine, personalised medicine, IVF, drug discovery, cell biology, biochemistry, and genomics research (Figure 2).

The acquisition of CM Technologies assets by the Japanese company Yokogawa is indicative of the importance of regenerative medicine and stem cell technologies in Japan. Japan offers a very favourable regulatory environment and recently has had the highest investment level into this area. The combination of CM Technologies capabilities with Yokogawa's established excellence in providing imaging instrumentation for the research community represents an important step forward in providing the right tools to deliver cell based therapies for a range of diseases.

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Bioengineering / Manufacturing

- Pharmaceutical companies are applying live cell imaging to perform automated screening assays as they reduce screening time and costs which allows for more rapid development of drugs
- Label free approaches to perform advanced screening for difficult biological targets and eliminate label-associate artefacts

Research

- Analysis of cell motility, morphology and intracellular process dynamics in living cells useful in research areas such as cancer and neurodegenerative diseases
- Scale-up of stem cell production and quality control is challenging and complex; stem cell research aided by ability to culture cells for longer periods in integrated systems and reproducibility of data
- Anti-cancer market expected to reach \$12.7 bn by 2016 (BCC Report 2012) while the stem cell therapy market is estimated to reach \$330m by 2020 (Markets and Markets 2014)

In-Vitro Testing

- Strong movement towards experimental methods of replacing in-vivo experiments due to humane concerns and legislation requiring the use of in-vitro testing whenever possible
- New methods may also be cheaper as it eliminates the need to house, feed and care for animals by trained technicians and veterinarians
- Live cell imaging is an essential means of observing and analyzing cellular activity during in-vitro experiments

Human IVF

- Global IVF market (comprising IVF technology and related instruments, reagents and media) for 2013 was estimated to be \$9.3 billion and projected to grow to \$21 billion by 2020E (Research & Markets 2014)
- Live cell imaging ideally suited to monitoring embryo development in both research and clinical settings using a combination of controlled, optimized environment ensuring cell viability, dynamic Z-stack and dedicated embryo tracker applications

Figure 2 Live-cell imaging – an important area for a wide variety of research areas

PharmaVentures Ranks Above Its Competitors

A recent survey amongst senior executives in the pharmaceutical and biotech industry around the world reveals that 58.1% rated PharmaVentures either ‘excellent’ or ‘above average’ in terms of transactions support placing it in top position against the competition. The next closest competitors achieved scores of 30.5% and 29.8%, respectively.

The survey also revealed that PharmaVentures was more likely to be recommended by respondents than any of the other 66 competitor firms named by the respondents themselves.

Two factors, which are the key strengths of PharmaVentures, were revealed by the survey to be the most critical when choosing an advisory firm, namely, track record, and technological expertise.

The value of communications during M&A



Nicole Yost | Head of Healthcare, Porter Novelli UK

With M&A activity in the biopharmaceutical sector showing no signs of slowing down, there has been some criticism of these deals in recent years. These acts of consolidation don't always reap the fruits they set out to bear and, if not managed well, may even result in a stifling of innovation, reduction in R&D productivity and decreased value of the companies.

In a recent study as part of an MBA project*, an anonymous survey and telephone interviews were conducted among a sample of biotech and pharmaceutical company employees and people close to M&A deals, to find out their experiences of M&A and to assess the value of staff communications during the M&A process. In this edition of *Termsheet*, these survey findings are summarised.

M&A activity in our industry is seen as a means of exit as well as, on the buyer side, growth and competitive advantage through access to new markets or geographies; growth in R&D pipelines; access to scientific expertise in a new therapy or technology area; access to sales and marketing expertise; complementary skills and company synergies. M&As have swept the industry and led to some high profile deals as seen with the likes of Pfizer, Teva, AstraZeneca, GlaxoSmithKline, Sanofi and Roche to name a few.

* the study was reported in 2012 as part of an MBA dissertation for Warwick Business School

What does M&A feel like for the employees of either firm? It has been shown that communicating with staff during M&A can reduce uncertainty, quell rumours and mitigate dysfunctional outcomes and can support employees through periods of change. Post-acquisition management is often key to success. Too often top management concentrates on getting the deal done and do not put enough effort into planning the post-acquisition phase.

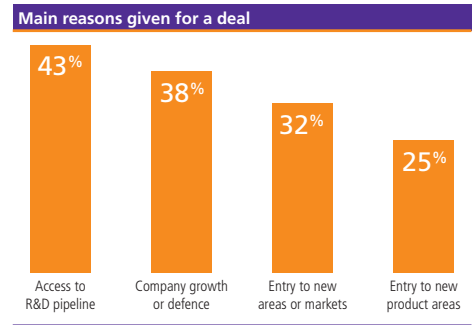
In the MBA study involving 70 participants, 92% said their company had previous experience of M&A within the organisation. This would imply that lessons had been learned through the experience and could suggest that the M&A process would run more smoothly as a result of past experiences. On the downside, this experience could also mean that most employees within the organisation had been through one or more M&As in the past and may not be happy about another one.

Many of the respondents had undergone their most recent deal within the past 12

months (25%) or within the past 12-18 months (46%) and most respondents said their organisation was planning for M&A activity in the next year (56.5%).

When responding about the most recent deal, 42.5% of respondents' organisations had acquired another company. The main reasons given for the deal were: access to R&D or pipeline (43%), company growth or defence (38%), entry to new areas or markets (32%), entry to new product areas (25%).

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Australia biopharma: A nation on the rise?



Dr Anna Lavelle | CEO, AusBiotech

As the mining boom fades, is Australia's burgeoning biotechnology industry poised to play a greater role in the nation's and the world's economy?



Australia already has a great track record in terms of its contribution to world-class biotechnology industry, and is currently ranked fourth in the world (*Scientific American: World View*).

This success was exemplified most recently when Australian-biotechnology company Spinifex Pharmaceuticals and Novartis announced the biggest deal on record in Australian biotech and, according to the *Australian Financial Review*, the "most successful exit in the history of Australia's burgeoning venture capital industry..." The company's acquisition for US\$200 million in upfront cash includes further potential significant payments related to development and regulatory

milestones of up to US \$500 million – taking the deal's value up to US\$700 million.

Spinifex is a wonderful home grown success story. It was established in 2005 at the University of Queensland based on research of Professor Maree Smith and Dr Bruce Wyse, who identified AT2 receptor antagonists as inhibitors of neuropathic pain in preclinical models. Financial backing came from a range of sources including university venture funds UniQuest and Uniseed, as well as from GBS Venture Partners and Brandon Capital and government programs such as Australia's renowned R&D Tax Incentive.

Australia's competitive edge in biopharmaceuticals is derived from its world-class science and medical research,

its capacity for international partnerships, its robust intellectual property (IP) system, its strong clinical trial capabilities and its effective and transparent regulatory system. The world's top 10 pharmaceutical companies alone invest about AUD \$200 million per year in clinical trials in Australia, and the Clinical Trials Notification (CTN) scheme – a unique initiative that facilitates faster approval processes – has been a global benchmark for reducing the regulatory burden on clinical trial sponsors. Regulatory reform underway in Australia is showing enormous promise for accelerated approvals of medicines.

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The value of communications during M&A

It's good to talk

Talking to staff is not the priority when doing a deal. As one interviewee said: "The main focus is the deal itself and the financial benefits, synergies and scale. Companies don't always think about the broader implications beyond this, so insufficient attention is paid to the communications imperatives of creating a new entity.

"Communicating with external stakeholders - especially shareholders - is prioritised in M&A. I have heard cases where employees first knew of a merger of their company by reading it in the business press".

All of the interviewees agreed that internal communication is vital in order to reduce the high levels of uncertainty and rumours that tend to develop among employees during M&A. They also agreed that communication with employees can support the M&A integration, improve staff productivity and help to achieve better M&A outcomes.

"Without employee communications, the 'water cooler conversations' take over. Employees become disengaged, motivation falls and no work is done, driving business performance through the floor," said one senior Manager.

"If you don't communicate, it is mayhem," said a former communications head of a large pharmaceutical company. "All other things being equal, without a planned internal communications programme, the desired M&A outcomes will be much more difficult to achieve."

All of the interviewees agreed that realistic communications were important during M&A so, even if the news is bad news (for

example site closures, job cuts), this should be communicated and a timeline of events made clear, and all internal communications should match what is being said externally.

"Concerns about job cuts, cost saving initiatives and so on will follow the M&A announcement," acknowledged one interviewee. "It is impossible to say 'don't worry, all jobs are safe', so you have to find ways to communicate what you do know and what will happen next, and give timelines on how long things will take."

Company culture

When the deal is done in order to access new markets or areas it could be that the parent company is acquiring an organisation in a different geography, with a different culture and different ways of working. This can make the integration process difficult. There is evidence that employee communications can support this process and in some cases a 'third culture' of the new organisation may be created.

The majority of respondents to the survey (88%) agreed that it was important to create a company with common values and behaviours for a M&A to succeed. And 80% said that the values and culture of their organisation were communicated and discussed after the M&A.

In describing the cultures of the two organisations in the M&A, 59% of respondents said the cultures were different or totally different, with 41% saying the two companies had similar or somewhat similar cultures. However, when questioned about the extent of cultural integration in their part of the business, 24% believed no cultural change was needed; 48% said there had been little cultural change and the minority of respondents, 28% said there

had been significant cultural change within their part of the business.

As one interviewee said: "Companies are bad at understanding their own culture, let alone the culture of others. Many organisations are bad at seeing and understanding the differences".

"Some pharma mergers have seen lots of clashes at different levels, especially where the companies coming together have very different cultures".

Vision and rationale

Communicating the reasons for the deal and the vision for the future can help to gain staff buy-in and support during the M&A process, despite the accompanying uncertainties of change. It can help employees to establish an identity with and a commitment to the new organisation.

With more and more deals being done and reported every day in our industry, the importance of good communications and employee buy-in becomes increasingly clear.

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Australia biopharma A nation on the rise?

AusBiotech has led the biotechnology industry's call for further tax reforms in Australia that provide more incentives for the launch and growth of innovative businesses and high-tech manufacturing companies. The improvements are intended to build on the success of the R&D Tax Incentive, which was very well received by the industry and make Australia event more globally competitive.

The annual AusBiotech *Biotechnology Industry Position Survey* demonstrates that its intact preservation remains the number one public policy issue within the local industry year after year. Companies report

undertaking R&D that they would otherwise be unable to fund, with many stating that the Incentive enables the fast-tracking of their R&D programmes, often cutting the time to initiate clinical trials by several years. It quite rightly is attracting biopharma companies from around the globe to conduct R&D in Australia.

AusBiotech is Australia's biotechnology industry organisation. It has been working on behalf of its members for almost 30 years to provide representation and services that promote the global growth of Australian biotechnology. It has a very well-connected network of over 3,000 members in the fields of therapeutics, medical technology (devices and diagnostics), food technology and the agricultural, environmental and industrial sectors.

deal update

MDxHealth Acquires NovioGendix to Expand Uro-Oncology Product Offering

In mid-September PharmaVentures was pleased to announce that it provided transaction support to NovioGendix in its sale to MDxHealth SA (Euronext: MDXH.BR).

NovioGendix is a privately-held molecular diagnostics company focused on the development of a non-invasive liquid biopsy test for prostate cancer. This mRNA biomarker test can also help identify men at increased risk of high-grade disease who may benefit most from a prostate biopsy procedure.

Nigel Borshell, Vice President, PharmaVentures Ltd, said: "We are delighted to support NovioGendix and its shareholders in achieving an exit".

Fintan Walton, Chief Executive, PharmaVentures Ltd said: "This is another important result for one of our clients. PharmaVentures has established itself as a leading advisor in M&A and Licensing".

