The Vaccine Maker Stock About to Pop on FDA Phase III Trials

Investors Alley

Novavax, Inc: An Undervalued Stock with Big Promise

One strategy I have repeatedly leveraged during my over two decades of investing in the biotech sector is being aware of key trial milestone and approval dates before entering a position in a developmental concern. As you hopefully already know or will learn, small developmental biotech and pharma stock prices revolve heavily around these dates and the news that follows.

If results are positive, you should expect further upside in the stock, however, it can be surprising how often large gains can occur in the weeks leading up to these types of events. I like investing in stocks that have upcoming catalysts such as dates for FDA approvals and trial readouts as it is one of the areas in the sector that I have seen some of my biggest successes and for the reasons I stated above. It is a reliable way to locate stocks with near-term upside as well as get in early before the rest of the investing crowd takes notice.

Given this, it is now time to highlight an intriguing vaccine development company with a key product that should announce critical Phase III trial results sometime near the end of September. If results are positive as expected, this should lead to FDA approval by the summer of 2017. Therefore, this key trial readout should be a nice catalyst for a stock with other attractive features.

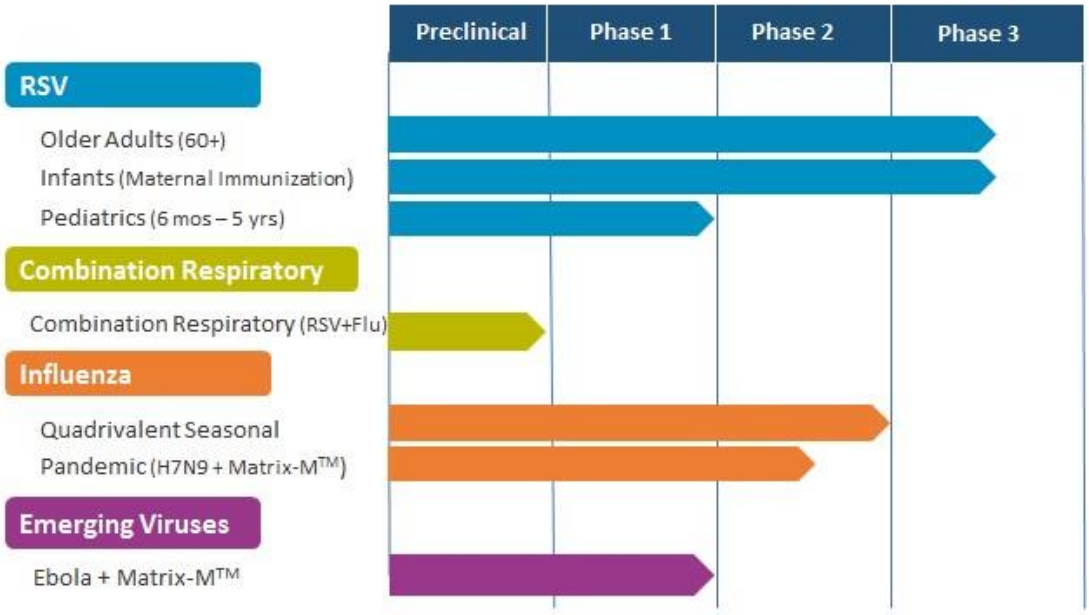
Company Overview:

Novavax, Inc. (NASDAQ: NVAX) is a clinical-stage small vaccine maker which focuses on recombinant nanoparticle vaccines and adjuvants. The company produces its vaccines using its proprietary recombinant nanoparticle vaccine technology and has several near term market catalysts on the horizon. The company currently sports a market capitalization of approximately $2 billion and trades around $7.20 a share as of this writing.

Pipeline:

Novavax owns a robust product pipeline which includes an important respiratory syncytial virus (RSV) vaccine candidate in Phase III clinical trials for elderly and maternal immunization, a pediatric RSV candidate in Phase I clinical trial, a seasonal quadrivalent influenza and pandemic H7N9 vaccine in Phase II clinical trials, a vaccine candidate against Ebola Virus in Phase I clinical trials, a combination respiratory vaccine candidate and seasonal influenza vaccine candidate in pre-clinical trials, and a rabies G protein vaccine candidate in Phase I/II clinical trial. What a mouthful, the pipeline chart on the next page will give you a better idea of the different vaccines and their developmental progress.

The company also has pre-clinical stage programs for various infectious diseases, including the Middle East respiratory syndrome coronavirus (MERS), and develops technology for the production of immune stimulating saponin-based adjuvants.



A number of the company's vaccine candidates focus on preventing illnesses that have serious impacts for vulnerable populations including infants, the elderly, and the developing world. The company reports there are some 37 million RSV infections annually in the US, EU, and Asia resulting in an estimated annual cost burden of roughly $80 to $100 billion. In the elderly (>65) U.S. population alone, there are around 4.3 million RSV, Influenza, and Pneumonia infections which result in over 800,000 hospitalizations and 50,000 deaths annually. And nearly 60% of infants in the United States are infected during their first RSV season with nearly all children having been infected at least once by age 3.

Let's take a closer look at some of Novavax's important candidates with upcoming catalysts.

RSV F Vaccine (Respiratory Syncytial Virus Fusion Protein Vaccine)

What it Does: It is a novel vaccine developed using recombinant nanoparticle technology to target the fusion protein, or F-protein, of the RSV virus.

Key Differentiator:

- RSV is a common illness with serious symptoms and dangers (including death) affecting the very young and the very old.
- EFFICACY: It is the First and ONLY candidate to demonstrate protection from RSV in any population, breakthrough efficacy in older adults, breakthrough proof-of-principle in maternal immunization.

Phase / Status:

- Key Phase III readout is expected very soon (official date is September 30th, but could be sooner) having been fast tracked for older adults. Assuming positive data, the company will file a BLA early in 2017.

- Top-line Phase II clinical trial results were positive, indicating the candidate is safe, well-tolerated and effective at protecting infants when they are most at risk, via maternal immunization. A Phase III trial is now underway in the United States, South America, Africa, and Australia and is now being expanded into Mexico, Europe, and Asia in alignment with intentions of an $89 million grant from the Bill & Melinda Gates Foundation. Preliminary results are now expected in 2018.
- A phase I clinical trial underway for pediatric use (6 months to 5 years).
- A phase II clinical trial being planned to assess the addition of a booster for older adults.

Expected Market: The company estimates worldwide RSV F Vaccine revenue opportunity at $6 to $8 billion per year. Initially, Novavax sees some 100 million individuals that would benefit from RSV immunization in the U.S. market including pregnancies >27 weeks, infants and toddlers, high risk patients between 50-59 years old, and all adults over 60. The price range of existing comparable vaccines is $30 to$75.

Other Considerations:

- This important vaccine was awarded a grant from the Bill and Melinda Gates Foundation for up to $89 million of development support with the goal of protecting infants via affordable maternal immunization in the developing world.
- Has the potential to be useful for other emerging viruses such as Ebola and H7N9.

	RSV	Influenza*	Pneumonia
Number of Infections	2,400,000	2,883,052	1,286,556
Hospitalization	203,600	262,095	339,853
Deaths	14,000	14,607	22,449

Influenza Vaccines

What it Does: Influenza (the flu) is a world-wide infectious disease that causes mild to life-threatening illness.

Key Differentiator:

- Novavax is using a recombinant baculovirus and insect cells for more rapid manufacture and adaptation to changing influenza strains.
- Use of a quadrivalent and novel influenza nanoparticle vaccine candidates may elicit broader protection from circulating influenza strains.

Phase / Status:

- Novavax has successfully completed Phase II clinical trials for the quadrivalent seasonal influenza vaccine)
- Expected Market: The Company expects seasonal influenza vaccines in the top seven markets to reach $5.3 billion by the 2021/2022 influenza season.

Other Considerations:

- There are currently four quadrivalent seasonal influenza vaccines licensed in the U.S. and additional quadrivalent seasonal influenza vaccines are expected to be licensed over the next several years.

The company is also optimistic about combining the RSV F and influenza nanoparticle vaccines in a pre-clinical trial. They are bringing together the vaccine approach that induces broadly neutralizing antibodies against both influenza and RSV (building on the strategy taken with the RSV vaccine). A vaccine covering both influenza and RSV, which together are the major cause of serious respiratory infections in older adults and pediatrics, would be a major advance for public health and would likely be in high demand. In addition, the company believes the new vaccine will have the capacity to neutralize the influenza virus across multiple strains.

Novavax is also working on leveraging its nanoparticle vaccine approach to quickly develop vaccines for emerging threats such as Ebola and MERS. Their pipeline is likely to continue to re-leverage existing capabilities for additional emerging diseases as the balance sheet supports this evolution.

Balance Sheet and Analyst Commentary:

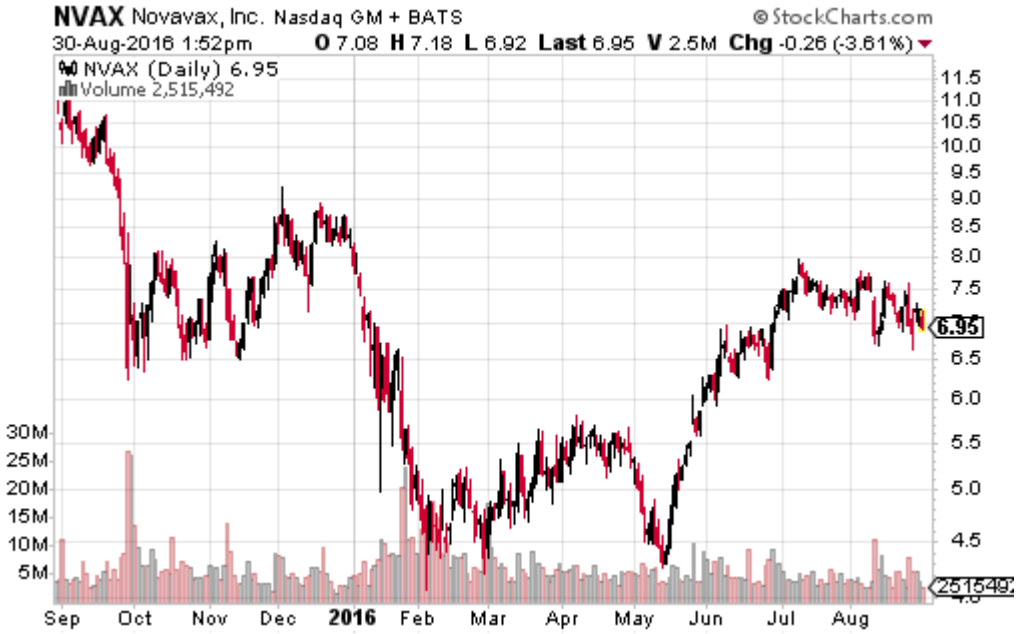
The financial results for the quarter ended June 30th, 2016 showed a cash burn rate of approximately $70 to $75 million, including significant R&D expenses related to ongoing trials. Novavax has over $365 million of cash on hand after strengthening its balance sheet through a $325 million convertible note offering earlier in 2016.

Revenue from a contract valued at up to $179 million over several years with BARDA to develop recombinant vaccines for the prevention of seasonal and pandemic influenza is winding down and set to conclude in September 2016. BARDA is the Office of Biomedical Advanced Research and Development Authority within the U.S. Department of Health and Human Services. However, the loss of this revenue is partially offset by the $89 million grant from the Bill & Melinda Gates Foundation for RSV F vaccine development.

Additionally, Novavax, is adding staff in preparation for a commercial launch of the RSV F Vaccine in the United States, assuming positive study results come out soon and the filing of a BLA (Biologic License Application) in 2017. Novavax is simultaneously exploring a number of potential partnerships for commercialization of the RSV F vaccine outside of the United States in anticipation of the upcoming Phase III data results announcements.

Looking ahead to the expected Phase III RSV vaccine data from Novavax by the end of September, Piper Jaffray indicated that Novavax could be an acquisition target by a larger vaccine player in late June and recommends the stock as Buy with a $14 price target. Piper's analyst further noted "Based on the Phase II study, we are confident the RSV Phase III trial is sufficiently powered to achieve statistical significance..."

In August, FBR Capital also recommended Novavax as a Buy with a price target of $17, indicating the global expansion of the Phase III trial for maternal immunizations is aligned with the intentions of the grant it was awarded, and in the near term they remain "focused on the anticipated 3Q16



release of top-line data from the RESOLVE Phase III study in elderly adults as a potentially positive catalyst for the stock."

Guggenheim on August 26th tagged Novavax as its "Best Idea" as it believes "If the RSV vaccine is safe and effective, we believe it will become the first active vaccine marketed for preventing RSV infection. A significant, global unmet medical need should position Novavax well in negotiations with potential partners seeking ex-U.S. commercial rights, we believe. Release of the Resolve data could create substantial share volatility and we remind investors that the company possesses other assets that could also create share value, namely, the seasonal influenza vaccine and programs in other infectious diseases such as Zika." The analyst firm put a whopping $25 price target on the shares.

Outlook:

The company is highly likely to receive approval for its RSV vaccine and have it on the market in 2017. Novavax is well funded, has a diverse pipeline aimed at addressable markets, and could also make a logical acquisition target. In addition, the stock has been hurt by the bear market that has existed on the biotech sector over the past year. The shares 52-week high is just over $14.00 a share, just under the median price target on the stock by the analysts that cover it. RSV puts some 200,000 elderly individuals in the hospital every year just in the States, so it is not a stretch to think that if the vaccine does hit the market that it will be in high demand from the public. The vaccine should be a major source of revenues in coming years and if Novavax's pipeline continues to develop, it will be the first of several significant recurring income streams.

Recommendation: Buy NVAX up to $8.50 a share.

Position: Long NVAX

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