



Health & Life Sciences

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Biotech's back to the credit wall: Coming out fighting



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Biotech's back to the credit wall: Coming out fighting

Much has been written about how the credit crisis will impact business; biotech and certain specialty pharma companies will be no exception. But while many industry observers have over-simplified the issue to "deep-pocketed pharma will acquire struggling developers", continued access to finance will be available to those biotechs with an advantaged view of where value lies.

The state of biotech financing

A quarter of US biotechs have 1 year or less of cash on hand – half have 2 years or less. The pressure to secure financing is constant.

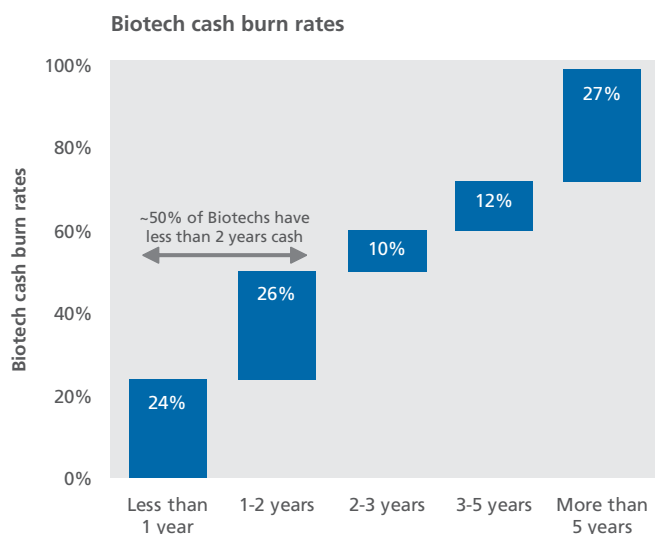
But it isn't financing pressure that has changed – what has changed is financing availability, as funding from venture, PIPEs, and other financing mechanisms have declined to their lowest levels since 2002, and are likely to get worse.

What of the "rich" licensing deals signed in recent years? Big pharma licensing remains a strong source of financing. With strong balance sheets,

the top 20 biggest pharma companies had net debt levels of only 6% of sales. Even with this cash on hand, some companies, like GSK and Wyeth, have noted that they are halting share buy-backs to "take advantage of market conditions". Biotech Exelixis had indicated it gave up on selling equity to raise cash. Instead, an agreement with BMS valued at \$240 million not only raised cash, it increased Exelixis' down-trodden shares by 33%

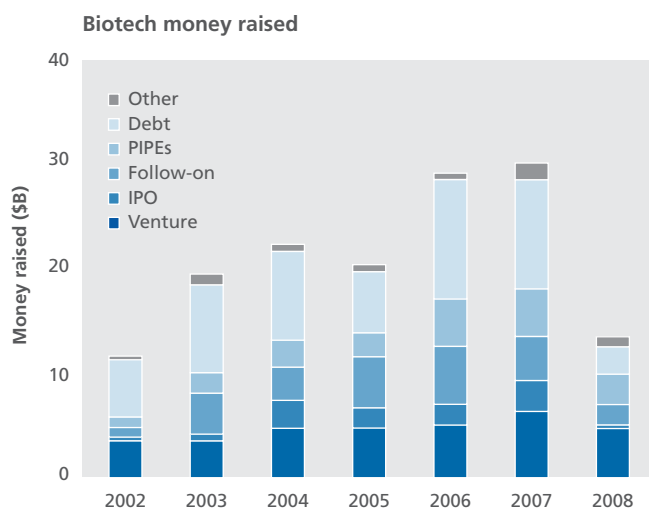
As Oliver Wyman's *Licensing to Win*¹ study showed, total announced deal values have increased at a 50% compounded rate over the past five years, with

Exhibit 1: 50% of biotech companies have less than 2 years cash on hand



Source: Ernst & Young Biotechnology Survival Index: Americas

Exhibit 2: The funding available to biotech companies has reduced dramatically in 2008



Source: BioCentury, 2009

an "average" biotech drug now being licensed at roughly **six times** what it was in 2003. But while this is true for the total value of licensing deals, the upfront portion of deals has remained a small portion of the total value, and has increased much more modestly, with less than 10% of the total increase in value being in upfront monies. Current licensing deals may be worth more, but still leave financing issues between milestones.

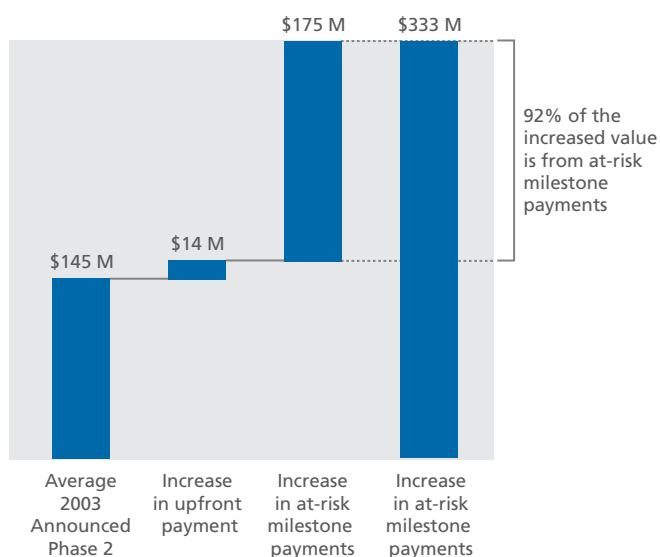
Biotechs have been optioning their compounds earlier – 1/3 of deals in the past few years have been pre-clinical, and more than ½ have been early-phase (pre-clinical or phase 1). For these companies, having their compounds reach competitively-attractive end-points, or demonstrate especially strong market potential, is the only way to ensure that licensing options are exercised, or of having the necessary arguments with which to secure other funding.

But, as the cost of clinical trials increases, how can a cash-tight biotech ensure that it is testing valuable endpoints and outcomes, and not spending itself into a tighter position?

Companies depending on licensing agreements for financing have substantial value potential in their typical big-pharma partners, but only with compelling investment cases, and only subject to managing the risk of funding and reaching those later milestone payments.

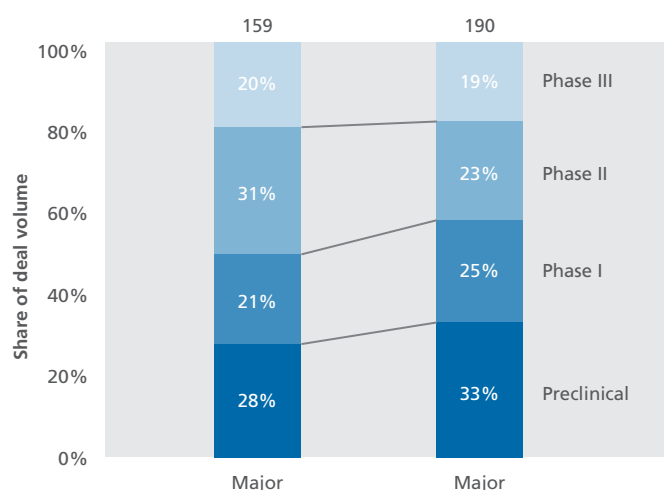
In short – cash is low, finding funding is difficult and will get worse, licensing will be among the very few readily available sources of funding², but not one without risks, and unlocking meaningful licensing value will require getting the balance just right between spending to demonstrate potential, and spending toward failure.

Exhibit 3: Average phase 2 licensing agreement, 2003 vs. 2007



Source: Re-Cap database; Oliver Wyman analysis

Exhibit 4: Big Pharma deals by phase: 2001-2003, 2004-2006



Source: Re-Cap database; Oliver Wyman analysis

1: To download a copy of *Licensing to Win*, please go to <http://www.oliverwyman.com/ow/health.htm>

2: To be clear, classic licensing agreements are not "the only" alternate source of funding, with milestone monetization and creative finance and risk-sharing agreements with investment funds can also be attractive, non-dilutive, low cost or low-risk venues to pursue.

Financing: What to do?

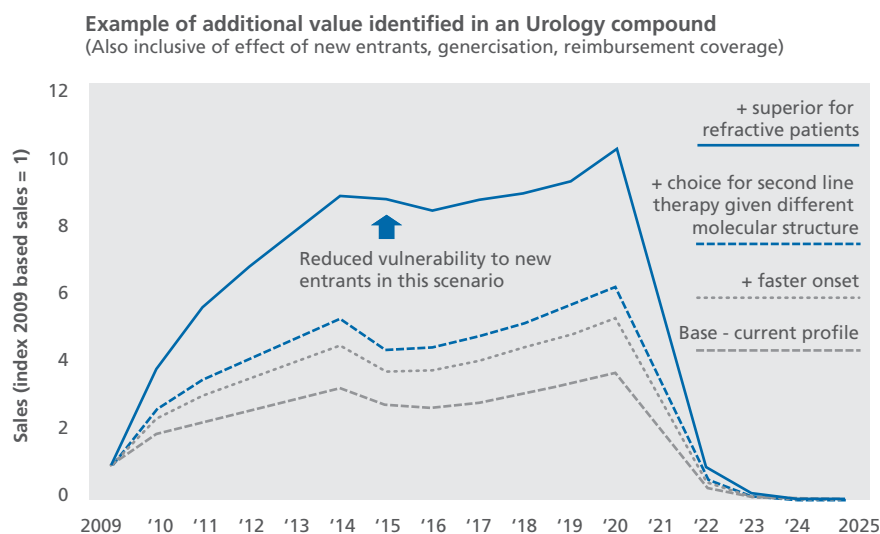
Attracting licensing or other funding is about demonstrating value and risks – both require trials. Trials are complex and costly, and decisions are often made to prioritize what will and won't be part of the trial protocol, and to what extent. The challenges are many; a cash-tight biotech may simplify trial design to prioritize getting to market – only to see value left on the table, or worse, to see their compound under-valued to the point where the company fails. Alternatively, a biotech may invest in unnecessary testing, as the potential value of the trial data ultimately doesn't justify the cost, and again, put themselves in a position to fail.

Examples of value biotechs have left on the table are numerous. In *Licensing to Win*, we detailed the example of an East-Coast biotech that had developed a therapy for a urological condition. Their analysis of how other companies promoted their alternative therapies, and of how physicians indicated they prioritized efficacy and side-effect considerations, led them to believe they had not only focused on the right research end-points, but also that they had developed a very competitive product to license.

In researching the demand elasticity for their compound, we found little demand for it "as advertized". While significantly better on several aspects of efficacy and side-effects, physicians felt that the performance of current therapies, for this particular condition, combined with their experience with them, was more valuable than the better performance of the new drug. As one physician commented "people buy microwave ovens to cook food fast – but once you had learned how to use the first oven, replacing it would require the next oven to be a lot – not just a little – faster." Bidding for the compound was not only less than half of what the biotech had hoped to raise, it was substantially more skewed towards milestones. In effect, less funding, and later than hoped.

In contrast, our research, including an audit of clinical data for both what others had and had not tested, revealed a set of attributes – earlier onset, a chemical structure different than alternatives, and more – that put the compound in a far more valuable light. Robust statistical analyses showed strong demand behind these attributes, and

Exhibit 5: Cutting edge techniques are available to identify 'hidden value' in compound TPPs



Source: Oliver Wyman analysis

dramatic increases in the forecasted value – all easily tested, if known in advance, and all left behind by the biotech.

A second example; a west-coast biotech had developed a technology platform in oncology and sought to license it for late-stage development and promotion. A key element of this strategy; developing two variations of a therapy, code-named 5 and 7, that would be targeted at specific sub-populations, and win dominant market shares in each. Specifically, late stage development budgets for 5 would be increased to help ensure it reached the market as soon as possible, so that a portion of its earnings could be re-invested in 7.

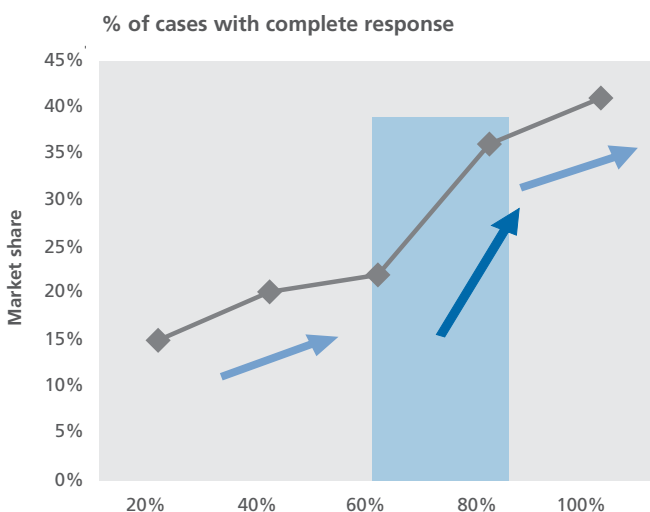
Our diligence revealed several key issues; first, our tools showed that oncologists adoption of the therapy was not a linear response to complete response, but more exponential up to a point. While all involved agreed that there would be differences in the two compounds in terms of complete response, the expected difference when modelled with our research, showed that substantially less adoption would occur than was

hoped. Simultaneously, there was strong agreement that there would be significant differences in the immunogenicity of the two therapies, but our research showed that these differences lay in a region where far less incremental adoption would occur as a result. The two compounds weren't different enough to generate significant adoption differences around complete response, and were both sufficiently better than alternatives in immunogenicity so that minimal incremental adoption would occur between the two as a result of that difference.

In short, the biotech was over spending on variation 5, and spending unnecessarily to develop variation 7, as the two would not command different niches but rather cannibalize one another; a significantly higher cash burn for very marginal incremental returns.

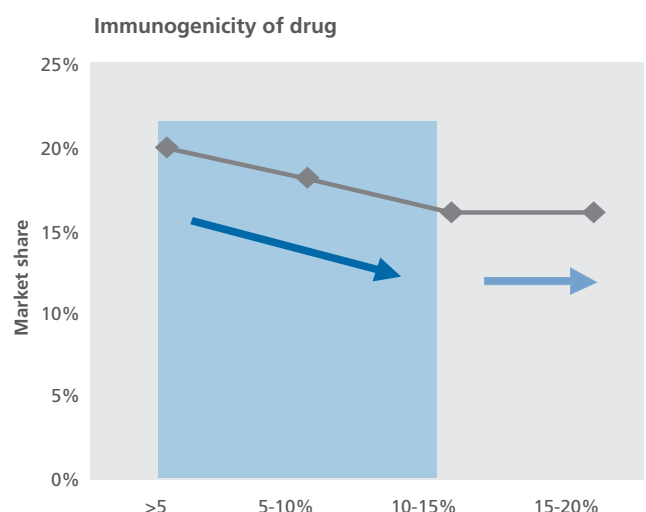
A third case – a small-cap biotech was developing a drug in an emerging class of cardio therapy. A large-cap pharma, developing another drug in this same TA, had recently published strong efficacy data for their compound.

Exhibit 6: Market share sensitivity of complete response profile
(Other attributes held constant)



Source: Oliver Wyman licensing research

Exhibit 7: Market share sensitivity of immunogenicity
(Other attributes held constant)



Source: Oliver Wyman licensing research

Licensing efforts were flagging, as potential partners saw a strong competitor in the wings of an as-yet un-proven class. Partners hesitated to buy-into a potential "distant second" compound.

Our research made clear the demand elasticity between efficacy and side-effects – the key question being how much better tolerated did a compound need to be, to make-up any potential efficacy gap?

Seeing more clearly the "shape" of the efficacy/side effects demand curve and the specific milestones at which the curve changed shape, made it clear that there was strong demand for a better-tolerated if less effective therapy, and clarified the nature of the development work to be done. This let the biotech not only re-invigorate the partnering and financing discussions, but also negotiate with a clearer sense of the financing commitments it required.

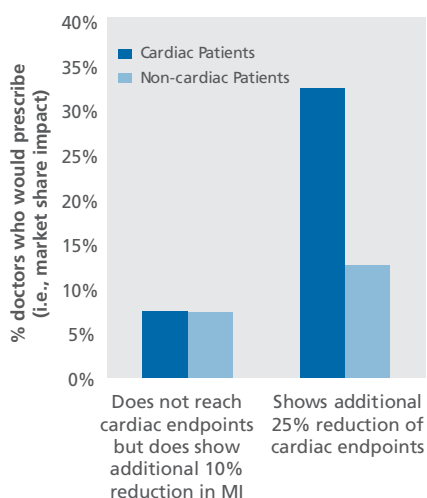
A final example: a European biotech out licensed an osteoporosis treatment early in phase 1, for terms that gave it a maximum value of \$125 million, to a US-based biotech. The US company completed the early phase research, and a short-while later sold the world-wide rights to a major pharma company for more than \$500 million in announced value.

Whether the US company explored specific new insights into what drove adoption, or the European firm simply sold the compound for too little, creating 4x the value in a few months time can only speak to the value-creation capabilities of developing compound with specific licensing end-points' value well understood.

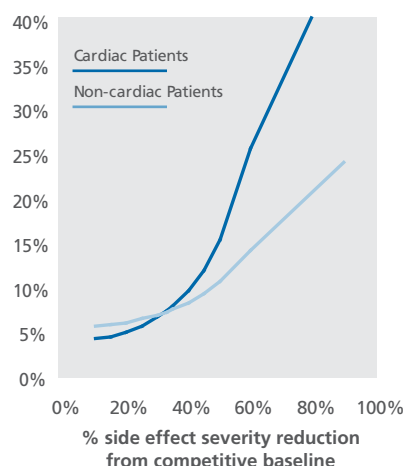
It should be clear that finding these sources of "latent value" and trial mis-spending is critical to forecasting, valuation and access to financing.

Exhibit 8: Efficacy or severity?

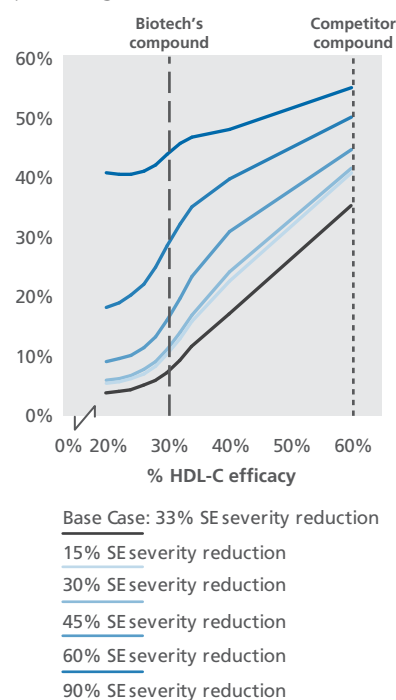
Impact of clinical trial outcomes on Cardiologist's willingness to prescribe
Weighted average



Impact of side effect severity on Cardiologist's prescribing behavior
Weighted average



Efficacy and side effect severity on Cardiologist's prescribing behavior
Weighted average across all prescribing occasions



Source: Oliver Wyman licensing research

The Opportunity for Biotechs

1. Stop overestimating what is known, and under-estimating what can be known

If your biotech company does not know quantitatively what a given piece of trial data is worth – literally, what having the data translates to in valuation terms – how can it justify investing in one aspect of a protocol vs. another? Interviewing a qualitative sample of KOL's will give some insight, but the best research techniques cut through the inaccuracies of recall, forced-ranking, and other insufficient techniques. The state of the art tools allow biotechs to synthesize to an investment-grade of accuracy how physicians, plans and others will choose, trade-off and ultimately prescribe a compound, today and against the backdrop of new generic and branded alternatives in the future. Understanding these elasticities has become a matter of whether a trial design will position a company for better licensing, further rounds of financing and higher valuation, or see it generate me-too compounds with marginal value.

2. Understand the risks, and factor them in

It is critical to have an accurate picture of the value, as generated by the valuation research tools demonstrated above, *and* of how that value is risk-adjusted at each development phase. Use qualitative measures at your own risk. If you feel that clinical risks are well understood, expect long discussions about safety, generic, commercial, pricing regulatory and many other forms of risk that may be used to "discount" your therapy. Understanding risk ensures that the biotech or specialty pharma isn't accepting unnecessary discounts and risk as part of its development milestones. If these valuation and risk models aren't parts of deal negotiations, the firm is taking on risk which it cannot afford, given the financing outlook, or selling short its real valuation.

Second, be cognizant of financing needs, and of the interplay between different licensing or co-development scenarios, and financing. A "richer" deal, later on in the process when cash may be tighter, carries with it significantly more risk. A less rich deal overall, that helps meet critical financing gaps, may prove far more beneficial. Modeling this accurately, and negotiating appropriately, takes risk out of the deal.

3. Write the right protocols

The insight we suggest developing here not only allows considering trade-offs for a compound – should the protocol include testing for onset, or not? – but also allows trading-off *between* compounds – at the margin, should the firm invest in onset research for compound A, or HDL-raising efficacy for compound B? Having the potential of each quantified, knowing what the incremental development costs are, and discounting these for the risks involved, allow the organization to write the right protocols, and help ensure not only the best odds of licensing/financing, but also of identifying the real potential in un-partnered compounds. When the real potential is determined in investment-grade research, cash will follow. ❖

Contributors



David Campbell

David works extensively with large-cap and specialty pharma and biotech companies, academic research centres, and investors in these industries, in North America, Europe and Asia. He co-developed Oliver Wyman's licensing forecasting and modelling platform, and co-authored the firm's 2008 research paper *Licensing to Win*. David holds an Honors Bachelor of Applied Science in Engineering from Queen's University at Kingston, Canada.



Andrew Chadwick-Jones

Andrew is a key contributor to Oliver Wyman's intellectual capital and authored both Oliver Wyman's first licensing paper *Rewriting the Rules* and co-authored *Licensing to Win*. Andrew's work ranges from supporting funds, biotechs and pharma companies on licensing transactions, as well broader growth strategies and operational improvement efforts. Before Oliver Wyman, Andrew worked at the Hongkong and Shanghai Banking Corporation and holds an MA in Biological Sciences from Christ Church, Oxford.



Sam Herbert

Sam is part of Oliver Wyman's Health & Life Sciences practice based in San Francisco. His work ranges from formulating high level licensing strategies to launching new distribution models to redesigning pharmaceutical development organisations. Before Oliver Wyman, Sam worked in banking and graduated cum laude in economics from Harvard College.



Charles Naaman

Charles is part of Oliver Wyman's Health & Life Sciences practice based in San Francisco. In addition to licensing strategy, Charles has worked across a broad range of health-related topics, including medical services go-to-market strategy, resource management for R&D and CRO organisations, and pharmaceutical due diligence. Charles holds a BSME from the University of Michigan and both an MBA and MEM from the Kellogg School of Management, Northwestern University.

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Health & Life Sciences Practice

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In biotech, Oliver Wyman conducts technical evaluations to support the development and growth of biotechnology companies, where identifying and evaluating the appropriate technologies, licences, or partners are key ingredients to success. In addition to providing assessment services, we provide strategic insight for long-term growth and also assist in the development of new capabilities such as R&D redesign.

In pharmaceuticals, scientific and deep analytics experience allows us to develop growth strategies for pharmaceutical companies from early stage to launch. We assist clients with R&D, go-to-market, and partner strategies, market and customer segmentation analysis, mature products lifecycle management, and licensing and alliance issues.

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