

Biotech correction sends Novavax on a ride



[Jonathan Gardner](#)

Having a catalyst in the midst of a biotech correction is unlucky, and even more so if it involves delivering data viewed as less than perfect. This is the lesson from Novavax's release of phase II data for its respiratory syncytial virus (RSV) vaccine in pregnant women.

Amid the announcement of the last of four major positive catalysts in this quarter alone, shares sank 21% to \$6.41 yesterday on a day when the Nasdaq biotech index registered its eighth straight day of losses. The 15% bounceback this morning signalled that investors took a deep breath overnight and took heart in announcement of two major phase III RSV programmes, one with significant grant funding.

The market tumble has been nearly as hard on mature companies like Gilead, Regeneron and Biogen as it has been on relative minnows like Novavax. Given the doubling of shares through August, and what Citigroup regarded as the most important readout of the third quarter – phase II RSV data in elderly patients – having already occurred, Novavax might now be more for the patient investor ([Novavax breathing easier with positive RSV data, August 11, 2015](#)).

The group expects that its next major events will not happen until the second half of 2016.

Ready for phase III

The phase II trial was to test whether vaccinating pregnant women would confer any protection against RSV in their babies; the company called the outcome positive, measuring antibody increases in both mothers and babies.

But some analysts raised questions about the levels of antibodies in the infants, particularly of the RSV B subtype. The data were disclosed in an investor presentation that revealed phase III RSV trial designs that will involve up to 19,000 patients.

This was the clearest sign of a path forward for any of Novavax's development assets, as its influenza vaccine programme is subject to a contract with the US government's Biomedical Advanced Research and Development Authority, while its Ebola vaccine appears well behind candidates from Merck & Co and Johnson & Johnson.

Novavax is fortunate that it has received non-dilutive backing for the RSV maternal phase III trial in up to 9,000 pregnant women in the form of a grant of up to \$89m from the Bill and Melinda Gates Foundation, as was announced yesterday. This free pass to test the maternal vaccination hypothesis ought to put to rest most criticism of the phase II data.

Within a year Novavax will be well under way with two pivotal trials. Although its competitors include AstraZeneca and GlaxoSmithKline, this is the only company with a phase III-ready asset, and that could cause many investors to take heed.

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