termsheet

PharmaVentures
Experts in deals and alliances

May 2015 Issue 14

Heads of Terms

Exiting: Trade sale vs IPO

All investors, and most entrepreneurs, look at when they can exit from their investments and businesses, and importantly, try and estimate what their return could be. Building the business to the point where it can exit, either through a trade sale or an IPO, requires huge amounts of skill, and, let's be honest, luck. The two exits are quite different. A trade sale can provide a quicker cash return to investors, although contingent elements can delay part of the return, whilst an IPO will only allow investors out after a restricted period, usually of about a year, when the share price may be either higher or lower. Also, controlling the amount of shares sold is important if investors want to avoid a crash on the share price.

So which exit is the most suitable?

Well, of course, it's to do with markets. With a trade sale, the question is whether there is a market out there for a buyer. What value can the target company provide to a buyer? If there is a strategic fit, can an argument for price be justified? With an IPO the appetite for flotation is determined by stock market timing. However, volatility in share price after the IPO can result in the company being dumped on the wrong side of a decent valuation. To avoid this, brokers like to keep the valuation relatively low on flotation in order to push the odds up on the price rising post IPO. Furthermore, it is vital that the company has the right management team in place to handle the ups and downs of a publicly traded company over the longer term.

My own view is that only certain companies can benefit from a public listing, provided they have a longer sustainable plan for their future. Being publicly quoted is beneficial as it enables the company to easily raise more capital in order to expand and grow, as well as to acquire other companies through cash, debt and stock.

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featured client

MOORLODGE BIOTECH

Disruptive Technologies in Nucleic Acid Purification and STI Diagnostics

MoorLodge Biotech Ventures (Moorlodge) is a privately funded company based in the UK. The company develops disruptive, patent protected, "near patient" technologies for life-science research and clinical use. The first products to emerge have been specifically designed to facilitate rapid, accurate and cost-effective diagnosis of a number of diseases and conditions. The company was established by Dr Stephen Minter, a recognised pioneer in the fields of DNA chemistry, food processing and supplements, microfluidics, surface chemistry and antibody diagnostics development.

Moorlodge holds over 30 diverse patents including intellectual property covering Purispin, a revolutionary Nucleic Acid purification technology.

Biotechnology researchers have ever growing needs to isolate DNA and RNA from a range of biological fluids and tissues. The personalised medicine revolution is being driven in part by a greater understanding of the genetics involved in health and disease. Key to this is the ability to isolate and purify the highest quality nucleic acid samples that can be used with other analytical techniques. The need is addressed currently by devices and technologies from major suppliers such as Qiagen, Thermo Fisher, Promega and Roche. There is room for significant improvement in time, ease of use, purity and quality of product and yields. To meet this need, Moorlodge have developed Purispin which provides the researcher with the highest purity and yield for any type of nucleic acid from a device that is simple and fast to use.

Use of Purispin in the field of diagnostics can permit many tests now to be performed in a near patient setting where speed of diagnosis is important. One such situation is with sexually transmitted infections such as Gonorrhoea and Chlamydia. Moorlodge has provided access to Purispin and further intellectual property to healthcare diagnostics Limited (HDL) to develop

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STOP PRESS STOP PRESS STOP PRESS

200 jobs saved as Merck & Co. divests its Puerto Rico manufacturing plant

PharmaVentures is delighted to announce that Merck & Co has sold its manufacturing plant in Arecibo to American Industrial Acquisition Corporation (AIAC), which will add it to the 5 dozen other plants it has around the world making industrial products. According to the Puerto Rico Industrial Development Co. (PRIDCO), AIAC will retain up to 200 Merck employees.

Immuno-Oncology – Revolution or Evolution?

Adrian Dawkes
VP PharmaVentures

The 2011 approval of BMS' immune checkpoint inhibitor antibody, Yervoy, signaled the dawn of Immuno-Oncology. The story, is however, much older.

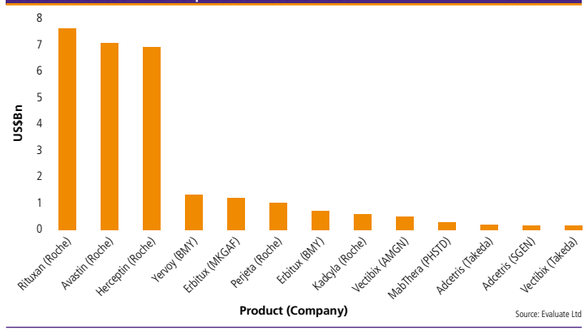
In the beginning

In the 1890s, surgeon and cancer researcher William Bradley Coley observed that cancer patients who experienced post-surgical infections had better outcomes than those who did not due to stimulation of the immune system. Coley was able to improve patient outcomes by deliberate infection and thus an immune approach to cancer treatment was born.

The path to checkpoint inhibitors

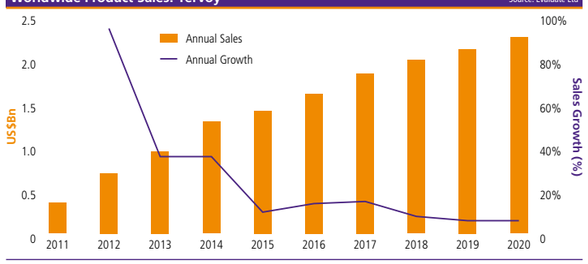
Immunotherapy has moved a long way since then, with much greater understanding of the immune system. Jim Allison was working on CTLA-4 and the immune checkpoint theory in the 1970's which ultimately led to series of deals culminating in January 2005 with Bristol Myers Squibb becoming the ultimate commercialiser of Yervoy.

Worldwide Sales of Anti-Neoplastic Antibodies in 2014 Source: Evaluate Ltd



Source: Evaluate Ltd

Worldwide Product Sales: Yervoy Source: Evaluate Ltd



Scientific success drives deals

Since then there have been a raft of deals with GSK, Pfizer, J&J and AZ all signing up to Jim Allison's Moon Shots and in the last three years there have been 20 licensing deals involving checkpoint inhibitor, with a disclosed aggregate value of $4.9 billion.

Where do we go from here?

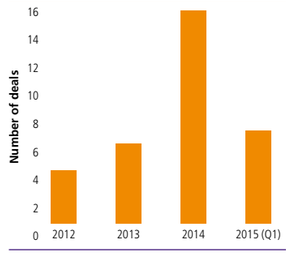
It looks as though this is only the beginning as the current batch of checkpoint inhibitors, whilst showing benefits in approximately 50% of cases, only deliver complete recovery in 20-30% of patients. Current thinking is that there are many more checkpoint inhibitors to be fully understood and exploited.

From a commercial perspective the antibody generation has been an unqualified success

Other immunotherapeutic approaches are also now in the clinic and showing excellent promise. One utilises chimeric antigen receptors (CARs) that allow T cells to recognise a specific tumour cell antigen. CAR-T, takes a patients' own T cells and engineers them to produce CARs on their surface. These are expanded in the laboratory and then infused back into the patient where they attack the cancer. This is a truly personalised treatment for each patient.

A second related approach uses T cell engagers. Immunocore has developed ImmTacs (Immune mobilising monoclonal TCRs against cancer). ImmTacs bridge the cancer cell with the T cell and allow killing of the cancer cell.

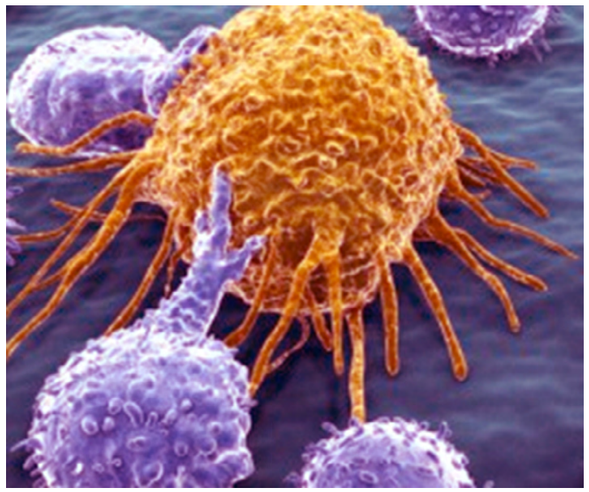
Checkpoint Inhibitor Deals



Cancer vaccines have been less successful with the best agents being prophylactic (Gardasil, $2.0bn sales 2014) rather than therapeutic. Although there are prominent sceptics about the potential of cancer vaccines, deal making has been rampant in recent years (74 deals, worth up to an estimated $3.8 billion).

We are entering a new age of cancer therapeutics where the focus is moving to harnessing the body's immune system and using biotechnology to remove the blocks cancer cells can throw up to facilitate their killing. We could be witnessing the first treatments that "cure" a range of cancers and as such, we can expect this to be a hot area for deal making for some time.

For more information you can download the full white paper: http://www.pharmaventures.com/content/immuno-oncology-revolution-or-evolution



A New Approach to Early-Stage Valuation – Finally Cracking the Nut

Nigel Borshell
VP PharmaVentures

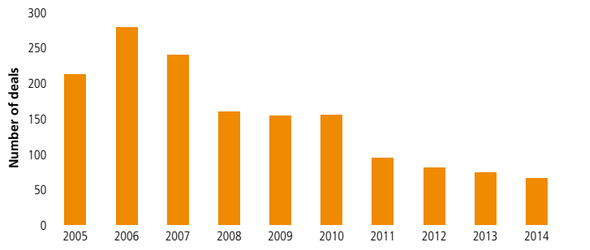
Every year the data on pipeline attrition rates for clinical stage development of drugs grows in both quantity and granularity. Today those of us engaged in valuation activity can employ increasingly significant data on therapy area, specific indication, molecule type, molecule precedence status, source of IP, license status, size of clinical developer, and more, to refine our appropriate risk factors when calculating expected net present values.

This luxury of clinical data, thanks to publically available information on clinical trials, is in sharp contrast to the more covert internal development stages that precede them.

The current collapse in earlier stage deal activity indicates a loss of appetite from big-pharma for those risky early stage collaborations.

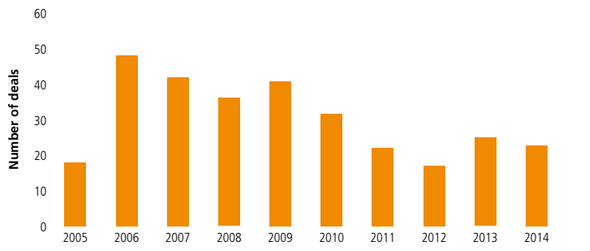
A quick review of discovery, lead molecule, and pre-clinical status licensing, co-development, and collaboration deals between biotechs and pharma companies shows a dramatic fall in the number of deals over the past ten years, according to data from RecapIQ.

Early-stage Deals



Many pundits speculate that this decline is offset by an increase in less risky 'option' activity where cost and decision-making is deferred to a less risky future event. Does the data support this premise? Apparently not, as shown below the RecapIQ data for the same early stages but this time just searching for option deals shows a noisy but somewhat reducing level of activity.

Option Deals



This depressed deal making climate highlights the importance to those early stage biotechs of ensuring a financial strength and funding plan that is not totally reliant on licensing fees to ensure continued development. Attracting money through further investment rounds (the probability of a successful IPO at this stage is extremely remote) is the probable way forward, however although such investors might appear less risk averse than some pharmas, in reality their horizon is often closer so the cash out reward calculation needs a strong justification of value today and growth potential in the investment.

So how do we determine values in such early stage biotechs? Here at PharmaVentures we have a proud history of helping clients in all sorts of deal making, including product or portfolio valuations in support of fund raising activity.

Traditionally we have used the two complementary methodologies of risk adjusted and discounted free cash flow financial modelling (DCF), with a benchmarking approach using real world comparable transactions, to determine clinical stage and marketed asset values. To this day these are the gold standard approaches within the industry, in many cases used by those we have taught in the past, and we continue to teach to new practitioners through our regular training workshops on Calculating and Negotiating Licensing Deal Terms.

Over the years we have developed a number of tools to facilitate the DCF approaches to valuation, along with models to help us understand those comparable deal benchmarks and understand deal term structures. All very straightforward when working with clinical stage projects because the market opportunities are more clearly determined from target product profiles allowing better DCF modelling with those well documented attrition rates I talked about earlier, and the comparable benchmarks are there in volume and reflect current activity, rather than the declining and small datasets shown in the earlier charts.

So what can be done with this early-stage challenge? Help is at hand with an approach we have developed at PharmaVentures based on a hybrid of the two complementary methodologies. Using cost, timescale, and attrition data gleaned from that 'covert' early stage from our many client projects, in conjunction with future early clinical milestone event comparables, we have been able to derive present values for these early stage projects or complete portfolios. Insight into the characteristics and drug design history of the subject is critical in determining appropriate parameters in our models. Comparison with publically available data on similar scale nano-cap companies can act as a reality check on the results. A hypothetical example of the approach is set out below.

	Today	Risks/Cost/Time	Deal Horizon	Benchmarks
eNPV	$25M	◀◀◀	$150M	◀◀◀◀◀
	▼			
Enterprise Value	$10M			
	▲▲▲			
Reality Check	$5M-$15M			

We believe this approach complements the early stage comparables approach. Sometimes these early stage so called 'comparable' deals are often unrepresentative of the potential for the majority of similar stage projects, and might represent true paradigm shifting technology when what we seek is good progressive advances in current scientific thinking.

If you want to know more about our Valuation services and their application to your specific needs we would love to hear from you here at PharmaVentures.

bioConclave

PharmaVentures was invited to attend **bioConclave 2015** which took place on 20 April 2015. The first ever conference to develop commercial partnerships between the UK and Indian health and life sciences sectors.

bioConclave 2015 is a platform that aims to promote the huge potential of the Indian biotechnology market, bringing together the NHS, UK health businesses and investors with nearly two-dozen of the fastest-growing Indian health and life science companies.

The Indian biotech market was worth US$4.3bn (£2.9bn) in 2013 and is forecast to grow to US$100bn (£68bn) by 2025. India's pharmaceutical industry is the third largest in the world by volume and the tenth largest by value, with production costs half that of the UK and Europe.

To date, UK companies have nowhere near maximised the potential of India. According to qualified leads from Healthcare UK, there are only £3m worth of health sector UK sales to India in the coming years – less than 0.03 per cent of the total leads– compared to £133m for Brazil, £123m for China and even £5.3bn for smaller countries such as Libya.

The conference at Imperial College heard from Professor Sir Malcolm Grant - chairman of NHS England, Patricia Hewitt – chair of the UK-India Business Council and former Health Secretary, and Indian Deputy High Commissioner Dr Virander Paul, himself with vast experience of healthcare, about the possibilities for collaboration and its challenges. Several young, innovative Indian companies gave presentations on their products They met more than 150 UK companies at the conference and subsequent trade mission to Leeds and Manchester.

Professor Sir Malcolm Grant, chairman of NHS England said that even reducing the NHS funding shortfall to £8bn required "an extraordinary efficiency and productivity transformation of the NHS".

Pratik Dattani, organiser of bioConclave, said:

"The market potential between the UK and India in life sciences and healthcare is huge and is currently a missed opportunity. bioConclave aims to maximise the opportunities for growth that will come from the smaller, innovative companies that currently find it difficult to find platforms to help them expand. In short, we want to say the Indian market is open for business."

The UK is by far the most popular business destination in Europe for Indian biotech companies – out of approximately 1,200 Indian firms in Europe, 700 operate out of the UK.

Patricia Hewitt, chair of the UK-India Business Council and former Health Secretary, said:

"Whilst as UK Health Secretary, I saw how much the NHS benefits from Indian doctors and other talent, helped by the strong connections in healthcare education, training and career opportunities."

"Now the flip side of that coin is the opportunity for innovative British companies and NHS trusts in the growing Indian healthcare market. British businesses should start their footprint in India – a country that will soon be setting the global pace for innovation in the life sciences and healthcare sector."

This is an interesting event and a great opportunity to meet with some of India's innovators and also UK companies looking to do business in India.

For more information on opportunities in Emerging Markets you can download the PharmaVentures White Paper: http://www.pharmaventures.com/content/opportunities-emerging-markets

BioNetwork PARTNERING SUMMIT

BioNetwork East

Miami Advice!

WBR staged the US East Coast equivalent of their successful BioNetwork Partnering Summit conference at the Trump International Beach Resort. Whilst the weather didn't live up to expectations, the conference certainly did. This focused on a gathering of senior dealmakers and executives from big pharma, biotechs and smaller companies and provided two days of insightful presentations, interactive panel discussions and one-on-one partnering opportunities. From case studies (the Pfizer/Merck KgAa immune-oncology alliance) to panels on deal structures, to academic interactions and doing business in emerging markets, there were opportunities for everyone to gain key learnings from those directly involved in these areas.

Look out for more early stage deals involving big pharma and increasing use of option structures.

If you are dealing in emerging markets, partnerships are critical, Argentina and Mexico are challenging and senior level staff turnover in China is the norm for the big Chinese pharma companies. One emerging company to watch is Mirna Therapeutics, who look to be ahead of the curve in harnessing microRNA for therapeutic use in Oncology.

The organisers struck a good balance between formal conference structure and a relaxed atmosphere, with time to engage with old and new contacts for meaningful discussions. This and the West Coast counterpart should definitely be on peoples' schedule.

10th Annual World StemCells Regenerative Medicine Congress 2015

PharmaVentures partnered with this year's **10th Annual World Stem Cells and Regenerative Medicine Congress**, 20-22 May in London, as the focus was on scaling-up, commercialisation and collaboration for market access. Honing in on the five key areas:

- **Finance and Investment**: Access investment advice and partnership opportunities through the Investor Forum
- **Scalable Manufacturing**: Identify best practices in technology and latest updates from biotechs, through interactive roundtables
- **Translational Medicine**: Discover how best to gain market access for cell therapies
- **Tissue Engineering**: Hear pioneering innovations in tissue engineering as well as organ regeneration and 3D bioprinting
- **Commercialisation**: Understand how industry leaders view the clinical and commercial futures of stem cells and regenerative medicine and the effect it will have on your business

With a large volume of deals generated over the years at this event, make sure you put this on your calendar for next year.

Graham Combe
Associate Editor/BD

Graham works within the Corporate Advisory team for PharmaVentures and is an Associate Editor for it's subsidiary PharmaTelevision. Graham has over 18 years' experience in marketing, media and event sales within pharmaceuticals, biotechnology and academia. Prior to joining PharmaVentures, he ran his own company Biosell Ltd., which specialised in providing sales and marketing solutions to media and event companies predominately within the Pharmaceutical and Biotechnology Partnering marketplace. Graham also worked in business development for eight years at the world leading scientific media organisation Nature Publishing Group (NPG), the publisher of Nature magazine and Scientific American. Graham has a degree in Chemistry from University College London (UCL).

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Gareth Blades
Business Analyst

Gareth has recently joined PharmaVentures as a Business Analyst. He holds a first class undergraduate degree in Neuroscience, graduating second in his year, from Cardiff University. After winning an EPSRC award to study at Cambridge University, Gareth completed an MPhil in Nanotechnology and Enterprise and learned more about the business of science through the University spin out environment. Subsequently, Gareth was awarded a scholarship from Jesus College Oxford and he completed a DPhil in Systems Biology – Biochemistry. With a desire to gain more commercial experience Gareth worked for a strategy consultancy in Oxford, enabling him to build his understanding of strategic business issues and gain experience in the Energy, Manufacturing, Charity, Not-for-Profit and Telecommunications sectors.

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PharmaTelevision

Enlightening industry insight direct from the industry leaders

The value of video marketing has long been recognised. Back in 1941 Bulova ran the first commercial on a New York TV station during a Yankee game. The power of video has continued to grow and in 2006, PharmaVentures CEO, Fintan Walton, anticipated this trend and launched PharmaTelevision, the world's first online, on demand Pharmaceutical Television Channel. He realised there was a real need for people to find out more about the key influencers in our industry. Since the inception Fintan has carried out in excess of 600 interviews with life science industry leaders, including most recently, members of the board of Boehringer Ingelheim when PharmaTelevision was invited to attend the annual conference.

Video is one of the most flexible communication tools we have, it can be used almost anywhere. People love stories and video is the easiest way to give your company a narrative that draws empathy from potential partners and investors. It is also a great way for you to learn more about your potential partners, clients and competitors.

Throughout the next few months we will be carrying out a series of interviews, both at our studio and on location at conferences so if you would like to tell your story to our audience now is the time to leverage the vast industry and video know how of PharmaTelevision. A PharmaTelevision interview is your opportunity to get your company's strategic focus noticed by investors and potential strategic partners.

If you would like to arrange an interview please contact:

Associate Editor, Graham Combe, graham@pharmaventures.com

or

Producer, Fiona Gardner, fiona@pharmatelevision.com

and they will be happy to help.

Planning to Divest R&D and Manufacturing Facilities?

Nigel Borshell
VP PharmaVentures

Jansen Jacob
Director PharmaVentures

Leading CMOs are developing acquisition strategies based on reinforcing their customer base, expanding their geographic reach and broadening their capabilities. Similarly, customers are increasingly demanding simpler sourcing models that can deliver speed and reliability.

Geographic trends tell an interesting story as leading CDMOs in Europe and the USA establish operations in territories outside their traditional core markets. Conversely, emerging market CDMOs such as Piramal Pharma Solutions are actively expanding to North America and Europe. Geographic convergence and competition is likely to intensify with M&A a favoured tool for executing this strategy. Recipharm, a European CDMO typifies this growing trend and is looking to expand its presence in the USA.

This tempo of M&A activity is clearly illustrated by Catalent, which in the last three years inked 10 deals worth over $600m covering various geographies and capabilities. Others are following Catalent's example. We are aware of a number of other consolidators who are expressing increased interest in acquiring Latin American and Eastern European assets. Key reasons for expansion include the acquisition of complementary technology, close proximity to clients and faster regulatory approval in regional markets.

Major CDMO Presence

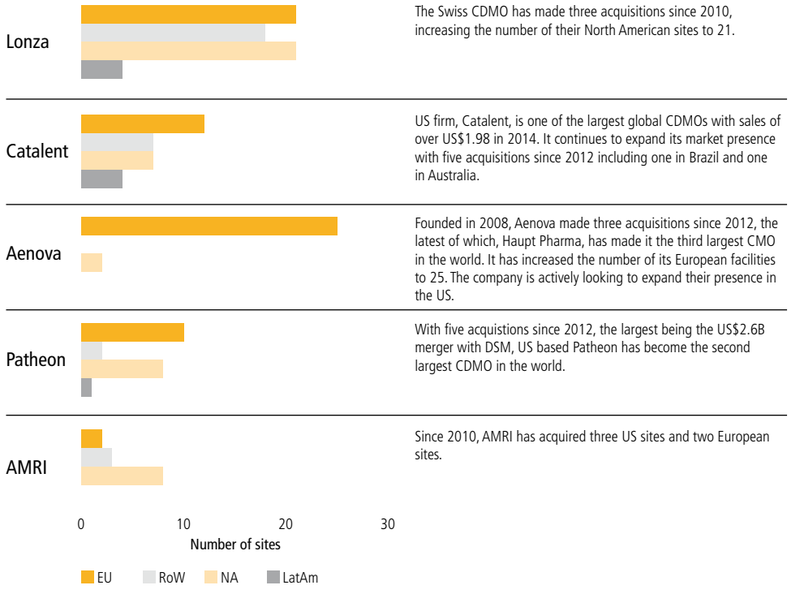

Figure 1

Pharmaceutical M&A Activity

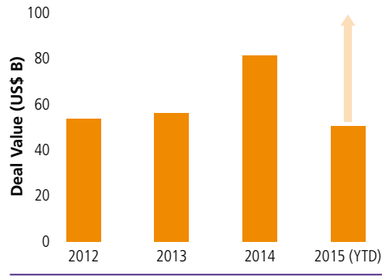

Figure 2

Success in M&A is significantly increased with a well planned and executed strategy. A critical component of this is a detailed review of all assets key to integration. R&D and manufacturing capabilities will naturally form part of this review.

M&A is a difficult process and several decades of research into its outcomes has clearly shown that the rate of failure is at least 50%, with over 80% of firms unable to fully realise the goals of the merger. Inadequate planning and difficulties in the implementation of the integration strategy are recognised as key reasons for failure.

M&A values have been on an upward trend since 2012. With activity in Q1 2015 having already reached 63% of total deal value in 2014, it looks like we are in for a bumper year (*Figure 2*).

Divestment is often the most favoured strategy for surplus manufacturing or R&D assets. Our experience has taught us that delays in the divestment process can significantly erode value and diminish attractiveness to buyers. Speed and control of the selling process is in a seller's best interest as site operating costs usually make up a significant part of business operations. Every month of delay could add unnecessary thousands, if not millions to operating costs prior to a sale.

When deciding to divest a facility, a key consideration for owners is whether they have sufficient internal resources to run a successful divestment process. Early and thorough planning sets companies up for the best outcome.

PharmaVentures' Buyers by Geography and Sector

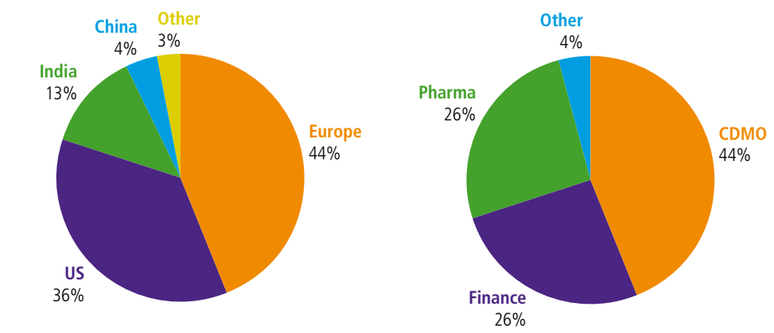

Figure 3

The Authors

Nigel Borshell

Nigel joined PharmaVentures in 2008. He has extensive experience in site divestments for major pharmaceutical corporation in the USA and Europe. He has specialist expertise in valuation, deal structuring modelling and pricing methodologies with a strong background in senior international commercial management roles in both diagnostics and biotechnology firms, Nigel gained his experience at Syva Company, Hoechst, Dade Behring, and as Business Development Director for molecular biology company Cepheid. Nigel is also the author of numerous Pharmaceutical/Biotech Industry reports, papers and articles.

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Jansen Jacob

Jansen is a healthcare transactions professional with expertise in M&A, licensing, commercial due-diligence and deal structuring. He has taken key roles in many M&A mandates, including: Merck's divestment of its US biologics facility as well as its UK R&D site, Sanofi's divestment of its Slovak manufacturing site as well as two of its European R&D sites, UCB sale of three of its manufacturing sites.

Jansen holds a chemistry degree from Gandhiji University, a PhD in Biochemistry from the University of Sussex and an MBA from Oxford Brookes University.

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Calculating and Negotiating Financial Terms Workshop

Following the success of our popular Calculating and Negotiating Financial Terms Workshops in 2014 we are delighted to be running another one in Oxford in September 2015.

There will be a drinks reception and dinner included on night one which is a fantastic networking opportunity.

Facilitated by Nigel Borshell, the course focuses on valuation techniques and negotiating skills. It is highly interactive with role-play sessions and small seminars which allow delegates to really enter into the spirit of negotiations. During the courses in March and June, it was great to see how the participants from big pharma and from biotech became immersed in the role-play and the feedback was superb.

Philippe Leca at Provepharm SAS:

These two days spent with the PharmaVentures' team were highly valuable for the following:

- The methodology was clear and exhaustive, introduced by highly skilled professionals
- The comprehensive knowledge of the process by the team was critical to make sure that the attendees now have control on all the inputs to run a win-win transaction
- Knowing that this methodology is accepted and shared by the major players in the industry gives undeniable credit to this workshop. I'd also add that this value was given in very pleasant and welcoming atmosphere
- I definitely recommend that people who are in the loop with pharma or biotech strategic alliances attend this seminar

If you would like to join us, please contact Fiona Gardner and she will be happy to help.
fiona@pharmaventures.com

SACHS ASSOCIATES

Sachs Workshop Spring 2015
Zurich

Licensing Agreements

Was what was written what was really meant?

The annual Sachs CEO Conference in Zurich provided a vehicle yet again, on the closing afternoon of day two, for a thought provoking workshop from PharmaVentures. This time attendees were taken through a series of challenging scenarios caused by poorly worded or badly drafted clauses in licensing agreements. The complexity of legalese or sometimes the failure to clarify intent in detail, can come back to haunt licensees, particularly at points in time when success and high value returns should be a cause for celebration rather than litigation. Fintan Walton and Nigel Borshell guided attendees through the process and gave everyone good reason to revisit the agreements that could be underpinning or undermining their business model.

PharmaVentures workshops have become a regular and rewarding occurrence for Sachs' attendees. We cover serious subjects in an interesting and informal way to aid learning and awareness of key issues facing bio/pharmaceutical executives on the road to success. Many attendees come back each time, a strong endorsement we are doing something right, after all, an hour or two of 'C' suite executives is a significant investment of time and money.

"It was great learning and I really enjoyed the session."

Markus Goebel
Managing Director NVF

Heads of Terms

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However, all of this requires a long term plan spanning many years. Moreover, you need to be listed on the most appropriate stock market to succeed. In this respect, European stock exchanges are not that favourable towards biotech and life science companies, whilst the NASDAQ is the most appropriate.

The best exit, in my view, is a trade sale. Investors, also like them, as a trade sale leads to a better price because they tend to be strategic in nature, and the exit for shareholders and management can be a lot faster. The current climate is perfect for selling.

Dr Fintan Walton
Chief Executive, PharmaVentures Ltd.

featured client

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MOORLODGE BIOTECH

molecular diagnostic technologies (tests and instrumentation) for a true "test and treat" scenario where patients can be diagnosed and treated in a single short visit to the clinic. Furthermore, use of Purispin uniquely allows isolation of cryptic plasmids. These plasmids are the key to understanding antibiotic resistance and ensuring each patient is treated with the most appropriate antibiotic. This will reduce the use of inappropriate antibiotics, minimise the generation of further antibiotic resistance and ensure a rapid successful outcome for the patient.

PharmaVentures is assisting Moorlodge in finding partners for the Purispin technology and HDL in finding licensees or acquirers for the STI applications.

Moorlodge is headquartered in Ascot, Berkshire, UK with laboratories in Hadfield, Derbyshire, UK.

For further information:
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