



Developing and deploying COVID-19 vaccines, therapeutics, and treatments: science, equity, and trust

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Forward-looking statements / Non-GAAP Financial Measures / Trademarks



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This presentation includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including, without limitation, statements regarding our ability to develop safe and effective treatments against the novel strain of coronavirus (SARS-CoV-2) causing COVID-19 disease using antibodies and produce viable COVID-19 vaccine candidates on the anticipated timelines and pave their potential pathway to licensure; our ability to address inequities amongst certain groups; sustainable competitive advantages; scalable capabilities, and future market opportunities and any other statements containing the words "will," "believes," "expects," "anticipates," "intends" "plans," "targets," "forecasts," "estimates" and similar expressions in conjunction with, among other things, discussions of the Company's outlook, strategic goals, product sales, government development or procurement contracts or awards, government appropriations, manufacturing capabilities, and the timing of certain clinical trials, receipt of Emergency Use Authorization, regulatory approvals or expenditures are forward-looking statements. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statements speak only as of the date of this presentation, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances. There are a number of important factors that could cause the Company's actual results to differ materially from those indicated by such forward-looking statements. Such risks include, but are not limited to, the impact of COVID-19 disease on global economic conditions, our operations, and employees as well as those of our customers and suppliers; the safety and effectiveness of the current COVID-19 product candidates we are working on; the level of viable convalescent plasma collected for such product candidates that rely on it; availability of U.S. government funding for procurement for our products and candidates; our ability to perform under our contracts with customers, including the timing of and specifications relating to deliveries; the continued exercise of discretion by the Biomedical Advanced Research Development Authority (BARDA) to procure additional doses of AV7909 (anthrax vaccine adsorbed (AVA), adjuvanted) prior to approval by the U.S. Food and Drug

Administration (FDA); our ability to secure licensure of AV7909 from the FDA within the anticipated timeframe, if at all; our ability to secure follow-on procurement contracts for our solutions to public health threats that are under procurement contracts that have expired or will be expiring; our ability to successfully appeal the recent patent litigation decision related to NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray; our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria; our ability and the ability of our contractors and suppliers to maintain compliance with Current Good Manufacturing Practices and other regulatory obligations; our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals; the procurement of products by U.S. government entities under regulatory exemptions prior to approval by the FDA and corresponding procurement by government entities outside of the United States under regulatory exemptions prior to approval by the corresponding regulatory authorities in the applicable country; the success of our commercialization, marketing and manufacturing capabilities and strategy; and the accuracy of our estimates regarding future revenues, expenses, and capital requirements and needs for additional financing. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. You should consider this cautionary statement as well as the risk factors identified in our periodic reports filed with the Securities and Exchange Commission when evaluating our forward-looking statements.

Trademarks

BioThrax® (Anthrax Vaccine Adsorbed), RSDL® (Reactive Skin Decontamination Lotion Kit), BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)], Anthrasil® (Anthrax Immune Globulin Intravenous [human]), CNJ-016® [Vaccinia Immune Globulin Intravenous (Human)], Trobigard® (atropine sulfate, obidoxime chloride), ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live), Vivotif® (Typhoid Vaccine Live Oral Ty21a), Vaxchora® (Cholera Vaccine, Live, Oral), NARCAN® (naloxone HCl) Nasal Spray and any and all Emergent BioSolutions Inc. brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. All other brands, products, services and feature names or trademarks are the property of their respective owners.



About Emergent BioSolutions

Our mission is simple –



To protect and enhance life

Emergent BioSolutions is a global life sciences company focused on providing specialty products and contract development and manufacturing services that address public health threats



Our products and services

Product types



Vaccines
(liquid, oral)



Therapeutics
(hyperimmune/mAb)



Medical devices
(device, drug-device
combination product)

Anthrax

Anthraxil®

[Anthrax Immune Globulin
Intravenous (human)]

AV7909*

[Anthrax Vaccine Adsorbed
(AVA), Adjuvanted]

BioThrax®

(Anthrax Vaccine Adsorbed)

raxibacumab injection

A fully human
monoclonal antibody

Smallpox

ACAM2000®

(Smallpox (Vaccinia)
Vaccine, Live)

VIGIV CNJ-016®

[Vaccinia Immune Globulin
Intravenous (Human)]

Travel Health

Vaxchora®

(Cholera Vaccine, Live, Oral)

Vivotif®

(Typhoid Vaccine Live Oral
Ty21a)

Opioids

NARCAN®

(naloxone HCl)
Nasal Spray

Chemical

RSDL®

(Reactive Skin
Decontamination
Lotion Kit)

Trobigard®*

(atropine sulfate, obidoxime
chloride
auto-injector)

Botulism

BAT®

[Botulism Antitoxin
Heptavalent
(A, B, C, D, E, F, G) - (Equine)]

Molecule-to-market CDMO offerings



Development services



Drug substance



Drug product &
packaging

Technology platforms

Mammalian • Microbial • Viral • Plasma
Advanced Therapies

Public health threats

CBERNE • Emerging Infectious Disease • Emerging Health Crises • Travel Health
Acute/Emergency Care

* Product candidates procured under specific circumstances. These products are not currently approved/licensed by any regulatory authority and safety or effectiveness have not been established

Helping to make a difference against a global pandemic



Therapeutics

- Hyperimmunes built on our proven platform
- Potential treatment and prophylaxis protection using antibodies

Vaccine Development

- Process development
- Analytical development
- Formulation development
- Non-GMP, lab-scale manufacturing


Vaccine Manufacturing

- Drug substance
- Drug product
- Pandemic manufacturing

Two candidates

- **COVID-HIG**
- **COVID-EIG**

Three candidates

- **AZD1222** 
- **COVID-19** 
- **NVX-CoV2373** 

Four agreements



Johnson & Johnson

AstraZeneca 

 **VAXART**

NOVAVAX

These product candidates are not currently approved/licensed by any regulatory authority and safety or effectiveness have not been established

Hyperimmune therapies to help address the COVID-19 burden on the healthcare system

COVID-HIG: Derived from convalescent Human Plasma

Plasma collection, clinical manufacturing runs underway

Proposed indication: Treatment of patients hospitalized or at risk of severe disease

Program status/ updates:

NIAID clinical trial in hospitalized patients	Phase 3, Q3 2020
NIAID clinical trial in outpatient population	Phase 2, Q4 2020

Proposed indication: Preventative/ prophylaxis for individuals at high risk of exposure, e.g., healthcare workers or military

Program status/ updates:

Pharmacokinetics/ pharmacodynamics	Phase 1 Q3 2020
Clinical program for prophylaxis in individuals at high risk of exposure	Phase 2, Q4 2020
Clinical trial for military personnel	Expanded access protocol

COVID-EIG: Derived from equine plasma

Scalable plasma source

Proposed indication: Treatment of hospitalized patients

Program status/ updates:

- ✓ Equine immunizations initiated
- ✓ Plasma collection and pilot manufacturing runs

Clinical trial in hospitalized patients	Phase 2 Q4 2020
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*To have a significant impact on COVID-19, it is critical to advance **multiple potential solutions** where we can leverage our **expertise and capabilities** across the continuum of care*

These product candidates are not currently approved/licensed by any regulatory authority and safety or effectiveness have not been established

COVID-19 vaccine development and manufacturing



SERVICE OFFERINGS		
Development Services	Drug Substance	Drug Product
COVID-19 PARTNERSHIP ACTIVITIES		
	●	●
	●	
●	●	
●	●	
●	●	●

Engaged in high-profile development & manufacturing agreements

- Five CDMO agreements, including only public-private CDMO partnership in history
- First COVID commercial supply agreement in industry
- 2 out of 3 outsourced Operation Warp Speed (OWS) candidates w/ Emergent for long term

Development services, drug substance, drug product





COVID-19 therapeutics and vaccines in development around the globe

Leading COVID-19 therapeutics in development

Drug Name	Company	Clinical Status
sarilumab	Regeneron/Sanofi	Phase III
eculizumab	Alexion Pharmaceuticals	Phase III
ASC09 + ritonavir	Ascletis Pharma Inc	Phase III
chloroquine/hydroxychloroquine	Sanofi	Phase III
LY-CoV555	Lilly	Phase III
COVID-HIG	Emergent BioSolutions	Phase III
COVID-HIG	Emergent BioSolutions	Phase II
siltuximab	EUSA Pharma	Phase II
tocilizumab	Roche/Chugai	Phase II
danoprevir + ritonavir	Ascletis Pharma Inc	Phase II
baricitinib	Eli Lilly	Phase II
RLF-100 (Aviptadil)	NeuroRx	Phase II
opaganib	RedHill Biopharma	Phase II
SNG001	Synairgen	Phase II
MK-4482	Merck/Ridgeback	Phase II

- Underway: 44 convalescent plasma trials, 40 mAbs, 29 stem cell therapy, 50 antiviral trials
- Grifols and Octapharma are evaluating approved IVIG products for use in treating COVID-19 infections
- Of the 15 ongoing hyperimmune trials in the U.S.:
 - Emergent BioSolutions COVID-HIG as well as those from CSL, Grifols and Tak-888 (Takeda), are in Phase III INSIGHT013 trial (NIH)
 - Separately, Emergent BioSolutions COVID-HIG is in two Phase 2 trials, PEP and early stage disease (INSIGHT012)
- Regeneron mAb cocktail (REGN10933 + REGN10987), Roche's Tocilizumab and a few other mAbs are in Phase 3

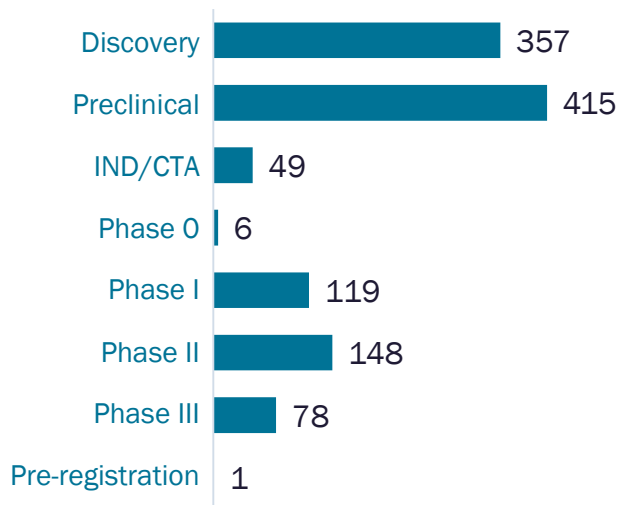
Source: GlobalData Pharmaceutical Intelligence Center, Accessed July 20, 2020

Emergent BioSolutions product candidates listed are not currently approved/licensed by any regulatory authority and safety or effectiveness have not been established

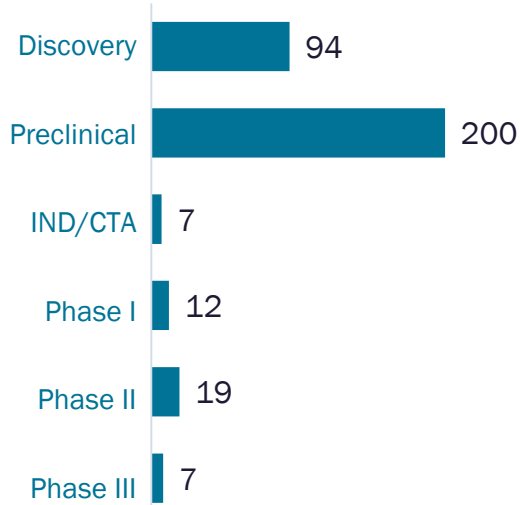
There are few approved therapeutics, but the COVID-19 therapeutics and vaccines pipeline is crowded

No approved vaccines thus far, but over 1,000 vaccines and therapeutics are in development
(as of 17 August 2020)

Landscape of Pipeline Tx Candidates for COVID-19, by Phase



Landscape of Vaccine Candidates for COVID-19, by Phase



Vaccine Candidates By Technology

Technology	No. of Vaccines
Live Attenuated	10
Inactivated	12
Virus-Like Protein	16
DNA	20
RNA	26
Undisclosed	33
Viral Vector	44
Protein-Subunit Vector	88

* Phase 1/2 trials included in Phase 2 count, Phase 2/3 trials included in Phase 3 count

** Numbers based on assets covered in the landscapes in this deck

Source: GlobalData Analysis; Client & Subject Matter Expert Interviews; Press Articles; Company Announcements; Verdict Media

Huge government and non-government spending to accelerate vaccine development, manufacture and distribution

- U.S. federal government allocated \$12 B to develop and manufacture COVID-19 vaccines
 - Includes \$2.5B for vaccine vials, syringes and manufacturing capacity
- In May 2020, European, Asian, and African governments, and U.S. and ex-U.S. non-governmental organizations, pledged \$8.1B to COVID-19 vaccines, treatments and diagnostics research, manufacture and distribution
- European commission plans to use an emergency fund of currently \$2.7B to buy coronavirus vaccines – 6 vaccines to cover 458M people
- To accelerate development, most companies running clinical trials in parallel
 - Reducing vaccine normal development timeline from 8 to 12 years to 12 to 18 months

Company	USG Funding	Doses by 2020
Moderna	\$2.5 B	100 M
Sanofi Pasteur/GSK	\$2.1 B	100 M
BioNTech/ Pfizer	\$1.95 B	100 M + 500 M option
Novavax	\$1.6 B	300 M
J& J	\$1.5 B	100 M
AZ	\$1.2 B	300 M
Emergent BioSolutions	\$628 M	
Merck	\$38 M	



Sources: USA Today, 10 Aug. 2020, Reuters, 4 May & 12 June, 2020 and Council on Foreign Relations

Clinical trial development timelines and anticipated Emergency Use Authorization and first-dose availability for leading COVID-19 vaccine candidates in the U.S.

COVID-19 VACCINE (COMPANY)	2020 JUN	2020 JUL	2020 AUG	2020 SEP	2020 OCT	2020 NOV	2020 DEC	2021 JAN
mRNA-1273 (MODERNA)								
BNT162b2 (PFIZER/BIONTECH)								
AZD1222 (ChAdOx1) (OXFORD UNIV./AZ)								
JNJ-78436735 (J&J)								
Ad5-nCoV (CANSINO BIOLOGICS)								
INO-4800 (INOVIO)								
NVX-CoV2373 (NOVAVAX)								

Phase 3 start date
 Anticipated EUA
 Phase 3 talks with FDA

- Two other COVID-19 vaccine candidates namely BBIBP-CorV (SinoPharma, China) and CoronaVac, previously PicoVacc, (Sinovac Biotech, China) have also begun their Phase III trials and may make their vaccines available by December 2020 if successful
- Inovio is in talks with the FDA to begin their Phase III trial of INO-4800 in September.
- Initial doses may be prioritized to be administered to high-risk individuals such as healthcare workers, nursing home staff & residents, emergency service personnel
- Moderna, BionTech/Pfizer's mRNA vaccine platforms and Inovio's DNA vaccine platform are truly novel. Novavax's vaccine platform has not yielded any vaccine approved by the regulators yet.

Source: McKinsey, press reports

Summary of vaccine development and deployment: rapid, unprecedented (r)evolution

The need:	Addressing the need
Many vaccine candidates	Many co-development, co-production agreements in place, across national and continental boundaries
Variety of robust approaches	Myriad methods: inactivated virus, mRNA, viral vector, protein-based
Rapid development	Race to develop more than 165 candidates, 32 in human trials* (7 in Phase 3)
Rapid and diverse clinical trials	Combined-phase clinical trials, centered in diverse areas of disease incidence, such as New York City. 1/5th of the subjects enrolled in the Moderna and Pfizer Phase 3 clinical trials are from minority groups
Expedited regulatory approvals	FDA: <ul style="list-style-type: none">• Threshold of 50% effectiveness• Expediting vaccine clinical trials by providing timely advice to and interactions with vaccine developers• Supporting product development and manufacturing scale up• Assistance in submission of emergency IND requests
Rapid, large-scale production of billions of doses to be deployed worldwide	<ul style="list-style-type: none">• Operation Warp Speed• CIADM surge capacity manufacturing facilities• Logistics of delivery

Public expectations & equity – and how Emergent is addressing these issues.

Therapeutics and vaccines: public expectations



**The expectation:
A return to
pre-pandemic life**

Needed:
Information
campaign
to address and
inform public
expectations

Equity issues – vaccine clinical trials

Disproportionate impact on minorities:

- Higher case rate, higher death rate
- Fauci: “Double whammy”:¹
 1. Higher proportion of essential workers
 2. Higher prevalence of underlying health conditions

Clinical trial recruitment challenges:

- Financial strain and work demands on potential volunteers during the pandemic²
- History of racial injustices, including unethical clinical trials²

Moderna: 18% minority enlistment in Phase 3 trial as of August 22³
Pfizer: Will locate Phase 3 trials in diverse communities

Concern among NIH/OWS officials about a vaccine tested for safety and efficacy primarily on a single ethnic group¹

To date, only 10% of vaccine trial registrants are Black or Latino (of 350,000 coronavirus clinical trial online registrations)¹

¹CNN.com [online article](#)

²CNN Health [online article](#)

³USA Today [online article](#)

Equity issues – vaccine distribution

Distributing to diverse communities:

- Financial strain, limited time away from work to wait in line for a vaccine
- Burden of travel to vaccine dosing site
- Health insurance disparities, vaccine cost

Medical mistrust:

- History of racial injustices, including unethical clinical trials
- Vaccine “doubters” and misinformation
- Fear of adverse events
- Concerns around the FDA 50% efficacy standard
- Misunderstanding of efficacy

Focus on overcoming economic, social, and historical barriers

Bedside to bedside: making a difference



- Manufacturing & regulatory expertise
- NIAID clinical trial partnership
- HHS & DoD support

- Facility & staff
- Testing capabilities
- 10,000+ patients
- State licensure
- Clinical trial network

- FDA source license
- Expertise for building & training new production facilities
- Integrated supply chain

Collaboration to add plasma collection capability and develop, manufacture, and conduct clinical trials to evaluate COVID-HIG for PEP

- Collection of source plasma from recovered COVID-19 patients
- Intended for preventative and therapeutic programs
- Clinical studies: post-exposure prophylaxis study in individuals at high risk of exposure to COVID-19, such as front-line health care workers and military personnel

¹New York City Department of Health
COVID-HIG is an investigational treatment and the safety or effectiveness have not been established



Diversity and Inclusion: Diverse population at the collection site. NYC COVID-19 death rates among Black and Latino people are five times those of white people¹

Innovation: Three parties with no past relationship work together to fight the pandemic

Inspiration: Many donors are healthcare practitioners from the hospitals

Application: Interest to replicate elsewhere, bringing plasma collection capabilities closer to recovered COVID-19 patients

Key takeaways

Needed: multi-part effort to promote diversity in clinical trials

Regulatory, industry efforts:

- **FDA:** FDA communication of clinical trial expectations (60+ guidance docs)
- **BioPharma:** Vaccine developers plan for trial locations in diverse communities
- **Trials:** Target % of minority participants
- **Sites:** Make distribution as easy as possible with many locations in diverse communities
- **Access:** No-cost / low cost options

Community outreach efforts:

- **Availability:** Many clinical trial sites in diverse communities
- **Education/Information:** Communication/ education campaigns to target audiences
- **Other:** Emphasis on diseases that disproportionately affect African Americans, and those having fewer treatment options. Can government incentivize to encourage more drug development for BIPOC communities?

COVID-19 is the public health threat of the century

- Discovery, development, manufacturing, logistics, regulatory efforts adapting at unprecedented pace
- Governments, industry, and NGOs must coordinate closely and effectively to meet the pandemic with safe, effective, and readily available therapeutics and vaccines

Substantial equity issues to overcome beyond COVID-19

- Small steps underway; larger measures needed
- Understand and address issues related to access, vulnerabilities, healthcare insurance, misinformation, mistrust
- Governments, industry, NGOs, and communities must coordinate closely and effectively to identify and address inequities

Recommendation: Task force of industry, government and community representatives to identify and discuss equity issues and develop measures to address them