RICHTER CONSULTING

COVID Update:
Vaccine Timeline & Outlook

December 13, 2020

Key Takeaways

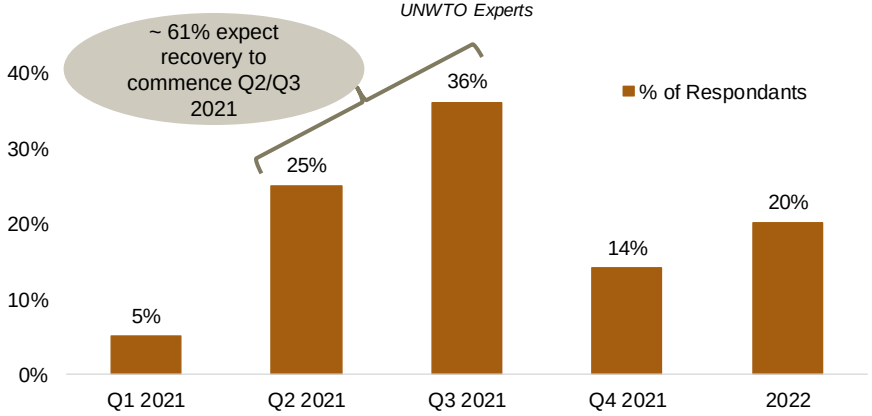
Consideration	Key Takeaway
Timeline	▪ COVID vaccine distribution in the US is expected to begin in Dec/20 and completed in a four-phased approach by Q3-Q4/21. The vaccines are forecasted to be available for ~50% of the US population by Q2/21 and 100% by Q4/21;
Vaccines under Development	▪ Four vaccines are currently in large scale Phase 3 trials in the US (Pfizer, Moderna, Novavax, J&J), two of which have preliminary efficacy rates of ~95% (Pfizer & Moderna). Novavax and J&J expect to release Phase 3 results in Q1/21; ▪ Eight additional vaccines are in Phase 3 trials globally, with ~40 others in various stages from pre-clinical to Phase 2;
FDA Approval Status	▪ The FDA authorized Pfizer's vaccine for emergency use on Dec 11th and will review the Moderna vaccine on Dec 17th; ▪ The first shipments of the Pfizer vaccine is expected to be delivered to all 50 states by Dec 14th;
Distribution Challenges	▪ Technical and safety obstacles related to transport & storage requirements may cause delays in deploying the vaccine;
Adoption	▪ Latest polls suggest that only ~ 60% of the population is willing to take the vaccine as of Dec 4th; ▪ Medical experts believe that at least 75-80% of the population needs to be vaccinated to achieve adequate coverage to significantly reduce the spread of the virus; ▪ Certain restrictions and requirements for travel, employment, and schools may accelerate adoption;
International Roll-Out	▪ International vaccine access is expected to commence in Q1/21, with widespread availability unlikely prior to mid-2021, which will vary by country and may result in supply disruptions; ▪ Vaccination in continental Europe will be earlier than other regions. The UK commenced inoculation Dec 8th;
Therapeutics	▪ Therapeutics are aimed to accelerate recovery and reduce risks of ventilation and mortality for patients; ▪ The FDA has approved two Phase 3 therapeutics for emergency use, including Eli Lilly's Bamlanivimab and Regeneron's REGN-COV2; ▪ Strong health systems and the aid of therapeutics may succeed in reducing COVID-related mortality rates to the point where the disease is far less feared and consumer confidence increases. In addition, therapeutics assist in containment of the virus allowing for a quicker economic recovery per the IMF;
Unknown Factors & Challenges	▪ Several factors may hinder the global effort to manage the pandemic, including: • Virus mutations / Duration of immunity / Vaccine side-effects / Efficacy in reducing transmission / Public confidence

Potential Impact of the Vaccine on Certain Industries

Travel & Tourism

- Key international travel operators including cruise lines, airlines, lodging/hotel companies anticipate a recovery commencing in 2H/21. While the vast consensus among industry experts is that Q3/21 and onwards will experience a meaningful recovery, some believe that travel will only substantially resume in 2022;
- "All scenarios point to a strong rebound in 2021 based on the assumption of a reversal of the evolution of the pandemic, significant improvement in traveler confidence and major lifting of travel restrictions by the middle of the year. The expected rebound is a consequence of the large pent-up demand following the unprecedented global lockdown and months of closed borders and travel bans." (UN World Tourism Organization, Oct/20);
- Countries and airlines will likely require proof of vaccination records to travel (POVR). "For international visitors coming out and people leaving the country, we think that's a necessity (POVR)." (Qantas CEO, Nov/20);
- The International Air Transport Association (IATA) announced on Nov 23rd that a digital health pass, which could include COVID vaccine information, is the key to opening borders and is expected to be launched in Q1/21.

Expected recovery date of the tourism industry based on a global survey of UNWTO Experts



Aviation

- Air cargo has supported global supply chains and should recover to 2019 levels by next year, but air travel will take several years. Vaccines and testing are expected to support global travel at 50% of 2019 levels next year, with significant gains later in the year. A return to 2019 travel volumes is only expected by 2024 (IATA, Nov/20 & IBISWorld, Aug/20);
- In Nov/20, the United CEO forecasted business travel, a vital source of revenue for airlines, will not recover to pre-pandemic levels until 2024 with a chance it never returns completely due to trends in the new remote work environment;
- "We're seeing a steady progression back [from pre-pandemic levels], and hopefully we can get [to 50%] by the spring of 2021 or early summer. We expect it to be two to three years before we're at a new normal, wherever that lands." (Delta CEO, Nov/20);
- World trade and air cargo volumes are expected to rebound strongly in 2021, however are forecasted to only reach half of pre-COVID global GDP spend (IATA, Nov/20).

Fitness

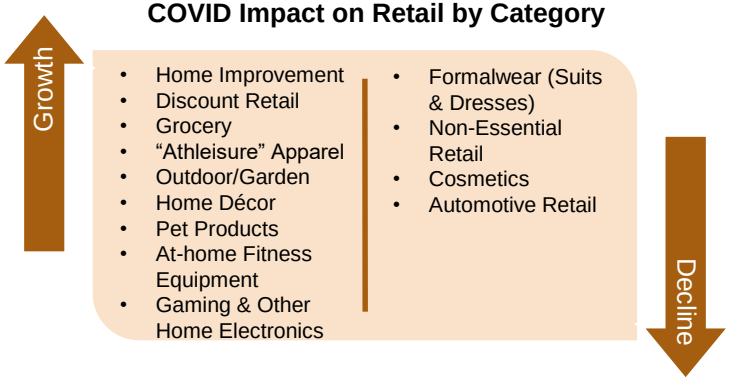
- IBIS forecasts industry revenue of US gyms, health, and fitness clubs to return to 88% of pre-COVID 2019 levels in 2021 (Oct/20);
- Though COVID vaccines could be authorized within days, Dave Long (OrangeTheory CEO) said they are modeling very conservatively for 2021. The goal is for revenue to total 55% to 65% of 2019 levels. "We'll still be in a position to bounce back even if this extends through the back half of next year." (Dec/20).

Potential Impact of the Vaccine on Certain Industries

Retail

- A meaningful recovery is anticipated for retailers over the next 12 months: “Our current 2021 forecast is for 6.2% growth in core retail sales, such a performance would be a substantial improvement over 2020." (Moody’s, Nov/20);
- COVID has fundamentally changed retail, with the following trends forecasted in 2021: (i) growth and improved profitability in DTC, (ii) accelerated supply chain transformation due to 5G and substantial investments in digital solutions, (iii) adoption of livestreaming and social commerce to supplement the physical model, and (iv) increase in touch-free technology, such as virtual fitting rooms (National Retail Federation, Dec/20);
- Retail sales are expected to improve disproportionately for online retailers compared to brick and mortar stores.
  - Physical retail has been under historic levels of pressure. 20K-25K US stores are expected to close in 2020, more than double 2019 closures (McKinsey, Dec/20);
  - Companies that have performed the best over recent months have had a strong Asia–Pacific focus, reflecting the economic strength of the region and the relatively lower impact of the pandemic there. E-commerce players, such as ASOS, FARFETCH UK, Revolve, and Zalando, have consistently outperformed in 2020 (McKinsey, Dec/20).

COVID Impact on Retail by Category



Entertainment

- Once a vaccine is available, disposable income is forecasted to increase from 2021-2025, thereby increasing spending on activities such as concert tickets, golf, and museum passes (IBISWorld, Nov/20);
- While the entertainment industry is expected to benefit from pent up demand, industry players still face strong headwinds until a vaccine has been widely distributed. The co-head of fundamental equity at Goldman Sachs indicated in Nov/20 that there will be a quick recovery once a vaccine is available as evidenced by 80% of Live Nation’s customers deciding to hold onto their tickets instead of getting a refund;
- “If the vaccine news is on track, that’s very exciting and is a very bright light at the end of the tunnel, but it’s a long tunnel and many of our companies are barely breathing air right now in terms of their liquidity.” (CEO of National Assoc. of Theater Owners, Nov/20).

Restaurants

- The restaurant industry has been severely impacted by the pandemic as 110,000 restaurants (17%) have permanently closed (National Restaurant Association, Dec/20);
- An industry recovery is likely only achievable subsequent to mass vaccinations, as it will allow them to operate at 100% capacity (Moody’s, Oct/20);
- The outlook for the US restaurant industry reflects slowly improving business conditions over the next 12-18 months, as restrictions implemented to curb the spread of the coronavirus are slowly eased and customers gradually return to dining out (Moody’s, Oct/20);
- The Single Location Full-Service Restaurants sector in the US is expected to grow significantly YoY (32.5% vs. 2020) as a result of forecasted increases in disposable income, putting the total estimated revenue above 2019 levels ($196B est. in 2021 vs. $178B in 2019) (IBISWorld, Nov/20).

Potential Impact of the Vaccine on Certain Industries

Trade Shows & Conferences

- Trade show and conference revenue is forecasted to increase at an annualized rate of 6.3% over the next five years, however, a recovery is only expected to begin in 2H/21 predicated on mass vaccination (IBISWorld, Sep/20);
  - "We are optimistic that we could have a vaccine, or two maybe, approved by the end of this calendar year and could see it start to get broadly distributed by sometime in the first half of 2021. And as that takes hold, we're optimistic that group business will come back […] and we'll start to see meaningfully more bookings when those vaccines start to take effect." (CEO, Marriott Q3 earnings call Nov/20).

Imports From Asia

- Mass vaccine distribution is essential for keeping factories open and avoiding supply chain disruptions:
  - While Asia-Pacific is beginning to recover, with China and many other economies having infection rates under control, certain significant exporters (i.e. India & Indonesia) have been struggling to contain the virus**.** Until vaccines are widely available and the population is immunized, the rebound is fraught with risks (S&P Global, Dec/20);
- China's manufacturing activity hit a multi-year high in Nov/20 representing 9 consecutive months of growth with recent production data showing manufacturing now at pre-pandemic levels, the first country to hit this milestone. (Reuters, Nov/20);
- China and Vietnam's stricter controls has allowed for relatively resilient exports and manufacturing (Barrons, Oct/20 & IMF, Nov/20). Growth in exports is expected to continue into 2021 (Bloomberg & IMF, Nov/20).

Estimated Change in Revenue (2021 vs. 2019) by Industry

Growth

- Tech – Software
- Consumer Staples
- Homebuilders & Developers
- Defense Contractors
- Retail Essential
- Telecom
- Healthcare – Pharmaceuticals
- Healthcare – Medical Products
- Utilities
- Engineering & Construction
- Packaging
- Business & Consumer Services
- Building Materials
- Restaurants

Moderate Decline (0-20%)

- Tech – Hardware
- Real Estate (REITs)
- Healthcare – Services
- Power
- Chemicals
- Ad Supported Media
- Oil & Gas
- Consumer Discretionary
- Metals & Mining
- Retail – Non-Essential
- Automotive

Significant Decline (>20%)

- Refining
- Fitness
- Hotels
- Out-of-Home Entertainment
- Commercial Aerospace
- Airlines
- Cruises

Source: Oct/20 Standard & Poor's Financial Services, LLC

Vaccine Outlook – 12 Vaccines in Phase 3 Trials. Pfizer Authorized for Emergency Use on Dec 11 and Moderna to be Reviewed Next Week

COVID Vaccine Status Tracker - Phase 3 Trials

As of Dec/20 Developer	Country	Start Date	# of Trials	# of Participants	Efficacy Rate	Production Capacity (# of doses) 2020	Production Capacity (# of doses) 2021	# Doses Reserved by US
North America								
1 Pfizer & BioNTech		27-Jul	7	44K	95.0%	50MM	1.3B	100MM
2 Moderna		27-Jul	3	30K	94.5%	20MM	500MM-1B	100MM
3 Johnson & Johnson		23-Sep	6	90K	N/A	N/A	1B	100MM
4 Novavax		24-Sep	5	39K	N/A	N/A	2B	110MM
5 Medicado & GSK		19-Nov	1	30K	N/A	N/A	76MM	N/A
Other								
6 Sinopharm		23-Jun	5	55K	N/A	N/A	1B	N/A
7 Sinovac		11-Aug	10	25K	N/A	N/A	300MM	N/A
8 AstraZeneca & Oxford		31-Aug	13	60K	62%-90%	200MM	2B	500MM
9 CanSino Biologics		15-Sep	6	41K	N/A	N/A	200MM	N/A
10 Gamaleya		07-Sep	10	42K	92.0%	10MM	24M-72M	N/A
11 Bharat Biotech		27-Oct	5	26K	N/A	N/A	300M-500M	N/A
12 Anhui Zhifei Longcom		06-Nov	1	29K	N/A	N/A	300MM	N/A

Vaccine Status & Outlook

- Operation Warp Speed, the federal government's COVID vaccine taskforce, has awarded $12B+ of its $18B budget for vaccine-related contracts;
- Recent vaccine prospects are encouraging, with 12 candidates in late-stage Phase 3 trials, including four in the US (WHO, Dec/20);
- ~40 other candidates in various stages from pre-clinical to Phase 2, including University of Melbourne (Phase 2, Australia) and Inovio Pharmaceuticals (Phase 2, US);
- Pfizer & Moderna are reporting > 90% vaccine efficacy rates based on Phase 3 clinical trials with distribution expected to commence in December;
  - **Pfizer:** Announced positive results from its trials, indicating 95% efficacy and received temporary emergency authorization in the following countries:
    - UK: approved on Dec 2nd and began distribution on Dec 8th;
    - Canada: approved on Dec 9th with distribution to begin the following week;
    - US: The FDA authorized the vaccine's emergency use on Dec 11th with delivery estimated to begin Dec 14th;
  - **Moderna:** Reported on Nov 16th that its vaccine is 94.5% effective. The FDA announced that it plans to review the request for use on December 17th;
- There are 2 additional US Phase 3 vaccine trials (Johnson & Johnson and Novavax) which are in process with expected FDA approval applications to be submitted by ~ Feb/21;
- AstraZeneca released interim vaccine trial data in mid-Nov. with initial efficacy rates of 90%, however subsequently disclosed that human error in administering correct dosage concentration levels resulted in significantly lower average efficacy level of ~70% (AstraZeneca.com, Nov/20). A request for US EUA by AstraZeneca could come in late Jan/21 (Operation Warp Speed, Dec/20);
- Prior to the completion of Phase 3 trials, several vaccines developed (#6, #9, #10 above) have been approved for use in China (primarily for military and frontline workers), UAE (#9) and in Russia (#7).

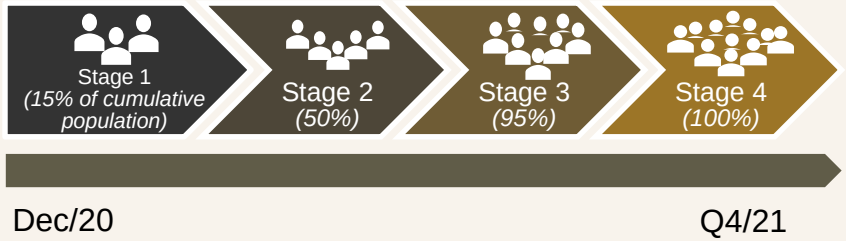
Vaccination US Distribution Timeline

Distribution Timeline

- Vaccination distribution speed, demographic prioritization, and adoption rates are key to overcoming the pandemic:
  - ~200MM Americans would need to be vaccinated to achieve community protection, and 60-70% of people worldwide in order to end the pandemic (New England Journal of Medicine, Dec/20);
- The distribution in the US is expected to be completed in a four phased approach from Dec/20-Q3/21 (Dr. Fauci, Dec/20):
  - "We will have potentially immunized 100MM people [by the end of Feb], which is really more or less the size of the significant at-risk population." (Dr. Moncef Slaoui, Chief Scientific Advisor for Operation Warp Speed, Dec/20).
  - Dr. Slaoui expects to see 20MM Americans vaccinated in Dec, 30MM in Jan, 50MM more in Feb, and estimates that if enough people are immunized, the pandemic should be under control in the 2H/21;
  - A significant number of challenges may delay the proposed timeline with widespread distribution only completed by Q4/21 (McKinsey, Nov/20);
- Once an EUA is issued, the US government expects that first vaccine shipments will be sent to healthcare facilities within 24-48 hours; however, it will likely take weeks to vaccinate some of the earliest batches of priority populations. Depending on supply, it will probably take 6 months or longer to vaccinate most of the country (Johns Hopkins Center for Health Security, Dec/20).

Distribution Prioritization

- Given the limited supply in the short to medium term, vaccines are likely to be prioritized for health workers at high risk of acquiring or transmitting infection and older adults. Eventually vaccination efforts will expand to target diverse populations (WHO, Dec/20);
- The CDC's Advisory Committee on Immunization Practices (ACIP) will decide the order in which various groups of people will receive the vaccine. The ACIP has incorporated guidance from the National Academies of Sciences, Engineering, and Medicine for the proposed a four-phased approach. Within those broad categories, individual state governments will then designate where and to whom their vaccine allotments will be distributed (Cleveland Clinic, Nov/20);
- On December 1st, the ACIP voted in favor of the including frontline healthcare workers and long-term care facility (LTCF) residents in Phase 1a. The recommendation will prioritize about 21MM healthcare workers and about 3MM adults currently residing in LTCFs. ACIP did not vote on allocation for the rest of Phase 1, but other Phase 1 tiers are expected to include non-medical essential workers and others at risk for severe disease and death, including adults aged 65 years and older and those with underlying medical conditions (Johns Hopkins Center for Health Security, Dec/20).



US Distribution Expected to be Completed in a Four-Staged Approach Dec/20 to Q3-Q4/21

Stage 1 (~15% of the population, ~50MM)

A) Front-line health care workers and first responders;

B) People with high risk underlying conditions;

C) > 65 years old in overcrowded settings;

Estimated to require 3-4 months (Feb-Mar/21).

Stage 2 (30-35%, ~110MM)

A) School and childcare workers;

B) Adults with moderately high-risk underlying conditions;

C) Essential workers including public transit and food supply;

D) People in overcrowded settings (prisons, jails, detention centers, etc.);

E) All others > 65 not included in Stage 1;

Estimated to require 2-3 months.

Stage 3 (40-45% of the population, 140MM)

A) Adults < 65;

B) Front-line workers (hospitality, financial services, retail, manufacturing);

C) Children (pending results of additional safety testing);

Estimated to require 2-3 months.

Stage 4 (5-10% of the population, ~30MM)

A) All others not included in Stages 1-3;

Sufficient supply expected for the entire population by Q3-Q4/21;

Estimated to require 1.5 months as there is an average 28-day lag between doses.

Source: National Academies of Sciences, Engineering, and Medicine

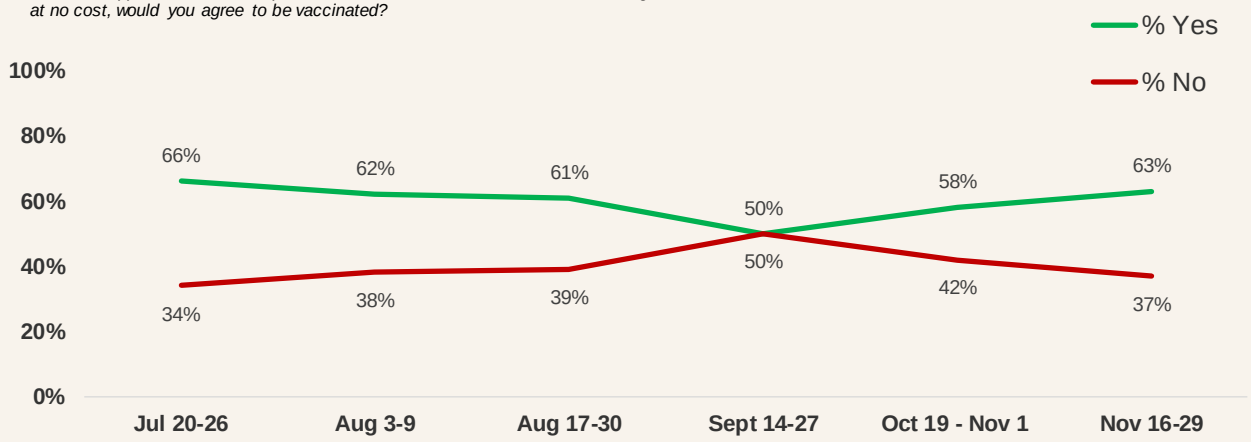
- The distribution and roll-out of a COVID vaccine is expected to be completed in the US by Q4/21;
  - The Advisory Committee on Immunization Practices (ACIP) advises the CDC on population groups and circumstances for vaccine use; however, state governors make final decisions about whom to vaccinate first with doses allocated based on adult populations by the federal government (CDC, Dec/20);
  - Operation Warp Speed plans to distribute 6.4MM doses of the Pfizer vaccine across the US within 72 hours of its emergency authorization on Dec 11, which will primarily go to front line health care workers (Operation Warp Speed, Dec/20).

Adoption Issues: 37%-39% Currently Reticent to Vaccinate

- In addition to the complexity of prioritizing the vaccine, certain significant challenges may delay the timing and impact of the roll-out, including:
  - Delayed adoption rates due to safety concerns, as November polls indicated a significant number of Americans were reticent to be vaccinated (39% per the Pew Research Center; 37% per Gallup, see table below);
    - Hesitation to vaccinate has been driven by the condensed timeline for the development of a COVID vaccine (<1 yr.) vs. traditional vaccines (10 yr. avg.);
  - Possible vaccine side effects given severely shortened approvals under emergency FDA orders (vs. a typical ~6-month FDA review timeline for fast-tracked applications);
  - Production/distribution supply chain issues such as specialized storage and transportation;
  - Administering multiple doses (with an avg. 28-day lag);
  - The effectiveness of the vaccine to reduce transmission remains unknown, likely requiring continued social distancing measures until widespread vaccination occurs.

Americans' Willingess to Receive COVID-19 Vaccination

If an FDA-approved vaccine to prevent coronavirus/COVID-19 was available right now at no cost, would you agree to be vaccinated?



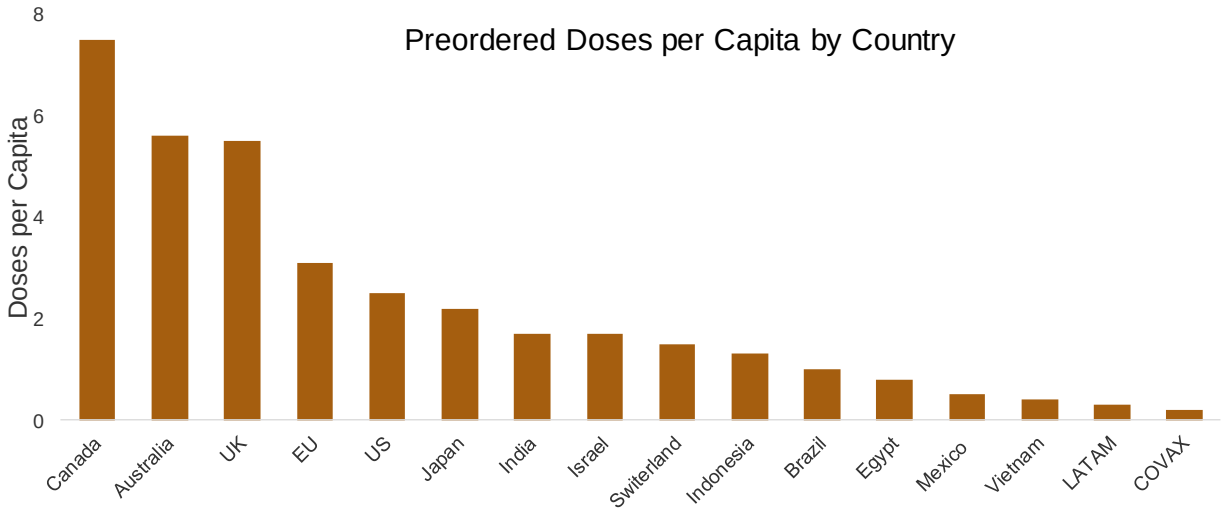
Source: Gallup Panel, 2020

Vaccine Availability in Certain Countries Could Disrupt Supply Chains

Worldwide Access and Availability of Vaccines

- While no vaccine has been approved, Duke University's "Launch & Scale Speedometer" tool estimates that 7.3B doses of potential vaccines have already been purchased, and another 2.5B are under negotiation or reserved as optional expansions of existing deals;
- Of the 7.3B doses procured, high-income countries currently hold a confirmed 3.9B doses (~53%), upper middle-income countries hold 1B doses (~14%), and lower middle-income countries hold ~1.7B (~23%) doses, with the remaining 0.7B doses (~10%) procured by COVAX (a WHO-related coalition created to accelerate the development and production of vaccines and to guarantee equitable access for every country);
  - No deals reported for low-income countries and will be entirely reliant on COVAX (Duke University, Dec/20);
- "Some middle-income countries with manufacturing capacity have also been able to negotiate large purchase agreements as part of manufacturing deals. While other countries with the infrastructure to host clinical trials - such as Brazil and Mexico - have been able to use that as leverage in procuring future vaccines." (BBC, Nov/20);
- **Limited vaccine availability for lower income countries could represent a high risk of supply chain disruptions for numerous import categories. The following major exporters have secured significantly less doses per capita than their western counterparts:**

Preorder Coverage (% of population)			
Mexico	25%	Indonesia	20%
Vietnam	20%	Taiwan	10-15%
Bangladesh	20%	Malaysia	< 10%



Source: Airfinity, Dec/20

Global Availability of the Vaccine Expected by Q3/21

Estimated Vaccine Distribution Timelines by Country

- While the timeline for a worldwide vaccine roll-out varies by region/country and is dependent on regional health/safety regulatory approval processes, the consensus is that access and availability to a vaccine for the global masses will not be widely distributed before mid-2021;
- **UK:** The UK Government has approved the Pfizer-BioNTech vaccine and the NHS began distribution on Dec 8th;
- **European Union:** Vaccinations expected to "optimistically" commence in the first quarter of next year and the EU has secured ~300MM doses (ECDC, Nov/20);
  - **France:** Aims to begin vaccinating in mid-Jan, announcing on Dec 3rd the three phases of vaccinations, in order of priority with a targeted completion in Jun/21;
  - **Spain:** 2.5MM people will be vaccinated in the initial 2 months starting Jan/21, prioritizing elderly care home residents and healthcare workers. The second stage of the campaign will begin in March and by June, ~50% of the population should be vaccinated;
  - **Germany:** Plan for vaccination centers to start administering the vaccine by mid-Dec, with 8MM vaccinations (10% of population) by Mar/21 with roll-out to the entire population by Fall 2021 (Health Minister, Dec/20);
- **Japan:** Aims to secure vaccine for all citizens in 1H/21 (Japan Times, Nov/20);
- **Australia:** On track to administer the first vaccines in Mar/21 prioritizing those at risk. The widespread rollout to the masses is expected to be "very" staggered throughout 2021;
- **Canada:** Approved the Pfizer vaccine on Dec. 9th and will begin distribution the following week. The Prime Minister estimates a majority of Canadians will be vaccinated by Sep/21;
- **Russia:** First country to produce and approve a vaccine in Aug/20, however, production issues and public distrust has resulted in lower vaccination rates with only 100K out of the 140M population (NYT, Dec/20).

Numerous Factors Challenge the Timing and Effectiveness of the Proposed Vaccine Roll-Out

Issue	Key Considerations
Medical: Dosage Multiple doses required including a lag in-between	▪ To be effective, the CDC reported on Dec 3rd that all but one of the vaccines currently in Phase 3 require two doses spaced out over several days (avg. 28), increasing roll-out timing;
Medical: Transmission Effectiveness of the vaccine to reduce transmission is unknown	▪ The vaccines' primary function is to prevent disease progression. However, researchers have yet to determine if vaccines will reduce transmission of the virus (Johns Hopkins University, Nov/20); ▪ Given the planned phased vaccine roll-out, social distancing measures will be necessary until a more widespread vaccination occurs as those that are vaccinated may still transmit the virus to others; ▪ Only the vaccine produced by AstraZeneca has shown results that indicated reduction in transmissibility;
Public Adoption Rates % of the population that will agree to vaccinate and the timing of when they will accept to vaccinate	▪ The adoption rate (% of the population that will be vaccinated) and willingness to be vaccinated are two critical variables in successfully curbing the pandemic: o "When you have 75-80% of the people vaccinated, you have an umbrella of protection over the community that the level of community spread will be really, really very low" (Dr. Fauci, Dec/20); o Overall, ~61% of Americans said that they would get vaccinated according to a poll conducted by the Pew Research Center ending Nov. 29, 2020 (vs. 51% in the September poll). The ~39% unwilling cited reasons such as the rushed development timeline and concerns about safety (Pew Research Center, Dec/20);
Supply Chain: Distribution Specific transport and complex storage requirements	▪ The Moderna & Pfizer vaccines are vulnerable to degradation at room temperature and will require doses to be frozen at specific temperatures (i.e. Pfizer: -70C) during transport and stored with additional complex requirements and specialized equipment (i.e. production and transportation of dry ice) (Pfizer Fact Sheet, Nov/20); ▪ This may lead to challenges particularly for parts of the rural United States that may lack ultracold freezers in pharmacies and doctor offices or facilities with less experienced staff (American Association for the Advancement of Science, Nov/20);
Supply Chain: Production Potential manufacturing delays may slow roll-out	▪ Delays may be caused by difficulties replicating certain technical specifications. Significant roll-out delays were experienced in Russia that led to a greater than one-month lag due to difficulties replicating production of the vaccine's technical specifications (WSJ, Nov/20).

Therapeutics – FDA Approval under EUA for Two Phase 3 Therapeutics, with a Third Pending Approval

Notable Developers by Phase

Phase 3

Eli Lilly (US), Humanigen/Catalent (US), Roche (EUR), NHLBI (US), Oncolmmune (US), Revive (CAN), Novartis (EUR), Regeneron (US), Gilead (US), Relief Therapeutics (CAN & EUR)

Phase 2

Abbvie (Eur), CytoDyn (CAN), PTC (US), ANA (US), Vir Biotech (US), Janssen (EUR), Lily & AbCellera (US)

Phase 1

BioCryst Pharmaceuticals (US), Pfizer (US), Takeda (Japan), AstraZeneca & Vanderbilt University (UK & US), Celltrio (US)

Therapeutics Considerations

- Therapeutics are aimed to accelerate recovery and reduce risks of ventilation and mortality for patients;
- There are > 50 therapeutics being developed, primarily in the US with research underway throughout Canada and Europe;
- **Strong health systems and the aid of therapeutics may succeed in reducing COVID-related mortality rates to the point where the disease is far less feared and consumer confidence increases. In addition, therapeutics assist in containment of the virus allowing for a quicker economic recovery per the IMF:**
  - "We emphasize the need for international cooperation to accelerate the research, development, manufacturing, and distribution of COVID-19 diagnostics, therapeutics and vaccines, with the aim of supporting equitable and affordable access for all, which is key to overcoming the pandemic and supporting global economic recovery." (IMF, Oct/20);
- Notable Phase 3 therapeutics include:
  - **Bamlanivimab (Eli Lilly):** FDA authorization issued under EUA on Nov 9th for use based on results of the Phase 3 trials (which showed a quicker recovery timeframe for patients who received the therapeutic);
  - **REGN-COV2 (Regeneron):** Received FDA approval under EUA on Nov 21st with ~30K treatments having been distributed since and distribution/production capacity for ~300K more treatments by Jan/21 (Regeneron Press Release, Nov/20);
  - **Lenzilumab (Humanigen/Catalent):** Currently pending FDA approval after successful trial results, which included 80% ↓ in risk of mortality and ventilation, and 37% ↑ recoveries in patients taking the therapeutics vs. standard care (Regulatory Affairs Professional Society, Dec/20);
  - **Tocilizumab (Actemra, developed by Roche):** ~4K participant trial. Evidence beginning to point to beneficial outcome for COVID patients in some, but not all, scenarios (Regulatory Affairs Professional Society, Dec/20).

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