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# Research not fit to print

**Some biotech companies now eschew traditional publication in peer-reviewed journals. Does it matter?**

Last month, Stéphane Bancel, the CEO of Moderna Therapeutics, held court at the annual January biotech investor schmoozefest in San Francisco, the JP Morgan Healthcare Conference. In front of a standing-room-only audience, Bancel provided a first glimpse of Moderna's "transition to a clinical stage company," announcing $350 million of investment over the next 12 months, human testing for six drug candidates by the end of 2016 and an additional $100 million earmarked each subsequent year for pipeline development.

Moderna's coming-out party was highly anticipated and breathlessly reported. But something was missing: Moderna's scientists have yet to publish a single paper describing its therapeutic platform. That makes it difficult for outsiders to get a read on the company. And the Boston-based firm isn't alone in deprioritizing journal publication. Other prominent biotechs like Theranos and Kadmon have also chosen stealth over disclosure of data. Is this the beginning of the end of publishing company research in peer-reviewed journals? And, if so, does it matter?

In biotech's early years, a company's publication record was a matter of pride. Corporate research groups competed with one another and with academics to engineer a protein or isolate a monoclonal antibody. A paper in *Science*, *Nature* or *Cell* was an intellectual currency that provided external validation of an enterprise's R&D effort, something that could attract investors. Academic founders of flagship companies like Genentech, Biogen, Immunex, Isis/Ionis and Regeneron brought with them the culture and expectation that publication increases engagement with the wider research community, builds corporate reputation and assures scientific quality.

Many biotech companies still encourage this activity. In 2013, for instance, the vast majority of the top 50 large-cap biotech companies published at least ten papers. R&D teams at Biogen, Gilead, Celgene, Isis/Ionis and Vertex each published over 80 papers; Amgen scientists authored nearly 1,000. Publication not only provides credibility for R&D, but also serves to attract scientific talent. When companies are downsizing internal R&D and seeking closer ties with academia, a record of active publishing from corporate research teams led by top-tier former academics helps provide kudos, leverage and security.

Another, more prosaic rationale for publication is that it engages important communities around a product or technology. Papers in *The New England Journal of Medicine*, *The Lancet* and *JAMA*, for instance, get noticed by clinicians and patient groups. Publication in specialist (e.g., cardiology or oncology) clinical journals can focus a peer-reviewed message on those most likely to prescribe an emerging product.

Thus, publication is not simply academic glad-handing or intellectual self-congratulation. Attracting collaborators and influencing clinical communities are vital components of the corporate machine. So why have papers become a devalued currency, at least for some companies?

One reason is that R&D groups in startups are smaller than in the past. Capital-efficient virtual models using service companies and contract research reduce the internal clamor for, and dependence on, publication. On the other hand, independent replication and scrutiny of the original work of academic founders has become more important than ever.

Changes in the startup environment have not dramatically reduced the number of corporate publications. A survey of three prominent life science journals—*Nature Biotechnology*, *Nature Medicine* and *Cell*—indicates that the proportion of corporate to academic authorship has remained unaltered at around 5–10% of the papers published over the past decade.

Flagship companies, like Alnylam and Agios, pioneering new technology, continue to publish. But companies like Moderna remain content keeping their technology under wraps. And why not? The company has already raised >$550 million. It has an impressive list of partners and deals: $240 million upfront from AstraZeneca in 2013, $125 million from Alexion in 2014 and, just last month, $100 million and $20 million for vaccine deals with Merck and the Gates Foundation, respectively. The presumption is that those investors and partners must know what they are doing.

Elsewhere, diagnostics play Theranos and its media darling CEO Elizabeth Holmes have built a staggering valuation of around $9 billion. And yet the company has still to publish a paper disclosing its proprietary small-volume blood-test/blood-draw technology. Despite the approach remaining a black box for 12 years, Theranos has raised >$400 million and clinched a distribution deal with Walgreens.

A last example is Kadmon. Founded by ImClone founder Sam Waksal in 2009, Kadmon raised ~$150 million around a venture built on in-licensing compounds, several of which are in clinical development. In October 2014, five years after its establishment, Kadmon still had no primary publications.

When contacted, these firms all indicated they do consider publication. But clearly, it is a low priority. Deal making and finance are the new peer review. Scientifically, stealth is king.

This journal's business depends on publishing papers, so we have a conflict in emphasizing the downsides of stealth. But, secrecy does leave credibility open to attack. Theranos found this out late last year as it lurched from the PR fallout of *The Wall Street Journal* investigation detailing accusations of cherry-picking of results/tampering with data. Second, glowing corner-office media profiles, TED talks and publication by press release are no substitute for peer-reviewed publication. Third, and most importantly, deals don't validate science. Biotech is littered with examples of big money acquisitions or licenses written off or abandoned subsequently (Sirna and OncoMed come to mind).

Moderna, Theranos, Kadmon and companies like them may think they are better off if no one knows what they do or how they do it. But there will come a time when they have to decide whether to trust the community with their data. If they don't, the community may start to ask whether these companies themselves can be trusted.