LAST UPDATED: FEBRUARY 11, 2022

RA CAPITAL'S COVID-19 MAP:
Map Update Log

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VACCINE UPDATES

VERSION 15 UPDATES: SEPTEMBER 24, 2021

NEW PROGRAMS ADDED (3):

1. **Icosavax (IVX-411):** Icosavax initiated Ph1/2 clinical trials in June 2021 for IVX-411, a VLP vaccine displaying the displaying the SARS-CoV-2 receptor-binding domain (RBD). The Ph1 will assess IVX-411 with and w/out Seqirus' MF59 adjuvant in participants naive to COVID-19, whereas the Ph2 will evaluate IVX-411 (adjuvanted or unadjuvanted) as a booster in vaccinated individuals.
2. **Providence/Everest Medicines:** Providence recently granted Everest license to develop and market its mRNA COVID-19 vaccine candidate, PTX-COVID19-B, in emerging markets in Asia. Ph1 data were positive, demonstrating ~10x higher neutralizing antibody titers in vaccinated individuals vs human convalescent control. A 40ug 2-dose regimen is currently being investigated in Ph2 trials in Canada. The company has an agreement with Emergent BioIsolutions to produce 10's of millions of doses in 2022 and an agreement with Northern RNA for essential raw materials.
3. **HDT Bio/Gennova:** HDT-301/HGC019 has been approved for Ph2/3 trials in India after demonstrating in Ph1 trials (run by Gennova, HDT's development partner in India) that the vaccine is "safe, tolerable, and immunogenic". HDT has received $8M in NIH funding.

UPDATES TO EXISTING PROGRAMS (23):

1. **Novavax/Emergent BioSolutions:** Novavax reported final efficacy data from its US/Mexico Ph3 trial in 2Q21 demonstrating 90% overall efficacy and 100% protection against moderate and severe disease. Novavax had previously reported final efficacy data for its Ph3 trial in the United Kingdom and its Ph2b trial in South Africa, where two doses of its nanoparticle based COVID-19 vaccine (5 ug NVX-CoV2373 + 50 ug Matrix M adjuvant, 7 days after the second dose) achieved 96% vaccine efficacy against the original strain of COVID-19, 86% efficacy against the UK strain, and 51% efficacy against the SA strain. Rolling reviews have commenced by the FDA, MHRA, EMA, Health Canada, and others. Novavax has recently reported data on a booster dose of their vaccine given 6 months after the prime series that demonstrated nAb titers ~4.3x the levels seen 28 days after the prime series. This is in line with what MRNA and PFE/BNTX are observing (4-5x WT nAb titers) from their booster doses. Novavax is also one of four vaccines in the UK "Com-COV2" study, which is evaluating the potential for combined regimens that mix vaccines from different manufacturers. An EUA for NVX-CoV2373 is expected 4Q21. Novavax has released preclinical data supporting the potential future development of variant-targeting and/or multivalent boosters, including: 1. NHP data for a next-gen vaccine targeting the B.1.351 South Africa variant demonstrating that a 3ug booster (NHPs originally received 2 doses of NVX-CoV2373) produced robust antibody levels above those seen following the original prime/boost regimen, and 2. Preclinical small animal data for a multivalent flu+COIVD-19 vaccine demonstrating strong antibody responses for both flu and covid as well as near sterilizing immunity in a hamster covid challenge study. Novavax was awarded $1.6B from Operation Warp Speed to support large-scale manufacturing of candidate NVX-CoV2373 by FUJIFILM Diosynth Biotechnologies and fund clinical development. In return, Novavax will supply 100M doses to the US. Together with their acquisition of Cyrus Poonawalla Group and their licensing agreement with the Serum Institute of India, Novavax is guiding to having 100M doses/month by the end of 3Q21 and 150M doses/month by 4Q21. Other global manufacturing agreements include: a partnership with Takeda to support the production for Japan (capacity for >250M

annually), a partnership with GSK to support production for the UK, a development and supply agreement with SK Bioscience for global manufacturing of the antigen component and vaccine supply for South Korea, an agreement with the UK government to purchase 60M doses, and agreements in principle to supply up to 1.1B doses to COVAX, 76M doses to Canada, 51 doses to Australia, 40M doses to South Korea,10M doses to New Zealand, 6M doses to Switzerland. Novavax is also in discussions with the EU to supply 200M doses with delivery beginning by YE21.

2. **Sanofi:** Based on interim Ph1 results announced December 2020, , Sanofi's vaccine elicited an immune response comparable to recovered COVID-19 patients in adults age 18 to 49 but failed to elicit a strong response in older adults. The company launched a Ph2b February 2021 to study an improved antigen formulation of their vaccine in combination with GSK's adjuvant, with interim results in May 2021 demonstrating neutralizing antibody responses comparable to HCS. The company plans to initiated a global Ph3 2Q21 with two separate candidates, one targeting the WT strain and one targeting the beta (SA) variant, both at a dose 2x that of NVAX (10ug) and adjuvanted with GSK's ASO3 (fluzone is adjuvanted with MF59). In parallel, the company also plans to run various vaccine combination booster trials at lower doses. Potential approval 4Q21. The company previously guided to producing 600M vaccine doses 2H21, and then scaling up to 1B doses annually by YE21. Sanofi was awarded $2.1B by Operation Warp Speed to supply the US with 100M doses in 2021 with the option for up to 500M doses. Similarly, Sanofi has entered agreements with the UK to supply up to 60M doses, with Canada to supply 72M doses, with the EU to supply up to 300M doses in 2021, and with the World Health Organization to supply 200M equitable doses. As they work to refine their own vaccine candidate, Sanofi has pledged to support other vaccine manufacturers such as J&J (provide fill and finish services for 12M doses/month starting 2021), Pfizer/BioNTech (manufacture 125M doses for the EU by summer 2021), and Moderna (manufacture up to 200M doses for the US starting in September 2021).

3. **Medicago/Mitsubishi Tanabe**: Leveraging a plant-based vaccine production platform. Medicago initiated a global 30,000 participant Ph3 trial in March 2021 after Ph1 data demonstrated modest neutralizing antibody titers (811 GMT with a low stringency 50% inhibition live virus assay) with the 3.75-ug dose that they are moving forward into further trials. Interim Ph2 safety and immunogenicity data results were positive with NAb titers ~10x those of convalescent sera. The company has guided to supplying 120M doses annually by 2021, with plans to double production capacity in 2022, and ultimately achieve greater than 1 billion doses of COVID-19 vaccines per year in 2023 after they complete building their large-scale factory in Quebec. The company previously signed an agreement with the Government of Canada to supply 76M doses of its vaccine and will also receive $173M in funding to support research and development.

4. **ExpreS2ion Biotechnology/AdaptVac/Bavarian Nordic:** Partnered with Bavarian Nordic A/S, Europe's largest independent vaccine developer, and sponsored by EU's PREVENT-nCoV vaccine research consortium, this program initiated a Ph1/2 in March 2021 investigating 3 dose levels (6ug, 12ug, and 25ug) with and without adjuvant. Ph1 safety and efficacy results were positive and a planned Ph2 is set to start in Germany to evaluate the vaccine as a booster candidate to individuals with previous COVID-19 disease or vaccination. If successful, it is unlikely that the vaccine candidate will factor into global supply until 2022.

5. **iBio:** Small company not funded to scale their VLP vaccines, although they estimate they could make about 500M doses annually once their vaccine candidate is approved. iBio has completed IND-enabling tox studies for IBIO-201 (S Protein fused with their patented LicKM booster molecule) with no adverse effects identified. The clinical timeline for iBIO-201 is unclear and it is unlikely to contribute to large-scale production before 2022. IBio is also developing a next-gen vaccine candidate (IBIO-202) targeting the N protein, which is more highly conserved than the S protein, and therefore new viral variants may be less likely to escape vaccine protection. PC data supports continued development. The company is expecting preclinical data for various antigen-adjuvant combinations of IBIO-202 1Q22.

6. **VBI Vaccines/National Research Council of Canada:** VBI initiated Ph1/2 clinical trials in March 2021 for VBI-2902, the company's monovalent enveloped virus-like particle (eVLP) COVID-19 vaccine candidate, with an aluminum phosphate adjuvant. Ph1 evaluated one- and two-dose regimens of its 5 ug eVLP candidate and demonstrated induction of NAbs in 100% of two-dose recipients that on average were ~4x higher

than convalescent sera and supported the assessment of the one-dose regimen as a booster candidate. The company also plans to initiate Ph 1/2 studies of a next-gen candidate targeting the B.1.351 variant (VBI-2905, with CEPI funding up to $33M for this vaccine) in MY21 as well as a pan-coronavirus trivalent vaccine candidate targeting COVID-19, SARS, and MERS (VBI-2901) later in 2021. VBI was previously awarded CAD $56M by the Canadian government to accelerate vaccine developments efforts through Ph2 testing.

7. **Clover Biopharmaceuticals:** In March 2021, Clover initiated a 22,000 participant ex-US global Ph2/3 trial of it's protein-based S-Trimer COVID-19 (2 doses of 30ug + Dynavax's CpG 1018+Alum adjuvant) and completed enrollment in July 2021. Previously, Clover published Ph1 clinical data February 2021 demonstrating good nAb titers in younger participants (GMT ~1,000, 1.5x HCS) but much lower levels in older adults (GMT 190, 25% of HCS). Interestingly, results from this study demonstrated superior titers with GSK's adjuvant (5-6x HCS in younger adults and 1-2x HCS in older adults), but the company has decided to move forward with Dynavax's adjuvant exclusively. In May 2021, Clover announced positive PC data for a 2nd-gen protein-based COVID-19 vaccine candidate against VoCs. Clover has in-house 2x2000L bioreactor capacity, which could translate to "hundreds of millions of doses" annually. CEPI recently expanded its partnership with Clover by investing up to $328M (including $69.5M previously announced) to fund the company's vaccine through licensure, including manufacturing scale up.

8. **Kentucky Bioprocessing, Inc:** Kentucky Bioprocessing is a wholly owned subsidiary of British American Tobacco leveraging a plant-based vaccine production platform. The company is still recruiting for its Ph1 trial and has guided to having the capacity to produce 1M-3M vaccine doses/week, which would be roughly 150M doses/year.

9. **Vaxxinity:** Vaxxinity (formed from merger of COVAXX and United Neuroscience) is developing a synthetic RBD-Fc vaccine formulated with T-cell epitopes and a proprietary adjuvant. They achieved high neutralizing antibody titers in guinea pigs (>32,000) and entered Ph2 testing February 2021 in Taiwan. The company reported Ph1 results demonstrating neutralizing antibodies induced in 100% of participants who received 2 doses of 100 ug of UB-612. The company has recently guided to producing 500M doses in 2021 (down from earlier guidance of 1B) and have entered a global distribution partnership with Maersk. Vaxxinity has announced purchase commitments of more than 140 million doses to multiple countries, including Brazil, Ecuador, and Peru contingent on the success of their Ph2/3 to launch in Brazil. Following the emergence of new COVID virus mutations, Vaxxinity has initiated preclinical work to develop a second vaccine candidate against the South African mutation. Received EUA in Tawain in 3Q21.

10. **Anhui Zhifei Longcom Biopharmaceutical/Chinese Academy of Sciences:** 3-dose protein subunit vaccine that was approved in China in June 2021 (the 7th Chinese-developed vaccine to receive approval). Trials investigating the mixing of Anhui's vaccine with CanSino's vaccine are ongoing in China. Little additional information is available publicly about this program's clinical timeline or manufacturing scale. The company has focused on the domestic Chinese market in 2021.

11. **Medigen/NIAID/Dynavax:** Recombinant stabilized prefusion SARS-CoV-2 spike protein vaccine adjuvanted with Dynavax's CpG1018+Alum with published Ph1 data demonstrating nAbs 2-4x HCS. Ph2 testing in Taiwan was completed in April 2021 and the vaccine received EUA in Taiwan in July 2021. The company has also initiated a booster study (as amendment to Ph1 trial) that is evaluating immunogenicity and safety of a 3rd dose 6 months after after completing dose 2 (data expected 3Q21). Concurrently, manufacturing and scale-up are planned to provide up to 200M doses by YE21. This program recently entered a partnership with Dynavax to supply CpG 1080 and Vaxess Technologies to develop a combination COVID-19 + seasonal influenza microneedle patch vaccine.

12. **VIDO-InterVac at the University of Saskatchewan:** VIDO-InterVac was awarded $23M by the Canadian government to accelerate COVID-19 vaccine development and the University of Saskatchewan was awarded another $59M to address COVID-19 and prepare for future infectious disease outbreaks. Recently partnered with McMaster University to accelerate vaccine development and Dalton Pharma and Biodextris for manufacturing and fill-finish. Ph1/2 clinical trials launched Feb 2021 and interim results demonstrated that it is safe and well-tolerated supporting its ongoing development in clinical trials.

13. **Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** Inactivated vaccine sponsored by the China National Pharmaceutical Group that in May became the first Chinese vaccine to receive EUA from the WHO, opening up the possibility of inclusion in the COVAX program. Sinopharm entered Ph1/2 testing in April 2020 with early data from this trial demonstrating relatively low levels of neutralizing antibodies (121-250 GMT with a low stringency PRNT50 assay), although they did not have a human convalescent comparator arm to benchmark these results to. The company has guided to supplying 1B doses in 2021. Sinopharm initiated a Ph3 trial in the UAE enrolling up to 15K volunteers and early data from this trial claims that the vaccine is 86% effective, although the company itself reported the vaccine is 79% effective. In September 2020, the UAE granted emergency use authorization for this vaccine candidate before clinical trials are complete, becoming the first program to be granted approval by a foreign country. More recently, Peru has suspended its Ph3 trial of Sinopharm's vaccine after a volunteer presented with serious neurological symptoms. Sinopharm's vaccine has been approved for WHO EUA in 64 countries so far.

14. **Bharat Biotech International/Ocugen:** Inactivated viral vaccine + ViroVax's Alhydroxiquim-II adjuvant with Ph3 data demonstrating 78% efficacy overall (based on 127 symptomatic cases of COVID-19). The company rolled out its first commercial batch of Covaxin from its commercial plants at the end of August 2021 and will be available for supply starting in September 2021. They have guided to producing 700M doses annually (up from previous guidance of 200M). Bharat Biotech was granted emergency use authorization by the Indian Central Drugs Standard Control Organization on the basis of non-human primate, Ph1, and Ph2 Ocguen has partnered with Bharat to develop Covaxin in the US (including clinical development, regulatory approval, and commercialization) in exchange or 45% profit sharing from sales in the US market.

15. **Valneva**: Valneva launched Ph3 testing for its inactivated, adjuvanted vaccine in April 2021 after releasing Ph1/2 data demonstrating neutralizing antibody titers at or above HCS levels. The UK Ph3 trial compared VLA2001 with AstraZeneca's conditionally approved vaccine head to head, allowing the company to run a smaller 4,000 patient trial, with possible approval in fall 2021- Valneva began the rolling submission process to the MHRA in the UK at the end of August 2021. The UK has now ordered 100M doses for supply in 2022 with options for 90M additional doses between 2023-2025, which will be manufactured at its facilities in Livingston, Scotland and Solna, Sweden. The total value of the 190M doses, if all options are exercised, is up to $1.7B. In addition, Valneva is in advanced discussions to supply the EU with up to 60M doses. Dynavax will supply its adjuvant for this agreement.

16. **Meissa Vaccines:** Meissa's COVID-19 vaccine candidate, MV-014-210, was derived by modifying the company's RSV LAV candidate, MV-012-968, and replacing the RSV glycoproteins with a functioning SARS-CoV-2 Spike protein. This platform offers potential advantages for global deployment and received. Dosing of the Ph1 trial was completed in 2Q21 proving to be safe and effective to support ongoing development.

17. **Moderna Therapeutics/Lonza:** Moderna has been granted EUA for their vaccine candidate in the US, UK, Canada, and several other countries after releasing primary efficacy data from their Ph3 efficacy trial demonstrating 94.1% vaccine efficacy 14 days after the second dose (in 196 COVID cases, with 30 severe cases in the placebo group, 33 older adults, and 42 participants from diverse communities) and 100% efficacy against severe disease. At this time, these data look equivalent to the efficacy generated by Pfizer/BioNtech's vaccine candidate (95% vaccine efficacy 7 days after the second dose) and we await further data readouts to assess durability of protection, protection after the first or second dose, and granular safety/efficacy breakdown between different subgroups. The biggest differentiating factor here is Moderna's cold chain storage advantage, as their vaccine can be stored at -20C, while the Pfizer/BioNtech candidate requires -70C storage. Moderna has submitted BLA for full approval, but this has not yet been granted. They have ongoing trials in pediatric populations, with the trial in teenagers recently demonstrating 96% efficacy. Interim data from trials for booster candidates has shown positive results demonstrating higher neutralizing antibodies against variants of concern than the original vaccine. They have also submitted application for approval of a 50 ug booster dose (half of each of the two 100 ug doses in the prime series). Data demonstrate that the vaccine maintains antibodies against VOCs and VOIs at 6 months. Moderna has guided to supplying 500M - 1B doses annually (100M in 1Q21 and 200M in 2Q21) and has committed 300M to the US (with the option

of an additional 200M), 160M to the EU, 50M to Japan, 40M to Canada, and 40M to South Korea. They have recently increased their global production estimate from 500M to 600M by YE21. They were awarded $56M by DARPA to develop a small-scale, mobile platform to enable fast, in-field automated manufacturing and deployment and are recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work. In March 2021, Moderna initiated Ph1 clinical trials of a next-gen vaccine (mRNA-1273.351) that specifically targets the Beta (South Africa) variant of concern (B.1.351). This is the first vaccine specifically targeting a variant of concern to enter the clinic. Some preclinical studies suggest that boosting against the B.1.351 variant produces significant cross reactivity against the original strain, suggesting that targeting the B.1.351 may be the best boosting approach in the near-term endemic setting.

18. **BioNTech/Pfizer:** Pfizer/BioNtech have been granted full approval for their vaccine candidate in the US and EUA in the EU, UK, Canada, and several other countries (including expansion to include adolescents aged 12-15 yrs after results from their Ph3 trial in this population demonstrated 100% VE) after completing their Ph3 trial demonstrating 95% efficacy 7 days after the second dose (in 170 COVID cases, 9 severe cases in the placebo group and 1 in the vaccine arm). These results provide validation for vaccines targeting the Spike protein and greatly surpass the benchmark set by the FDA (50% vaccine efficacy). Longer term data were recently reported, demonstrated 91% vaccine efficacy overall from months 1-6 (down from 95% during months 1-3) showing that efficacy wanes over time, though it remained quite high. Pfizer/BioNtech have also submitted Ph1 booster data to the FDA and EMA demonstrating higher neutralizing antibody titers against the WT, Beta, and Delta strains after a 3rd dose (30ug) administered 8-9 months after the 2nd dose than those seen after the 2-dose primary series alone. They plan to submit Ph3 data (expected imminently) for licensure of a third dose in all adults via a supplemental BLA. A 3rd dose is currently authorized only for immunocompromised individuals 12 years of age and older. Pfizer/BioNtech are guiding to manufacturing scaling up to 2B doses in 2021 with the recent acquisition of a GMP facility in Germany and manufacturing supply agreements for 500M doses to the US (and an additional 500M doses to be distributed by the US government to the world's poorest nations), 300M to the EU (with the option of an additional 200M), 120M to Japan, 100M to China, 30M to the UK, and 40M to COVAX (purchased at a not-for-profit cost). Originally recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.

19. **CureVac/Bayer:** Curevac reported final data from a 35,000 patient global Ph2b/3 data for 2 doses of 12ug demonstrating 48% overall VE and 53% VE (77% protection against severe disease and 100% protection against hospitalization or death) in younger participants (age 18-60). Curevac continues to seek regulatory approval (rolling admission to the EMA is expected to finalize 3Q21) despite significantly lower VE than current EUA vaccines. Interim immunogenicity data generated from their Ph1 trial demonstrated that the 12-ug dose generated neutralizing antibodies equivalent to HCS (1:113, microneutrlaization assay). The company has several manufacturing agreements: 1. Agreement with Novartis to produce up to 50M doses by YE21 and an additional 200M doses in 2022 at Novartis' Austria manufacturing site, 2. Agreement with Celonic to manufacture 100M doses in Germany, 3. Agreement with Wacker Chemie AG and plans to begin production 1H21 at 100M doses/year, and 4. Agreement with Bayey to support further development, supply, and key territory operations of CureVac's vaccine candidate. The company was previously in advanced talks with the EU to supply 225M doses of their vaccine candidate, with an option for 180M more, but given low Ph3 VE it is unclear whether this order will be executed. The company was previously awarded 252M euros by the German Federal Ministry of Education and Research to advance vaccine development.

20. **Translate Bio/Sanofi:** Sanofi and Translate Bio (Sanofi recently acquired Translate Bio for $3.2B in August 2021) initiated a Ph1/2 clinical trial of their mRNA vaccine candidate in March 2021 and interim results are expected 3Q21. Previously released preclinical NHP data in Oct 2020 demonstrated peak neutralizing antibody titers of 1,877, which places this vaccine in the middle of the pack for RNA candidates. Pfizer/BioNTech (GMT 962) and Moderna (GMT 3481), which both used similar assays to Sanofi (50% inhibition live virus assay), observed similar neutralizing antibody titers in human convalescent serum (GMT 41-94). Translate Bio has established 100g single-batch production with its clinical-stage mRNA therapeutics platform and build-out of dedicated manufacturing space, initiated through a contract manufacturing partner to accommodate at least two 250-gram batches/month.

21. **BioNTech/Pfizer:** Began Ph1/2 trials in Germany at the end of April 2020 and in the US in early May 2020 with small cohorts of patients to identify dose and schedule; expanded to larger cohorts in July 2020. They are testing doses between 1-100 mg and, depending on which doses work.

22. **Arcturus/Duke University:** Arcturus has competed enrollment of a 600 participant Ph2 trial in the US/ Singapore with interim data reviewed by the DSMB supporting advancement of a single 5ug dose regimen into Ph3 studies. Ph3 studies have not yet initiated but the company reported that ARCT-021 has been selected to be sponsored and funded through Ph3 trials by an undisclosed "global entity". The Ph2 study is ongoing and the company remains blinded to full trial data; data including neutralizing antibody and T-cell data is expected 2H21. The company previously announced topline results from a Ph1/2 trial in Singapore demonstrating that a single dose of their vaccine candidate generates neutralizing antibodies in the same range as human convalescent control (GMT 1:147). Preclinical studies demonstrated that a single 2-µg dose of their LUNAR-COV19 vaccine provided immunity (seroconversion in 100% of animals vs 0% at this dose for standard mRNA). The company is also advancing two next generation mRNA vaccine candidates targeting variants of concern (ARCT-154 and ARCT-165) that have reportedly demonstrated 15-25x higher neutralizing antibodies (including antibodies against multiple variants of concern) vs ARCT-021 in NHPs. These next generation candidates are approved to begin Ph1 clinical trials in Singapore and Vietnam as either a primary vaccination series or as a 3rd shot booster following 2 doses of Cormirnaty. Arcturus signed a partnership with Catalent to help them scale up to 100M doses in 2021 and have completed stockpiling of greater than 10 million doses of lyophilized ARCT-021. Also signed an agreement with CDMO Recipharm to support manufacturing, but have not provided additional dosing guidance. Arcturus also recently announced a collaboration with Vinbiocare to establish a manufacturing facility in Vietnam. Vinbiocare will pay Arcturus $40M upfront for rights to manufacture and sell their STARR platform covid vaccines in Vietnam.

23. **Imperial College London:** Imperial College London recently reported interim Ph1 data for its LNP saRNA vaccine candidate (LNP-nCoVsaRNA) demonstrating seroconversion of up to 87% of participants (doses ranged from 0.1mg to 10mg) and was well tolerated with no vaccine-related serious adverse events. Imperial will need to make modifications to optimize humoral responses before moving forward with further clinical development of this program. Previously secured £22.5 ($28M) in funding from the UK government for thebPh1 trial. Unclear what partnerships they would seek to scale up manufacturing.

VACCINE UPDATES
VERSION 14 UPDATES: MAY 21, 2021

NEW PROGRAMS ADDED (3):

1. **SK Bioscience (GBP510):** Recombinant protein vaccine candidate that initiated trials in South Korea in February 2021. The company has $14M in CEPI funding to develop GBP510 against variants of concern as well as $12.5M in additional funding to build out manufacturing capacity for hundreds of millions of doses. This vaccine is likely to be used primarily in Korea.
2. **GSK:** GSK's wholly-owned self-amplifying mRNA packaged in a lipid nanoparticle that initiated Ph1 trials in February 2021. As one of the largest vaccine producers in the world, GSK has the potential to play a major role in the endemic covid-19 market with this vaccine if clinical trials are successful. GSK will be able to GSK is also supporting NVX-CoV2373 production in the UK and supplies adjuvant (ASO3) for several other covid-19 vaccine developers such as Sanofi, SK Bioscience, and Medicago.
3. **Gritstone Oncology:** Heterologous prime/boost regimen consisting of one dose of chimpanzee adenovirus serotype 68 (ChAd68) followed by one dose of self-amplifying mRNA (SAM). Expresses spike protein plus additional SARS-CoV-2 T cell epitopes that the company claims will result in longer-lasting cellular immunity. It remains unclear whether the company intends to boost with the self-amplifying mRNA portion of this vaccine regimen, as the ChAd68 vaccine is likely non-redoseable. Preliminary results from the UK Com-COV heterologous study demonstrated that mixing Astrazeneca's ChAdOx1 vaccine with PFE/BNTX's RNA vaccine resulted in more side effects than either on it's own, which suggests that Gritstone's approach may face tolerability issues.

UPDATES TO EXISTING PROGRAMS (33):

1. **Novavax/Emergent BioSolutions:** Novavax reported final efficacy data for its Ph3 trial in the United Kingdon and its Ph2b trial in South Africa, where two doses of its nanoparticle based COVID-19 vaccine (5 ug NVX-CoV2373 + 50 ug Matrix M adjuvant, 7 days after the second dose) achieved 96% vaccine efficacy against the original strain of COVID-19, 86% efficacy against the UK strain, and 51% efficacy against the SA strain. Rolling reviews have commenced by the FDA, MHRA, EMA, Health Canada, and others as NVAX awaits topline data (expected 2Q21) from its fully enrolled US Ph3 trial, which recently expanded to include pediatric participants (ages 12-17) and initiated a crossover phase (so placebo participants can have access to active vaccine). Novavax is also one of four vaccines in the UK "Com-COV2" study, which is evaluating the potential for combined regimens that mix vaccines from different manufacturers. An EUA for NVX-CoV2373 is expected June 2021 at the earliest. Novavax recently released preclinical data supporting the potential future development of variant-targeting and/or multivalent boosters, including: 1. NHP data for a next-gen vaccine targeting the B.1.351 South Africa variant demonstrating that a 3ug booster (NHPs originally received 2 doses of NVX-CoV2373) produced robust antibody levels above those seen following the original prime/boost regimen, and 2. Preclinical small animal data for a multivalent flu+COIVD-19 vaccine demonstrating strong antibody responses for both flu and covid as well as near sterilizing immunity in a hamster covid challenge study. Novavax was awarded $1.6B from Operation Warp Speed to support large-scale manufacturing of candidate NVX-CoV2373 by FUJIFILM Diosynth Biotechnologies and fund clinical development. In return, Novavax will supply 100M doses to the US. Together with their acquisition of Cyrus Poonawalla Group and their licensing agreement with the Serum Institute of India, Novavax is guiding to having 100M doses/month by the end of 3Q21 and 150M doses/month by 4Q21. Other global manufacturing agreements include: a partnership with Takeda to support the production for Japan (capacity for >250M annually), a partnership

with GSK to support production for the UK, a development and supply agreement with SK Bioscience for global manufacturing of the antigen component and vaccine supply for South Korea, an agreement with the UK government to purchase 60M doses, and agreements in principle to supply up to 1.1B doses to COVAX, 76M doses to Canada, 51 doses to Australia, 40M doses to South Korea,10M doses to New Zealand, 6M doses to Switzerland. Novavax is also in discussions with the EU to supply 200M doses with delivery beginning by YE21.

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4. **ExpreS2ion Biotechnology/AdaptVac/Bavarian Nordic:** Moved to human trials; Partnered with Bavarian Nordic A/S, Europe's largest independent vaccine developer, and sponsored by EU's PREVENT-nCoV vaccine research consortium, this program initiated a Ph1/2 in March 2021 investigating 3 dose levels (6ug, 12ug, and 25ug) with and without adjuvant. An interim safety update (April 2021) for the first 18 participants revealed no untoward safety signal and the study is proceeding as planned. If successful, it is unlikely that the vaccine candidate will factor into global supply until 2022.

5. **VBI Vaccines/National Research Council of Canada:** Moved to human trials; VBI initiated Ph1/2 clinical trials in March 2021 for VBI-2902, the company's monovalent enveloped virus-like particle (eVLP) COVID-19 vaccine candidate, with an aluminum phosphate adjuvant. Initial data is expected by the end of 2Q21. The company also plans to initiate Ph 1/2 studies of a next-gen candidate targeting the B.1.351 variant (VBI-2905, with CEPI funding up to $33M for this vaccine) in MY21 as well as a pan-coronavirus trivalent vaccine candidate targeting COVID-19, SARS, and MERS (VBI-2901) later in 2021.

6. **iBio (IBIO-201):** Small company not funded to scale their VLP vaccines, although they estimate they could make about 500M doses annually once their vaccine candidate is approved. iBio has completed IND-enabling tox studies for IBIO-201 (S Protein fused with their patented LicKM booster molecule) with no adverse effects identified. The clinical timeline for iBIO-201 is unclear and it is unlikely to contribute to large-scale production before 2022. IBio is also developing a next-gen vaccine candidate (IBIO-202) targeting the N protein, which is more highly conserved than the S protein, and therefore new viral variants may be less likely to escape vaccine

protection. The company is expecting preclinical data for various antigen-adjuvant combinations of IBIO-202 1Q22.

7. **Clover Biopharmaceuticals:** In March 2021, Clover initiated a 22,000 participant ex-US global Ph2/3 trial of it's protein-based S-Trimer COVID-19 (2 doses of 30ug + Dynavax's CpG 1018+Alum adjuvant), with an interim analysis for vaccine efficacy potentially MY21. Previously, Clover published Ph1 clinical data February 2021 demonstrating good nAb titers in younger participants (GMT ~1,000, 1.5x HCS) but much lower levels in older adults (GMT 190, 25% of HCS). Interestingly, results from this study demonstrated superior titers with GSK's adjuvant (5-6x HCS in younger adults and 1-2x HCS in older adults), but the company has decided to move forward with Dynavax's adjuvant exclusively.
8. **Vaxxinity (UB-612): Formerly Covaxx;** Vaxxinity (formed from merger of COVAXX and United Neuroscience) is developing a synthetic RBD-Fc vaccine formulated with T-cell epitopes and a proprietary adjuvant. They achieved high neutralizing antibody titers in guinea pigs (>32,000) and entered Ph2 testing February 2021 in Taiwan. The company reported Ph1 results demonstrating neutralizing antibodies induced in 100% of participants who received 2 doses of 100 ug of UB-612, but have not yet released quantitative results. The company has recently guided to producing 500M doses in 2021 (down from earlier guidance of 1B) and have entered a global distribution partnership with Maersk. Vaxxinity has announced purchase commitments of more than 140 million doses to multiple countries, including Brazil, Ecuador, and Peru contingent on the success of their Ph2/3 to launch in Brazil. Following the emergence of new COVID virus mutations, Vaxxinity has initiated preclinical work to develop a second vaccine candidate against the South African mutation.
9. **Baylor College of Medicine/Biological E:** Biological E received approval to initiate a Ph3 study after completing a Ph1/2 trial that started in Nov 2020 (results not yet released).
10. **Anhui Zhifei Longcom Biopharmaceutical/Chinese Academy of Sciences:** 3-dose protein subunit vaccine that has been issued EUA in China in March 2021 (the 5th to receive EUA in China) and approval in Uzbekistan. Trials investigating the mixing of Anhui's vaccine with CanSino's vaccine are ongoing in China.
11. **Medigen/NIAID/Dynavax (MVC-COV1901):** Recombinant stabilized prefusion SARS-CoV-2 spike protein vaccine adjuvanted with Dynavax's CpG1018+Alum with published Ph1 data demonstrating nAbs 2-4x HCS. Ph2 testing in Taiwan was completed in April 2021 with potential to support EUA fillings in Taiwan June 2021 (authorization in the US unlikely prior to Ph3 data) and possible vaccine launch 3Q21.
12. **VIDO-InterVac at the University of Saskatchewan:** Moved to Human Trials; VIDO-InterVac was awarded $23M by the Canadian government to accelerate COVID-19 vaccine development and the University of Saskatchewan was awarded another $59M to address COVID-19 and prepare for future infectious disease outbreaks. Recently partnered with McMaster University to accelerate vaccine development and Dalton Pharma and Biodextris for manufacturing and fill-finish. Ph1/2 clinical trials launched Feb 2021.
13. **WRAIR/USAMRIID:** Moved to Human Trials; US Department of Defense-sponsored research effort that initiated a Ph 1 study in April 2021 (delayed from original projections to enter the clinic by Dec 2020). Historically focused on vaccines for military applications and has limited manufacturing.
14. **Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** Inactivated vaccine sponsored by the China National Pharmaceutical Group that in May became the first Chinese vaccine to receive EUA from the WHO, opening up the possibility of inclusion in the COVAX program. Sinopharm entered Ph1/2 testing in April 2020 with early data from this trial demonstrating relatively low levels of neutralizing antibodies (121-250 GMT with a low stringency PRNT50 assay), although they did not have a human convalescent comparator arm to benchmark these results to.
15. **Bharat Biotech International/Ocugen:** Inactivated viral vaccine + ViroVax's Alhydroxiquim-II adjuvant with Ph3 data demonstrating 78% efficacy overall (based on 127 symptomatic cases of COVID-19). The company expects their vaccine to broadly hit the market summer 2021 and has recently guided to producing 700M doses annually (up from previous guidance of 200M). Bharat Biotech was granted emergency use authorization by the Indian Central Drugs Standard Control Organization on the basis of non-human primate,

Ph1, and Ph2 data. Ocguen has partnered with Bharat to develop Covaxin in the US (including clinical development, regulatory approval, and commercialization) in exchange or 45% profit sharing from sales in the US market.

16. **Valneva (VLA2001):** Moved to Human Trials; Valneva launched Ph3 testing for its inactivated, adjuvanted vaccine in April 2021 after releasing Ph1/2 data demonstrating neutralizing antibody titers at or above HCS levels. The UK Ph3 trial will compare VLA2001 with AstraZeneca's conditionally approved vaccine head to head, allowing the company to run a smaller 4,000 patient trial, with possible approval in fall 2021. The UK has now ordered 100M doses for supply in 2022 with options for 90M additional doses between 2023-2025, which will be manufactured at its facilities in Livingston, Scotland and Solna, Sweden. The total value of the 190M doses, if all options are exercised, is up to $1.7B. In addition, Valneva is in advanced discussions to supply the EU with up to 60M doses. Dynavax will supply its adjuvant for this agreement.
17. **Moderna Therapeutics/Lonza (mRNA-1273):** They have ongoing trials in pediatric populations, with the trial in teenagers recently demonstrating 96% efficacy. Interim data from trials for booster candidates has shown positive results demonstrating higher neutralizing antibodies against variants of concern than the original vaccine. Moderna has guided to supplying 500M - 1B doses annually (100M in 1Q21 and 200M in 2Q21) and has committed 300M to the US (with the option of an additional 200M), 160M to the EU, 50M to Japan, 40M to Canada, and 40M to South Korea. They have recently increased their global production estimate from 500M to 600M by YE21. They were awarded $56M by DARPA to develop a small-scale, mobile platform to enable fast, in-field automated manufacturing and deployment and are recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work. In March 2021, Moderna initiated Ph1 clinical trials of a next-gen vaccine (mRNA-1273.351) that specifically targets the South Africa variant of concern (B.1.351). This is the first vaccine specifically targeting a variant of concern to enter the clinic. Some preclinical studies suggest that boosting against the B.1.351 variant produces significant cross reactivity against the original strain, suggesting that targeting the B.1.351 may be the best boosting approach in the near-term endemic setting.
18. **BioNTech/Pfizer (BNT162):** Longer term data were recently reported, demonstrated 91% vaccine efficacy overall from months 1-6 (down from 95% during months 1-3) showing that efficacy wanes over time, though it remained quite high. They are also investigating 3rd dose boosters against variants of concern and have recently received an expansion to their EUA to include adolescents (age 12-15 yrs) after results from their Ph3 trial in this population demonstrated 100% VE (n=2,260; 18 infections all in placebo group)
19. **CureVac/Bayer:** Curevac submitted their vaccine for rolling EMA submission in February and has also recently submitted for approval in Switzerland. Curevac initiated a 35,000 participant global Ph2b/3 study and a 2,500 participant Ph3 trial in Germany, both in January 2021. Interim immunogenicity data generated from their Ph1 trial demonstrated that the 12-ug dose generated neutralizing antibodies equivalent to HCS (1:113, microneutrlaization assay). The Ph2b/3 study was recently expanded to determine efficacy against select variants. The company has several manufacturing agreements: 1. Agreement with Novartis to produce up to 50M doses by YE21 and an additional 200M doses in 2022 at Novartis' Austria manufacturing site, 2. Agreement with Celonic to manufacture 100M doses in Germany, 3. Agreement with Wacker Chemie AG and plans to begin production 1H21 at 100M doses/year, and 4. Agreement with Bayey to support further development, supply, and key territory operations of CureVac's vaccine candidate. The company is in advanced talks with the EU to supply 225M doses of their vaccine candidate MY21, with an option for 180M more. The company was previously awarded 252M euros by the German Federal Ministry of Education and Research to advance vaccine development.
20. **Translate Bio/Sanofi:** Moved to Human Trials; Sanofi and Translate Bio initiated a Ph1/2 clinical trial of their mRNA vaccine candidate in March 2021 and interim results are expected 3Q21.
21. **University of Tokyo/Daiichi Sankyo:** Moved to Human Trials; initiated Ph1/2 in Japan in March 2021.
22. **BioNTech/Pfizer (BNT162):** Began Ph1/2 trials in Germany at the end of April 2020 and in the US in early May 2020 with small cohorts of patients to identify dose and schedule; expanded to larger cohorts in

July 2020. They are testing doses between 1-100 mg and, depending on which doses work, have guided to producing hundreds of millions of doses in 2021.

23. **Arcturus/Duke University:** One Dose, Arcturus has competed enrollment of a 600 participant Ph2 trial in the US/Singapore with interim data reviewed by the DSMB supporting advancement of a single 5ug dose regimen into Ph3 studies (study not yet initiated). The Ph2 study is ongoing and the company remains blinded to full trial data; data including neutralizing antibody and T-cell data is expected 2H21. Arcturus signed a partnership with Catalent to help them scale up to 100M doses in 2021 and have completed stockpiling of greater than 10 million doses of lyophilized ARCT-021.
24. **JNJ/Emergent Biosolutions:** J&J's single dose Ad26 vaccine was granted EUA from the WHO on March 12, CMA from the European Commission on March 11 and EUA by the FDA on February 27, 2021 following topline data from a global Ph3 demonstrating 72% efficacy against the original strain of COVID, 66% efficacy in Latin America, and 57% efficacy in South Africa 28 days post vaccination. The FDA and CDC have recommended that the use of J&J's vaccine be resumed in the US after blood clots were identified as a rare side effect of vaccine administration, which resulted in a temporary pause in vaccine rollout. Rollout has also resumed in the EU. BARDA committed $454M to support this and a concurrent Ph3 trial implementing a 2-dose regimen that began in November. Ad26 is less common than Ad5 so risk of pre-existing immunity is lower. They have a large manufacturing capacity and are targeting 1B doses on a not-for-profit basis (with 200M doses pledged to the US, 200M pledged to the EU with an option for 200M additional, and 220M pledged to AVAT with an option for 180M additional). J&J had been guiding towards delivery of 100M doses to the US by the end of May but several setbacks including the clinical hold and manufacturing contaminations (15M doses lost at the Emergent plant) may significantly reduce these estimates. J&J recently entered a $480M, five-year manufacturing agreement with Emergent Biosolutions as well as a partnership with Merck to assist in manufacturing its COVID-19 vaccine.
25. **ASTRAZENECA/Vaccitech/ University of Oxford (AZD1222):** Originally recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work, Astrazeneca's COVID-19 vaccine since been authorized by The WHO, UK, EU, India, and other countries after Ph3 efficacy trial data demonstrated >70% efficacy overall. The FDA, on the other hand, has not yet granted EUA for Astrazeneca's vaccine. AstraZeneca's vaccine has a logistical advantage (can be shipped at stored at 2-8oC) and the company has signed agreements to provide hundreds of millions of doses around the world (100M UK, 300M US, 400M Serum Institute of India to provide for poorer countries, 300M CEPI/GAVI, and 300M EU). They also reached a licensing deal with Chinese firm BioKangtai for 200M doses annually. However, blood clot concerns and manufacturing delays have tempered demand for this vaccine despite recent WHO guidance stating that the benefits of vaccination outweigh the risks for this candidate. The company has also faced legal battles from the EU for delayed shipment of doses, and the EU has not signed any additional contracts for doses beyond June 2021.
26. **ReiThera/Leukocare/Univercells (GRAd-COV2):** Recently completed enrollment of 900 participants in the Ph2 part of its Ph2/3 clinical trial in Italy. Both 1 and 2-dose regimens are being investigated in the Ph2/3 trial.
27. **ImmunityBio/NantKwest (Ad5COVID-S/N):** The company launched a US Ph1 trial in October and a Ph1 trial in South Africa. There were no SAEs observed during an initial safety review of the low-dose Ph1 cohorts. Interim Ph1b data demonstrated S and N specific T cell responses equivalent to those from previously infected convalescent SARS-CoV-2 patients. The company previously reported plans to build capacity for 100 million doses of vaccine by YE20 (delayed).
28. **Cansino Biologics (Ad5-nCoV):** Approved in China
29. **Gamaleya Research Institute:** The vaccine has since been authorized in 63 countries which altogether comprise a population of 3.2B people. Russia has recently authorized a single dose "Sputnick Light" version, that demonstrated 79.4% efficacy in data analyzed 28 days after the injection, to allow for larger number of immunizations in a shorter timeframe. Gamaleya have also recently suggested increasing the interval between

the first and second dose from 21 days to up to 3 months, which they claim will not effect efficacy, and may actually enhance or prolong it.

30. **Inovio/Beijing Advaccine Biotechnology (INO-4800):** Positive Ph2 trials recently read out informing the 2.0 mg dose given 4 weeks apart for Ph3 trials. Inovio also recently released data that showed INO-4800 induced a T cell response against all spike protein variants of concern, but had a reduction in neutralizing activity of 2-7x compared to WT.
31. **Genexine/Binex:** Recently signed a deal to supply vaccines to Indonesia
32. **Altimmune (AdCOVID)/Vigene Biosciences/UAB:** Moved to Human Trials; IND was approved in February 2021 and Ph1 trial enrollment has begun.
33. **Meissa Vaccines (MV-014-210):** Received IND clearance to begin Ph1 trials in March 2021.

VACCINE UPDATES
VERSION 13 UPDATES: FEBRUARY 12, 2021

NEW PROGRAMS ADDED (1):

1. **VIDO-InterVac at the University of Saskatchewan:** VIDO-InterVac was awarded $23M by the Canadian government to accelerate COVID-19 vaccine development and the University of Saskatchewan was awarded another $3.6M. Recently partnered with Dalton Pharma and Biodextris for manufacturing and fill-finish. Clinical trials launched Jan 2021.
2. **EpiVax/University of Georgia:** EPV-CoV-19 is a T cell epitope based vaccine entering the clinic April 2021. As a T cell directed vaccine, this candidate is designed to reduce the impact of severe COVID-19 disease, but is unlikely to provide sterilizing immunity, and efficacy from spike based approaches have limited read through here.

UPDATES TO EXISTING PROGRAMS (16):

1. **Novavax/Emergent BioSolutions:** Novavax reported topline efficacy data for its Ph3 trial in the United Kingdon and its Ph2b trial in South Africa, where two doses of its nanoparticle based COVID-19 vaccine (5 ug NVX-CoV2373 + 5 ug Matrix M adjuvant, 7 days after the second dose) achieved 96% vaccine efficacy against the original strain of COVID-19, 86% efficacy against the UK strain, and 60% efficacy against the SA strain. This is the first data we've gotten on the effectiveness of vaccines designed against the original SARS2 strain against new emerging variants, and it appears that they are less effective against at least the SA strain. Novavax has announced they will begin testing a next-gen vaccine 2Q21 this year designed against the new variants, in what may become a multivalent annual booster. The company expects the Ph3 UK trial to complete in the next 2-3 months, after which they will seek early use authorizations from multiple global government agencies. Novavax was awarded $1.6B from Operation Warp Speed to support large-scale manufacturing of candidate NVX-CoV2373 by FUJIFILM Diosynth Biotechnologies and fund clinical development. Together with their acquisition of Cyrus Poonawalla Group and their licensing agreement with the Serum Institute of India, Novavax is guiding to having 100M-150M doses/month this year and reach a total capacity of 2B doses annually. Other global manufacturing agreements include: a partnership with Takeda to support the production of over 250M annually for Japan, a development and supply agreement with SK Bioscience for global manufacturing of the antigen component and vaccine supply for South Korea, an agreement with the UK government to purchase 60M doses, and agreements in principle to supply up to 76M doses to Canada, 51 doses to Australia, and 10M doses to New Zealand.
2. **Sanofi:** Based on interim Ph1 results announced December 2020, , Sanofi's vaccine elicited an immune response comparable to recovered COVID-19 patients in adults age 18 to 49 but failed to elicit a strong response in older adults. The company will launch a Ph2b February 2021 to study an improved antigen formulation of their vaccine, which pushes back their global Ph3 to 2Q21, and potential approval 4Q21. As they work to refine their own vaccine candidate, Sanofi has pledged to support BioNTech and manufacture 125M doses of the Pfizer/BioNTech vaccine for the EU by summer 2021. Sanofi guided to producing 600M vaccine doses 2H21, and then scaling up to 1B doses annually by YE21. However, since protection requires 2 doses this is enough to vaccinate only 50M-300M people. Sanofi was recently awarded $2.1B by Operation Warp Speed to supply the US with 100M doses in 2021 with the option for up to 500M doses. Similarly, Sanofi has entered agreements with the UK to supply up to 60M doses, with Canada to supply 72M doses, with the EU to supply up to 300M doses in 2021, and with the World Health Organization to supply 200M equitable doses. Ph1/2 testing launched September 2020.
3. **Sinovac Biotech:** Inactivated vaccine candidate for which Ph2 data demonstrated induction of neutralizing

antibodies in above 90% of volunteers. Preclinically, NHP challenge experiment for SARS-CoV-2 demonstrated protection without enhancement, though doses seemed too high for efficient manufacturing. This program is run by the Chinese government and entered into a collaboration with the Brazilian Institute to initiate a Ph3 trial (committing 60M-100M doses through this agreement), in addition to a supply deal with Indonesia (committing 40M doses). This vaccine candidate was granted emergency use authorization in China August 2020 before Ph3 data. As of January 2021, there are three different efficacy rates attributed to this vaccine from various global sites: 50% Brazil (large trial), 91% Turkey (small trial), and 65% Indonesia (small trial). Sinovac currently has the capacity to produce ~100M doses annually and is aiming to triple capacity to ~300M doses in 2021.

4. **Medicago/Mitsubishi Tanabe:** Leveraging a plant-based vaccine production platform. Medicago initiated Ph2/3 trials in Nov 2020 after Ph1 data demonstrated modest neutralizing antibody titers (811 GMT with a low stringency 50% inhibition live virus assay) with the 3.75-ug dose that they are moving forward into further trials. The company has guided to supplying 120M doses annually by 2021, with plans to double production capacity in 2022, and ultimately achieve greater than 1 billion doses of COVID-19 vaccines per year in 2023 after they complete building their large-scale factory in Quebec. The company previously signed an agreement with the Government of Canada to supply 76M doses of its vaccine and will also receive $173M in funding to support research and development.

5. **ExpreS2ion Biotechnology/AdaptVac/Bavarian Nordic:** Partnered with Bavarian Nordic A/S, Europe's largest independent vaccine developer, and sponsored by EU's PREVENT-nCoV vaccine research consortium, this program submitted a Ph1 CTA January 2021. If successful, it is unlikely that the vaccine candidate will factor into global supply until the end of 2021 or even 2022.

6. **VBI Vaccines/National Research Council of Canada:** Enveloped VLP pan-coronavirus trivalent vaccine candidate targeting COVID-19, SARS, and MERS. VBI was recently awarded CAD $56M by the Canadian government to accelerate vaccine developments efforts through Ph2 testing. VBI selected two lead candidates to take into Ph1/2 1Q21 that generated robust neutralizing antibody titers in mice and hamsters.

7. **Clover Biopharmaceuticals:** This program recently published preclinical data in a nonhuman primate challenge model demonstrating that Clover's vaccine candidate elicited strong neutralizing antibody titers (in the 1000s), which reduced viral load in the lungs and nasal canal after challenge, but did not confer sterilizing immunity. Interestingly, GSK's adjuvant elicited a superior antibody response relative to Dynavax's adjuvant in this head-to-head comparison, but Clover has decided to move forward with the Dynavax adjuvant exclusively. Clover announced positive Ph1 clinical data December 2020 (titers in the 1000s-1800s), with plans to launch a Ph2/3 1H21. They have in-house 2x2000L bioreactor capacity, which could translate to "hundreds of millions of doses" annually. CEPI recently expanded its partnership with Clover by investing up to $328M (including $69.5M previously announced) to fund the company's vaccine through licensure, including manufacturing scale up.

8. **Kentucky Bioprocessing, Inc:** Kentucky Bioprocessing is a wholly owned subsidiary of British American Tobacco leveraging a plant-based vaccine production platform. The company plans to initiate Ph1 testing 1H21 with early data expected MY21 and has guided to having the capacity to produce 1M-3M vaccine doses/week, which would be roughly 150M doses/year.

9. **Covaxx:** Covaxx is a spinout company of United Biomedical Inc developing a synthetic RBD-Fc vaccine formulated with T-cell epitopes and a proprietary adjuvant. They achieved high neutralizing antibody titers in guinea pigs (>32,000) and entered Ph1 testing September 2020 in Taiwan. They have guided to producing 100M doses by 1Q21 with the capacity to scale up to 1B by YE21 and have entered a global distribution partnership with Maersk. Covaxx recently announced purchase commitments of more than 140 million doses to multiple countries, including Brazil, Ecuador, and Peru contingent on the success of their Ph2/3 to launch in Brazil. Following the emergence of new COVID virus mutations, Covaxx has initiated preclinical work to develop a second vaccine candidate against the South African mutation.

10. **Medigen/NIAID/Dynavax:** Ph2 testing initiated in Taiwan January 2021, with possible vaccine launch

3Q21. Concurrently, manufacturing and scale-up are planned to provide up to 200M doses by YE21. This program recently entered a partnership with Dynavax to supply CpG 1080 and Vaxess Technologies to develop a combination COVID-19 + seasonal influenza microneedle patch vaccine.

11. **IMV:** This program remains preclinical and clinical timelines are unclear (the company originally planned to begin Ph1 trials in Canada in MY20 and Ph2 by YE20). They were previously granted CAD $10M by the Canadian government to progress their candidate DPX-COVID-19 through Ph1.
12. **WRAIR/USAMRIID:** Clinical timelines unclear (originally projected to enter the clinic by Dec 2020). US Department of Defense-sponsored research effort. Historically focused on vaccines for military applications and has limited manufacturing.
13. **Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** Inactivated vaccine sponsored by the China National Pharmaceutical Group that entered Ph1/2 testing in April 2020. Early data from this trial demonstrated that participants generate relatively low levels of neutralizing antibodies (121-250 GMT with a low stringency PRNT50 assay), although they did not have a human convalescent comparator arm to benchmark these results to. The company has guided to supplying 1B doses in 2021. Sinopharm initiated a Ph3 trial in the UAE enrolling up to 15K volunteers and early data from this trial claims that the vaccine is 86% effective, although the company itself reported the vaccine is 79% effective. In September 2020, the UAE granted emergency use authorization for this vaccine candidate before clinical trials are complete, becoming the first program to be granted approval by a foreign country. More recently, Peru has suspended its Ph3 trial of Sinopharm's vaccine after a volunteer presented with serious neurological symptoms.
14. **Bharat Biotech International:** In Ph3 clinical testing with ViroVax's Alhydroxiquim-II adjuvant. Bharat Biotech reported that this vaccine has a "positive" reactogenicity profile and are collecting sera to study immunogenicity. The company expects their vaccine to broadly hit the market summer 2021 and has guided to producing 200M doses annually. Bharat Biotech was recently granted emergency use authorization by the Indian Central Drugs Standard Control Organization on the basis of non-human primate, Ph1, and Ph2 data. Ph3 data is expected to be available March 2021.
15. **Valneva:** Valneva launched Ph1/2 testing Dec 2020, with data expected 2Q21 and possible approval 2H21. They have recently reached an agreement with the UK to provide 100M doses 2H21 (purchased for 470M euros), with options for an additional 90M doses 2022-2025, which will be manufactured at its facilities in Livingston, Scotland and Solna, Sweden. In addition, Valneva is in advanced discussions to supply the EU with up to 60M doses. Dynavax will supply its adjuvant for this agreement.
16. **Moderna Therapeutics/Lonza:** Moderna has been granted EUA for their vaccine candidate in the US, UK, Canada, and several other countries after releasing primary efficacy data from their Ph3 efficacy trial demonstrating 94.1% vaccine efficacy 14 days after the second dose (in 196 COVID cases, with 30 severe cases in the placebo group, 33 older adults, and 42 participants from diverse communities) and 100% efficacy against severe disease. At this time, these data look equivalent to the efficacy generated by Pfizer/BioNtech's vaccine candidate (95% vaccine efficacy 7 days after the second dose) and we await further data readouts to assess durability of protection, protection after the first or second dose, and granular safety/efficacy breakdown between different subgroups. The biggest differentiating factor here is Moderna's cold chain storage advantage, as their vaccine can be stored at -20C, while the Pfizer/BioNtech candidate requires -70C storage. Moderna has guided to supplying 500M - 1B doses annually (100M in 1Q21 and 200M in 2Q21) and has committed 300M to the US (with the option of an additional 200M), 160M to the EU, 50M to Japan, 40M to Canada, and 40M to South Korea. They were awarded $56M by DARPA to develop a small-scale, mobile platform to enable fast, in-field automated manufacturing and deployment and are recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work. The company has an ongoing Ph2/3 study in adolescents (data expected Spring 2021).
17. **BioNTech/Pfizer:** Pfizer/BioNtech have been granted EUA for their vaccine candidate in the US, EU, UK, Canada, and several other countries after completing their Ph3 trial demonstrating 95% efficacy 7 days after

the second dose (in 170 COVID cases, 9 severe cases in the placebo group and 1 in the vaccine arm). These results provide validation for vaccines targeting the Spike protein and greatly surpass the benchmark set by the FDA (50% vaccine efficacy). Pfizer/BioNtech are guiding to manufacturing scaling up to 2B doses in 2021 with the recent acquisition of a GMP facility in Germany and manufacturing supply agreements for 200M doses to the US (with the option of an additional 400M), 300M to the EU (with the option of an additional 200M), 120M to Japan, 100M to China, 30M to the UK, and 40M to COVAX (purchased at a not-for-profit cost). Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work and awarded 375M euros by the German Federal Ministry of Education and Research to advance vaccine development.

18. **CureVac/Bayer:** Curevac recently initiated a 35,000 participant global Ph2b/3 study and a 2,500 participant Ph3 trial in Germany, both in January 2021. Based on interim immunogenicity data generated from their Ph1 trial, the 12-ug dose of their vaccine candidate (which they intend to take into Ph2/3 possibly YE20) generates neutralizing antibodies equivalent to a panel of human convalescent control sera (1:113, microneutrlaization assay). The company announced that they are in advanced talks with the EU to supply 225M doses of their vaccine candidate MY21, with an option for 180M more. CureVac has signed a manufacturing contract with Wacker Chemie AG and plans to begin production 1H21 at 100M doses/year. Curevac recently entered an agreement with Bayer, which will support further development, supply, and key territory operations of CureVac's vaccine candidate. The company was previously awarded 252M euros by the German Federal Ministry of Education and Research to advance vaccine development.

19. **Translate Bio/Sanofi:** Clinical timelines are unclear as Sanofi has not provided an update on this vaccine candidate. Previously released preclinical NHP data in Oct 2020 demonstrated peak neutralizing antibody titers of 1,877, which places this vaccine in the middle of the pack for RNA candidates. Pfizer/BioNTech (GMT 962) and Moderna (GMT 3481), which both used similar assays to Sanofi (50% inhibition live virus assay), observed similar neutralizing antibody titers in human convalescent serum (GMT 41-94). Translate Bio has established 100g single-batch production with its clinical-stage mRNA therapeutics platform and build-out of dedicated manufacturing space, initiated through a contract manufacturing partner to accommodate at least two 250-gram batches/month.

20. **eTheRNA:** Clinical timelines are unclear for this program. TriMix mRNA technology is designed to enhance T-cell responses (caTLR4, CD40L, and CD70) to its vaccine candidate. Recently granted 35M euros ($38M) to fund its mRNA platform, including its Covid-19 program.

21. **Arcturus/Duke University:** Arcturus was recently cleared to initiate a 600 participant Ph2 trial in the US/Singapore and anticipate interim data from this trial 1H21. Arcturus is targeting a global Ph3 trial to start 2Q21 with EUA as early as 1H21. The company previously announced topline results from a Ph1/2 trial in Singapore demonstrating that a single dose of their vaccine candidate generates neutralizing antibodies in the same range as human convalescent control (GMT 1:147). Preclinical studies demonstrated that a single 2-µg dose of their LUNAR-COV19 vaccine provided immunity (seroconversion in 100% of animals vs 0% at this dose for standard mRNA). Arcturus signed a partnership with Catalent to help them scale up to 100M doses in 2021. Recently signed an agreement with CDMO Recipharm to support manufacturing, but have not provided additional dosing guidance.

22. **Imperial College London:** Recently announced that they will be refocusing the program on boosters and targeting emerging variants. Secured £22.5 ($28M) in funding from the UK government. The funding will help them move through Ph1 trial, which started in June 2020. Unclear what partnerships they would seek to scale up manufacturing.

23. **JNJ/Emergent Biosolutions:** Topline Ph3 data from the single-dose global trial being run in multiple countries demonstrated that JnJ's Ad26 vaccine is 72% effective against the original strain of COVID, 66% effective in Latin America, and 57% effective in South Africa 28 days post vaccination. Importantly, the vaccine was 85% effective in preventing severe COVID-19 and the company expects to file for EUA with the FDA February 2021. BARDA committed $454M to support this and a concurrent Ph3 trial implementing a 2-dose regimen that began in November. Ad26 is less common than Ad5 so risk of pre-existing immunity is lower.

They have a large manufacturing capacity and are targeting 1B doses on a not-for-profit basis (with 100M doses pledged to the US and 200M pledged to the EU with an option for 200M additional). Recently signed a $480M, five-year manufacturing agreement with Emergent Biosolutions to manufacture its COVID-19 vaccine.

24. **ASTRAZENECA/Vaccitech/ University of Oxford:** Recent topline data from the Ph3 efficacy trial demonstrated that Astrazeneca's vaccine was 70% effective on average, 90% in a subpopulation of volunteers (n = 2,741) who received a half dose followed by the full dose of the vaccine 1 month later and 62% effective (n = 8,895) in the population who received two full doses. It is not immediately clear why the lower dose regimen generated superior vaccine efficacy, but it is unsurprising that these data on average appear inferior to mRNA vaccines based on the Ph1 immunogenicity profiles of these programs. AstraZeneca's vaccine has a logistical advantage (can be shipped at stored at 2-8oC) and the company has signed agreements to provide hundreds of millions of doses to be delivered starting YE20 (100M UK, 300M US, 400M Serum Institute of India to provide for poorer countries, 300M CEPI/GAVI, and 300M EU). They also reached a licensing deal with Chinese firm BioKangtai for 200M doses annually. Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work. As of January 2021, AstraZeneca's vaccine has been granted EUA in the UK, India, and the EU but has not announced clear timelines to file with the FDA yet.

25. **ImmunityBio/NantKwest:** First dual antigen (both spike and nucleocapsid proteins) vectorized vaccine candidate. The company recently released NHP data demonstrating a neutralizing antibody response in 9/10 NHPs using a low stringency 20% inhibition assay (no GMTs were reported) and complete protection in the lungs and nose 7 days post-challenge. They launched a US Ph1 trial in October and recently announced a Ph1 trial in South Africa. There were no SAEs observed during an initial safety review of the low-dose Ph1 cohorts. The company previously reported plans to build capacity for 100 million doses of vaccine by YE20.

26. **Cansino Biologics:** Published Ph1 trial results demonstrated that ~50% of participants have pre-existing immunity to Ad5, which greatly impedes immunogenicity and makes this vaccine candidate less relevant for the broader population. Low levels of neutralizing antibodies were reproduced in their expanded Ph2 cohort, signaling that this vaccine may not provide strong protection. The company started a Ph3 trial November 2021 in Mexico, Russia, Pakistan, Brazil, and Chile and we expect Ph3 efficacy results February 2021. China has approved this vaccine for military use and while current in-house manufacturing capacity sits at 80M doses annually, a new factory under construction in China will allow the production of 100-200M doses/year starting 1H21. Cansino has a 35M dose advance purchase agreement with Mexico. In August the National Research Council of Canada announced that collaboration with CanSino ended upon delays in vaccine shipments. At the same time, CanSino has entered talks with several countries to get emergency use authorization for its COVID-19 candidate. Concurrently, they are initiating a Ph1 trial of a two-dose regimen for this vaccine after concerns were raised by the scientific community about the limited efficacy of this vaccine.

27. **Gamaleya Research Institute:** Gamaleya started Ph1 trials 2Q20 for their adenovirus based vaccine (now called Sputnik V) and applied for conditional registration on August 12th, before any efficacy data was presented. Based on Ph1 immunogenicity data, neutralizing antibody titers are similar to other adenovirus vaccines. However, a global group of scientists have called into question the reliability of these data after highly unlikely data patterns were identified throughout the publication. Russia recently published Ph3 data demonstrating 91.6% efficacy with 78 cases and has submitted a certification request to the WHO. While Russia expected to produce between 2 and 10 million doses of this vaccine in 2020 manufacturing projections for 2021 are premature at this time and Russia is in early negotiations with other countries to license the use of this vaccine.

28. **Zydus Cadila:** Large Indian pharmaceutical company that was awarded funding by the Indian Department of Biotechnology to develop a COVID-19 vaccine. DCGI recently approved a 30k participant Ph3 study for this candidate. The company previously initiated a Ph2 trial 3Q20 and is guiding towards 100M doses annually starting 2Q21.

29. **Genexine/Binex:** Small Korean biotech companies without the manufacturing capacity to supply beyond the Korean domestic market. Initiated Ph1/2 trials in June but has not yet released data. The company has recently guided that Ph2/3 efficacy trials could start 1H21, which would make 2H21 the earliest timeframe for

approval.

30. **Osaka University/AnGes/Takara:** This Japanese program entered the clinic in summer 2020. They are focused on the Japanese domestic market with approval projected for MY21.
31. **Altimmune (AdCOVID)/Vigene Biosciences/UAB:** The FDA has placed a hold on the planned Ph1 trial due to protocol and chemistry, manufacturing, and controls (CMC) data issues. The company is scaling up manufacturing to reach 100M doses annually with Vigene Biosciences and Lonza. They recently presented preclinical data at the World Vaccine Conference, demonstrating the generation of neutralizing titers in mice.
32. **Vaxart/Emergent Biosolutions/Kindred Biosciences:** Vaxart recently announced Ph1 data demonstrating that their oral vaccine was able to elicit a mucosal IgA immune response in the nasal cavity and a CD8 T cell response against the Spike protein. However, at variance with all other Ph3 programs in which efficacy data included generation of systemic neutralizing antibodies, Vaxart did not detect any neutralizing antibodies in participants' sera and IgG responses were not detected in most subjects, raising concerns that the success of other Ph3 programs will have limited read through to Vaxart. The company has a development agreement with Emergent BioSolutions to prepare bulk cBMP oral COVID-19 vaccine. They have also contracted KindredBio to manufacture its lead vaccine candidate at a large scale. Selected by Operation Warp Speed to participate in a NHP challenge study
33. **Merck/Institut Pasteur/University of Pittsburgh:** Discontinued due to poor immune response. Consortium headed by the Institute Pasteur and backed by CEPI. The University of Pittsburgh developed the candidate, while Merck (which acquired Themis) was responsible for supporting the clinical trial and manufacturing. Ph1 dosing started in Belgium September 2020.
34. **University of Hong Kong:** Clinical timeline is unclear (the company originally expected to start clinical trials in July 2020). Awarded $620K by CEPI. No partners declared yet but will likely rely on manufacturers in mainland China.
35. **University of Wisconsin-Madison/FluGen/Bharat Biotech International:** Clinical timeline is unclear (the company originally expected to start clinical trials in Fall 2020). Bharat Biotech can produce 300 million doses/year.
36. **Merck/International AIDS Vaccine Initiative:** Discontinued. Previously recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.
37. **Symvivo:** No clinical timeline since this company launched a Ph1 clinical trail in 2Q20. They have received funding of up to $2.8M from the National Research Council of Canada Industrial Research Assistance Program (NRC IRAP) and recently announced a collaboration with Merck, which receives option for exclusive license to Symvivo's bacTRL platform technology.

VACCINES:
VERSION 12 UPDATES: DECEMBER 22, 2020

UPDATES TO EXISTING PROGRAMS (16):

1. **Novavax/Emergent BioSolutions:** Novavax reported Ph1/2 RCT data for two doses (5 ug and 25 ug) of NVX-CoV2373 + 50 ug of its Matrix-M adjuvant. Neutralizing antibody titers were the highest produced by any vaccine candidate to date (3906 GMT, assessed by a stringent 100% inhibition live virus assay) and the tolerability profile was largely superior to other published COVID vaccine candidates, as well as common marketed common flu vaccines. The Ph2 portion of trial started August 2020 and reactogenicity data from this study demonstrated that NVX-CoV2373 is well tolerated in an expanded adult population, including elderly patients. Novavax was awarded $1.6B from Operation Warp Speed to support large-scale manufacturing of candidate NVX-CoV2373 by FUJIFILM Diosynth Biotechnologies and fund clinical development. A Ph3 RCT started recruiting September 2020 in the UK and a second Ph3 RCT is expected to start in the US/Mexico December 2020, with efficacy data expected early 1Q21 followed by rapid submission. Together with their acquisition of Cyrus Poonawalla Group, Novavax is guiding to having 100M doses ready by late 2020 and reach 1B doses/year run rate by YE21. The company recently entered an exclusive licensing agreement with the Serum Institute of India to support an additional 1B doses for India and low- and middle-income countries, a partnership with Takeda to support the production of over 250M annually for Japan, a development and supply agreement with SK Bioscience for global manufacturing of the antigen component and vaccine supply for South Korea, an agreement with the UK government to purchase 60M doses, and agreements in principle to supply up to 76M doses to Canada and up to 40M doses to Australia.
2. **University of Queensland/CSL Behring:** This technology leverages a molecular clamp to stabilize the viral antigen. Based on early Ph1 data announced December 2020, the University of Queensland and CSL will discontinue Ph2/3 development of this vaccine, due to false positive results to HIV tests that participants received against fragments of a protein (gp41) used to stabilize the vaccine. Although the vaccine clearly doesn't cause HIV infection, re-enginering the vaccine to prevent interference with well-established HIV testing procedures would take 12 months, and both groups have elected not to pursue this option.
3. Sanofi: Sanofi guided to producing 600M vaccine doses 2H21, and then scaling up to 1B doses annually by YE21. However, since protection requires 2 doses this is enough to vaccinate only 50M-300M people. Sanofi was recently awarded $2.1B by Operation Warp Speed to supply the US with 100M doses in 2021 with the option for up to 500M doses. Similarly, Sanofi has entered agreements with the UK to supply up to 60M doses, with Canada to supply 72M doses, with the EU to supply up to 300M doses in 2021, and with the World Health Organization to supply 200M equitable doses. Ph1/2 testing launched September 2020. Based on interim results announced December 2020, Sanofi's vaccine elicited an immune response comparable to recovered COVID 19 patients in adults age 18 to 49 but failed to elicit a strong response in older adults. Sanofi will launch a Ph2b February 2021 to study an improved antigen formulation of their vaccine, which pushes back their global Ph3 to 2Q21, and potential approval 4Q21.
4. **Sinovac Biotech (PiCoVacc):** Inactivated vaccine candidate for which preliminary Ph2 data were recently reported and demonstrated induction of neutralizing antibodies in above 90% of volunteers. Preclinically, NHP challenge experiment for SARS-CoV-2 demonstrated protection without enhancement, though doses seemed too high for efficient manufacturing. This program is run by the Chinese government and entered into a collaboration with the Brazilian Institute to initiate a Ph3 trial (committing 60M-100M doses through this agreement), in addition to a supply deal with Indonesia (committing 40M doses). Although immunogenicity data from this trial had not yet been published, this vaccine candidate was granted emergency use authorization in China August 2020, with an efficacy readout expected January 2021, and entry into a Ph1/2

pediatric trial shortly thereafter. The Ph3 recently resumed after a temporary suspension due to a serious adverse event that was later found to be unrelated to the vaccine. Sinovac currently has the capacity to produce ~100M doses annually and is aiming to triple capacity to ~300M doses in 2021.

5. **Clover Biopharmaceuticals:** This program recently published preclinical data in a nonhuman primate challenge model demonstrating that Clover's vaccine candidate elicited strong neutralizing antibody titers (in the 1000s), which reduced viral load in the lungs and nasal canal after challenge, but did not confer sterilizing immunity. Interestingly, GSK's adjuvant elicited a superior antibody response relative to Dynavax's adjuvant in this head-to-head comparison. Clover announced positive Ph1 clinical data December 2020 (titers in the 1000s-1800s), with plans to launch a Ph2/3 by YE20. They have in-house 2x2000L bioreactor capacity, which could translate to "hundreds of millions of doses" annually. CEPI recently expanded its partnership with Clover by investing up to $328M (including $69.5M previously announced) to fund the company's vaccine through licensure, including a global Ph2/3 starting by YE20 and manufacturing scale up.

6. **Covaxx:** Covaxx is a spinout company of United Biomedical Inc developing a synthetic RBD-Fc vaccine formulated with T-cell epitopes and a proprietary adjuvant. They achieved high neutralizing antibody titers in guinea pigs (>32,000) and entered Ph1 testing September 2020 in Taiwan. They have guided to producing 100M doses by 1Q21 with the capacity to scale up to 1B by YE21 and have entered a global distribution partnership with Maersk. Covaxx recently announced purchase commitments of more than 140 million doses to multiple countries, including Brazil, Ecuador, and Peru contingent on the success of their Ph2/3 to launch in Brazil.

7. **Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** Inactivated vaccine sponsored by the China National Pharmaceutical Group that entered Ph1/2 testing in April 2020. Early data from this trial demonstrated that participants generate relatively low levels of neutralizing antibodies (121-250 GMT with a low stringency PRNT50 assay), although they did not have a human convalescent comparator arm to benchmark these results to. The company has guided to supplying 1B doses in 2021. Sinopharm initiated a Ph3 trial in the UAE enrolling up to 15K volunteers and early data from this trial claims that the vaccine is 86% effective. In September 2020, the UAE granted Emergency Use Authorization for this vaccine candidate before clinical trials are complete, becoming the first program to be granted approval by a foreign country. More recently, Peru has suspended its Ph3 trial of Sinopharm's vaccine after a volunteer presented with serious neurological symptoms.

8. **Bharat Biotech International (Covaxin):** Recently entered Ph3 clinical testing and will use ViroVax's Alhydroxiquim-II adjuvant. They reported that this vaccine has a "positive" reactogenicity profile and are collecting sera to study immunogenicity. The company expects their vaccine to hit the market summer 2021 and has guided to producing 200M doses annually. Bharat Biotech recently applied to the Indian Central Drugs Standard Control Organization for emergency authorization for their vaccine based on non-human primate, Ph1, and Ph2 data, but the committee requested additional safety/efficacy data from ongoing Ph3 studies.

9. **Altimmune (AdCOVID)/Vigene Biosciences/UAB:** NDA submitted and Ph1 set to start 4Q20 with topline safety and serology data expected 2021. The company is scaling up manufacturing to reach 100M doses annually with Vigene Biosciences and Lonza. They recently presented preclinical data at the World Vaccine Conference, demonstrating the generation of neutralizing titers in mice.

10. **Codagenix/Serum Institute of India:** Codagenix launched a Ph1 clinical trial for their vaccine candidate COVI-VAC in the UK December 2020. Late stage clinical testing is expected to begin MY21. Their partnership with the Serum Institute of India provides manufacturing capacity on the scale of hundreds of millions of doses.

11. **JNJ/Emergent Biosolutions:** While their lead candidate failed to provide sterilizing immunity in an NHP model, it did provide protection from severe disease. Ph1/2 trial started July 2020, the Ph2 portion initiated the first week of September in Europe. BARDA has committed $454M to support the ongoing Ph3 trial which started in late September after positive Ph1/2a interim results and is planned to enroll up to 60K participants across 3 continents. This trial resumed after being put on pause due to the unexpected illness in one participant, although details from this case have not been disclosed, and a concurrent Ph3 trial of a 2-dose

regimen started in November. Enrollment was recently scaled down to 40K due to the high attack rate in the US, with topline data slated for end of January 2021. Ad26 is less common than Ad5 so risk of pre-existing immunity is lower. They have a large manufacturing capacity and are targeting 1B doses on a not-for-profit basis (with 100M doses pledged to the US and 200M pledged to the EU with an option for 200M additional). Recently signed a $480M, five-year manufacturing agreement with Emergent Biosolutions to manufacture its COVID-19 vaccine.

12. **ImmunityBio/NantKwest (Ad5COVID-S/N):** First dual antigen (both spike and nucleocapsid proteins) vectorized vaccine candidate. The company recently released NHP data demonstrating a neutralizing antibody response in 9/10 NHPs using a low stringency 20% inhibition assay (no GMTs were reported) and complete protection in the lungs and nose 7 days post-challenge. They launched a US Ph1 trial in October and plan to have capacity for 100 million doses of vaccine by YE20. There were no SAEs observed during an initial safety review of the low-dose Ph1 cohorts.

13. **Moderna Therapeutics/Lonza (mRNA-1273):** Moderna released primary efficacy data from their Ph3 efficacy trial and reported 94.1% vaccine efficacy 14 days after the second dose (in 196 COVID cases, with 30 severe cases in the placebo group, 33 older adults, and 42 participants from diverse communities) and 100% efficacy against severe disease. At this time, these data look equivalent to the efficacy generated by Pfizer/BioNtech's vaccine candidate (95% vaccine efficacy 7 days after the second dose) and we await further data readouts to assess durability of protection, protection after the first or second dose, and granular safety/efficacy breakdown between different subgroups. The biggest differentiating factor here is Moderna's cold chain storage advantage, as their vaccine can be stored at -20C, while the Pfizer/BioNtech candidate requires -70C storage. Moderna's recent EUA filing with the FDA which will be discussed during a Dec 17th advisory committee. Moderna has also initiated rolling submissions with the UK and Canada. Moderna has guided to supplying 500M - 1B doses annually (20M by YE20) and has committed 200M to the US (with the option of an additional 300M), 80M to the EU (with the option of an additional 80M), 40M to Canada, and 50M to Japan. They were awarded $56M by DARPA to develop a small-scale, mobile platform to enable fast, in-field automated manufacturing and deployment and are recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work. The company recently started a Ph2/3 study in adolescents (data expected Spring 2021).

14. **BioNTech/Pfizer (BNT162):** Pfizer/BioNtech have been granted EUA for their vaccine candidate in the US, UK, Canada, and several other countries after completing their Ph3 trial demonstrating 95% efficacy 7 days after the second dose (in 170 COVID cases, 9 severe cases in the placebo group and 1 in the vaccine arm). The companies have also formally submitted for CMA and are expecting a decision by YE20. These results provide validation for vaccines targeting the Spike protein and greatly surpass the benchmark set by the FDA (50% vaccine efficacy). Pfizer/BioNtech are guiding to manufacturing 50M doses by YE20, scaling up to 2B doses in 2021 with the recent acquisition of a GMP facility in Germany and manufacturing supply agreements with the UK (60M), the US (100M-600M), the EU (200M), and Japan (120M). Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work and awarded 375M euros by the German Federal Ministry of Education and Research to advance vaccine development.

15. **CureVac:** This program is in Ph1 testing in Germany and Belgium and initiated a Ph2a trial September 2020 in Panama and Peru. Based on interim immunogenicity data generated from their Ph1 trial, the 12-ug dose of their vaccine candidate (which they intend to take into Ph2/3 possibly YE20) generates neutralizing antibodies equivalent to a panel of human convalescent control sera (1:113, microneutrlaization assay). The company announced that they are in advanced talks with the EU to supply 225M doses of their vaccine candidate MY21, with an option for 180M more. CureVac has signed a manufacturing contract with Wacker Chemie AG and plans to begin production 1H21 at 100M doses/year. Recently awarded 252M euros by the German Federal Ministry of Education and Research to advance vaccine development.

16. **Inovio/Beijing Advaccine Biotechnology (INO-4800):** Announced that they should have 1M doses available by YE20 and that they are working to scale up to hundreds of millions in capacity pending future funding and investment. Recent data from an NHP challenge model demonstrated that INO-4800 did not

provide complete protection in the lungs or nasal cavity against COVID-19, which is a weak signal moving into clinical trials. From the Ph1 trial, 94% (34/36) volunteers seroconverted but no additional data have been released. Ph2 trials have recently started dosing in the US and China, but the Ph3 segment is on partial hold by the FDA due to additional questions around the CELLECTRA 2000 delivery device. Inovio must await FDA partial hold clearance and Ph2 results before initiating the Ph3. Inovio was granted $71M from the DoD to support manufacturing of their intradermal DNA delivery device. Selected by Operation Warp Speed to participate in a NHP challenge study

VACCINES:
VERSION 11 UPDATES: NOVEMBER 25, 2020

UPDATES TO EXISTING PROGRAMS (19):

1. **Novavax/Emergent BioSolutions:** Novavax reported Ph1/2 RCT data for two doses (5 ug and 25 ug) of NVX-CoV2373 + 50 ug of its Matrix-M adjuvant. Neutralizing antibody titers were the highest produced by any vaccine candidate to date (3906 GMT, assessed by a stringent 100% inhibition live virus assay) and the tolerability profile was largely superior to other published COVID vaccine candidates, as well as common marketed common flu vaccines. The Ph2 portion of trial started August 2020 and reactogenicity data from this study demonstrated that NVX-CoV2373 is well tolerated in an expanded adult population, including elderly patients. Novavax was awarded $1.6B from Operation Warp Speed to support large-scale manufacturing of candidate NVX-CoV2373 by FUJIFILM Diosynth Biotechnologies and fund clinical development. A Ph3 RCT started recruiting September 2020 in the UK and a second Ph3 RCT is expected to start in the US/Mexico November 2020, with efficacy data expected early 1Q21 followed by rapid submission. Together with their acquisition of Cyrus Poonawalla Group, Novavax is guiding to having 100M doses ready by late 2020 and reach 1B doses/year run rate by YE21. The company recently entered an exclusive licensing agreement with the Serum Institute of India to support an additional 1B doses for India and low- and middle-income countries, a partnership with Takeda to support the production of over 250M annually for Japan, a development and supply agreement with SK Bioscience for global manufacturing of the antigen component and vaccine supply for South Korea, an agreement with the UK government to purchase 60M doses, and agreements in principle to supply up to 76M doses to Canada and up to 40M doses to Australia.
2. **Sinovac Biotech (PiCoVacc):** Inactivated vaccine candidate for which preliminary Ph2 data were recently reported and demonstrated induction of neutralizing antibodies in above 90% of volunteers. Preclinically, NHP challenge experiment for SARS-CoV-2 demonstrated protection without enhancement, though doses seemed too high for efficient manufacturing. This program is run by the Chinese government and entered into a collaboration with the Brazilian Institute to initiate a Ph3 trial (committing 60M-100M doses through this agreement), in addition to a supply deal with Indonesia (committing 40M doses). Although immunogenicity data from this trial have not yet been published, this vaccine candidate was granted emergency use authorization in China August 2020, with an efficacy readout expected November 2020, and entry into a Ph1/2 pediatric trial shortly thereafter. The Ph3 recently resumed after a temporary suspension due to a serious adverse event that was later found to be unrelated to the vaccine. Sinovac currently has the capacity to produce ~100M doses annually and is aiming to triple capacity to ~300M doses largely for domestic supply in 2021.
3. **Medicago/Mitsubishi Tanabe:** Leveraging a plant-based vaccine production platform. Medicago recently released Ph1 data demonstrating modest neutralizing antibody titers (811 GMT with a low stringency 50% inhibition live virus assay) with the 3.75-ug dose for which they plan to move forward in clinical trials. Ph2 trials are expected to start in November with Ph3 following shortly thereafter in December. The company has guided to supplying 120M doses annually by 2021, with plans to double production capacity in 2022, and ultimately achieve greater than 1 billion doses of COVID-19 vaccines per year in 2023 after they complete building their large-scale factory in Quebec. The company recently signed an agreement with the Government of Canada to supply 76M doses of its vaccine and will also receive $173M in funding to support research and development.
4. **Clover Biopharmaceuticals:** This program recently published preclinical data in a nonhuman primate challenge model demonstrating that Clover's vaccine candidate elicited strong neutralizing antibody titers (in the 1000s), which reduced viral load in the lungs and nasal canal after challenge, but did not confer sterilizing immunity. Interestingly, GSK's adjuvant elicited a superior antibody response relative to Dynavax's adjuvant in this head-to-head comparison. Ph1 clinical trials started 2Q20 with initial data expected 4Q20. They have

in-house 2x2000L bioreactor capacity, which could translate to "hundreds of millions of doses" annually. CEPI recently expanded its partnership with Clover by investing up to $328M (including $69.5M previously announced) to fund the company's vaccine through licensure, including a global Ph2/3 starting by YE20 and manufacturing scale up.

5. **Baylor College of Medicine/Biological E:** Ph1/2 trial started in Nov 2020 with results expected Feb 2021. Baylor College of Medicine licensed their subunit vaccine candidate to Biological E to help manufacture and develop. Biological E expects to manufacture hundreds of million doses annually, although little information about this program is available within the public domain.
6. **VIDO-InterVac at the University of Saskatchewan:** VIDO-InterVac was awarded $23M by the Canadian government to accelerate COVID-19 vaccine development and the University of Saskatchewan was awarded another $3.6M. Recently partnered with Dalton Pharma and Biodextris for manufacturing and fill-finish. Clinical trials are expected to start by Jan 2021.
7. **Bharat Biotech International (Covaxin):** Recently entered Ph3 clinical testing and will use ViroVax's Alhydroxiquim-II adjuvant. They reported that this vaccine has a "positive" reactogenicity profile and are collecting sera to study immunogenicity. The company expects their vaccine to hit the market summer 2021 and has guided to producing 200M doses annually
8. **Altimmune (AdCOVID)/Vigene Biosciences/UAB:** Ph1 set to start 4Q20 with topline safety and serology data expected 2021. The company is scaling up manufacturing to reach 100M doses annually with Vigene Biosciences and Lonza. They recently presented preclinical data at the World Vaccine Conference, demonstrating the generation of neutralizing titers in mice.
9. **JNJ/Emergent Biosolutions:** While their lead candidate failed to provide sterilizing immunity in an NHP model, it did provide protection from severe disease. Ph1/2 trial started July 2020, the Ph2 portion initiated the first week of September in Europe and the Ph3 started in late September after positive Ph1/2a interim results and is planned to enroll up to 60K participants across 3 continents. BARDA has committed $454M to support the ongoing Ph3 trial. This trial has resumed after being put on pause due to the unexpected illness in one participant, although details from this case have not been disclosed. A concurrent Ph3 trial of a 2-dose regimen started in November. Ad26 is less common than Ad5 so risk of pre-existing immunity is lower. They have a large manufacturing capacity and are targeting 1B doses on a not-for-profit basis (with 100M doses pledged to the US and 200M pledged to the EU with an option for 200M additional). Recently signed a $480M, five-year manufacturing agreement with Emergent Biosolutions to manufacture its COVID-19 vaccine.
10. **Astrazeneca/Vaccitech/University of Oxford:** Ph3 clinical trials for this vaccine candidate resumed everywhere after a clinical hold was triggered by a possible case of transverse myelitis. Although AstraZeneca has not released any medical details about this situation, they do report that an independent review deemed the safety signal was not likely associated to the vaccine itself, although there is insufficient evidence to say for certain. Recent topline data from this Ph3 efficacy trial demonstrated that Astrazeneca's vaccine was 70% effective on average, 90% in a subpopulation of volunteers (n = 2,741) who received a half dose followed by the full dose of the vaccine 1 month later and 62% effective (n = 8,895) in the population who received two full doses. It is not immediately clear why the lower dose regimen generated superior vaccine efficacy, but it is unsurprising that these data on average appear inferior to mRNA vaccines based on the Ph1 immunogenicity profiles of these programs. AstraZeneca's vaccine has a logistical advantage (can be shipped at stored at 2-8oC) and the company has signed agreements to provide hundreds of millions of doses to be delivered starting YE20 (100M UK, 300M US, 400M Serum Institute of India to provide for poorer countries, 300M CEPI/GAVI, and 300M EU). They also reached a licensing deal with Chinese firm BioKangtai for 200M doses annually. Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.
11. **ImmunityBio/NantKwest (Ad5COVID-S/N):** First dual antigen (both spike and nucleocapsid proteins) vectorized vaccine candidate. They launched a US Ph1 trial in October and plan to have capacity for 100 million doses of vaccine by YE20. There were no SAEs observed during an initial safety review of the low-dose Ph1 cohorts.

12. **Cansino Biologics (Ad5-nCoV):** Publication of Ph1 trial results demonstrated that ~50% of participants have pre-existing immunity to Ad5, which greatly impedes immunogenicity and makes this vaccine candidate less relevant for the broader population. Low levels of neutralizing antibodies were reproduced in their expanded Ph2 cohort, signaling that this vaccine may not provide strong protection. The company started a Ph3 trial in Mexico in November and plans to soon expand in Russia, Pakistan, Brazil, and Chile. China has approved this vaccine for military use and while current in-house manufacturing capacity sits at 80M doses annually, a new factory under construction in China will allow the production of 100-200M doses/year starting 1H21. Cansino has a 35M dose advance purchase agreement with Mexico. In August the National Research Council of Canada announced that collaboration with CanSino ended upon delays in vaccine shipments. At the same time, CanSino has entered talks with several countries to get emergency use authorization for its COVID-19 candidate. Concurrently, they are initiating a Ph1 trial of a two-dose regimen for this vaccine after concerns were raised by the scientific community about the limited efficacy of this vaccine.

13. **Gamaleya Research Institute:** Gamaleya started Ph1 trials 2Q20 for their adenovirus based vaccine (now called Sputnik V) and applied for conditional registration on August 12th, before any efficacy data was presented. Based on Ph1 immunogenicity data, neutralizing antibody titers are similar to other adenovirus vaccines. However, a global group of scientists have called into question the reliability of these data after highly unlikely data patterns were identified throughout the publication. Russia recently announced that this vaccine has achieved 92% vaccine efficacy in a Ph3 trial on the basis of 20 COVID cases and has submitted a certification request to the WHO. While Russia expects between 2 and 10 million doses of this vaccine to be produced by the end of the year, manufacturing projections for 2021 are premature at this time and Russia is in early negotiations with other countries to license the use of this vaccine.

14. **Moderna Therapeutics/Lonza (mRNA-1273):** Moderna released topline data from their Ph3 efficacy trial and reported 94.5% vaccine efficacy 14 days after the second dose (in 95 COVID cases, with 11 severe cases in the placebo group, 15 older adults, and 20 participants from diverse communities). At this time, these data look equivalent to the efficacy generated by Pfizer/BioNtech's vaccine candidate (95% vaccine efficacy 7 days after the second dose) and we await further data readouts to assess durability of protection, protection after the first or second dose, and granular safety/efficacy breakdown between different subgroups. The biggest differentiating factor here is Moderna's cold chain storage advantage, as their vaccine can be stored at -20C, while the Pfizer/Biontech candidate requires -70C storage. Moderna has guided to supplying 500M - 1B doses annually (20M by YE20) and has committed 100M to the US (with the option of an additional 400M), 80M to the EU, and 50M to Japan. They were awarded $56M by DARPA to develop a small-scale, mobile platform to enable fast, in-field automated manufacturing and deployment and are recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work. Moderna has initiated rolling submissions with the UK and Canada and intends to file for EUA with the FDA after completing their final analysis (151 COVID cases, and a median follow-up of more than 2 months)

15. **BioNTech/Pfizer (BNT162):** Pfizer/BioNtech completed the final efficacy analysis of their Ph3 trial and demonstrated that their vaccine is 95% efficacious 7 days after the second dose (in 170 COVID cases, 9 severe cases in the placebo group and 1 in the vaccine arm). These results provide validation for vaccines targeting the Spike protein and greatly surpass the benchmark set by the FDA (50% vaccine efficacy). Pfizer/BioNtech are the first vaccine developer to submit a EUA request to the FDA, which could be granted as early as 3-4 weeks from submission. The FDA will host an Adcom early in December to assess these data for approval. Pfizer/BioNtech are guiding to manufacturing 50M doses by YE20, scaling up to 2B doses in 2021 with the recent acquisition of a GMP facility in Germany and manufacturing supply agreements with the UK (60M), the US (100M-600M), the EU (200M), and Japan (120M). Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work and awarded 375M euros by the German Federal Ministry of Education and Research to advance vaccine development. The company initiated rolling submissions for BNT162b2 for both the EMA and Canada in October, with formal submissions to follow demonstration of vaccine efficacy and safety from Ph3 analysis.

16. **CureVac:** This program is in Ph1 testing in Germany and Belgium and initiated a Ph2a trial September 2020 in Panama and Peru. Based on interim immunogenicity data generated from their Ph1 trial, the 12-ug dose of

their vaccine candidate (which they intend to take into Ph2/3 possibly YE20) generates neutralizing antibodies equivalent to a panel of human convalescent control sera (1:113, microneutrlaization assay). The company announced that they are in advanced talks with the EU to supply 225M doses of their vaccine candidate MY21, with an option for 180M more. Recently awarded 252M euros by the German Federal Ministry of Education and Research to advance vaccine development.

17. **Arcturus/Duke University:** Completed preclinical studies demonstrating that a single 2-µg dose of their LUNAR-COV19 vaccine provided immunity (seroconversion in 100% of animals vs 0% at this dose for standard mRNA). They announced a Ph1/2 clinical trial to begin 3Q20 in Singapore and topline results from this trial demonstrated that a single dose of their vaccine candidate generates neutralizing antibodies in the same range as human convalescent control (GMT 1:147). Arcturus signed a partnership with Catalent to help them scale up to 100M doses in 2021. Recently signed an agreement with CDMO Recipharm to support manufacturing, but have not provided additional dosing guidance.
18. **Inovio/Beijing Advaccine Biotechnology (INO-4800):** Announced that they should have 1M doses available by YE20 and that they are working to scale up to hundreds of millions in capacity pending future funding and investment. Recent data from an NHP challenge model demonstrated that INO-4800 did not provide complete protection in the lungs or nasal cavity against COVID-19, which is a weak signal moving into clinical trials. From the Ph1 trial, 94% (34/36) volunteers seroconverted but no additional data have been released. A Ph2/3 trial is expected to start late summer, but has been put on partial hold by the FDA due to additional questions around the CELLECTRA 2000 delivery device. While the Ph2 portion of Inovio's Ph1/2 has been cleared to start, this program remains on partial hold and Inovio must await FDA partial hold clearance and Ph2 results before initiating the Ph2/3. Inovio was granted $71M from the DoD to support manufacturing of their intradermal DNA delivery device. Selected by Operation Warp Speed to participate in a NHP challenge study
19. **Genexine/Binex (GX-19):** Small Korean biotech companies without the manufacturing capacity to supply beyond the Korean domestic market. Initiated Ph1/2 trials in June and expects data 4Q20. The company has recently guided that Ph2/3 efficacy trials could start 1H21, which would make 2H21 the earliest timeframe for approval.

VACCINES:
VERSION 10 UPDATES: NOVEMBER 6, 2020

NEW PROGRAMS ADDED (2):

UPDATES TO EXISTING PROGRAMS (19):

1. **Novavax/Emergent BioSolutions:** Novavax reported Ph1/2 RCT data for two doses (5 ug and 25 ug) of NVX-CoV2373 + 50 ug of its Matrix-M adjuvant. Neutralizing antibody titers were the highest produced by any vaccine candidate to date (3906 GMT, assessed by a stringent 100% inhibition live virus assay) and the tolerability profile was largely superior to other published COVID vaccine candidates, as well as common marketed common flu vaccines. The Ph2 portion of trial started August 2020 and reactogenicity data from this study demonstrated that NVX-CoV2373 is well tolerated in an expanded adult population, including elderly patients. Novavax was awarded $1.6B from Operation Warp Speed to support large-scale manufacturing of candidate NVX-CoV2373 by FUJIFILM Diosynth Biotechnologies and fund clinical development. A Ph3 RCT started recruiting September 2020 in the UK and a second Ph3 RCT is expected to start in the US/Mexico November 2020, with efficacy data expected early 1Q21 followed by rapid submission. Together with their acquisition of Cyrus Poonawalla Group, Novavax is guiding to having 100M doses ready by late 2020 and reach 1B doses/year run rate by YE21. The company recently entered an exclusive licensing agreement with the Serum Institute of India to support an additional 1B doses for India and low- and middle-income countries, a partnership with Takeda to support the production of over 250M annually for Japan, a development and supply agreement with SK Bioscience for global manufacturing of the antigen component and vaccine supply for South Korea, an agreement with the UK government to purchase 60M doses, and an agreement in principle with Canada to supply up to 76M doses.
2. **Sanofi:** Sanofi guided to producing 600M vaccine doses between YE20 and 2H21, and then scaling up to 1B doses annually by YE21. However, since protection requires 2 doses this is enough to vaccinate only 50M-300M people. Sanofi was recently awarded $2.1B by Operation Warp Speed to supply the US with 100M doses in 2021 with the option for up to 500M doses. Similarly, Sanofi has entered agreements with the UK to supply up to 60M doses, with Canada to supply 72M doses, with the EU to supply up to 300M doses in 2021, and with the World Health Organization to supply 200M equitable doses. Ph1/2 testing launched September 2020, with data expected December 2020 and the initiation of a Ph3 trial shortly thereafter, with possible regulatory approval 1H21. Early data showing the minimum dose needed to achieve protective immunity will be critical to determine how quickly Sanofi could make a dent in global vaccine need.
3. **Sinovac Biotech:** Inactivated vaccine candidate for which preliminary Ph2 data were recently reported and demonstrated induction of neutralizing antibodies in above 90% of volunteers. Preclinically, NHP challenge experiment for SARS-CoV-2 demonstrated protection without enhancement, though doses seemed too high for efficient manufacturing. This program is run by the Chinese government and entered into a collaboration with the Brazilian Institute to initiate a Ph3 trial (committing 60M-100M doses through this agreement), in addition to a supply deal with Indonesia (committing 40M doses). Although immunogenicity data from this trial have not yet been published, this vaccine candidate was granted emergency use authorization in China August 2020, with an efficacy readout expected November 2020, and entry into a Ph1/2 pediatric trial shortly thereafter. Sinovac currently has the capacity to produce ~100M doses annually and is aiming to triple capacity to ~300M doses largely for domestic supply in 2021.
4. **Medicago/Mitsubishi Tanabe:** Leveraging a plant-based vaccine production platform. Ph1 testing started July 2020, Ph2 trials are expected to start in early November with Ph3 following shortly thereafter in December. The company has guided to supplying 120M doses annually by 2021, with plans to double

production capacity in 2022, and ultimately achieve greater than 1 billion doses of COVID-19 vaccines per year in 2023 after they complete building their large-scale factory in Quebec. The company recently signed an agreement with the Government of Canada to supply 76M doses of its vaccine and will also receive $173M in funding to support research and development.

5. **Covaxx:** Covaxx is a spinout company of United Biomedical Inc developing a synthetic RBD-Fc vaccine formulated with T-cell epitopes and a proprietary adjuvant. They achieved high neutralizing antibody titers in guinea pigs (>32,000) and entered Ph1 testing September 2020 in Taiwan. They have guided to producing 100M doses by 1Q21 with the capacity to scale up to 1B by YE21 and have entered a global distribution partnership with Maersk.
6. **Vaxil BioTherapeutics:** Vaxil has recently entered a cooperative research and development agreement with USAMRIID to test its vaccine candidate (CorVax) in mice. They are assessing several contractors to develop a scaled GMP process.
7. **WRAIR/USAMRIID:** US Department of Defense-sponsored research effort whose lead COVID vaccine (SpFN) expects to be in the clinic by December 2020. Historically focused on vaccines for military applications and has limited manufacturing.
8. **Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** Inactivated vaccine sponsored by the China National Pharmaceutical Group that entered Ph1/2 testing in April 2020. Early data from this trial demonstrated that participants generate relatively low levels of neutralizing antibodies (121-250 GMT with a low stringency PRNT50 assay), although they did not have a human convalescent comparator arm to benchmark these results to. The company has guided to supplying 1B doses in 2021. Initiated a Ph3 trial in the UAE enrolling up to 15K volunteers. In September 2020, the UAE granted Emergency Use Authorization for this vaccine candidate before clinical trials are complete, becoming the first program to be granted approval by a foreign country.
9. **Vaxart/Emergent Biosolutions/Kindred Biosciences:** Vaxart announced FDA clearance of their COVID-19 vaccine candidate IND in September 2020 and have released hamster challenge study data demonstrating no systemic weight loss, an indicator of protection against COVID-19 in this animal model. They have a development agreement with Emergent BioSolutions to prepare bulk cBMP oral COVID-19 vaccine. Vaxart has also contracted KindredBio to manufacture its lead vaccine candidate at a large scale. Selected by Operation Warp Speed to participate in a NHP challenge study
10. **JNJ/Emergent Biosolutions:** While their lead candidate failed to provide sterilizing immunity in an NHP model, it did provide protection from severe disease. Ph1/2 trial started July 2020, the Ph2 portion initiated the first week of September in Europe and the Ph3 started in late September after positive Ph1/2a interim results and is planned to enroll up to 60K participants across 3 continents. This trial has resumed after being put on pause due to the unexpected illness in one participant, although details from this case have not been disclosed. Ad26 is less common than Ad5 so risk of pre-existing immunity is lower. They have a large manufacturing capacity and are targeting 1B doses on a not-for-profit basis (with 100M doses pledged to the US and 200M pledged to the EU with an option for 200M additional). Rå≈ecently signed a $480M, five-year manufacturing agreement with Emergent Biosolutions to manufacture its COVID-19 vaccine.
11. **ASTRAZENECA/Vaccitech/ University of Oxford:** Clinical trials for this vaccine candidate have resumed everywhere after a clinical hold was triggered by a possible case of transverse myelitis. Although AstraZeneca has not released any medical details about this situation, they do report that an independent review deemed the safety signal was not likely associated to the vaccine itself, although there is insufficient evidence to say for certain. AstraZeneca has signed agreements to provide hundreds of millions of doses to be delivered starting YE20 (100M UK, 300M US, 400M Serum Institute of India to provide for poorer countries, 300M CEPI/GAVI, and 300M EU). They also reached a licensing deal with Chinese firm BioKangtai for 200M doses annually. Early data from a Ph1/2 RCT trial enrolling >1,000 patients showed that AZD1222 produced neutralizing antibodies at best on par with human convalescent control, which may not be enough to provide sterilizing immunity but could protect from severe disease. This trial is large enough that, if over the next several months

when 4% of people might be expected to become infected, it might demonstrate vaccine efficacy if it cuts the infection rate in half (e.g., 20 unvaccinated patients getting sick vs. 10 vaccinated patients). However, with all the social distancing measures, 4% prevalence of COVID-19 might be an unreasonably high attack rate to model, and therefore it will take a larger study to prove efficacy; Oxford is preparing to run with an additional trial with 5,000 subjects. Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.

12. **Cansino Biologics:** Publication of Ph1 trial results demonstrated that ~50% of participants have pre-existing immunity to Ad5, which greatly impedes immunogenicity and makes this vaccine candidate less relevant for the broader population. Low levels of neutralizing antibodies were reproduced in their expanded Ph2 cohort, signaling that this vaccine may not provide strong protection. The company plans to start Ph3 trials soon in Russia, Brazil, Saudi Arabia, and Chile. China has approved this vaccine for military use and while current in-house manufacturing capacity sits at 80M doses annually, a new factory under construction in China will allow the production of 100-200M doses/year starting 1H21. Cansino has a 35M dose advance purchase agreement with Mexico. In August the National Research Council of Canada announced that collaboration with CanSino ended upon delays in vaccine shipments. At the same time, CanSino has entered talks with several countries to get emergency use authorization for its COVID-19 candidate. Concurrently, they are initiating a Ph1 trial to two-dose regimen for this vaccine after concerns were raised by the scientific community about the limited efficacy of this vaccine.
13. **ImmunityBio/NantKwest:** First dual antigen (both spike and nucleocapsid proteins) vectorized vaccine candidate. They launched a US Ph1 trial in October and plan to have capacity for 100 million doses of vaccine by YE20.
14. **GeoVax/BravoVax:** Vaccine developer BravoVax in Wuhan will provide testing and manufacturing support as well as interactions with Chinese authorities to enable GeoVax to pursue regulatory paths in both China and the US. GeoVax has secured a patent license agreement with the NIH for a stabilized spike protein.
15. **Moderna Therapeutics/Lonza:** Moderna published Ph1 data testing 25/100/250 ug doses and reported levels of neutralizing antibodies for the 100 ug dose at 14 days after the boost that were ~4X greater than levels in their human convalescent sera control. Early Ph1 data in elderly patients suggest neutralizing titers levels do not drop off in older patients, which is supported by work from their RSV program. While Moderna is testing 50/100 ug doses in a 600-patient Ph2 trial, they have moved forward with the 100 ug in a 30K volunteer Ph3 trial (enrollment completed in October, $955M total support from BARDA) due to reactogenicity concerns with the 250 ug dose. Moderna has guided to supplying 500M - 1B doses annually (20M by YE20) and has committed 100M to the US (with the option of an additional 400M), 80M to the EU, and 50M to Japan. They were recently awarded $56M by DARPA to develop a small-scale, mobile platform to enable fast, in-field automated manufacturing and deployment and are recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work. Moderna has initiated rolling submissions the UK and Canada and has confirmed eligibility to submit for EMA marketing authorization.
16. **BioNTech/Pfizer:** Interim data from Ph1/2 trials in Germany and the US demonstrated that the modRNA vaccine candidate 162b1 (RBD, 30 ug prime/boost) induced neutralizing antibodies levels ~3-4x greater than levels with human convalescent sera control. However, the company will move forward with a new lead candidate 162b2 (full length spike, 30 prime/boost ug) for their Ph2b/3 RCT starting July (recently expanded to enroll 44K volunteers), which elicited a broader T cell response in elderly volunteers while maintaining similar neutralizing antibody titers and a better reactogenicity profile. They are guiding to manufacturing 100M doses by YE20, scaling up to 2B doses in 2021 with the recent acquisition of a GMP facility in Germany and manufacturing supply agreements with the UK (60M), the US (100M-600M), the EU (200M), and Japan (120M). Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work and awarded 375M euros by the German Federal Ministry of Education and Research to advance vaccine development. The company initiated rolling submissions for BNT162b2 for both the EMA and Canada in October, with formal submissions to follow demonstration of vaccine efficacy and safety from Ph3 analysis.
17. **Translate Bio/Sanofi:** Sanofi recently doubled down on a $425M commitment to fund Translate Bio's

mRNA vaccine, with a trial to start November 2020. The company recently released preclinical NHP data demonstrating peak neutralizing antibody titers of 1,877, which places this vaccine in the middle of the pack for RNA candidates, between Pfizer/BioNTech (GMT 962) and Moderna (GMT 3481) which both used similar assays to Sanofi (50% inhibition live virus assay) and observed similar neutralizing antibody levels in human convalescent serum (GMT 41-94). Translate Bio has established 100-g single-batch production with its clinical-stage mRNA therapeutics platform. Build-out of dedicated manufacturing space is underway through a contract manufacturing partner to accommodate at least two 250-gram batches/month. Depending on the final human dose, they're guiding to 90-360M by 1H21.

18. **Entos Pharmaceuticals/EpiVax:** Lead candidate selected 2Q20. Entos announced receiving a $4.2M award from the Canadian government to support development of its vaccine candidate through Ph1/2 trials, which will begin late July 2020. They are working with Applied Pharmaceutical Innovation (API) in scaling up in-house development and manufacturing capacity to provide millions of doses of an approved product within 1 year.
19. **Symvivo:** This company launched a Ph1 clinical trail in 2Q20 and will beginning enrolling <100 patients by the end of the quarter. They have received funding of up to $2.8M from the National Research Council of Canada Industrial Research Assistance Program (NRC IRAP).

VACCINES:
VERSION 9 UPDATES: OCTOBER 16, 2020

UPDATES TO EXISTING PROGRAMS (18):

1. **Sanofi:** *Sanofi guided to producing 100M-600M vaccine doses between YE20 and 2H21, and then scaling up to 1B doses annually by YE21. However, since protection requires 2 doses this is enough to vaccinate only 50M-300M people. Sanofi was recently awarded $2.1B by Operation Warp Speed to supply the US with 100M doses in 2021 with the option for up to 500M doses. Similarly, Sanofi has entered agreements with the UK to supply up to 60M doses, with Canada to supply 72M doses, and has finalized negotiations with the EU to supply up to 300M doses in 2021. Ph1/2 testing launched September 2020, with data expected December 2020 and the initiation of a Ph3 trial shortly thereafter, with possible regulatory approval 1H21. Early data showing the minimum dose needed to achieve protective immunity will be critical to determine how quickly Sanofi could make a dent in global vaccine need.*
2. **Clover Biopharmaceuticals:** *This program recently published preclinical data in a nonhuman primate challenge model demonstrating that Clover's vaccine candidate elicited strong neutralizing antibody titers (in the 1000s), which reduced viral load in the lungs and nasal canal after challenge, but did not confer sterilizing immunity. Interestingly, GSK's adjuvant elicited a superior antibody response relative to Dynavax's adjuvant in this head-to-head comparison. Ph1 clinical trials started 2Q20 with initial data expected 4Q20. They have in-house 2x2000L bioreactor capacity, which could translate to "hundreds of millions of doses" annually. CEPI recently expanded its partnership with Clover Biopharma by investing an additional $66M to fund clinical testing and manufacturing scale up.*
3. **Covaxx:** *Covaxx is a spinout company of United Biomedical Inc developing a synthetic RBD-Fc vaccine formulated with T-cell epitopes and a proprietary adjuvant. They achieved high neutralizing antibody titers in guinea pigs (>32,000) and entered Ph1 testing September 2020 in Taiwan. They have guided to producing 100M doses by 1Q21 with the capacity to scale up to 1B by YE21.*
4. **IMV:** *Plans to begin Ph1 trials in Canada in MY20 and Ph2 by YE20. They have recently been granted CAD $10M by the Canadian government to progress their candidate DPX-COVID-19 through Ph1.*
5. **Chinese Academy of Medical Sciences:** *IST sponsored inactivated vaccine trial initiated MY20 that demonstrated relatively low levels of neutralizing antibodies (43-55 GMT), lagging behind both Sinovac and Sinopharm.*
6. **Bharat Biotech International (Covaxin):** *Recently entered Ph2 clinical testing and will use ViroVax's Alhydroxiquim-II adjuvant. They reported that this vaccine has a "positive" reactogenicity profile and are collecting sera to study immunogenicity. The company expects their vaccine to hit the market summer 2021 and has guided to producing 200M doses annually*
7. **Colorado State University:** *Academic initiative led by the Infectious Disease Research Center. They will not be in the clinic for another year, but they offer access to relevant animal models to assess key vaccine enhancement safety concerns. They have $3.1M in NIH grant funding but are not partnered/funded for scaled-up manufacturing.*
8. **Altimmune (AdCOVID)/Vigene Biosciences/UAB:** *Ph1 set to start 4Q20 with topline safety and serology data expected 2021. The company is scaling up manufacturing to reach 100M doses annually with Vigene Biosciences and recently presented preclinical data at the World Vaccine Conference, demonstrating the generation of neutralizing titers in mice.*
9. **JNJ/Emergent Biosolutions:** *WWhile their lead candidate failed to provide sterilizing immunity in an NHP*

model, it did provide protection from severe disease. Ph1/2 trial started July 2020, the Ph2 portion initiated the first week of September in Europe and the Ph3 started in late September after positive Ph1/2a interim results and is planned to enroll up to 60K participants across 3 continents. This trial is currently on hold as the Data and Safety Monitoring board investigate an unexpected illness one participant came down with. Ad26 is less common than Ad5 so risk of pre-existing immunity is lower. They have a large manufacturing capacity and are targeting 1B doses on a not-for-profit basis (with 100M doses pledged to the US and 200M pledged to the EU with an option for 200M additional). Rå≈ecently signed a $480M, five-year manufacturing agreement with Emergent Biosolutions to manufacture its COVID-19 vaccine.

10. **ASTRAZENECA/Vaccitech/ University of Oxford (AZD1222):** *Clinical trials for this vaccine candidate have resumed in the UK, Brazil, South Africa, India, and Japan (still on hold in the US) after a clinical hold was triggered by a possible case of transverse myelitis. Although AstraZeneca has not released any medical details about this situation, they do report that an independent review deemed the safety signal was not likely associated to the vaccine itself, although there is insufficient evidence to say for certain. AstraZeneca has signed agreements to provide hundreds of millions of doses to be delivered starting YE20 (100M UK, 300M US, 400M Serum Institute of India to provide for poorer countries, 300M CEPI/GAVI, and 300M EU). They also reached a licensing deal with Chinese firm BioKangtai for 200M doses annually. Early data from a Ph1/2 RCT trial enrolling >1,000 patients showed that AZD1222 produced neutralizing antibodies at best on par with human convalescent control, which may not be enough to provide sterilizing immunity but could protect from severe disease. This trial is large enough that, if over the next several months when 4% of people might be expected to become infected, it might demonstrate vaccine efficacy if it cuts the infection rate in half (e.g., 20 unvaccinated patients getting sick vs. 10 vaccinated patients). However, with all the social distancing measures, 4% prevalence of COVID-19 might be an unreasonably high attack rate to model, and therefore it will take a larger study to prove efficacy; Oxford is preparing to run with an additional trial with 5,000 subjects. Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.*

11. **German Center for Infection Research (DZIF):** *This program has entered Ph1 clinical testing in Germany, which is the third COVID-19 vaccine trial to launch in that country after BioNTech and CureVac.*

12. **Bharat Biotech International/Thomas Jefferson University:** *This program initiated Ph2 testing September 2020 and is the first domestic vaccine in India to enter the clinic; Bharat Biotech can produce hundreds of millions of doses/year.*

13. **Moderna Therapeutics/Lonza (mRNA-1273):** *Moderna published Ph1 data testing 25/100/250 ug doses and reported levels of neutralizing antibodies for the 100 ug dose at 14 days after the boost that were ~4X greater than levels in their human convalescent sera control. Early Ph1 data in elderly patients suggest neutralizing titers levels do not drop off in older patients, which is supported by work from their RSV program. While Moderna is testing 50/100 ug doses in a 600-patient Ph2 trial, they will move forward with the 100 ug for a 30K volunteer Ph3 trial July 2020 (with total $955M support from BARDA) due to reactogenicity concerns with the 250 ug dose. Moderna has guided to supplying 500M - 1B doses annually (20M by YE20) and has committed 100M to the US (with the option of an additional 400M), 80M to the EU, and 40M to Japan. They were recently awarded $56M by DARPA to develop a small-scale, mobile platform to enable fast, in-field automated manufacturing and deployment and are recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.*

14. **BioNTech/Pfizer (BNT162):** *Interim data from Ph1/2 trials in Germany and the US demonstrated that the modRNA vaccine candidate 162b1 (RBD, 30 ug prime/boost) induced neutralizing antibodies levels ~3-4x greater than levels with human convalescent sera control. However, the company will move forward with a new lead candidate 162b2 (full length spike, 30 prime/boost ug) for their Ph2b/3 RCT starting July (recently expanded to enroll 44K volunteers), which elicited a broader T cell response in elderly volunteers while maintaining similar neutralizing antibody titers and a better reactogenicity profile. They are guiding to manufacturing 100M doses by YE20, scaling up to 2B doses in 2021 with the recent acquisition of a GMP facility in Germany and manufacturing supply agreements with the UK (60M), the US (100M-600M), the EU (200M), and Japan (120M). Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates*

most likely to work and awarded 375M euros by the German Federal Ministry of Education and Research to advance vaccine development. The company initiated a rolling submission for the EMA for BNT162b2 in October, with the formal MAA submission to follow demonstration of vaccine efficacy and safety from Ph3 analysis.

15. **CureVac:** *This program is in Ph1 testing in Germany and Belgium and initiated a Ph2a trial September 2020 in Panama and Peru. The company announced that they are in advanced talks with the EU to supply 225M doses of their vaccine candidate MY21, with an option for 180M more. Recently awarded 252M euros by the German Federal Ministry of Education and Research to advance vaccine development.*
16. **Arcturus/Duke University:** *Completed preclinical studies demonstrating that a single 2-µg dose of their LUNAR-COV19 vaccine provided immunity (seroconversion in 100% of animals vs 0% at this dose for standard mRNA). They announced a Ph1/2 clinical trial to begin 3Q20 in Singapore and a recent partnership with Catalent will help them scale up to 100M doses in 2021. Recently signed an agreement with CDMO Recipharm to support manufacturing, but have not provided additional dosing guidance.*
17. **Inovio/Beijing Advaccine Biotechnology (INO-4800):** *Announced that they should have 1M doses available by YE20 and that they are working to scale up to hundreds of millions in capacity pending future funding and investment. Recent data from an NHP challenge model demonstrated that INO-4800 did not provide complete protection in the lungs or nasal cavity against COVID-19, which is a weak signal moving into clinical trials. From the Ph1 trial, 94% (34/36) volunteers seroconverted but no additional data have been released. A Ph2/3 trial is expected to start late summer, but has been put on partial hold by the FDA due to additional questions around the CELLECTRA 2000 delivery device. Inovio was granted $71M from the DoD to support manufacturing of their intradermal DNA delivery device.*
18. **BioNet-Asia:** *Part of a consortium with several health organizations in Thailand. Ph1 testing started in Australia, sponsored by the University of Sydney in collaboration with Technovalia and Pharmajet. Their production capacity is somewhere between 50M-100M doses/year and they will likely focus on supply to southeast Asia in 2021.*

VACCINES:
VERSION 8 UPDATES: SEPTEMBER 25, 2020

NEW PROGRAMS ADDED (2):

1. SpyBiotech / Serum Institute of India
2. Meissa Vaccines (MV-014-210)

UPDATES TO EXISTING PROGRAMS (20):

1. **Novavax/Emergent BioSolutions:** *Novavax reported Ph1/2 RCT data for two doses (5 ug and 25 ug) of NVX-CoV2373 + 50 ug of its Matrix-M adjuvant. Neutralizing antibody titers were the highest produced by any vaccine candidate to date (3906 GMT, assessed by a stringent 100% inhibition live virus assay) and the tolerability profile was largely superior to other published COVID vaccine candidates, as well as common marketed common flu vaccines. The Ph2 portion of trial started August 2020. Novavax was awarded $1.6B from Operation Warp Speed to support large-scale manufacturing of candidate NVX-CoV2373 by FUJIFILM Diosynth Biotechnologies and fund a pivotal 30K volunteer Ph3 RCT to begin September 2020, with data plausibly January 2021, submission Feb 2021, and launch March 2021. Together with their acquisition of Cyrus Poonawalla Group, Novavax is guiding to having 100M doses ready by late 2020 and reach 1B doses/year run rate by YE21. The company recently entered an exclusive licensing agreement with the Serum Institute of India to support an additional 1B doses for India and low- and middle-income countries, a partnership with Takeda to support the production of over 250M annually for Japan, a development and supply agreement with SK Bioscience for global manufacturing of the antigen component and vaccine supply for South Korea, an agreement with the UK government to purchase 60M doses (and run a Ph3 in the UK as part of an expanded collaboration with FUJIFILM Diosynth Biotechnologies, starting 3Q20), and an agreement in principle with Canada to supply up to 76M doses.*
2. **University of Queensland/CSL Behring:** *This technology leverages a molecular clamp to stabilize the viral antigen. Ph1 trials started 3Q20, with data expected by YE20 before initiation of a large scale Ph3 study. The program has multiple additional partners (Cytiva, Viroclinics Xplore, Lonza, and Thermo Fisher Scientific) and recently announced an agreement with the Australian government to supply 51M doses. CSL expects the first doses to be available MY21 with capacity for up to 100M doses YE21.*
3. **Sanofi:** Sanofi guided to producing 100M-600M vaccine doses between YE20 and 2H21, and then scaling up to 1B doses annually by YE21. However, since protection requires 2 doses this is enough to vaccinate only 50M-300M people. Sanofi was recently awarded $2.1B by Operation Warp Speed to supply the US with 100M doses in 2021 with the option for up to 500M doses. Similarly, Sanofi has entered agreements with the UK to supply up to 60M doses and has finalized negotiations with the EU to supply up to 300M doses in 2021. Ph1/2 testing launched September 2020, with data expected December 2020 and the initiation of a Ph3 trial shortly thereafter, with possible regulatory approval 1H21. Early data showing the minimum dose needed to achieve protective immunity will be critical to determine how quickly Sanofi could make a dent in global vaccine need.
4. **Sinovac Biotech (PiCoVacc):** Inactivated vaccine candidate for which preliminary Ph2 data were recently reported and demonstrated induction of neutralizing antibodies in above 90% of volunteers. Preclinically, NHP challenge experiment for SARS-CoV-2 demonstrated protection without enhancement, though doses seemed too high for efficient manufacturing. This program is run by the Chinese government and entered into

a collaboration with the Brazilian Institute to initiate a Ph3 trial (committing 60M-100M doses through this agreement), in addition to a supply deal with Indonesia (committing 40M doses). Although immunogenicity data from this trial have not yet been published, this vaccine candidate was granted emergency use authorization in China August 2020 and intends to launch a Ph1/2 pediatric trial shortly. Sinovac currently has the capacity to produce ~100M doses annually and is aiming to triple capacity to ~300M doses largely for domestic supply in 2021.

5. **SpyBiotech / Serum Institute of India:** A Ph1/2 study has been initiated in Australia. This platform uses a proprietary SpyCatcher/SpyTag "superglue" technology to display the Spike protein on the surface of Hepatitis B surface antigen VLPs.
6. **Vaxine Pty/Medy-Tox/Oxford Expression Technologies:** Small, Australian biotech company leveraging its proprietary adjuvant (Advax-CpG55.2) and its previous experience developing a SARS-CoV1 vaccine candidate to develop COVAX-19. They are partnered with South Korea's Medy-Tox and the UK's Oxford Expression Technologies to develop this program. Unclear clinical timelines or manufacturing scale.
7. **Medigen/NIAID/Dynavax:** Ph1 testing is expected to start September 2020. The company plans to finish the preclinical development and CMC by Fall 2020 to proceed with clinical trials to be done by June 2021. Concurrently, manufacturing and scale-up are planned to provide up to 200M doses by YE21. This program recently entered a partnership with Vaxess Technologies to develop a combination COVID-19 + seasonal influenza microneedle patch vaccine.
8. **Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** Inactivated vaccine sponsored by the China National Pharmaceutical Group that entered Ph1/2 testing in April 2020. Early data from this trial demonstrated that participants generate relatively low levels of neutralizing antibodies (121-250 GMT with a low stringency PRNT50 assay), although they did not have a human convalescent comparator arm to benchmark these results to. The company has guided to supplying 200M doses annually. Initiated a Ph3 trial in the UAE enrolling up to 15K volunteers. In September 2020, the UAE granted Emergency Use Authorization for this vaccine candidate before clinical trials are complete, becoming the first program to be granted approval by a foreign country.
9. **Valneva:** Valneva expects to enter clinical studies by YE20 with potential regulatory approval 2H21. They have recently reached an agreement with the UK to provide 60M doses 2H21 (purchased for 470M euros), with options for an additional 130M doses 2022-2025, which will be manufactured at its facilities in Livingston, Scotland and Solna, Sweden. Dynavax will supply its adjuvant for this agreement. Valenva has a marketing and distribution agreement for Seqirus' quadrivalent seasonal influenza vaccines in Austria. This prior relationship provides possible access to MF59 and discussions are ongoing.
10. **Vaxart/Emergent Biosolutions/Kindred Biosciences:** Vaxart announced FDA clearance of their COVID-19 vaccine candidate IND in September 2020 and expect additional preclinical data to be released October 2020. They have a development agreement with Emergent BioSolutions to prepare bulk cBMP oral COVID-19 vaccine. Vaxart has also contracted KindredBio to manufacture its lead vaccine candidate at a large scale. Selected by Operation Warp Speed to participate in a NHP challenge study
11. **Meissa Vaccines (MV-014-210):** Meissa's COVID-19 vaccine candidate, MV-014-210, was derived by modifying the company's RSV LAV candidate, MV-012-968, and replacing the RSV glycoproteins with a functioning SARS-CoV-2 Spike protein. This platform offers potential advantages for global deployment and clinical trials are expected to begin early 2021.
12. **Vaxess Technologies/Medigen:** MIMIX platform allows for combination of multiple antigens (COVID and Flu) for the development of a pentavalent, single dose, self-applied vaccine. Vaxess recently announced a partnership with Medigen to use their COVID-19 vaccine candidate for this combination patch. Their microneedle technology is silk-based and the antigen is room temperature stable. It is unlikely that this program will contribute to the first wave of COVID vaccines. A more likely market is for future seasonal vaccine cycles.

13. **ASTRAZENECA/Vaccitech/ University of Oxford (AZD1222):** Clinical trials for this vaccine candidate have resumed after a clinical hold was triggered by a possible case of transverse myelitis. Although AstraZeneca has not released any medical details about this situation, they do report that an independent review deemed the safety signal was not likely associated to the vaccine itself, although there is insufficient evidence to say for certain. AstraZeneca has signed agreements to provide hundreds of millions of doses to be delivered starting YE20 (100M UK, 300M US, 400M Serum Institute of India to provide for poorer countries, 300M CEPI/GAVI, and 300M EU). They also reached a licensing deal with Chinese firm BioKangtai for 200M doses annually. Early data from a Ph1/2 RCT trial enrolling >1,000 patients showed that AZD1222 produced neutralizing antibodies at best on par with human convalescent control, which may not be enough to provide sterilizing immunity but could protect from severe disease. This trial is large enough that, if over the next several months when 4% of people might be expected to become infected, it might demonstrate vaccine efficacy if it cuts the infection rate in half (e.g., 20 unvaccinated patients getting sick vs. 10 vaccinated patients). However, with all the social distancing measures, 4% prevalence of COVID-19 might be an unreasonably high attack rate to model, and therefore it will take a larger study to prove efficacy; Oxford is preparing to run with an additional trial with 5,000 subjects. Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.

14. **Cansino Biologics (Ad5-nCoV):** Publication of Ph1 trial results demonstrated that ~50% of participants have pre-existing immunity to Ad5, which greatly impedes immunogenicity and makes this vaccine candidate less relevant for the broader population. Low levels of neutralizing antibodies were reproduced in their expanded Ph2 cohort, signaling that this vaccine may not provide strong protection. The company plans to start Ph3 trials soon in Russia, Brazil, Saudi Arabia, and Chile. China has approved this vaccine for military use and while current in-house manufacturing capacity sits at 80M doses annually, a new factory under construction in China will allow the production of 100-200M doses/year starting 1H21. In August the National Research Council of Canada announced that collaboration with CanSino ended upon delays in vaccine shipments. At the same time, CanSino has entered talks with several countries to get emergency use authorization for its COVID-19 candidate. Concurrently, they are initiating a Ph1 trial to two-dose regimen for this vaccine after concerns were raised by the scientific community about the limited efficacy of this vaccine.

15. **Gamaleya Research Institute:** Russian program with very little publicly available information. They started Ph1 trials 2Q20 for their adenovirus based vaccine and recently announced this candidate is expected to get conditional registration on August 12th, only requiring trials on another 1,600 people with production likely to start in September. This program recently published Ph1 data , placing neutralizing antibody titers in a similar range as AstraZeneca's vaccine candidate (1:40 vs 1:30). However, a global group of scientists have called into question the reliability of these data after highly unlikely data patterns were identified throughout the publication.

16. **Moderna Therapeutics/Lonza (mRNA-1273):** Moderna published Ph1 data testing 25/100/250 ug doses and reported levels of neutralizing antibodies for the 100 ug dose at 14 days after the boost that were ~4X greater than levels in their human convalescent sera control. Early Ph1 data in elderly patients suggest neutralizing titers levels do not drop off in older patients, which is supported by work from their RSV program. While Moderna is testing 50/100 ug doses in a 600-patient Ph2 trial, they will move forward with the 100 ug for a 30K volunteer Ph3 trial July 2020 (with total $955M support from BARDA) due to reactogenicity concerns with the 250 ug dose. Moderna has guided to supplying 500M - 1B doses annually (20M by YE20) and has committed 100M to the US (with the option of an additional 400M), 80M to the EU, and 40M to Japan. Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.

17. **BioNTech/Pfizer (BNT162):** Interim data from Ph1/2 trials in Germany and the US demonstrated that the modRNA vaccine candidate 162b1 (RBD, 30 ug prime/boost) induced neutralizing antibodies levels ~3-4x greater than levels with human convalescent sera control. However, the company will move forward with a new lead candidate 162b2 (full length spike, 30 prime/boost ug) for their Ph2b/3 RCT starting July (recently expanded to enroll 44K volunteers), which elicited a broader T cell response in elderly volunteers while maintaining similar neutralizing antibody titers and a better reactogenicity profile. They are guiding to manufacturing 100M doses by YE20, scaling up to 2B doses in 2021 with the recent acquisition of a GMP

facility in Germany and manufacturing supply agreements with the UK (60M), the US (100M-600M), the EU (200M), and Japan (120M). Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work and awarded 375M euros by the German Federal Ministry of Education and Research to advance vaccine development.

18. **CureVac:** Expects to start Ph1 clinical trials in summer 2020. Received regulatory clearance to begin trials in Germany and Belgium; if successful they could progress to Ph2 trials in August 2020. The company announced that they are in advanced talks with the EU to supply 225M doses of their vaccine candidate MY21, with an option for 180M more. Recently awarded 252M euros by the German Federal Ministry of Education and Research to advance vaccine development.
19. **Takis Biotech/Applied DNA Sciences:** Ph1 trials to begin in Italy late 2021; their manufacturing capacity is currently unclear. The company has recently announced the launch of a veterinary trial to study the immune response in companion felines of humans.
20. **Merck/Institut Pasteur/University of Pittsburgh:** Consortium headed by the Institute Pasteur and backed by CEPI. The University of Pittsburgh will develop a candidate, while Merck (which acquired Themis) is responsible for supporting the clinical trial and manufacturing. Ph1 dosing has started in Belgium September 2020.

VACCINES:
VERSION 7 UPDATES: SEPTEMBER 4, 2020

NEW PROGRAMS ADDED (1):

1. Baylor College of Medicine/Biological E

UPDATES TO EXISTING PROGRAMS (17):

2. **Novavax/Emergent BioSolutions:** *The Ph2 portion of trial started August 2020. The company recently entered an exclusive licensing agreement with the Serum Institute of India to support minimum of 1B doses for India and low- and middle-income countries, a partnership with Takeda to support the production of over 250M annually for Japan, a development and supply agreement with SK Bioscience for global manufacturing of the antigen component and vaccine supply for South Korea, and an agreement with the UK government to purchase 60M doses (and run a Ph3 in the UK as part of an expanded collaboration with FUJIFILM Diosynth Biotechnologies, starting 3Q20)*
3. **Sinovac Biotech (PiCoVacc):** *Although immunogenicity data from this trial have not yet been published, this vaccine candidate was granted emergency use authorization in China August 2020. Recently entered a supply deal with Indonesia to supply 40M doses by 1Q21.*
4. **VBI Vaccines/National Research Council of Canada:** *VBI selected two lead candidates to take into Ph1/2 YE20 that generated robust neutralizing antibody titers in mice.*
5. **Baylor College of Medicine/Biological E:** *Baylor College of Medicine recently licensed their subunit vaccine candidate to Biological E to help manufacture and develop. Unspecified clinical timelines. Biological E expects to manufacture hundreds of million doses annually.*
6. **VIDO-InterVac at the University of Saskatchewan:** *VIDO-InterVac was awarded $23M by the Canadian government to accelerate COVID-19 vaccine development and the University of Saskatchewan was awarded another $3.6M. Recently partnered with Dalton Pharma and Biodextris for manufacturing and fill-finish. Clinical trials are expected to start 4Q20.*
7. **Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** *Early data from this trial demonstrated that participants generate relatively low levels of neutralizing antibodies (121-250 GMT with a low stringency PRNT50 assay), although they did not have a human convalescent comparator arm to benchmark these results to.*
8. **Bharat Biotech International (Covaxin):** *They reported that this vaccine has a "positive" reactogenicity profile and are collecting sera to study immunogenicity.*
9. **Valneva:** *Valenva has a marketing and distribution agreement for Seqirus' quadrivalent seasonal influenza vaccines in Austria. This prior relationship provides possible access to MF59 and discussions are ongoing. Valneva is also testing Dynavax's adjuvant.*
10. **JNJ/Emergent Biosolutions:** *the company is guiding that the Ph2 portion will initiate the first week of September in Europe. Ph3 is planned to enroll up to 60K participants in South America.*
11. **ReiThera/Leukocare/Univercells:** *European Consortium developing a vaccine candidate that entered the clinic August 2020 in Italy.*

12. **Cansino Biologics (Ad5-nCoV):** *In August the National Research Council of Canada announced that collaboration with CanSino ended upon delays in vaccine shipments. At the same time, CanSino has entered talks with several countries to get emergency use authorization for its COVID-19 candidate*
13. **Moderna Therapeutics/Lonza (mRNA-1273):** *Early Ph1 data in elderly patients suggest neutralizing titers levels do not drop off in older patients. Moderna has guided to supplying 500M - 1B doses annually and has committed 100M to the US (with the option of an additional 400M), 80M to the EU, and 40M to Japan.*
14. **BioNTech/Pfizer (BNT162):** *However, the company will move forward with a new lead candidate 162b2 (full length spike, 30 prime/boost ug) for their Ph2b/3 RCT starting July, which elicited a broader T cell response in elderly volunteers while maintaining similar neutralizing antibody titers and a better reactogenicity profile.*
15. **CureVac:** *The company announced that they are in advanced talks with the EU to supply 225M doses of their vaccine candidate MY21, with an option for 180M more.*
16. **Translate Bio/Sanofi:** *Sanofi recently doubled down on a $425M commitment to fund Translate Bio's mRNA vaccine, with a trial to start November 2020.*
17. **Generex/EpiVax (il-key platform):** *They recently announced an agreement with Bintai Kinden to advance the development and commercialization of their vaccine candidate for Malaysia.*

VACCINES:
VERSION 6 UPDATES: AUGUST 14, 2020

NEW PROGRAMS ADDED (2):

SUBUNIT VACCINES:

1. Kentucky Bioprocessing
2. Covaxx

UPDATES TO EXISTING PROGRAMS (22):

SUBUNIT VACCINES:

1. **Novavax/Emergent Biosolutions (NVX-CoV2373):** *Novavax reported Ph1/2 RCT data for two doses (5 ug and 25 ug) of NVX-CoV2373 + 50 ug of its Matrix-M adjuvant. Neutralizing antibody titers were the highest produced by any vaccine candidate to date (3906 GMT, assessed by a stringent 100% inhibition live virus assay) and the tolerability profile was largely superior to other published COVID vaccine candidates, as well as common marketed common flu vaccines. The company recently entered an exclusive licensing agreement with the Serum Institute of India to support minimum of 1B doses for India and low- and middle-income countries, as well as a partnership with Takeda to support the production of over 250M annually for Japan.*
2. **Medicago:** *Leveraging a plant-based vaccine production platform.*
3. **VBI Vaccines/National Research Council of Canada:** *VBI was recently awarded CAD $56M by the Canadian government to accelerate vaccine developments efforts through Ph2 testing. The initiation of clinical studies is expected by YE20.*
4. **Sanofi:** *Sanofi was recently awarded $2.1B by Operation Warp Speed to supply the US with 100M doses in 2021 with the option for up to 500M doses. Similarly, Sanofi has entered agreements with the UK to supply up to 60M doses and is in negotiations with the EU to supply up to 300M doses in 2021. Ph1/2 testing is expected to begin September 2020, with Ph3 to start YE20 and possible regulatory approval 1H21.*
5. **Biological E:** *Ph1 testing is expected to start September 2020. The company claims it has the manufacturing capacity to produce 80M-100M doses/month with this platform, although little information about this program is available within the public domain.*
6. **IMV:** *Ph2 by YE20. They have recently been granted CAD $4.15M by the Canadian government to progress their candidate DPX-COVID-19 through Ph1.*
7. **Intravacc/EpiVax/CimCure/Celonic Group**: *The program plans to be in the clinic in 2021, and has recently entered a research agreement with Celonic Group (CDMO), although the manufacturing capacity of this joint venture is unclear.*
8. **Medigen/NIAID/Dynavax**: *Ph1 testing is expected to start 4Q20.*

WHOLE VIRUS VACCINES:

9. **Sinovac Biotech (PiCoVacc):** *This program is run by Chinese government and recently entered into a collaboration with the Brazilian Institute to initiate a Ph3 trial, committing to share 60M-100M doses through this agreement. Sinovac currently has the capacity to produce ~100M doses annually and is aiming to triple capacity to ~300M doses largely for domestic supply in 2021.*
10. **Bharat Biotech International (Covaxin):** *Recently entered Ph2 clinical testing.*
11. **Valneva:** *Valneva expects to enter clinical studies by YE20 with potential regulatory approval 2H21. They have recently reached an agreement with the UK to provide up to 100M doses of its inactivated whole virus candidate, which will be manufactured at its facilities in Livingston, Scotland and Solna, Sweden.*

ADENOVIRUS VECTOR VACCINES:

12. **JNJ/Emergent Biosolutions:** *While their lead candidate failed to provide sterilizing immunity in an NHP model, it did provide protection from severe disease. Ph1/2 trial started July 2020. 100M doses pledged to the US and negotiations for 200M to the EU.*
13. **AstraZeneca/Vaccitech/ University of Oxford (AZD1222):** *Faster into clinical development than JNJ. They also reached a licensing deal with Chinese firm BioKangtai for 200M doses annually. Early data from a Ph1/2 RCT trial enrolling >1,000 patients showed that AZD1222 produced neutralizing antibodies at best on par with human convalescent control, which may not be enough to provide sterilizing immunity but could protect from severe disease.*
14. **Cansino Biologics (Ad5-nCoV):** *Low levels of neutralizing antibodies were reproduced in their expanded Ph2 cohort, signaling that this vaccine may not provide strong protection.*
15. **Gamaleya Research Institute:** *Russian program with very little publicly available information. They started Ph1 trials 2Q20 for their adenovirus based vaccine and recently announced this candidate is expected to get conditional registration on August 12th, only requiring trials on another 1,600 people with production likely to start in September. Although – concerningly – the world has seen no clinical data from this program, this could be the first registered COVID-19 vaccine.*
16. **Altimmune (AdCOVID)/Vigene Biosciences/UAB:** *Ph1 set to start 4Q20 with topline safety and serology data expected 2021. The company is scaling up manufacturing to reach 100M doses annually with Vigene Biosciences.*

MRNA VACCINES:

17. **Moderna Therapeutics/Lonza (mRNA-1273):** *While Moderna is testing 50/100 ug doses in a 600-patient Ph2 trial, they will move forward with the 100 ug for a 30K volunteer Ph3 trial July 2020 (with total $955M support from BARDA) due to reactogenicity concerns with the 250 ug dose.*
18. **BioNTech/Pfizer (BNT162):** *Interim data from Ph1/2 trials in Germany and the US demonstrated that the modRNA vaccine candidate 162b1 (RBD, 30 ug prime/boost) induced neutralizing antibodies levels ~2x greater than levels with human convalescent sera control. However, the company will move forward with a new lead candidate 162b2 (full length spike, 30 prime/boost ug) for their Ph2b/3 RCT starting July, which elicited a broader T cell response in elderly volunteers. They are guiding to manufacturing 100M doses by YE20, scaling up to 1.3B doses in 2021 with recent manufacturing agreements with the UK (60M), the US (100M-600M), and Japan (120M).*
19. **Arcturus/Duke University:** *They announced a Ph1/2 clinical trial to begin 3Q20 in Singapore and a recent partnership with Catalent will help them scale up to 100M doses in 2021.*

DNA VACCINES:

20. **Inovio/Beijing Advaccine Biotechnology (INO-4800):** *Recent data from an NHP challenge model demonstrated that INO-4800 did not provide complete protection in the lungs or nasal cavity against COVID-19, which is a weak signal moving into clinical trials.*
21. **Zydus Cadila:** *Initiated a Ph2 trial 3Q20 and guiding towards 100M doses annually starting 2Q21.*

MEASLES VECTOR:

22. **Merck/Institut Pasteur/University of Pittsburgh:** *The University of Pittsburgh will develop a candidate, while Merck (which acquired Themis) is responsible for supporting the clinical trial and manufacturing. The company plans to enter clinical testing 3Q20.*

VACCINES:
VERSION 5 UPDATES: JULY 22, 2020

NEW PROGRAMS ADDED (6):

1. Anhui Zhifei Longcom Biopharmaceutical/ Institute of Microbiology, Chinese Academy of Sciences
2. Vaccine Pty Ltd/Medytox
3. Institute of Medical Biology , Chinese Academy of Medical Sciences
4. Bharat Biotech International
5. Verndari Inc
6. People's Liberation Army (PLA) Academy of Military Sciences/Walvax Biotech

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UPDATES TO EXISTING VACCINE PROGRAMS (18):

1. **Novavax/Emergent Biosolutions (NVX-CoV2373):** *Recognized by Operation Warp Speed (OWS). Partnered with BARDA.*
2. **ExpreS2ion Biotechnology/AdaptVac/Bavarian Nordic:** *Partnered with Bavarian Nordic A/S, Europe's largest independent vaccine developer, this program is expected to start Ph1 trials in December 2020 with early data available 2021*
3. **Medicago:** *Phase 1 testing started July 2020 and Ph2/3 is expected to start October 2020 with possible approval 2H21*
4. **Saiba/AGC Biologics:** *Recently partnered with AGC biologics to manufacture and distribute at national scale.*
5. **Sanofi:** *Company guided to producing 100M-600M vaccine doses between YE20 and 2H21, and then scaling up to 1B doses annually YE21.*
6. **Clover Biopharmaceuticals:** *Expanded CEPI partnership with additional funding.*
7. **University of Queensland/CSL Behring:** *Phase 1 Trials started 3Q20.*
8. **Sinopharm Group/Wuhan Institute of Biological Products/Beijing Institute of Biological Products:** *Recently initiated Phase 3 trial in the UAE enrolling up to 15k volunteers.*
9. **JNJ/Emergent Biosolutions:** *Ph1 trial to start in July 2020 and the company is guiding that a Ph3 trial could start as early as September 2020. Recently signed a $480M, five-year manufacturing agreement with Emergent Biosolutions to manufacture its COVID-19 vaccine.*
10. **ASTRAZENECA/Vaccitech/ University of Oxford (AZD1222):** *Signed agreements to provide hundreds of millions of doses to be delivered starting YE20 (100M UK, 300M US, 400M Serum Institute of India to provide for poorer countries, 300M CEPI/GAVI, and 300M EU).*
11. **Cansino Biologics (Ad5-nCoV):** *Publication of Ph1 trial results demonstrated that ~50% of participants have pre-existing immunity to Ad5, which greatly impedes immunogenicity and makes this vaccine candidate less relevant for the broader population.*

12. **Gamaleya Research Institute:** *Recently announced that Ph3 trials could start as early as mid-August 2020.*
13. **Moderna/Lonza (mRNA-1273):** *Moderna published Ph1 data testing 25/100/250 ug doses and reported levels of neutralizing antibodies for the 100 ug dose at 14 days after the boost that were ~4X greater than levels in their human convalescent sera control.*
14. **BioNTech/Pfizer (BNT162):** *Interim data from this study demonstrated that the modRNA vaccine candidate 162b1 (30 ug prime/boost) induced neutralizing antibodies levels ~2x greater than levels with human convalescent sera control. The company will move forward with a dose between 10 and 30 ug for their Ph2b/3 starting July.*
15. **Inovio/Beijing Advaccine Biotechnology (INO-4800):** *From the Ph1 trial, 94% (34/36) volunteers seroconverted but no additional data have been released. A Ph2/3 trial is expected to start late summer.*
16. **Zydus Cadila:** *Initiated a Ph1 trial 3Q20 and guiding towards 100M doses annually starting 2Q21.*
17. **Osaka University/AnGes/Takara:** *Initiated a Ph1 trial and are focused on the Japanese domestic market with approval projected for MY21*
18. **BioNet-Asia:** *Ph1 testing is projected to start November 2020 with 10,000 doses.*

VACCINES:
VERSION 4 UPDATES: JULY 2, 2020

NEW PROGRAMS ADDED (6):

1. VBI Vaccines/National Research Council of Canada
2. Gamaleya Research Institute
3. Memgen (MemVax)
4. Ntx
5. eTheRNA
6. University of Tokyo/Daiichi-Sankyo

UPDATES TO EXISTING VACCINE PROGRAMS (13):

1. **Sanofi:** *Phase 1/2 trial moved up to September and the goal is to have it fully licensed by June 2021.*
2. **Clover Biopharmaceuticals:** *Initiated Phase 2 2Q20. Preliminary results are expected in August 2020.*
3. **University of Queensland/CSL:** *Guiding to 100 million doses YE20 with recent CSL collaoration.*
4. **Sinovac:** *Preliminary study results announced.*
5. **Sinopharm/Wuhan/Beijing Institute of Biological Products:** *100% Seroconversion rate reported from phase 1/2. nAbs not reported. Aiming to produce 200M doses a year.*
6. **Vaxart/Emergent Biosolutions/KindredBio:** *Vaxart has been selected to participate in a NHP challenge study, organized by OWS.*
7. **Moderna/Lonza (mRNA-1273):** *Agreement with Catalent to provide vial filling, packaging capacity, and additional 24/7 staffing requirements to support an initial 100M doses 3Q20.*
8. **CureVac:** *CureVac received regulatory clearance to begin Phase 1 trials in Germany and Belgium.*
9. **Translate Bio/Sanofi**
10. **Imperial College London:** *Initiated Phase 1 June 2020.*
11. **Inovio/Beijing Advaccine Biotechnology (INO-4800):** *Inovio receives $71M contract fro DoD to manufacture intradermal DNA delivery device. Guiding to report Phase1 clinical trial results in late June.*
12. **Genexine/Binex (GX-19):** *Initiated Phase 1/2 trials in June and guiding towards data September 2020.*
13. **Entos Pharma/Epivax/Fusogenix:** *Initiated Phase 1/2 trials with data expected in September and the final product exptected YE21.*

VACCINES:
VERSION 3 UPDATES: JUNE 15, 2020

NEW PROGRAMS ADDED (5):

1. Abnova/PharmaJet
2. Immunity Bio/NantKwest (Ad5COVID-S/N)
3. Intravacc/EpiVaxx
4. Ntx (multivalent mRNA)
5. Vaxess Technologies

UPDATES TO EXISTING VACCINE PROGRAMS (4):

1. **BioNTech/Pfizer (BNT162):** *Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.*
2. **BioNTech/Pfizer (BNT162):** *Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.*
3. **Novavax/Emergent (NVX-CoV2373):** *Moved to human trials*
4. **Moderna/Lonza (mRNA-1273):** *Recognized by Operation Warp Speed (OWS) as one of five vaccine candidates most likely to work.*

VACCINES:
VERSION 2 UPDATES: MAY 22, 2020

NEW PROGRAMS ADDED (7):

1. Bharat Biotech/Thomas Jefferson University
2. Entos Pharma/Epivax/Fusogenix
3. Indian Immunologicals Ltd/Griffith University
4. Medigen Vaccine Biologics Corporation/NIAID/Dynavax
5. Sensei Biotherapeutics
6. Symvivo
7. University of Wisconsin–Madison/FluGen/Bharat Biotech (CoroFlu)

THERAPEUTICS UPDATES:

VERSION 15 UPDATES: FEBRUARY 11, 2022

NEW PROGRAMS ADDED (1):

TARGET VIRAL REPLICATION:

1. Sorrento Therapeutics (STI-1558)

UPDATES TO EXISTING PROGRAMS (73):

TARGET VIRAL REPLICATION:

1. **Regeneron/Roche (REGEN-COV/ (casirivimab + imdevimab):** *EUA revised due to omicron variant*
2. **Eli Lilly/AbCellera Biologics/Junshi Biosciences (LY-CoV555+LY-COV016 / bamlanivimab+etesevimab):** *EUA revised due to omicron variant*
3. **AstraZeneca (Evusheld/tixagevimab+cilgavimab): EUA**
4. **Novartis/Molecular Partners (MP0420/ensovibep):** *Positive top-line data in the outpatient setting*
5. **Jemincare (JMB2002):** *Completed Phase 1*
6. **BeiGene/Singlomics Biopharmaceuticals (BGB-DXP593):** *Completed Phase 2*
7. **IGM Biosciences (IGM-6268):** *Moved to human trials*
8. **HiFiBio/ABL Bio (HFB30132A): DISCONTINUED**
9. **Eureka (Invismask): DISCONTINUED**
10. **Sorrento Therapeutics (STI-4398/COVIDTRAP): DISCONTINUED**
11. **Neoleukin Therapeutics (NL-CVX1): DISCONTINUED**
12. **pHion Therapeutics (PTX-G1): DISCONTINUED**
13. **Kintor (GT0918/proxalutamide): FAILED**
14. **COVISTAT/Ensysce (nafamostat):** *Completed Phase 1*
15. **Ridgeback Biotherapeutics/Merck (EIDD-2801/molnupiravir): EUA**
16. **COVISTAT/Ensysce (nafamostat):** *Completed Phase 1*
17. **Gilead (Descovy/emtricitabine + tenofovir alafenamide fumarate):** *Completed Phase 3*
18. **FUJIFILM Toyama Chemical/ Appili Therapeutics (Avigan/favipiravir): FAILED**
19. **Gilead (GS-5245):** *Moved to human trials*
20. **Gilead (Veklury/remdesivir):** *Approved in both the hospitalized and outpatient settings*
21. **Immunic (IMU-838): FAILED**
22. **Pfizer (Paxlovid/nirmatrelvir + ritonavir): EUA**
23. **Pfizer (PF-07304814): DISCONTINUED**

24. **DalCor Pharmaceuticals (dalcetrapib): FAILED**
25. **Blade Therapeutics (BLD-2660): FAILED**
26. **eFFECTOR Therapeutics (eFT226/zotatifin): DISCONTINUED**
27. **Sixty Degrees Pharma (Arakoda/tafenoquine):** *Completed Phase 2*
28. **Blade Therapeutics (BLD-2660): FAILED**
29. **(fluvoxamine): FAILED**

TARGET THE IMMUNE RESPONSE

30. **Genexine/NeoImmuneTech (NT-I7/GX-I7):** *Partnered with Genexine*
31. **Oncotelic (OT-101):** *Completed Phase 1/2*
32. **MiNK Therapeutics/Agenus (AgenT-797):** *Partnered with MiNK Therapeutics*

TREAT OR PREVENT ARDS:

33. **Biocad (BCD-089/levilimab):** *Positive Phase 3 Data (Russia)*
34. **R-Pharm/Cromos Pharma (olokizumab): APPROVED**
35. **CSL Behring (clazakizumab): DISCONTINUED**
36. **JNJ (Plivensia/sirukumab) : DISCONTINUED**
37. **GSK (otilimab): DISCONTINUED**
38. **Roivant Sciences (gimsilumab): FAILED**
39. **Nobelpharma (sargramostim):** *Completed Phase 2/3*
40. **Kiniksa Pharmaceuticals (mavrilimumab): FAILED**
41. **R-Pharm/Cromos Pharma (RPH-104): DISCONTINUED**
42. **Bristol-Myers Squibb (BMS-986253): FAILED**
43. **INmune Bio (Quellor/XPro1595): DISCONTINUED**
44. **AVM (AVM0703/dexamethasone): DISCONTINUED**
45. **(methylprednisolone):** *Recommended if dexamethasone is not available*
46. **Pfizer (Xeljanz/tofacitinib):** **Positive signal in a Ph2 RCT in inpatient setting*
47. **CTI Biopharma (Enpaxiq/pacritinib): FAILED**
48. **(methylprednisolone):** *Completed Phase*
49. **NGM Biopharma (NGM-621): DISCONTINUED**
50. **NantKwest (BM-Allo.MSC): DISCONTINUED**
51. **Pluristem (PLX-PAD): FAILED**
52. **Kaleido Biosciences (KB109): DISCONTINUED**
53. **AB Science (masitinib + isoquercetin):** *Launched a new Phase 2*

54. **Vanda Pharmaceuticals (tradipitant): FAILED**
55. **Can-Fite (CF101/piclidenoson): DISCONTINUED**
56. **Aclaris Therapeutics (ATI-450): DISCONTINUED**
57. **Secura Bio(Copiktra/duvelisib): DISCONTINUED**
58. **Merck KGaA (M5049):** *Completed Phase 2*
59. **Denali Therapeutics/Sanofi (DNL-758/SAR443122):** *Completed Phase 1b*
60. **Opko (Rayaldee/calcifediol ER):** *Completed Phase 2*
61. **Pfizer (PF-06650833): DISCONTINUED**
62. **Opko (Rayaldee/calcifediol ER):** *Completed Phase 2*
63. **Bristol-Myers Squibb (Orencia/abatacept): DISCONTINUED**
64. **Implicit Bioscience (IC14): FAILED**
65. **Opko (Rayaldee/calcifediol ER):** *Completed Phase 1*
66. **BioAegis (rhu-pGSN):** *Completed Phase 2*
67. **Sage Therapeutics (Zulresso/brexanolone): DISCONTINUED**
68. **Shaperon (NuSepin):** *Completed Phase 2*
69. **Roche (Pulmozyme/dornase alfa): FAILED**
70. **Shaperon (NuSepin):** *Completed Phase 1b/2*
71. **Thirty Respiratory (RESP301):** *Completed Phase 2/3*

PREVENT ORGAN FAILURE BEYOND THE LUNGS:

72. **(apixaban): FAILED**
73. **Takeda (Takhyzro/lanadelumab):** *Completed Phase 3*

THERAPEUTICS UPDATES:

VERSION 14 UPDATES: SEPTEMBER 24, 2021

NEW PROGRAMS ADDED (5):

TARGET VIRAL REPLICATION:

1. Abbvie (ABBV-2B04)
2. IGM Biosciences (IGM-6268)
3. Gilead (GS-621763)
4. Shionogi (S-217622)
5. Entana Pharmaceuticals (EDP-235)

UPDATES TO EXISTING PROGRAMS (75):

TARGET VIRAL REPLICATION:

1. **Regeneron/Roche (REGEN-COV/ (casirivimab + imdevimab):** *EUA for high-risk, outpatient setting; seeking EUA for post-exposure prophylaxis*
2. **Eli Lilly/AbCellera Biologics/Junshi Biosciences (LY-CoV555+LY-COV016/bamlanivimab + etesevimab):** *EUA for high-risk, outpatient setting; seeking EUA for post-exposure prophylaxis*
3. **AstraZeneca (AZD7442/AZD8895+AZD1061):** *Positive top-line data in the PrEP setting*
4. **Brii Biosciences (BRII-196+BRI-198):** *Positive toppling data in the outpatient setting*
5. **National Resilience/ Ology Bioservices (ADM03820):** *RCT*
6. **BMS/Rockefeller University (C144-LS + C135-LS/BMS-986414 + BMS-986413):** *RCT*
7. **BeiGene/Singlomics Biopharmaceuticals (BGB-DXP593 + BGB-DXP604):** *Completed Phase 1*
8. **Vir Biotechnology/GSK (VIR-7831/sotrovimab):** *EUA for outpatient setting*
9. **Exevir (XVR-011):** *Entered human trials; IV*
10. **Vir Biotechnology/GSK (VIR-7832):** *Entered human trials; IV*
11. **AbbVie/Harbour BioMed (ABBV-47D11):** *Completed Phase 1*
12. **Sorrento Therapeutics (COVI-DROPS/STI-2099):** *Entered human trials*
13. **Alphamab/Institut Pasteur Shanghai: DISCONTINUED**
14. **Boehringer Ingelheim/University of Cologne (BI 767551/DZIF-10c): DISCONTINUED**
15. **SAB Biotherapeutics/CSL Behring (SAB-185):** *Positive Interim Data (Ph2), moving to Ph3*
16. **Kamada/Kedrion:** *Completed Phase 1*

17. **Systimmune (SI-F019):** *Entered human trials; IV*
18. **Kintor (GT0918/proxalutamide):** *RCT*
19. **Mithra Pharma (estetrol): FAILED**
20. **Sagent Pharma/Nichi-Iko (camostat mesilate): FAILED**
21. **Nichi-Iko/Daiichi Sankyo/ University of Tokyo/ RIKEN (nafamostat): DISCONTINUED**
22. **Airway Therapeutics (AT-100):** *Entered human trials; Intratracheal*
23. **Jubilant Pharma (remdesivir):** *Completed Phase 1*
24. **Gilead (remdesivir) {inhaled): DISCONTINUED**
25. **Bausch Health (Virazole/ribavirin):** *Completed Phase 1*
26. **Clear Creek Bio (brequinar):** *Completed Phase 2*
27. **Pardes Biosciences (PBI-0451):** *Entered human trials; Oral*
28. **Pfizer (PF-07304814):** *Completed Phase 1; Phase2/3 in planning*
29. **DalCor Pharmaceuticals (dalcetrapib):** *Completed Phase 2*
30. **Vir Biotechnology/Alnylam Pharmaceuticals (VIR-2703/ALN-COV): DISCONTINUED**

TARGET THE IMMUNE RESPONSE AGAINST THE VIRUS:

31. **AIM Immunotech (Ampligen/rintatolimod):** *Entered human trials*
32. **Pulmotect (PUL-042):** *Completed Phase 2*
33. **Revelation (REVTx-99): DISCONTINUED**
34. **Nektar (NKTR-214/bempegaldesleukin):** *Completed Phase 1*
35. **Corvus (CPI-006): FAILED**
36. **Celularity/Sorrento Therapeutics (CYNK-001): DISCONTINUED**
37. **Altimmune (T-COVID): DISCONTINUED**

TREAT OR PREVENT ARDS:

38. **EUSA Pharma (Sylvant/siltuximab): DISCONTINUED**
39. **JNJ (Plivensia/sirukumab):** *Completed Phase 2*
40. **Humanigen (lenzilumab):** *Positive Top Line Data; Initial EUA declined. Awaiting additional data*
41. **GSK (otilimab):** *Completed Phase 2*
42. **Izana Bioscience (namilumab): DISCONTINUED**
43. **Avalo (AVTX-002):** *Completed Phase 2*
44. **INmune Bio (Quellor/XPro1595):** *Completed Phase 2/3*
45. **(colchine): FAILED**
46. **Theravance Biopharma (TD0903): FAILED**

47. **Pfizer (Xeljanz/tofacitinib):** *Positive signal in a Ph2 RCT in inpatient setting*
48. **Cytocom/Immune Therapeutics (Lodonal/low dose naltrexone): DISCONTINUED**
49. **Innate Pharma (IPH5401/avdoralimab): FAILED**
50. **NantKwest (BM-Allo.MSC):** *Completed Phase 1b*
51. **Sorrento (COVI-MSC):** *Completed Phase 2*
52. **Aspire (ACT-20): DISCONTINUED**
53. **4D Pharma (MRx-4DP0004): DISCONTINUED**
54. **Abbvie/JNJ (Imbruvica/ibrutinib): DISCONTINUED**
55. **AB Science (masitinib + isoquercetin):** *Completed Phase 2*
56. **Oryzon (vafidemstat):** *Completed Phase 2*
57. **RedHill Biopharma (Yeliva/opaganib): FAILED**
58. **Fulcrum Therapeutics (losmapimod): DISCONTINUED**
59. **Aclaris Therapeutics (ATI-450):** *Completed Phase 2a*
60. **Laurent Pharmaceuticals (LAU-7b/fenretinide):** *Completed Phase 2a*
61. **(Vitamin D):** *Completed Phase 4*
62. **AstraZeneca (AZD1658):** *Completed Phase 4*
63. **NeuroActiva (NA-831): DISCONTINUED**
64. **CalciMedica (Auxora/CM-4620-IE):** *Completed Phase 4*
65. **Grifols (Gamunex-C/immune globulin): DISCONTINUED**
66. **Biotest (Trimodulin): FAILED**
67. **Chimerix (dociparstat): DISCONTINUED**
68. **Edesa Biotech (EB05):** *Positive top line data in severe patients. Phase 3 is ongoing.*
69. **Horizon Therapeuticcs/Viela Bio (VIB7734): DISCONTINUED**
70. **Galecto Biotech (GB-0139): DISCONTINUED**
71. **Diffusion Pharma (trans sodium crocetinate):** *Completed Phase 4*
72. **Novartis (MAS825): DISCONTINUED**
73. **Angion (ANG-3777): FAILED**
74. **(Aspirin): FAILED**
75. **(heparin): FAILED**

THERAPEUTICS UPDATES:

VERSION 13 UPDATES: MAY 21, 2021

NEW PROGRAMS ADDED (28):

TARGET VIRAL REPLICATION:

1. National Resilience/Ology Bioservices (ADM03820)
2. BMS/Rockefeller University (C144-LS + C135-LS)
3. BeiGene/Singlomics Biopharmaceuticals (BGB-DXP593 + BGB-DXP604)
4. Aridis (AR-712/AR-711+AR-713)
5. Eli Lilly/AbCellera Biologics (LY-CoV1404)
6. Boehringer Ingelheim/ University of Cologne (BI 767551/DZIF-10c)
7. Jemincare (JMB2002)
8. Hengenix/ Sanyou/Shanghai ZJ Bio-Tech (HLX70)
9. Luye Pharma (LY-CovMab)
10. Eureka (Invismask)
11. Sorrento Therapeutics (COVI-DROPS/STI-2099)
12. GC Pharma (GC5131A)
13. Neoleukin Therapeutics (NL-CVX1)
14. Kintor (GT0918/proxalutamide)
15. Jubilant Pharma (remdesivir)
16. Rhizen (RP7214)
17. Pfizer (PF-07321332)
18. Pardes Biosciences
19. Sixty Degrees Pharma
20. Union Therapeutics (UNI91103/nicloasamide)
21. (fluvoxamine)

TREAT OR PREVENTS ARDS:

22. Nobelpharma (sargramostim)
23. Omeros (narsoplimab)
24. Stemedica (Stemedyne-MSC)
25. Sorrento (COVI-MSC)
26. Cartesian Therapeutics (Descartes-30)
27. Foresee Pharmaceuticals (FP-025)

PREVENT ORGAN FAILURE BEYOND THE LUNG :

28. Boehringer Ingelheim (Actilyse/alteplase)

UPDATES TO EXISTING PROGRAMS (64):

TARGET VIRAL REPLICATION:

1. **Regeneron/Roche (REGEN-COV/ (casirivimab + imdevimab):** *EUA for high-risk, outpatient setting; seeking EUA for post-exposure prophylaxis*
2. **Eli Lilly/AbCellera Biologics/Junshi Biosciences (LY-CoV555+LY-COV016/bamlanivimab + etesevimab):** *Testing as a monotherapy and in combo with bamlanivimab and etesevimab*
3. **Vir Biotechnology/GSK (VIR-7831/sotrovimab):** *Seeking EUA for outpatient setting*
4. **Eli Lilly/AbCellera Biologics (LY-CoV555/bamlanivimab):** *EUA revoked as monotherapy, due to loss of potency against emerging variants*

5. **Celltrion (CT-P59/regdanvimab):** *Positive topline data in outpatient setting; conditionally approved in South Korea*
6. **Sorrento Therapeutics (COVI-GUARD/STI-1499): DISCONTINUED**
7. **Inmunova (INM005): FAILED**
8. **Grifols/GigaGen (GIGA-2050):** *Partnered with Grifols*
9. **GC Pharma (GC5131A):** *Completed trial*
10. **CoVIg-19 Plasma Alliance: FAILED**
11. **Emergent BioSolutions (COVID-HIG): FAILED**
12. **Grifols:** *Hyperimmune globulin from CoVIg-19 Plasma Alliance, Emergent Biosolutions, and Grifols were tested together in hospitalized patients in an NIH-sponsored Ph3 trial and failed. Grifols is testing in the outpatient setting*
13. **(convalescent plasma):** *Failed to show benefit in NIH-sponsored Ph3 RCT*
14. **Vir Biotechnology/Alnylam Pharmaceuticals: DISCONTINUED**
15. **BerGenBio (bemcentinib): FAILED**
16. **Nichi-Iko/Daiichi Sankyo/ University of Tokyo/ RIKEN (nafamostat):** *Moved to Human Trials*
17. **Vir Biotechnology/Alnylam Pharmaceuticals: DISCONTINUED**
18. **Selva Therapeutics (SLV213)**
19. **Ridgeback Biotherapeutics/Merck (molnupiravir/EIDD-2801): DISCONTINUED** *Ph2 in hospitalized patients and not moving to Ph3. Outpatient study moving to Ph3.*
20. **Gilead (Veklury/remdesivir):** *Approved for hospitalized patients, the outpatient Ph3 was halted due to challenges in enrolling the study*
21. **Immunic (IMU-838): FAILED**
22. **Ascletis (ASC09 + ritonavir): DISCONTINUED**
23. **SaNOtize Research and Development (NORS):** *Completed trial; Seeking EUA in UK and Canada*
24. **NeuroBo Pharmaceuticals (ANA001/niclosamide)**
25. **AzurRx BioPharma/First Wave Bio (FW-1022/niclosamide):** *Partnered with AzuRx BioPharma*
26. **Romark Laboratories (NT-300/nitazoxanide): FAILED**
27. **(ivermectin): FAILED**
28. **Abivax (ABX-464): FAILED**
29. **Zydus Cadila (Virafin/peginterferon alfa-2b):** *Approved in India*
30. **Revelation (REVTx-99):** *Completed Ph1*
31. **Oncotelic (OT-101):** *Moved to Human Trials*
32. **Adicet Bio/resTORbio (RTB101): FAILED**

PROTECT THE LUNG FROM INJURY

33. **Roche (UTTR1147A/RG7880): FAILED**

TREAT OR PREVENT ARDS:

34. **Roche (Actemra/tocilizumab): FAILED** + *remdesivir;* **APPROVED** *+dexamethasone: approved in UK in critically ill patients*
35. **Humanigen (lenzilumab): EFFFECTIVE**
36. **Roche (RG-6149/AMG-282): DISCONTINUED**
37. **(infliximab):** *Completed trial*
38. **(methylprednisolone): FAILED**
39. **Covis Pharma (Alvesco/ciclesonide): FAILED**
40. **Algernon Pharma (ifenprodil): FAILED**
41. **AbbVie (Cenicriviroc): FAILED**
42. **Apellis (APL-9): FAILED**
43. **Caladrius (CLBS119): DISCONTINUED**
44. **Kaleido Biosciences (KB109):** *Completed trial*
45. **Enlivex Therapeutics (Allocetra):** *Completed trial*
46. **BeiGene (Brukinsa/zanubrutinib): FAILED**
47. **Exvastat (imatinib):** *Completed trial*
48. **Vanda Pharmaceuticals (tradipitant): DISCONTINUED**
49. **Amgen (Otezla/apremilast): DISCONTINUED**
50. **Verona Pharma (ensifentrine): FAILED**
51. **Denali Therapeutics/Sanofi (DNL-758/SAR443122): DISCONTINUED**
52. **Merck/OncoImmune (Saccovid/CD24Fc): DISCONTINUED**
53. **Octapharma (Octagam/Immune Globulin):** *Completed trial*
54. **Takeda (Finazyr/icatibant): FAILED**
55. **Fibrogen (pamrevlumab): DISCONTINUED**
56. **NeuroRx/Relief Therapeutics (RLF-10/aviptadil):** *EUA rejected*
57. **Bellerophon Therapeutics (INOpulse): DISCONTINUED**
58. **Boehringer Ingelheim (BI 764198): FAILED**
59. **Aerpio Pharmaceuticals (razuprotafib): DISCONTINUED**

PREVENT ORGAN FAILURE BEYOND THE LUNG:

60. **AstraZeneca (Farxiga/dapagliflozin): FAILED**

61. **Durect (DUR-928): DISCONTINUED**
62. **Reata (bardoxolone methyl):** *Completed trial*
63. **Applied Therapeutics (AT-001):** *Completed trial*
64. **Amarin (Vascepa/icosapent ethyl):** *Completed trial*

THERAPEUTICS UPDATES:

VERSION 12 UPDATES: FEBRUARY 12, 2020

NEW PROGRAMS ADDED (6):

TARGET VIRAL REPLICATION:

1. Brii Biosciences (BRII-196+BRI-198)
2. Formycon (FYB207)
3. RedHill Biopharma (upamostat)
4. DalCor Pharmaceuticals (dalcetrapib)
5. Aldeyra (ADX-1612)

TREAT OR PREVENTS ARDS:

6. Roche (RG-6149/AMG-282)

UPDATES TO EXISTING PROGRAMS (51):

TARGET VIRAL REPLICATION:

1. **Vir Biotechnology/GSK (VIR-7831/GSK4182136):** *RCT Trial*
2. **Celltrion (CT-P59):** *Positive Top-Line Data*
3. **SInocelltech (SCTA01):** *RCT Trial*
4. **Sorrento Therapeutics (COVI-AMG/STI-2020):** *RCT Trial*
5. **BeiGene/Singlomics Biopharmaceuticals (BGB-DXP593):** *RCT Trial*
6. **Abpro/Mabwell (ABP 300/MW33):** *RCT Trial*
7. **CORAT Therapeutics/Yumab (COR-101):** *Moved to Human Trials*
8. **CoVIg-19 Plasma Alliance:** *RCT Trial*
9. **Emergent BioSolutions (COVID-HIG):** *RCT Trial*
10. **Grifols:** *RCT Trial*
11. **Mithra Pharmaceuticals (estetrol):** *Moved to Human Trial*
12. **Selva Therapeutics (SLV213):** *Completed Ph1 Trial; moved to Human Trial*
13. **Gilead (Veklury/remdesivir):** *Approved, also testing in outpatients*
14. **Biocryst (galidesivir): DISCONTINUED**
15. **Clear Creek Bio (brequinar):** *RCT Trial*

16. **PTC Therapeutics (PTC299):** *RCT Trial*
17. **Karyopharm (Xpovio/selinexor): FAILED**
18. **PharmaMar (Apilidin/plitidepsin):** *Completed Trial*
19. **Veru (VERU-111):** *Completed Ph2 Trial;* **POSITIVE TOP-LINE DATA**
20. **Union Therapeutics (UNI911/nicloasamide):** *Completed Ph1 Trial*
21. **(Pepcid/famotidine):** *Completed Ph3 Trial*
22. **(azithromycin): FAILED**

TARGET THE IMMUNE RESPONSE:

23. **Zydus Cadila (peginterferon alfa-2b):** *Company added*
24. **Merck KGaA (Rebif/interferon beta-1b): FAILED**
25. **Corvus (CPI-006):** *RCT Trial*

TREAT OR PREVENTS ARDS:

26. **Biocad (BCD-089/levilimab):** *Completed Ph3 Trial*
27. **R-Pharm/Cromos Pharma (olokizumab):** *Completed Ph2/3 Trial*
28. **Sanofi/Regeneron (Kevzara/sarilumab):** *+dexamethasone: Approved in UK in critically ill patients*
29. **Roche (Actemra/tocilizumab):** *+dexamethasone:Approved in UK in critically ill patients*
30. **Sobi (Kineret/anakinra): DISCONTINUED**
31. **R-Pharm/Cromos Pharma (RPH-104):** *Completed Ph2/3 Trial*
32. **Sobi (Gamifant/emapalumab): DISCONTINUED**
33. **Syndax (axatilimab/SNDX-6352): DISCONTINUED**
34. **(colchicine): EFFECTIVE**
35. **Incyte/Novartis (Jakafi/ruxolitinib): FAILED**
36. **Cytocom/Immune Therapeutics (Lodonal/low dose naltrexone):** *RCT Trial*
37. **Alexion (Ultomiris/ravulizumab): FAILED**
38. **Apellis (APL-9):** *RCT Trial*
39. **Amyndas (AMY-101):** *RCT Trial*
40. **Novartis/Mesoblast (remestemcel-L): FAILED**
41. **Cellenkos (CK0802):** *RCT Trial*
42. **aTyr (ATYR1923):** *Completed Ph2 Trial*
43. **Ampio (Ampion):** *RCT Trial*
44. **BioAegis (rhu-pGSN):** *Moved to Human Trial, RCT*
45. **Novartis (Adakveo/crizanlizumab):** *Completed Ph2 Trial*

46. **Diffusion Pharmaceuticals (trans sodium crocetinate):** *RCT Trial*
47. **Aerpio (razuprotafib):** *Moved to Human Trials*
48. **Merck (MK-5475): DISCONTINUED**
49. **Eli Lilly (LY3127804): FAILED**

PREVENT ORGAN FAILURE:

50. **CSL Behring (CSL312/garadacimab):** *Completed Ph2 Trial*
51. **Roche (TNKase/tenecteplase):** *RCT Trial*

THERAPEUTICS UPDATES:

VERSION 11 UPDATES: DECEMBER 7, 2020

NEW PROGRAMS ADDED (1):

TREAT OR PREVENTS ARDS:

1. Sage Therapeutics (Zulresso/brexanolone)

UPDATES TO EXISTING PROGRAMS (34):

TARGET VIRAL REPLICATION:

1. **Regeneron (REGN-COV2/casirivimab + imdevimab):** *Approved for EUA*
2. **AstraZeneca (AZD7442/AZD8895+AZD1061:** *Data readout moved to MY21*
3. **Novartis/Molecular Partners (MP0420):** *Moved to human trials*
4. **Tychan (TY027):** *Data readout moved to 3Q21*
5. **Brii Biosciences (BRII-196):** *Data readout moved to MY21*
6. **Brii Biosciences (BRII-198):** *Data readout moved to MY21*
7. **SInocelltech (SCTA01):** *Data readout moved to MY21*
8. **Sorrento Therapeutics (COVI-GUARD/STI-1499):** *Moved to human trials; Data readout moved to 1Q21*
9. **Abpro/Mabwell (ABP 300/MW33):** *Partnered wuth Abpro; Data readout moved to 2Q21*
10. **AbbVie/Harbour BioMed (ABBV-47D11):** *Moved to human trials; Data readout moved to MY21*
11. **HiFiBio/ABL Bio (HFB30132A):** *Moved to human trials; Data readout moved to MY21*
12. **Kamada/Kedrion:** *Data readout moved to MY21*
13. **Jiangsu Pacific Meinuoke Bio Pharmaceutical (meplazumab):** *Data readout moved to 2Q21*
14. **Ridgeback Biotherapeutics/Merck (molnupiravir/EIDD-2801):** *Data readout moved to 2Q21*
15. **PTC Therapeutics (PTC299):** *Data readout moved to 1Q21*
16. **Immunic (IMU-838):** *Data readout moved to 4Q21*
17. **eFFECTOR Therapeutics (eFT226/zotatifin):** *Moved to human trials, RCT Data readout moved to 4Q21*
18. **MedinCell (ivermectin):** *Moved to human trials*
19. **Nektar (NKTR-214/bempegaldesleukin):** *Data readout moved to 1Q21*
20. **Adicet Bio/resTORbio (RTB101):** *Data readout moved to 1Q21; Partnered with Adicet Bio*
21. **NPO Petrovax Pharma (Polyoxidonium/azoximer bromide):** *Data readout moved to 1Q21*

PROTECT THE LUNG:

22. **Vicore Pharma (VPO1/C21):** *Phase 2 trial completed*
23. **Roche (UTTR1147A):** *Data readout moved to 1Q21*

TREAT OR PREVENTS ARDS:

24. **(dexamethasone):** *Being testing in another trial + remdesivir*
25. **Eli Lilly (Olumiant/baricitinib):** *Approved for EUA*
26. **Novartis/Mesoblast (remestemcel-L):** *Partnered with Novartis*
27. **AI Therapeutics (apilimod mesylate/LAM-002A):** *Data readout moved to 1Q21*
28. **Equillium/Biocon (itolizumab):** *Decided not to initiate Ph3*
29. **Merck/OncoImmune (Saccovid/CD24Fc):** *Partnered with Merck*
30. **PhaseBio (PB1046): FAILED**
31. **Orpheris (OP-101)**
32. **Boehringer Ingelheim (Ofev/nintedanib):** *Data readout moved to 1Q21*
33. **NeuroRx/Relief Therapeutics (RLF-10/aviptadil):** *Route of delivery hanged to Inhaled*
34. **Bayer/JNJ (Xarelto/rivaroxaban):** *Partnered with JNJ, data readout moved to 1Q21*

THERAPEUTICS UPDATES:
VERSION 10 UPDATES: NOVEMBER 13, 2020

NEW PROGRAMS ADDED (5):

TARGET VIRAL REPLICATION:

1. Novartis/Molecular Partners (MP0423)
2. Nichi-Iko/Sagent Pharmaceuticals (camostat mesylate)

TARGET THE IMMUNE RESPONSE:

3. Nektar (NKTR-214/bempegaldesleukin)

TREAT OR PREVENTS ARDS:

4. Novartis (Adakveo/crizanlizumab)
5. Boehringer Ingelheim (BI 764198)

UPDATES TO EXISTING PROGRAMS (14):

TARGET VIRAL REPLICATION:

1. **Eli Lilly/AbCellera Biologics/Junshi Biosciences (LY-CoV555/bamlanivimab+LY-COV016/etesevimab)**
2. **Novartis/Molecular Partners (MP0420):** *partnership with Novartis*
3. **Eli Lilly/AbCellera Biologics (LY-CoV555/bamlanivimab:** *EUA Filed; RCT testing combo with remdesivir in hospitalized patients failed*
4. **BioSig Technologies/ViralClear Pharmaceuticals (merimepodib): FAILED**
5. **Pfizer (PF-07304814):** *Data readout moved to 2Q21*
6. **ANA Therapeutics (ANA001/niclosamide):** *Moved to human trials, Data readout moved to 2Q21*

TREAT OR PREVENTS ARDS:

7. **Novartis (Ilaris/canakinumab): FAILED**
8. **CTI Biopharma (Enpaxiq/pacritinib):** *Data readout moved to 1Q21*
9. **Alexion (Ultomiris/(ravulizumab):** *Data readout moved to 1Q21*
10. **Pluristem (PLX-PAD):** *Data readout moved to 1Q21*
11. **Capricor (CAP-1002):** *Data readout moved to 1Q21*

12. **AstraZeneca (Calquence/acalabrutinib): FAILED**
13. **AI Therapeutics (apilimod mesylate/LAM-002A):** *Data readout moved to 1Q21*
14. **Equillium/Biocon (itolizumab)**: *Ph3 RCT to start 4Q20; Data readout 1Q21*

THERAPEUTICS UPDATES:
VERSION 9 UPDATES: OCTOBER 23, 2020

NEW PROGRAMS ADDED (10):

TARGET VIRAL REPLICATION:

1. Sorrento Therapeutics (COVI-AMG/STI-2020)

TARGET THE IMMUNE RESPONSE:

2. Revelation (REVTx-99)

TREAT OR PREVENTS ARDS:

3. Abbvie (Skyrizi/risankizumab)
4. ReAlta Life Sciences (RLS-0071)
5. NGM Biopharma (NGM-621)
6. Pfizer (PF-06650833)
7. SynAct Pharma AB (AP1189)
8. AstraZeneca (AZD1656)
9. Asklepion (L-Citrulline)
10. Shaperon (NuSepin)

UPDATES TO EXISTING PROGRAMS (12):

TARGET VIRAL REPLICATION:

1. **Regeneron/Roche (REGN-COV2/REGN10933+REGN10987):** *Positive Interim Data; filed for EUA*
2. **Eli Lilly/AbCellera Biologics/Junshi Biosciences (LY-CoV555+LY-COV016):** *Positive Interim Data*
3. **Eli Lilly/AbCellera Biologics (LY-CoV555/LY3819253) :** *Positive Interim Data; filed for EUA*
4. **CoVIg-19 Plasma Alliance:** *Data readout moved to 2Q21; Hyperimmune globulin from CoVIg-19 Plasma Alliance, Emergent Biosolutions, and Grifols are all being tested together in an NIH-sponsored Ph3 trial*
5. **Emergent BioSolutions (COVID-HIG):** *Moved to human trials; Data readout moved to 2Q21; Hyperimmune globulin from CoVIg-19 Plasma Alliance, Emergent Biosolutions, and Grifols are all being tested together in an NIH-sponsored Ph3 trial*
6. **Grifols:** *Moved to human trials; Data readout moved to 2Q21; Hyperimmune globulin from CoVIg-19 Plasma Alliance, Emergent Biosolutions, and Grifols are all being tested together in an NIH-sponsored Ph3 trial*
7. **Atea/Roche (AT-527):** *Partnered with Roche*

8. **Gilead (Veklury/remdesivir):** *Approved for Hospitalized COVID-19 Patients*
9. **Jiangsu Pacific Meinuoke Bio Pharmaceutical (meplazumab):** *Data readout moved to 1Q21*
10. **Ridgeback Biotherapeutics/Merck (molnupiravir/EIDD-2801):** *Data readout moved to 1Q21*
11. **Clear Creek Bio (brequinar):** *Data readout moved to 1Q21*
12. **Union Therapeutics (UNI911/nicloasamide):** *Moved to Human Trials*

THERAPEUTICS:
VERSION 8 UPDATES: SEPTEMBER 30, 2020

NEW PROGRAMS ADDED (15):

TARGET VIRAL REPLICATION:

1. Mabwell (MW33)
2. HiFiBio/ABL Bio (HFB30132A)
3. Xenothera (XAV-19)
4. Selva Therapeutics (SLV213)
5. NeoImmuneTech (NT-I7)

TARGET THE IMMUNE RESPONSE:

6. Evive Biotech (F-652)

TREAT OR PREVENTS ARDS:

7. Pliant (PLN-74809)
8. G(Vitamin D)
9. OPKO (Rayaldee/calcifediol ER)
10. Galera (GC4419/avasopasem manganese)
11. Galecto Biotech (GB-0139)
12. Grifols (alpha1-proteinase inhibitor)

PREVENT ORGAN FAILURE:

13. (apixaban)
14. (aspirin)
15. Durect (DUR-928)

UPDATES TO EXISTING PROGRAMS (43):

**All 3Q20 data readouts have been updated to 4Q20 unless otherwise noted below*

TARGET VIRAL REPLICATION:

1. **CORAT Therapeutics/Yumab:** *CORAT Therapeutics added*
2. **SAB Biotherapeutics/CSL Behring (SAB-185) + BARDA:** *Moved to human trials*
3. **Kamada/Kedrion (IgG Product):** *Moved to human trials; UCT data readout moved to 1Q21*
4. **Jiangsu Pacific Meinuoke Bio Pharmaceutical (meplazumab):** *Trial completed*
5. **Atea (AT-527):** *RCT data readout moved to 1Q21*
6. **Viriom (Elsulfavirine):** *RCT data readout moved to 1Q21*
7. **Henan Zhenshi Biotechnology (azvudine):** *RCT data readout moved to 1Q21*
8. **(favipiravir):** *RCT data readout moved to 1Q21*
9. **Gilead (remdesivir)- Inhaled:** *RCT data readout moved to 1Q21*
10. **Biocryst (galidesivir):** *RCT data readout moved to 2Q21*
11. **BioSig Technologies/ViralClear Pharmaceuticals (merimepodib):** *RCT data readout moved to 1Q21*
12. **Atriva Therapeutics (ATR-002):** *RCT data readout moved to 1Q21*
13. **First Wave Bio (niclosamide):** *RCT data readout moved to 3Q21*
14. **Romark Laboratories (NT-300/nitazoxanide):** *RCT data readout moved to 2Q21*
15. **MedinCell (ivermectin):** *RCT data readout moved to 2Q21*
16. **(ivermectin):** *RCT data readout moved to 2Q21*
17. **(Pepcid/famotidine:** *RCT data readout moved to 1Q21*
18. **(amiodarone):** *RCT data readout moved to 1Q21*
19. **(verapamil):** *RCT data readout moved to 1Q21*

TARGET IMMUNE RESPONSE:

20. **Partner Therapeutics (Leukine/sargramostim):** *RCT data readout moved to MY21*
21. **Celularity/Sorrento Therapeutics (CYNK-001):** *RCT data readout moved to 2Q21*

TARGET RENIN-ANGIOTENSIN SYSTEM (RAS):

22. **(losartan):** *RCT data readout moved to 1Q21*

TREAT OR PREVENTS ARDS:

23. **JNJ (Plivensia/sirukumab):** *RCT data readout moved to 1Q21*
24. **AVM (AVM0703/dexamethasone):** *RCT data readout moved to 2Q21*

25. **InflaRx (IFX-1:** *RCT data readout moved to 2Q21*
26. **Mesoblast (remestemcel-L):** *RCT data readout moved to 2Q21*
27. **Athersys/Healios (Multistem/HLCM051):** *RCT data readout moved to 3Q21*
28. **NantKwest (BM-Allo.MSC):** *RCT data readout moved to 1Q21*
29. **Caladrius (CLBS119):** *RCT data readout moved to MY21*
30. **Celltex Therapeutics (AdMSCs):** *RCT data readout moved to 3Q21*
31. **Rapa Therapeutics (RAPA-501):** *RCT data readout moved to 4Q21*
32. **Can-Fite (CF101/piclidenoson):** *RCT data readout moved to 1Q21*
33. **RedHill Biopharma (Yeliva/opaganib):** *RCT data readout moved to 1Q21*
34. **Can-Fite (CF101/piclidenoson):** *RCT data readout moved to 1Q21*
35. **CalciMedica (Auxora/CM-4620-IE):** *RCT data readout moved to 1Q21*
36. **CalciMedica (Auxora/CM-4620-IE):** *RCT data readout moved to 1Q21*
37. **CalciMedica (Auxora/CM-4620-IE):** *RCT data readout moved to 1Q21*
38. **Chimerix (dociparstat):** *RCT data readout moved to 1Q21*
39. **Implicit Bioscience (IC14):** *RCT data readout moved to 1Q21*
40. **NeuroRx/Relief Therapeutics (RLF-10/aviptadil:** *Emergency Use Authorization filed*
41. **Bellerophon Therapeutics (INOpulse):** *RCT data readout moved to 1Q21*
42. **Mallinckrodt (INOmax):** *RCT data readout moved to 1Q21*
43. **Takeda (Takhyzro/lanadelumab):** *RCT data readout moved to 1Q21*

THERAPEUTICS:
VERSION 7 UPDATES: SEPTEMBER 15, 2020

NEW PROGRAMS ADDED (17):

TARGET VIRAL REPLICATION:

1. Eli Lilly/AbCellera Biologics (LY-CoV555 + LY-CoV016)
2. AstraZeneca (AZD7442/ AZD8895 + AZD1061)
3. Beigene/Singlomics (BGB DXP593)
4. Immunome (synthetic convalescent plasma)
5. Pfizer (PF-07304814)
6. RA Capital's Incubator

TARGET THE IMMUNE RESPONSE:

7. Primmune (PRTX007)
8. Fate Therapeutics (FT-516)

TREAT OR PREVENTS ARDS:

9. Kancera AB (AZD-8797/KAND567)
10. Dompe (reparixin)
11. Verona Pharma (ensifentrine)
12. Viela Bio (VIB7734)
13. Boehringer Ingelheim (Ofev/nintedanib)
14. Mereo (alvelestat)

PREVENT ORGAN FAILURE:

15. Bayer (Xarelto/rivaroxaban)
16. Daiichi Sankyo (Savaysa/edoxaban)
17. Takeda (Takhzyro/lanadelumab)

UPDATES TO EXISTING PROGRAMS (19):

TARGET VIRAL REPLICATION:

18. **Regeneron/Roche (REGN-COV2/REGN10933+REGN10987):** *Partnered with Roche*
19. **Vir Biotechnology/GSK (VIR-7831/GSK4182136)**: *Moved to human trials*
20. **Sorrento Therapeutics (COVI-GUARD/STI-1499)**: *Moved to human trials*
21. **Convalescent Plasma**: *Approved for Emergency Use Authorization*
22. **Ansun Biopharma (DAS181): FAILED**

TARGET IMMUNE RESPONSE:

23. **Romark Laboratories (NT-300/nitazoxanide):** *RCT readout moved to 4Q20*
24. **Synairgen (SNG001/Interferon beta 1a):** *RCT readout moved to 1Q21*

PROTECT THE LUNG FROM INJURY:

25. **Constant Therapeutics (TXA127/Angiotensin 1-7):** *RCT readout moved to 4Q20*

TREAT OR PREVENT ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS):

26. **(dexamethasone):** *Standard of Care*
27. **Eli Lilly (Olumiant/baricitinib):** *Positive Ph3 Trial*
28. **Pharming (Ruconest/recombinant C1 esterase inhibitor)**: *RCT readout moved to 1Q21*
29. **Enlivex Therapeutics (Allocetra)**: *RCT readout moved to 4Q20*
30. **AstraZeneca (acalabrutinib)**: *RCT readout moved to 4Q20*
31. **BeiGene (Brukinsa/zanubrutinib)**: *RCT readout moved to 1Q21*
32. **Sorrento Therapeutics (STI-5656/abivertinib maleate)**: *RCT readout moved to 1Q21*
33. **Biohaven (BHV-3500/zavegepant)**: *RCT readout moved to 4Q20*
34. **Vanda pharmaceuticals (tradipitant)**: *RCT readout moved to 4Q20*
35. **Verastem (Copiktra/ duvelisib)**: *RCT readout moved to 1Q21*
36. **Biotest (Trimodulin)**: *RCT readout moved to 1Q21*

THERAPEUTICS:
VERSION 6 UPDATES: AUGUST 14, 2020

NEW PROGRAMS ADDED (20):

TARGET VIRAL REPLICATION:

1. Adagio
2. Brii Biosciences (BRII-196)
3. Brii Biosciences (BRII-198)
4. SInocelltech (SCTA01)

TARGET THE IMMUNE RESPONSE:

5. (peginterferon alfa-2b)

TREAT OR PREVENTS ARDS:

6. AbbVie (cenicriviroc)
7. Rapa Therapeutics (RAPA-501)
8. Denali Therapeutics/ Sanofi (DNL758/SAR443122)
9. AI Therapeutics (apilimod mesylate/LAM-002A)
10. NeuroActiva (Traneucorin/NA-831)
11. Grifols (Gamunex-C)
12. Bristol-Myers Squibb (Orencia/abatacept)
13. Takeda (Finazyr/icatibant)
14. BioAegis (rhu-pGSN)
15. Heron (Cinvanti/aprepitant)
16. Monopar Therapeutics/ NorthStar Medical Radioisotopes (MNPR-101 radiolabelled)
17. Thirty Respiratory (RESP301)
18. ReviveMed (bucillamine/REV-002)
19. Angion (ANG-3777)

PREVENT ORGAN FAILURE:

20. Reata (bardoxolone methyl)

UPDATES TO EXISTING PROGRAMS (12):

TARGET VIRAL REPLICATION:

21. **Bausch Health (Virazole/ribavirin):** *RCT readout moved to 4Q20*
22. **JNJ (Prezcobix/darunavir + cobicistat): FAILED**
23. **Ascletis (ASC09 + ritonavir):** *Completed trial*
24. **Karyopharm (Xpovio/selinexor):** *Completed trial*
25. **(azithromycin + hydroxychloroquine): FAILED**
26. **(azithromycin + chloroquine): FAILED**

TARGET IMMUNE RESPONSE:

27. **Synairgen (SNG001/Interferon beta 1a):** *Completed trial*

PROTECT THE LUNG FROM INJURY:

28. **Constant Therapeutics (TXA127/Angiotensin 1-7):** *RCT readout moved to 4Q20*

TREAT OR PREVENT ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS):

29. **Roche (Actemra/tocilizumab): FAILED**
30. **Cytodyn (leronlimab):** *RCT readout moved to 4Q20*
31. **Abbvie/JNJ (Imbruvica/ibrutinib):** *RCT readout moved to 1Q21*
32. **Amgen (Otezla/apremilast):** *RCT trial started, readout date is 4Q20*
33. **Aerpio Pharmaceuticals (razuprotafib):** *RCT trial started, readout date is 4Q20*

THERAPEUTICS:
VERSION 5 UPDATES: JULY 22, 2020

NEW PROGRAMS ADDED (10):

1. Arrowhead Pharmaceuticals (ARO-COV)
2. Rigel (Tavlesse/fostamatinib)
3. Merck KGaA (M5049)
4. Equillium/Biocon (itolizumab)
5. Apeptico (solnatide)
6. Roche (Pulmozyme/dornase alfa)
7. Chrysalis (TP508)
8. Akebia Therapeutics (vadadustat)
9. Chiesi (Curosurf/poractant alfa)
10. Sedana Medical (IsoConDa/isoflurane)

UPDATES TO EXISTING THERAPEUTICS PROGRAMS (3):

11. **Celltrion:** *Moved to Human Trials. RCT readout expected 4Q20*
12. **EUSA Pharma (Sylvant/siltuximab):** *RCT readout expected 4Q20*
13. **InflaRx (IFX-1):** *RCT readout expected 4Q20*

THERAPEUTICS:
VERSION 4 UPDATES: JULY 2, 2020

NEW PROGRAMS ADDED (45):

1. Aridis (AR-701)
2. Formycon
3. Alphamab/Institut Pastuer Shangai
4. pHion Therapeutics (PTX-G1)
5. Mithra Pharmaceuticals (estetrol)
6. (favipiravir)
7. Gilead (remdesivir) inhaled
8. PTC Therapeutics (PTC299)
9. Geneone (GLS-1200)
10. SaNOtize (NORS)
11. Union (UNI911/nicloasamide)
12. Leidos/Orgenesis (ranpirnase)
13. NPO Petrovax (polyoxidonium/azoximer bromide)
14. (ramipril)
15. Novoteris/Mallinckrodt (Thiolanox)
16. Actelion (Ventavis/iloprost)
17. Diffusion (trans sodium crocetinate)
18. Merck (MK-5475)
19. Novartis (MAS825)
20. (infliximab)
21. Syndax (axatilimab/SNDX-6352)
22. AVM (AVM0703/dexamethasone)
23. Cytocom/Immune Therapeutics (Lodonal/low dose naltrexone)
24. Dimerix (DMX-200)
25. Argenx (ARGX-117)
26. Caladrius (CLBS119)
27. Stemedica Cell Technologies (CLBS119)
28. Celltex (AdMSCs)
29. Hope Biosciences
30. Aspire (ACT-20)
31. Pluristem (PLX-PAD)
32. Sorrento Therapeutics (STI-5656/abivertinib maleate)
33. Fulcrum (losmapimod)
34. Aclaris (ATI-450)
35. Verastem (Copiktra/ duvelisib)
36. Laurent (LAU-7b/fenretinide)
37. Edesa (EB05)
38. (ulinastatin)
39. Implicit (IC14)
40. Ampio Pharmaceuticals (Ampion)
41. Palatin (PL8177)
42. CSL Behring (garadicimab/CSL312)
43. Boehringer Ingelheim (Aggrenox)
44. Fulcrum Pharma/SIRS Therapeutics (FX06)
45. Amarin (Vascepa/icosapent ethyl)

UPDATES TO EXISTING THERAPEUTICS PROGRAMS (6):

1. **Tychan (TY027):** *Moved to human trials*
2. **Pharmstandard (Arbidol/umifenovir): FAILED**
3. **(lopinavir + ritonavir): FAILED**
4. **Genoscience Pharma (GNS561): SUSPENDED**
5. **(chloroquine): FAILED**
6. **(interferon beta-1b):** *Completed Phase 2 trial*
7. **Sanofi/Regeneron (Kevzara/sarilumab): FAILED**

THERAPEUTICS:
VERSION 3 UPDATES: JUNE 15, 2020

NEW PROGRAMS ADDED (43):

1. Abbvie/Harbour BioMed (47D11)
2. AB Science (masitinib + isoquercetin)
3. Aerpio Pharmaceuticals (razuprotafib)
4. Agenus (AgenT-797)
5. Altimmune (T-COVID)
6. Anivive (GC376)
7. Apogenix (asunercept)
8. Applied Therapeutics (AT-001)
9. ARCA Biopharma
10. Ashvattha (OP-101)
11. Atriva (ATR-002)
12. Biocad (levilimab/BCD-089)
13. Biophytis (Sarconeos/BIO101)
14. BLife Therapeutics (AP-003/Interferon α2b)
15. Brii Biosciences/Tsinghua University/3rd People's Hospital of Shenzen
16. Cellenkos (CK0802)
17. Cerecor (CERC-002)
18. Edesa Biotech/NovImmune (EB06)
19. Enlivex (Allocetra)
20. Ennaid Therapeutics/Catalent (ENU200)
21. Ensysce (nafamostat)
22. Exvastat (imatinib)
23. Faron (Traumakine/interferon beta-1a)
24. Fibrogen (pamrevlumab)
25. GSK (otilimab)
26. IDBiologics/Vanderbilt University
27. INmune Bio (XPro1595) Yumab
28. Leading BioSciences (LB1148/tranexamic acid)
29. MedinCell (ivermectin)
30. Nichi-Iko/Daiichi Sankyo/University of Tokyo/RIKEN (nafamostat)
31. Octapharma (Octagam/Immune Globulin Intravenous)
32. Partner Therapeutics (Leukine/sargramostim)
33. PhaseBio (PB1046)
34. PureTech (LYT-100 /deupirfenidone)
35. RedHill (Yeliva/opaganib)
36. Renibus (RBT-9)
37. resTORbio (RTB101)
38. Sun Pharma (nafamostat)
39. Trevana (TRV027)
40. Tychen (TY027)
41. UCB (zilucoplan)
42. Veru (VERU-111)
43. Yumab

UPDATES TO EXISTING THERAPEUTICS PROGRAMS (6):

1. **AbCellera/Eli Lilly (LY-CoV555):** *moved to human trials*
2. **(dexamethasone): EFFECTIVE**
3. **(hydroxychloroquine): FAILED**
4. **Junshi Biosciences/Eli Lilly (JS016):** *moved to human trials*
5. **Merck/Ridgeback Biotherapeutics (EIDD-2801):** *moved to phase 2*
6. **Regeneron (REGN-COV2/REGN10933 + REGN10987) + BARDA:** *moved to phase 1*

THERAPEUTICS:
VERSION 2 UPDATES: MAY 22, 2020

NEW PROGRAMS ADDED (41):

1. Abbvie/JNJ (Imbruvica/ibrutinib)
2. Abivax (ABX-464)
3. Acer Therapeutics (emetine)
4. Alderya (ADX-1612)
5. Alderya (ADX-629)
6. (almitrine)
7. Amgen (Otezla/apremilast)
8. (amiodarone)
9. Amyndas (AMY-101)
10. Apellis (APL-9)
11. BeiGene (Brukinsa/zanubrutinib)
12. Bristol-Myers Squibb (BMS-986253)
13. Bukwang (clevudine)
14. Can-Fite (CF101/piclidenoson)
15. Clear Creek Bio (brequinar)
16. CTI Biopharma (Enpaxiq/pacritinib)
17. eFFECTOR (eFT226/zotatifin)
18. Emergent BioSolutions (COVID-EIG)
19. Evelo (EDP1815)
20. (Futhan/nafamostat mesylate)
21. IGM Biosciences/Atreca/Beigene
22. Immunic (IMU-838)
23. ImmunityBio (N-803)
24. Innate Pharma (IPH5401/avdoralimab)
25. (ivermectin)
26. JNJ (Plivensia/sirukumab)
27. Kaleido Biosciences (KB109)
28. Molecular Partners
29. Oryzon Genomics (vafidemstat)
30. (prazosin)
31. RevImmune (CYT107)
32. Roche (MTPS9579A/astegolimab)
33. Roche (UTTR1147A)
34. Romark (NT-300/nitazoxanide)
35. R-Pharm/Cromos Pharma (olokizumab)
36. R-Pharm/Cromos Pharma (RPH-104)
37. Sorrento (COVI-GUARD/STI-1499)
38. Sorrento (COVI-SHIELD)
39. (telmisartan)
40. (valsartan)
41. (verapamil)

DIAGNOSTICS UPDATES:

VERSION 10 UPDATES: SEPTEMBER 24, 2021

NEW PROGRAMS ADDED (4):

COVID SCREENING TESTS:

1. OraSure Technologies, Inc. (InteliSwab COVID-19 Rapid Test)

QUANTATIVE PLATFORMS:

2. Bio-Rad Laboratories (BioPlex 2200 SARS-CoV-2 IgG)
3. Siemens Healthcare Diagnostics Inc. (ADVIA Centaur SARS-CoV-2 IgG (sCOVG))
4. DiaSorin, Inc. (LIAISON SARS-CoV-2 TrimericS IgG)

DIAGNOSTICS UPDATES:
VERSION 9 UPDATES: MAY 21, 2021

NEW PROGRAMS ADDED (7):

COVID SCREENING TESTS:

1. Quidel Corporation [QuickVue At-Home COVID-19 Test [Prescription and OTC test]

COVID DIAGNOSTICS TESTS:

2. Cue Health [Over the counter home test]
3. NeuMoDx Molecular (NeuMoDxTMFluA-B/RSV/SARS-CoV-2VantageAssay)
4. Abbott Molecular Inc. [Alinity m Resp-4-Plex - SARS-CoV-2/influenza A/Influenza B/RSV]

QUANTATIVE PLATFORMS:

5. Inova Diagnostics [QUANTA Flash® SARS-CoV-2 IgG Reagents]Phadia (EliA SARS-CoV-2-Sp1 IgG Test on Phadia 250 instrument)
6. Immunodiagnostic Systems Ltd. (IDS SARS-CoV-2 IgG on IDS-iSYS Multi-Discipline Automated System
7. Symbiotica Inc. [COVID-19 Self-Collected Antibody Test System]

UPDATES TO EXISTING THERAPEUTICS PROGRAMS (2):

1. **BioFire Diagnostics, LLC (BioFire Respiratory Panel 2.1 (RP2.1)):** *6000 NDU/mL*
2. **Lucira Health [approved for use with a prescription for symptomatic patients and also as over the counter test]:** *Sens: 91.7%, Spec: 98.2%*

DIAGNOSTICS:
VERSION 8 UPDATES: FEBRUARY 12, 2021

NEW PROGRAMS ADDED (2):

COVID SCREENING TESTS:

1. Ellume [Instrument-free lateral flow assay approved as over-the-counter test]
2. Abbott Diagnostics Scarborough, Inc. (BinaxNOW COVID-19 Ag Card Home Test) [Instrument free, approved as prescription test]
3. Quidel Corporation (QuickVue SARS Antigen Test)
4. Ortho Clinical Diagnostics, Inc. (VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack)
5. Quanterix Corp. (Simoa SARS-CoV-2 N Protein Antigen Test)

COVID DIAGNOSTICS TESTS:

6. Quidel (Solana)

QUANTATIVE PLATFORMS:

7. Quanterix Corporation (Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody Test on Quanterix HD-X analyzer)
8. Phadia (EliA SARS-CoV-2-Sp1 IgG Test on Phadia 250 instrument)
9. Kantaro Biosciences, LLC (COVID-SeroKlir, Kantaro Semi-Quantitative SARS-CoV-2 IgG Antibody Kit)
10. Union Biomedical Inc. (UBI SARS-CoV-2 ELISA)

QUALITATIVE LATERAL FLOW ASSAYS:

11. ACON Laboratories Inc. (ACON SARS-CoV-2 IgG/IgM Rapid Test)
12. Innovita (Tangshan) Biological Technology Co., Ltd. (Innovita 2019-nCoV Ab Test (Colloidal Gold))
13. Advaite (RapCovTM Rapid COVID-19 Test)

UPDATES TO EXISTING THERAPEUTICS PROGRAMS (2):

1. **T2 Biosystems, Inc. (T2SARS-CoV-2 Panel; T2Dx System):** *18,000 NDU/ml*

DIAGNOSTICS:
VERSION 7 UPDATES: DECEMBER 9, 2020

NEW PROGRAMS ADDED (2):

COVID SCREENING TESTS:

1. Luminostics, Inc. (Clip COVID Rapid Antigen Test)

COVID DIAGNOSTICS TESTS:

2. Cepheid (GeneXpert Omni)

UPDATES TO EXISTING THERAPEUTICS PROGRAMS (2):

1. **Cue Health (Cue COVID-19 Test):** *60,000 NDU/ml*
2. **Visby Medical, Inc. (Visby Medical COVID-19):** *54,000 NDU/ml*

DIAGNOSTICS:
VERSION 6 UPDATES: NOVEMBER 20, 2020

NEW PROGRAMS ADDED (4):

COVID DIAGNOSTICS TESTS:

1. Lucira Health (approved for use with a prescription for symptomatic patients)
2. T2 Biosystems, Inc. (T2SARS-CoV-2 Panel; T2Dx System)

QUANTATIVE PLATFORMS:

3. Quotient Suisse SA (MosaiQ COVID-19 Antibody Magazine)
4. GenScript USA Inc. (cPass SARS-CoV-2 Neutralization Antibody Detection Kit)

DIAGNOSTICS:
VERSION 5 UPDATES: NOVEMBER 2, 2020

NEW PROGRAMS ADDED (13):

COVID DIAGNOSTICS TESTS:

1. Access Bio, Inc. (CareStart COVID-19 Antigen test) Instrument-free
2. Celltrion USA, Inc (Sampinute COVID-19 Antigen MIA)
3. Quidel (Sofia 2 Flu + SARS Antigen FIA)
4. BioFire Diagnostics, LLC; BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ)
5. Becton, Dickinson & Company (BD SARS-CoV-2Reagents for BD MAX System)
6. DiaSorin Molecular LLC (Simplexa COVID-19 Direct assay) LIAISON® MDX instrument
7. GenMark Diagnostics, Inc. (ePlex Respiratory Pathogen Panel 2)
8. Roche Molecular Systems, Inc. (Cobas SARS-CoV-2 & Influenza A/B)

QUANTATIVE PLATFORMS:

9. Quotient Suisse SA (MosaiQ COVID-19 Antibody Magazine on MosaiQ 125 instrument)
10. ZEUS Scientific, Inc. (ZEUS ELISA SARS-CoV-2 IgG Test System)
11. Thermo Fisher Scientific (OmniPATH COVID-19 Total Antibody ELISA Test)
12. Genalyte, Inc. [Maverick SARS-CoV-2 Multi-Antigen Serology Panel v2] (IgG and IgM)

QUALITATIVE LATERAL FLOW ASSAYS:

13. NanoEntek America, Inc. (FREND COVID-19 total Ab)

UPDATES TO EXISTING THERAPEUTICS PROGRAMS (18):

1. **Roche Molecular Systems, Inc. (cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System):** *[IV-C]*
2. **Cepheid (Xpert Xpress SARS-CoV-2 test):** *LoD = 0.01-0.02 PFU/mL [LV-C] (250 copies/mL [RV-C])*
   LoD: 5400 NDU/ml*
3. **Mesa Biotech (Accula SARS-Cov-2 Test):** *LoD = 100 [SARS-B]-200 [SARS-C] copies/mL*
   LoD = under review*
4. **Cue Health (Cue COVID-19 Test):** *LoD = 1300 copies/mL [SARS-C]*
   LoD = Data not returned*
5. **Abbott Diagnostics (ID NOW COVID-19):** *LoD = 125 copies/mL [SARS-C]*

LoD: 300000 NDU/ml***

6. **Hologic, Inc. (Panther Fusion SARS-CoV-2 Assay):** *LoD = 0.01 TCID50/mL [IV-C]*
   LoD = 600 NDU/mL*
7. **Roche Molecular Systems, Inc. (Cobas SARS-CoV-2- used with Cobas® 6800/8800):** *Note added*
   **up to 6 samples can be pooled for this test and*
   LoD = 0.004 TCID50/mL [46 copies/ml]
   LoD = 1800 NDU/ml*
8. **Becton, Dickinson & Company (BD) (BioGX SARS-CoV-2 Reagents for BD MAX System):** *LoD = 640 genomic copies/mL [IV-C]*
   LoD = 5400 NDU/mL*
9. **Abbott Molecular Inc. (Alinity m SARS-CoV-2 assay):** *LoD = 100 copies/mL [RV-S] or 0.0037 TCID50/mL [IV-B]*
   LoD: Data not returned*
10. **BioFire Defense, LLC (BioFire COVID-19 Test):** *LoD = 330 copies/mL or TCID50/mL = 0.022 [LV-U]*
    LoD: 5400 NDU/ml*
11. **GenMark Diagnostics, Inc. (ePlex SARS-CoV-2 Test):** *LoD = 1,000 copies/mL [SARS-U]*
    LoD = Data uninterpretable*
12. **Luminex Corporation (ARIES SARS-CoV-2 Assay):** *LoD = 333 copies/mL or 0.0548 TCID50/mL [IV-C]*
    LoD=180000 NDU/ml*
13. **NeuMoDx Molecular, Inc. (NeuMoDx SARS-CoV-2 Assay):** *LoD = 150 copies/mL [SARS-C]*
    LoD = 5400 NDU/ml*
14. **Visby Medical, Inc. (Visby Medical COVID-19):** *LoD=1112 copies/mL [IV-C]*
15. **BioFire Diagnostics, LLC (BioFire Respiratory Panel 2.1 (RP2.1)):** *LoD = 160 copies/mL [LV-C] (0.01 TCID50/mL) [LV-C] or 500 copies/mL [IV-S] (0.069 TCID50/mL) [IV-S]*
    LoD = Data uninterpretable*
16. **QIAGEN GmbH (QIAstat-Dx Respiratory SARS-CoV-2 Panel):** *LoD = 250 copies/ml (0.01 TCID50/mL) [IV-C]*
17. **Illumina (COVIDSeq Test):** *LoD = 500-1000 copies/mL [IV-C]*
    LoD = 5400 NDU/mL*
18. **Helix OpCo LLC (dba Helix) (Helix COVID-19 NGS Test):** *LOD = 125 copies/mL [IV-C]*
    LoD = 1800 NDU/mL*

DIAGNOSTICS:
VERSION 4 UPDATES: OCTOBER 7, 2020

NEW PROGRAMS ADDED (5):

COVID DIAGNOSTICS TESTS:

1. Cepheid (Xpert Xpress SARS-CoV-2/Flu/RSV)

QUANTATIVE PLATFORMS:

2. Quotient Suisse SA (MosaiQ COVID-19 Antibody Magazine)
3. NanoEntek America, Inc. (FREND COVID-19 total Ab)

QUALITATIVE LATERAL FLOW ASSAYS:

4. Jiangsu Well Biotech Co., Ltd. (Orawell IgM/IgG Rapid Test)
5. Nirmidas Biotech, Inc. (Nirmidas COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit)

UPDATES TO EXISTING THERAPEUTICS PROGRAMS (2):

1. **Example: Labcorp (Pixel):** *There are more than 20 kits for home collection with EUA approval.*
2. **Hologic, Inc. (Panther Fusion SARS-CoV-2 Assay):** **up to 5 samples can be pooled for this test*

DIAGNOSTICS:
VERSION 3 UPDATES: SEPTEMBER 21, 2020

NEW PROGRAMS ADDED (6):

COVID DIAGNOSTICS TESTS:

1. Roche Molecular Systems, Inc. (cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System)
2. Visby Medical, Inc. (Visby Medical COVID-19)

QUANTATIVE PLATFORMS:

3. University of Arizona Genetics Core for Clinical Services (COVID-19 ELISA pan-Ig Antibody Test)
4. Shenzhen New Industries Biomedical Engineering Co., Ltd. (MAGLUMI 2019-nCoV IgM/IgG

QUALITATIVE LATERAL FLOW ASSAYS:

5. TBG Biotechnology Corp. (TBG SARS-CoV-2 IgG / IgM Rapid Test Kit)
6. Sugentech, Inc. (SGTi-flex COVID-19 IgG)

UPDATES TO EXISTING THERAPEUTICS PROGRAMS (3):

1. **Example: Labcorp (Pixel):** *There are 21 kits for home collection with EUA approval.*
2. **Example:** *Thermo Fisher (SARS-Cov-2): There are over 100 kits released under the EUA program. CLIA labs will often use one of these detection kits in combination with other general purpose extraction kits and instruments to validate an assay and get an EUA for their lab.*
3. **Example: Phosphorus Diagnostics LLC (Phosphorus COVID-19 RT-qPCR Test):** *There are over 50 labs with EUA approval.*

DIAGNOSTICS:
VERSION 2 UPDATES: SEPTEMBER 4, 2020

NEW PROGRAMS ADDED (7):

COVID SCREENING TESTS:

1. Abbott Diagnostics Scarborough, Inc. (BinaxNOW COVID-19 Ag Card)
2. Quidel Corporation (Sofia SARS Antigen FIA)
3. Becton Dickinson and Company (BD) (BD Veritor System for Rapid Detection of SARS-CoV-2)
4. LumiraDx UK Ltd. (LumiraDx SARS-CoV-2 Ag Test)

COVID DIAGNOSTICS TESTS:

5. Helix OpCo LLC (dba Helix) (Helix COVID-19 NGS Test)

QUANTATIVE PLATFORMS:

6. bioMérieux SA (VIDAS SARS-CoV-2 IgG)
7. BioCheck, Inc. (BioCheck SARS-CoV-2 IgG and IgM Combo Test)
8. Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. (WANTAI SARS-CoV-2 Ab ELISA)

QUALITATIVE LATERAL FLOW ASSAYS:

9. Biocan Diagnostics Inc. (Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test)