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MDx Success Not All About Commercial Nous – Tech Talk Is Critical

by Tina Tan

Molecular diagnostic companies are often considered to be almost as capital-intensive as biotechs with similar high risks and steep R&D costs, making them less popular among investors compared to the more traditional medical device start-ups. However, the rewards can be significant, with the market for molecular diagnostics expected to expand much faster than other IVD segments over the next few years. So, what are the leadership traits that can help navigate a molecular diagnostic firm through the first stages of growth and into commercial success?

There are a number of generic attributes that characterize a good business leader, regardless of what industry the company is in. But in molecular diagnostics, it takes certain leadership qualities to navigate these businesses through the many hurdles specific to this market.

According to a recent Talent Equity *report* by the life-sciences executive search firm RSA Group, MDx firms do not attract as much investor attraction as other medtech start-ups because they are often as capital-intensive as biotechs, with similar high risks and steep R&D costs. There are also sector-specific risks such as the challenging scientific validation of the technology and the regulatory hoops that MDx firms have to jump through.

However, MDx technologies – supported by advancements in signal amplification, multiplex assays and DNA – are expected to be a key driver of innovation in the clinical diagnostic product and, subsequently, contribute to the expansion of clinical diagnostics market. Figures from *Meddevicetracker* show that MDx sales contributed $5.5bn to the $53.1bn global clinical diagnostics market in 2015, and this is expected to grow at a five-year CAGR of 5.4% to $7.2bn by 2020.

“There is a lot of wonderful science [in the MDx space] but a huge amount of this wonderful

science gets left on the shelf," said Alex Bennett, CEO of the RSA Group. So, what type of leader would be able to successfully commercialize these technologies?

The Talent Equity report authors studied 476 companies across the globe and of these, picked the top 12 highest-performing MDx and genomics companies – based on their ability to have attracted significant funding, commercialized a product, IPO-ed and/or be acquired by a large company – founded in the past 10 years. These companies were: Foundation Medicine, Curetis, Biocartis, Lifecode Health, Guardant Health, Astute Medical, Quanterix, Genapsys, AltheaDx, Gensignia, Qvella and Genalyte.

One of the key findings is that specific to MDx firms were the strong scientific/technical skillset possessed by the leaders of these companies and ability to know how to leverage their established relationships with the clinical community for the benefit of the business – 67% of the CEOs in the Talent Equity report's cohort of 12 successful MDx companies were PhD holders, and 75% were founders. Additionally, a CEO in this cohort holds, on average, 19 patents and patent applications.

"CEOs of MDx companies are often entrepreneurial scientists who have the asset/technical knowledge and know how to prioritize the pipeline and be able to speak the same language as the key opinion leaders," said Bennett. "If you look at a CEO of a companion dx company and one from a broader IVD company, there are transferable [leadership] skills but the true technical enablers [in MDx firms] should not be undervalued either," he told *Medtech Insight*.

Bennett acknowledged that there might be "a skew" with the findings in the Talent Equity report because the 12 companies in the cohort are in small, earlier-stage companies, so many of the CEOs would be scientist-founders. "If we were to extrapolate the findings, we might see a different focus for a bigger global organization. But for this [earlier-stage] level of companies, especially in MDx, this level of understanding of what the technology and the science is a real critical component."

Knowing also when to bring in the commercial nous to take the company to the next stage is also critical, as is the timing of this next move. "Being able to articulate, scientifically and technically exactly what your asset pipeline looks like and to speak passionately about where the innovation is driven from and where it could be applied to is significant in the initial stages. It's when you need to upscale the talent to enable you to either continue down the R&D or product-development pipeline piece, which again may require further financial investment to develop the pipeline, or to acquire the talent that would take you to the next level, which increases the incremental value of the company. That's the kind of key learning from our perspective."

Below is a table from the RSA Group's Talent Equity report on the molecular and genomic diagnostics sector that compares the CEOs and chief technology officers – across nine separate

measures – of the 12 MDx companies in the study cohort. The table provides a "real-world" profile for successful leaders in these roles, according to RSA.

	CEO	CTO
Tenure (median years)	5	5
No. of publications (average)	39	19
No. of patents (average	19	11
Operational experience	58%	0%
Research experience	25%	75%
Product development experience	17%	25%
Founders	75%	33%
Academic background	25%	50%
PhDs	67%	92%

Measures are a % of MDx cohort group (unless stated otherwise).

Source: Source: RSA Group

From the editors of Clinica