



Instead of setting up costly in-house systems to begin drug development, some biotechs are outsourcing the work to CEO Chuck Finn's RRD International. Photo by Joanne S. Lawton

RRD expands as biotech firms seek new model for operation

By Bill Flook

For a young biotech company, getting a product to clinical trials means investing millions of dollars in people, space and hardware – all for a drug candidate that could fizzle out like a faulty sparkler.

Trying to skirt those dangers, an increasing number of companies are turning to RRD International LLC of Rockville, which provides soup-to-nuts outsourcing of the earliest and most uncertain stages of drug development so biotechs don't have to build an infrastructure they might need to dismantle later.

"People are more and more realizing it doesn't make a lot of sense to build infrastructure especially in a new company before they even know whether they have a product or not," said RRD CEO Chuck Finn. "There is a big difference between a product candidate and a product that's been through the early stages of development – through the toxicology studies and maybe through Phase 1 – to find out whether you have something that has legs."

In recent months, RRD has added staff, moved to a larger headquarters and beefed up its leadership team. In late August, the company brought on former MiddleBrook Pharmaceuticals Inc. executive Beth Burnside, a pharma veteran who helped develop several popular drugs, including attention-deficit disorder treatment Adderall XR.

The concept of outsourcing parts of drug development isn't new. Contract research organizations, or CROs, already occupy a critical space in the biotech ecosystem.

But RRD executives draw a distinction between their company and a traditional CRO. In many ways, RRD mimics a biotech company itself, drawing on the technical and regulatory expertise of about 30 in-house staffers and outsourcing other functions.

The company typically manages product development from the neonatal stage of a new drug's life – before federal regulators have granted permission to begin human testing – all the way to midstage "proof of concept" trials. RRD also works with larger companies to supplement their resources.

RRD's model is grounded in broad, national changes in biotech funding. Early money remains scarce, and startups are being pressured to cut their cash burn rates and quickly advance viable drug candidates.

In the pre-recession boom, entrepreneurs

could "start a company, build a company and, even if you didn't have any products, go public and get rewarded for that," Finn said. "That's just not possible anymore."

Today investors "don't want to see you spend a year building a team," said RRD Chairman and Chief Scientific Officer Frank Hurley. "They want to see you move the product down the field."

In September, RRD moved into a 13,000-square-foot office at 7361 Calhoun Place, twice the size of its previous headquarters in the same building. It has added a half dozen employees in the past six months, Finn said. He declined to disclose revenue.

Hurley and Finn are former top executives at the BioMetric Research Institute, bought in 1997 by Quintiles Transnational Corp., a Durham, N.C.-based contract research organization. After Quintiles expanded to 20,000 employees within four years – an unmanageable size, Hurley and Finn say – the two left and founded RRD in 2002.

They initially established ties with New York-based private equity company Symphony Capital LLC, serving as clinical development partner for a \$500 million fund working in seven development companies. When biotech investment dropped precipitously after the downturn hit in 2008, RRD realized the prospect of raising a second fund was a distant one, Hurley said. The company began to seek new clients.

The biotech world is generally embracing the concept of an outsourced "virtual company" over one that keeps its operations internal, said biotech entrepreneur Glenn Batchelder, who used RRD at two of his companies, Cambridge, Mass.-based Acceleron Pharma Inc. and Bind Biosciences Inc.

"If you reel back five, 10 years, groups like RRD really weren't around in the same way," he said. "Today [with] our ability to access expertise in all different dimensions of the product development process, there are a lot more opportunities to do that."

A "one-stop shop" has its advantages, agreed Bruce Robertson, managing director of biotech venture capital fund H.I.G. Bioventures, not specifically about RRD, but he added it is critical to make sure the company has the "capabilities, relationships and scale" to meet the differing requirements of early- and later-stage trials.

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