



FEATURED ARTICLE

PREPARING FOR KEY DEVELOPMENT CHALLENGES IN 2011: Q&A WITH NEIL MACALLISTER, PRESIDENT OF AVOS CONSULTING & EVP OF INC RESEARCH

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Recognizing the challenges faced by customers in today's healthcare environment, INC Research has integrated AVOS Life Sciences, a strategic consulting and research products firm, into its full-service offering. AVOS will operate as an autonomous division within INC Research and continue its focus on leading-edge issues and problem areas, providing valuable insight and guidance to its pharmaceutical and biotechnology customers.

We sat down with Neil MacAllister, President of AVOS Consulting and Executive Vice President, INC Research, to discuss key issues facing customers in the coming year. A former executive within Quintiles Transnational, Neil has experience leading a CRO organization through periods of significant growth.

Given your insight into key market and industry issues, what do you see as the key challenges for 2011?

Among the shaping issues for our industry in 2011, I would call out two that I see as perhaps most critical - continued R&D productivity challenges and capital efficiency in terms of making optimal capital investment decisions on a risk/return basis.

Our customers are often aware of these needs yet we see that the stakes are higher this year than last due to a maturing industry drug portfolio. To this point, the step-change solutions that have been implemented are insufficient to deal with the patent cliff and issues of capital allocation and R&D efficiencies, which currently plague the pharmaceutical and biotech markets.

With 2011 being a significant year in terms of patent expirations in particular, these two issues, R&D productivity and capital allocation, will be in the forefront of the minds of investors and executives alike. These two issues work hand-in-hand and have a clear influence on one another.

Capital allocation has two meanings in this particular sense, one at a "big picture" corporate level and one within R&D

specifically. The question of allocation is becoming an increasingly important one as investors and financial institutions are paying close attention to expenditures in both public and private companies. This increased attention has impacted share price and valuation of these organizations in the recent years and will continue to do so into 2011.

The question of spend is increasingly important within R&D as investors and executives evaluate the R&D productivity and efficiency within organizations. In a general sense, companies will be asked to do more with less and more quickly. One reason for this is the industry-wide patent cliff, which will see blockbusters and smaller products alike losing exclusivity, resulting in millions and in some cases, billions, in lost sales.

The other reason is increasing sophistication in development. Whereas R&D has historically been a rather regimented process with clear, distinct phases, new development models will lead to shorter development times with faster results while requiring less spend.

Now more than ever, we see the need for proactive, analytical planning, thought leadership and therapeutic expertise, and performance excellence helping existing and prospective customers with these challenges.

How can sponsors best prepare to handle these issues?

We have found that the most valuable “best practices” are observed outside the pharma/biotech industry, in other industries with similar financial pressures or business models. We are continually developing tools based on these observations that give customers the analytical rigor and capability to facilitate market understanding and decision making.

Here are a few example solutions from AVOS, which are aimed to help pharma/biotechs to position themselves for success in the future and to provide value to their customers.

At the macro, company-level, we have developed the Total Shareholder Return (TSR) tool that provides insight into which performance measures drive share price and valuation within the industry. The TSR tool focuses on standard financial measures, capital allocation ratios, strategic pharma/biotech industry measures, and pipeline composition variables to determine the true drivers of value creation within customer organizations. While taking elements of R&D into account, it evaluates all aspects of an organization, including strategic, operational and financial concerns.

Another offering we’ve developed is the Value Maximization tool that focuses on capital allocation across the whole spectrum of R&D and commercialization. Within R&D, we have a Portfolio Optimization tool that enables the simulation of changes to the composition of the portfolio and the resultant impact on the expected return. We use this tool as part of the greater Value Maximization offering which has additional components focused more on commercialization and post-approval activities. This combination of tools allows for complete analysis of an organization’s pipeline and marketed products, ensuring customers maximize the potential of their assets and capabilities.

While part of the Value Maximization offering, the Portfolio Optimization tool is also a stand-alone service we offer. Unlike other net present value (NPV) only portfolio optimization techniques, the AVOS Portfolio Optimization offering incorporates real uncertainty and a risk-return framework within its modeling, along with the ability to consider product interdependencies in the analysis. This analysis provides a more realistic assessment with outputs which are in a report form that can be used and understood across all functions within our customers.

Finally, our previous experience within the CRO industry has helped to demonstrate the value of reducing timelines and

cost in R&D while simultaneously improving productivity. We have put this experience and knowledge to use as we've assisted many customers in the creation and implementation of accelerated development models. The objective in these scenarios was to get to proof of concept faster and cheaper while carrying these efficiencies over to the later stages of clinical development.

This experience in accelerated development will prove to be indispensable to INC Research's customers as they look to reduce expenditures while increasing R&D productivity.

What type of Alliance Partnership models do you see becoming dominant in 2011?

From a definitional standpoint, alliance models range from slight variations of straight-forward fee for service constructs to personnel and infrastructure deals which accompany commitments involving development work. The approach CROs and other organizations take to adopt these models typically reflects the differing levels of risk associated with each construct and the given company's risk appetite. In our view, the types of Alliance Partnerships that are most likely to provide the greatest impact are those where a solution is tailored quite specifically to a partner's strategic and financial objectives.

Our clients, ranging from large cap pharma through to small-cap pharma or biotechnology companies, are redefining their strategic alternatives for the future and in many cases establishing a new approach and set of objectives for outsourcing. Because of this refocus, we expect that in 2011 a significant portion of outsourcing awards will be granted in structures other than straight fee for service agreements.

In terms of the evolution of outsourced clinical development activity, service entities that are willing and able to define tailored solutions designed for the specific client are well placed to lead and engage in these strategic discussions. Ultimately, both parties must find their way to a deal structure that appropriately "prices" each party's view of the risk and arrives at a set of economics that are acceptable.

The resource flexibility of CROs, as well as their proven capabilities, such as therapeutic expertise, a track record within a particular indication or process excellence, are all aspects that mitigate risk. If we begin to see a trend toward longer term commitments between sponsors and CRO partners, as I believe we will, these risk mitigating capabilities should support more multi-compound or even full portfolio partnerships, and a continued evolution toward shared financial and executional risk.

Product divestitures, deals where parties share in compound risk, or infrastructure deals such as "lift and shift" examples would also fit within my definition of Alliance Partnerships. These agreements are highly visible, but less frequently used types of deals.

Patent expiries and a general reduction in infrastructure and personnel spend within the industry have caused R&D organizations within pharma and biotech companies to be stretched thin. This has led to opportunities for CROs and other organizations to step in and acquire "surplus" products or resources, often through product equity stakes or acquisition of resources, assets, and/or personnel.

While this level of risk may be beyond the comfort zone of certain CROs within the industry, the opportunity to diversify their revenue base and bring in more consistent revenue streams makes these constructs an appealing proposition to many.

How do customers benefit from the complementary consulting services from AVOS and INC Research?

The focus of AVOS is to provide solutions to our customers' issues, whether they are one-time problems, ongoing issues, or preparation for issues likely to manifest in the future. We assist our customers with their highest priority needs, which not surprisingly are often the complex or even thorny issues facing their business. To maintain thought leadership in these key areas, our AVOS team has leveraged our talent, collective experiences and analytical capabilities in areas such as capital allocation, portfolio optimization, accelerated drug development models and pricing and market access.

AVOS also provides INC Research with additional capabilities and expertise that will provide immediate value to INC customers. Here's an example: We have focused much of our business effort on commercial issues related to technology opportunity assessment, product launch and commercial readiness, and pricing and market access concerns.

Historically, these commercial issues and their interface with clinical drug development would be addressed late - usually with a compound already in Phase III clinicals. However, market and competitive pressures are compelling more of an integrated commercial-clinical effort now throughout clinical development. Regulatory approval is often no longer "good enough" in a therapeutic market where poor reimbursement status essentially blocks product usage for a considerable volume of patients.

AVOS assists customers with embedding this commercial thinking alongside drug development efforts in terms of clinical trial design or issues related to patient accrual and site selection, to give a couple of examples. Within the INC Research family, we can broaden our joint offering and capabilities to customers.

This is a real exciting time for AVOS Consulting, INC Research and our customers. We look forward to an exciting and successful 2011.

For more information about AVOS Consulting and insights that can prepare you for key development challenges in 2011, contact Neil MacAllister at nmacallister@avosconsulting.com.