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NVAX

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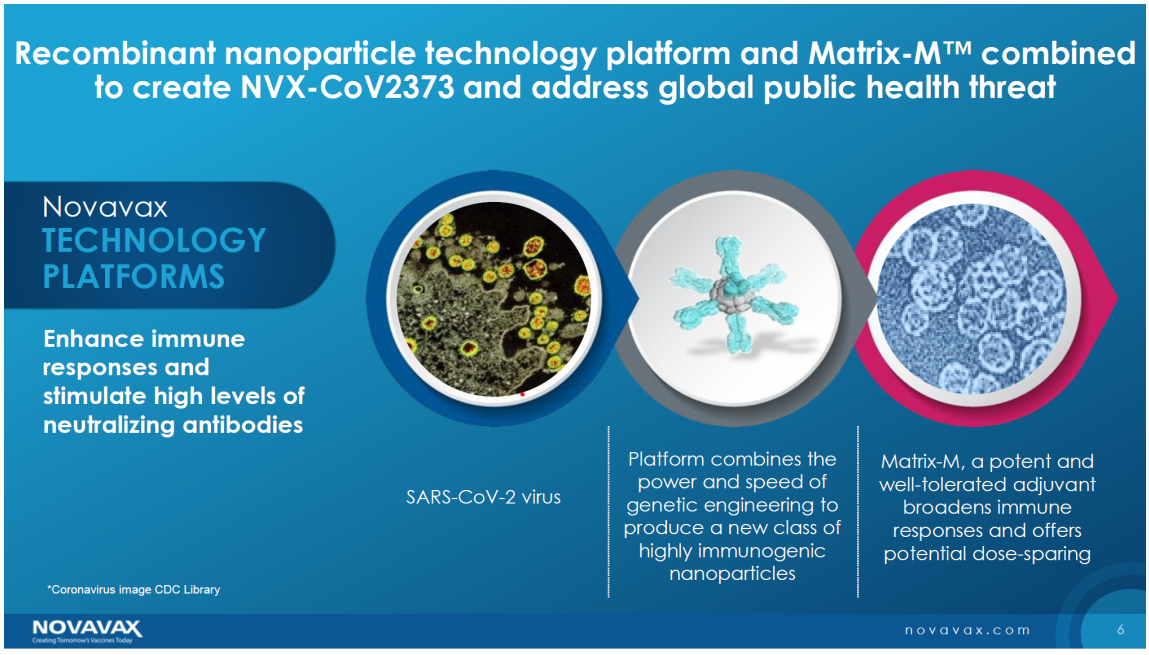
*OMAR **GUZMAN***
*2021 **10 20***

novavax

Creating tomorrow's vaccines today.



Novavax started off the year 2020 with a **market cap** slightly above **$105.778 million** and **26.577 million shares outstanding** and a **share price** of **$3.98**.

The company began the week with a **market cap** of **$12.383** and **74.484 million shares** outstanding and a share price of **$166.25**, representing a **4,077.14%** return since December 31, 2019.

The company identified its COVID-19 vaccine candidate, NVX-CoV2373 in April 2020, and thereafter began receiving funding from various sources to aid in the fight against the pandemic, including:

Coalition for Epidemic Preparedness Innovations (CEPI) — **$388 million**
U.S. Department of Defense — **$60 million**
U.S. Operation Warp Speed — **$1.6 billion**
TOTAL — $2.048 billion

Past 10 Days' Stock Price History and Volume

October 7	$165.68	3,160,000
October 8	$164.05	3,289,000
October 11	$163.39	2,675,000
October 12	$163.22	2,234,000
October 13	$166.39	4,455,000
October 14	$169.74	2,594,000
October 15	$161.95	3,147,000
October 18	$166.25	2,635,000
October 19	$160.55	3,315,000
October 20	**$143.61**	22,721,000 *shares traded*

On October 19, 2021, **Politico** published an article titled ***'They rushed the process': Vaccine maker's woes hamper global inoculation campaign*** in which they highlight manufacturing problems the company is facing according to "three people familiar with Novavax' difficulties."

The article states "*The methods it used to test the purity of the vaccine have **fallen short of regulators' standards** and the **company has not been able to prove that it can produce a shot that is consistently up to snuff**.*"

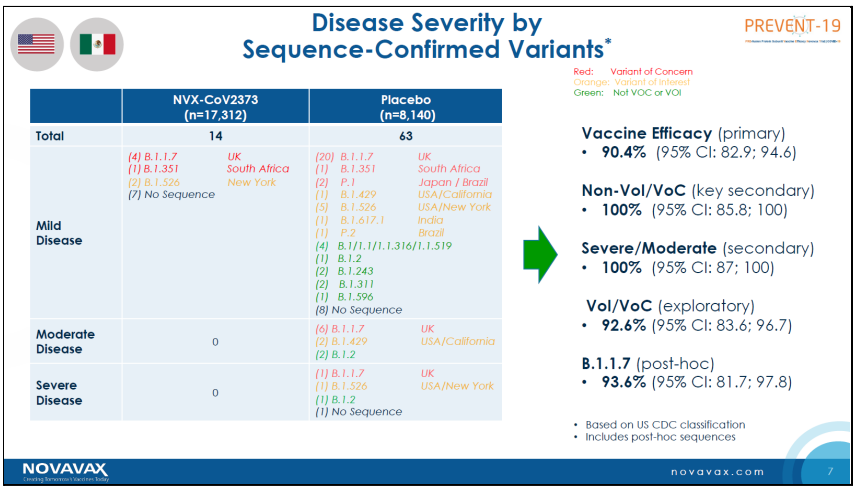
Among other issues that are highlighted:

- the FDA's June 2020 guidance requires vaccine batches to reach at least 90% purity; "the **company has struggled to attain anywhere close to that**" and that "Novavax has **recently shown purity levels hovering around 70%**"
- the three people familiar with the matter said "they are not confident the company has the resources needed to reproduce a high-quality vaccine on a consistent basis" but also that "**Novavax could potentially fix its manufacturing issues and reach full licensure by the end of 2022**"

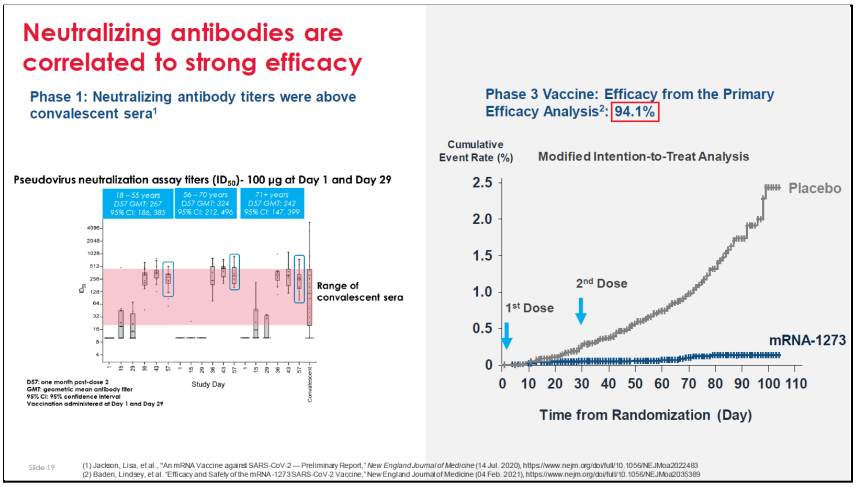
Novavax share prices plummeted overnight as a response, falling from the market close of **$160.55** to as low as **$115.00 per share** —**almost a 30% drop**— before settling at **$119.50**, an overall decline of **25.5%**.

Up to this point, Novavax has appeared to be a promising newcomer to the COVID-19 vaccine space, and in particular, the multi-billion dollar booster market. The company has met several critical milestones, including the completion of Phase 3 trials of its vaccine candidate in the UK and in the US and Mexico (their PREVENT-19 trial which involved nearly 30,000 participants), and appeared on track to achieving its goal of becoming the first major protein subunit vaccine to enter the market.

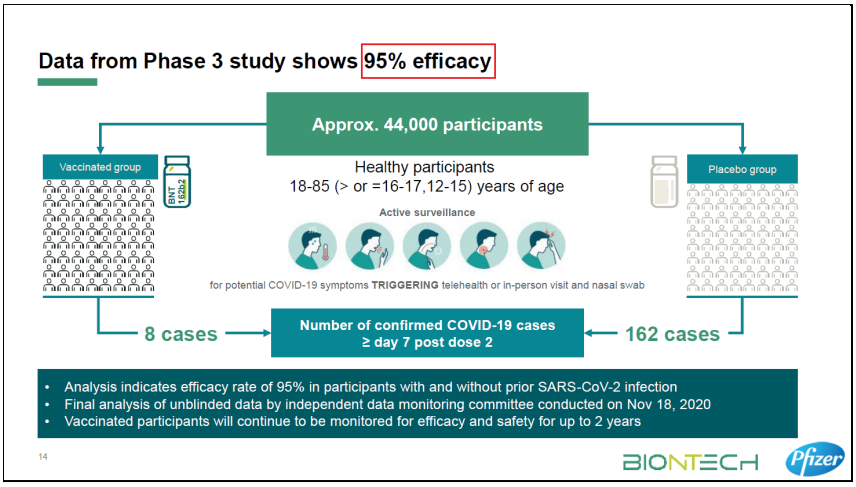
Participants in the PREVENT-19 Phase 3 trial received two doses comprising 5µg (micrograms) of vaccine and 50µg of Matrix-M™ adjuvant on Days 0 and 21. This resulted in **90% overall efficacy 7 days following the second dose**. Of note, participants achieved 100% efficacy against non-Variants-of-Interest (VoI) and Variants-of-Concern (VoC), as perhaps most importantly, **100% protection** against **severe** and **moderate disease** at the time of the trial. In comparison, Moderna reported 94.1% efficacy.



Source: Novavax Q2 2021 earnings call



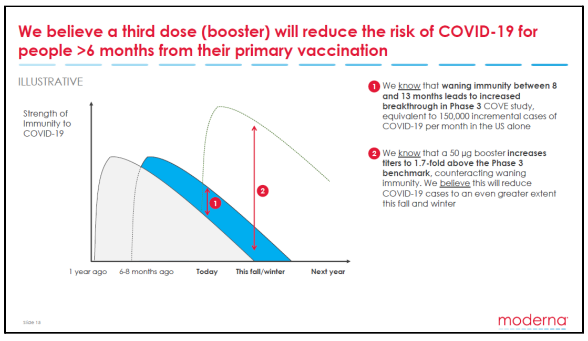
Source: Moderna 2nd Annual Vaccines Day — April 14, 2021

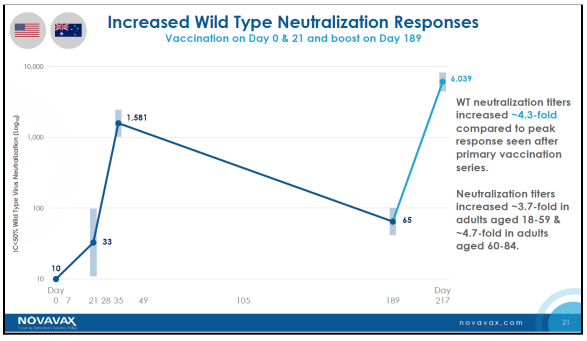


Source: *BioNTech Update on our COVID-19 Vaccine — December 22, 2020*

Novavax' vaccine effectiveness has thus far seemed in line with Pfizer/BioNTech's and Moderna's, while exhibiting **less severe adverse events** such as fever, headaches, and fatigue, and **requiring less dosage** — Pfizer's is **30µg** of **mRNA** while Moderna's is **100µg** of mRNA (the two are possibly related). Novavax also reported a **96% efficacy against the original COVID-19 strain** in its UK trial, which beat **Pfizer's 95%** and **Moderna's 94.1%**.

Additionally, Novavax's booster appears to be very robust. Moderna's booster increases neutralizing titres to **1.7-fold above its phase 3 benchmark**, while a recent study showed **Novavax' neutralizing titers increased 4.3-fold** compared to peak response seen after the primary vaccination series.



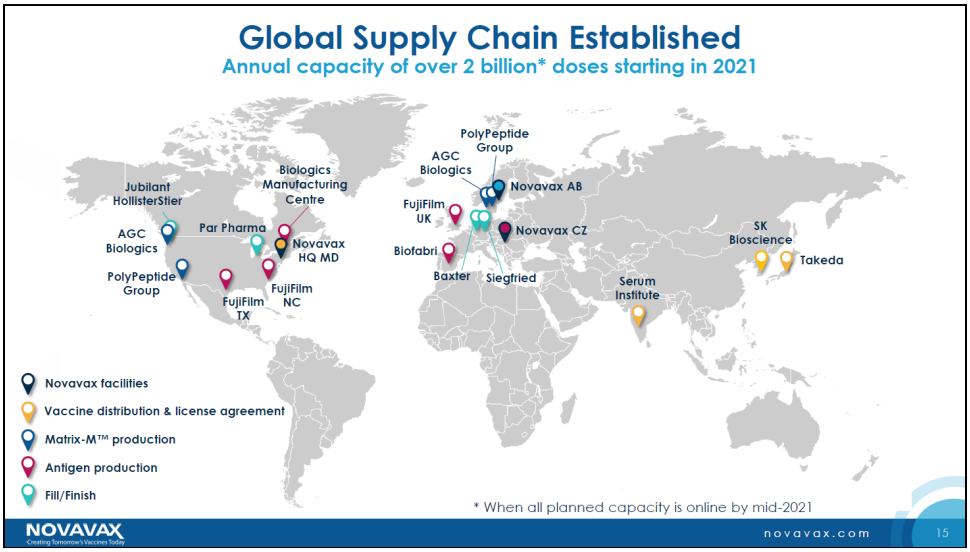


So based on the information provided by Novavax so far, its vaccine candidate has seemed like a very much viable contender.

It's important to note the Politico article did not dispute the efficacy of Novavax' vaccine candidate. Rather, they pointed out the difficulties the company has been facing with regards to scaling up its production and manufacturing at a global level.

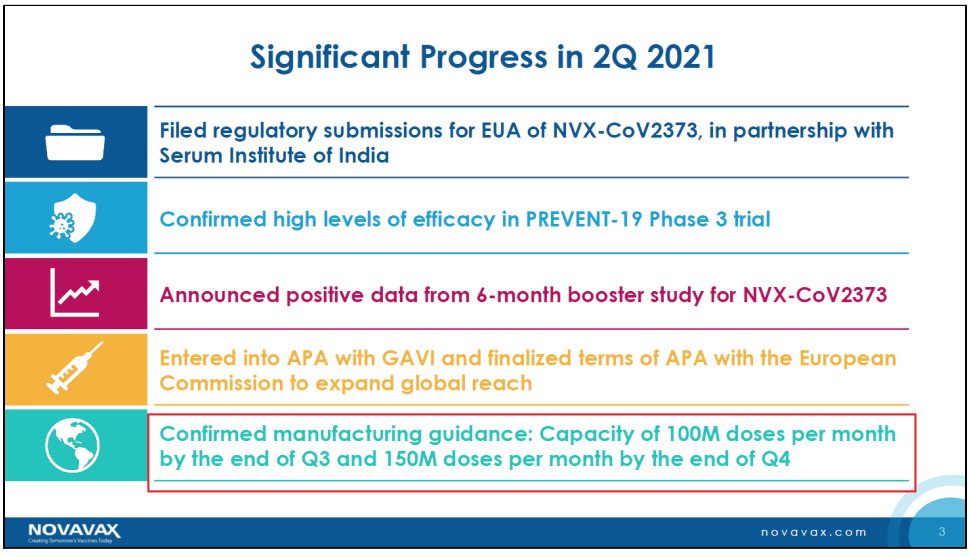
On September 10, 2020, the company noted the network of supply chain partners it was beginning to establish to increase its capacity by 2021.

On their 2020 earnings call on March 2021, the company reported an expanding network of partners while aiming for an annual capacity of 2 billion doses.



On their Q1 2021 earnings call on May 2021, the company adjusted downward their implied annual capacity from 2 billion doses to1.8 billion beginning in 4Q 2021.

Most recently on their Q2 2021 earnings call on August 5, 2021, the company essentially reaffirmed their manufacturing guidance of 150 million doses per month by the end of Q4 2021.



Indeed, during that call, company management acknowledged the manufacturing issues brought up by Politico's article. An analyst asked about language in the corresponding 10-Q that stated "*The U.S. government has recently instructed us to prioritize alignment with the FDA on our analytic methods before conducting additional U.S. manufacturing and further indicated that the U.S. government will not fund additional U.S. manufacturing until such agreement has been made.*"

From the 2021 Q2 Earnings Call:

Eric Joseph
Okay. And maybe just one follow-up, if I could, I'm just trying to understand...better understand some of the language in your most recent filing here, as it relates to your agreement with the U.S. government, saying that **it would like to see FDA alignment on your analytical methods before conducting additional U.S. manufacturing**. I guess...how to understand that? **Does that suggest some kind of authorization or approval before continued U.S. production?** And, would this have any bearing...

Stan Erck
Yes, that's sort of the source of some of the delay with the FDA is we have this USG—the U.S. government—that is our partner in developing this vaccine, and they are the gate to our submitting to the FDA. So there has to be some negotiation with the U.S. government, and does [sic] the validation activities meet their standards, and then we take it to the FDA, and there's always a time lag with the FDA these days. And so it's...but we need...what they want us to get... FDA to concurrence...**that our assay is fully validated**. And that's what the time difference is.

Eric Joseph
Okay. Would this have **any impact** on the originally-planned delivery of the **100 million doses** under the **original Warp Speed agreements**, and the **originally expected delivery…**

Stan Erck
Sure, it does, because the time—the original timetable called for starting to deliver those doses in the fourth quarter, and through the second quarter of next year. And I think that **probably we won't get many doses shipped in the fourth quarter**. And it will just push it back to the first and second quarter. **We have stockpiled those doses**. So it's...**it will come in a rush once we get the FDA approval**.

Eric Joseph
Okay, great. Okay. Thanks for taking the questions, guys. Thank you.

In a recent fireside chat during the **United Nations General Assembly** on **September 21, 2021**, **Chief Business and Commercial Officer** **John Trizzino** related to the matter:

Jenny Lei Ravelo
Now the question, I guess on everyone's mind is—**when is the Novavax Covid-19 vaccine going to be made available to populations globally?** Can you give us a sense of the timelines you're working on to get this to people's arms?

John Trizzino
Yes. Let me just first just comment on just one or two quick things.

The regulatory submissions—the final package that goes to these various regulatory authorities—is a culmination of a lot of activities that have taken place within the company from the Phase I/II trials back in early last year to the Phase IIb in South Africa, the two Phase III's—one in U.K., one in the U.S. and Mexico—it's this collective effort that gets put into that final regulatory package.

Along the way there's a number of challenging things that have to be done from **manufacturing scale-up** in addition to the **great clinical data** that we have, and then a **demonstration** of kind of **consistency of manufacturing across a network of manufacturing sites** around the globe—in the **U.S.**, in the **U.K. facilities**, **owned facilities** and **contracted facilities** in **Europe**; our important and strategic partnership with **Serum Institute**; work that we're doing in **South Korea** with **SK Bio**; and our partnership with **Takeda** in **Japan**. And so all of these interfaces create some regulatory challenges that we are making our way through.

We've been in constant communication with these authorities under rolling review and rolling submissions. And so therefore, **we're now at a point in time at which all of that feedback and all that conversation has been incorporated into these documents**. So we should be seeing a coordinated effort of getting these very similar regulatory filings being submitted within the next couple of months.

Lastly on the topic of manufacturing, a recent article published on July 19, 2021 by ***Modern Healthcare***[1] provides additional light on Novavax' manufacturing struggles. Novavax partnered with **Fujifilm Diosynth Biotechnologies** and its plants in **North Carolina**, **Texas**, and the **UK**, and it appears the Texas plant, which was originally set up in the aftermath of the 2009 H1N1 pandemic, didn't have as much experience producing vaccines and thus *"it's taken us a bit longer to ramp that up"* according to John Trizzino.

"*A March inspection by the Food and Drug Administration found overcrowded and unorganized storage areas, a failure to consistently follow cleaning procedures and questions about why there was a backlog of batches. The backup formed because bulk drug substance was being made faster than the facility could review produced batches, Fujifilm's Jackman said.*"

"*FDA inspectors called Fujifilm's operations 'sub optimal quality,' according to an April response memo written by Gerry Farrell, Fujifilm's chief operating officer for the facility. He said the criticism resonated and promised a thorough review with* ***fixes completed in April and May***."

"*Novavax's manufacturing process is complicated because the vaccine is made in steps in different places.* ***One plant makes the protein antigen****, and* ***another makes the adjuvant****. Then the* ***two components go to a final fill-and-finish facility where they are combined into 10-dose vials****.*

Its Matrix-M relies on quillaja extract from soapbark trees. The extract is also an additive in root beer and Slurpees. Novavax warned investors in its December 2020 financial filings that an inability to secure enough of the extract could delay production and prevent it from meeting 'obligations under our various collaborations and supply agreements.' Still, Trizzino said that supply is "not an obstacle to total number of doses."

[1] https://www.modernhealthcare.com/supply-chain/novavaxs-effort-vaccinate-world-zero-not-quite-warp-speed

Consistency of manufacturing across a network of manufacturing sites across the globe is what has been contributing to Novavax' delays, in particular the aforementioned Texas plant.

Despite this, a series of developments in the past few months have contributed to my optimism towards the company:

> **August 4, 2021** — Novavax and **European Commission** Finalize **Advance Purchase Agreement** for up to **200 million doses** of COVID-19 Vaccine
>
> **August 5, 2021** — Novavax and **Serum Institute of India** Announce **Submission to Regulatory Agencies** in **India**, **Indonesia**, **Philippines** for **Emergency Use Authorization** of Novavax' Recombinant Nanoparticle COVID-19 Vaccine
>
> **September 10, 2021** — Novavax and **Takeda** Agreement to Provide **150 Million Doses** of NVX-CoV2373 to the **Government of Japan**
>
> **September 23, 2021** — Novavax and **Serum Institute of India** Announce **Submission to World Health Organization** for **Emergency Use Listing** of Novavax' COVID-19 Vaccine

Further, last week (10/13) CEO Stan Erck met with **India's Minister of Finance Nirmala Sitharaman** as well as **European Commissioner Thierry Breton**, who tweeted "Meeting CEO Stanley Erck to discuss the scale-up of @Novavax global supply chains. Pleased to see Novavax production sites across Europe getting ready to supply vaccines to the world. The Task Force stands ready to help resolve #supplychain bottlenecks."

It appears that Novavax has indeed endured manufacturing struggles, and those definitely occurred at the Texas plant operated by their partner Fujifilm Diosynth Biotechnologies.

It also appears **"*additional required analytical work*" has been underway**, according to a local article[2] published by WTAW, a College Station-based media outlet, and according to them, "*both companies **expect to submit the vaccine candidate for EMA sometime between October 1** and **the end of the year***" and that "*the companies are **collaborating to advance commercial manufacturing** that involves **restarting manufacturing at FDB's facility** in the **Bryan/College Station biocorridor***."

So to sum:

- There were indeed manufacturing problems
- Those problems were limited to the Texas facility
- Novavax has been working to remedy said problems
- Manufacturing in other parts of the world has remained on track, as evidenced by:
    - Regulatory submissions
    - Purchase agreements with European partners
    - Recent meetings with high-level government officials
    - Novavax' response to the Politico article in the form of a press release issued on the morning of October 20

[2] https://wtaw.com/update-from-fujifilm-diosynth-biotechnologies-novavax-about-their-pandemic-vaccine-candidate/

Oct. 20, 2021 — Novavax Reconfirms Confidence in Regulatory Filing Timelines and Manufacturing Quality[3]

In response to a recent news article citing anonymous sources, Novavax **confirms our confidence in our ability to deliver our high-quality vaccine**. Further, we underscore our ongoing commitment to the stringent standards of production and manufacturing for our recombinant nanoparticle protein-based COVID-19 vaccine candidate with Matrix-M™ adjuvant. Since March 2020, Novavax has worked diligently, methodically and transparently to develop our novel COVID-19 vaccine candidate, taking on the challenge of developing and producing at large scale a proven biologic-based vaccine amid unprecedented circumstances. Throughout, we have maintained active conversations with various regulatory agencies in key markets and have incorporated their feedback into the submissions for authorization that we are in the process of completing.

We have made significant progress in mobilizing a global manufacturing network over the past 18 months with sites that are now routinely producing high-quality product at commercial scale at multiple sites across the world. Our global supply chain is expected to achieve a capacity of 150 million doses per month by the end of the fourth quarter through:

- Partnership with the **Serum Institute of India (SII)**, the world's largest vaccine manufacturer
- A state-of-the-art, wholly owned manufacturing site in the **Czech Republic**
- Manufacturing at established vaccine makers including **SK bioscience** in **South Korea** and **Takeda** in **Japan**
- Additional manufacturing arrangements around the world

We expect to complete multiple **ongoing rolling regulatory submissions** within the next couple of weeks in **key markets**, including the **United Kingdom**, **Europe**, **Canada**, **Australia** and **New Zealand**. We, along with SII, have already filed for authorization in **India**, **Indonesia** and **The Philippines**, as well as for **Emergency Use Listing** (**EUL**) with the **World Health Organization** (**WHO**). The WHO EUL will allow Novavax and SII to deliver on our combined commitment to the COVAX Facility for a cumulative 1.1 billion doses of our vaccine, around which we maintain ongoing conversations with **CEPI**, **Gavi** and **UNICEF**. Additionally, we expect to file for **Emergency Use Authorization** in the **U.S. before the end of 2021**.

"We are confident that our vaccine will soon play a significant role in the global COVID-19 vaccine arsenal, differentiated by its potential to help address two major issues slowing the world's ability to end the pandemic: global distribution challenges and vaccine hesitancy," said Stanley C. Erck, President & Chief Executive Officer, Novavax.

Novavax would like to thank the hardworking Novavax employees, manufacturing and other partners, and clinical community who are working diligently every day to deliver the first COVID-19 protein-based vaccine with Phase 3 data showing a robust safety profile, strong immunogenicity, and high efficacy against multiple strains of the coronavirus. The company also extends its deepest appreciation to the clinical trial participants who made a vital contribution during a global pandemic.

[3] https://ir.novavax.com/Novavax-Reconfirms-Confidence-in-Regulatory-Filing-Timelines-and-Manufacturing-Quality

In a recent analysis I conducted on Novavax, I examined the potential revenue opportunities given the remaining unvaccinated population as well as the annual booster market that follows. After accounting for population growth, countries' varying income levels and accompanying price points, and a modest market penetration on the part of Novavax's vaccine candidate, their share price could easily reach **$500**, implying a market cap north of $37 billion, and this is taking into account only potential booster revenues. Novavax' pipeline includes a **combination Flu/COVID-19** vaccine as well as one for **Respiratory Syncytial Virus** (**RSV**), so if their underlying recombinant nanoparticle vaccine technology is proven to work, Novavax has enormous potential to become the next big biopharmaceutical company.

**The Politico article even acknowledges they expect Novavax to receive full licensure by the end of 2022*