

# Reanalogizacija v službi človekovega obstanka – Drugi del

(Prepis govora z viri)

*Opomba: V Kazenskemu zakoniku (KZ-1) stojita **280. in 281. člen**, ki pravita, da **smo državljani dolžni prijaviti če vemo, da nekdo pripravlja ali izvaja kaznivo dejanje**, za katerega je predvidena zaporna kazen 15 ali več let zapore, **kar genocid vsekakor je**.*

*Potemtakem je naša dolžnost, da javimo naprej sume, ki jih je celo možno potrditi in dokazati na podlagi verodostojnih virov (EMA, VAERS, ClinicalTrials.gov, uradne vladne strani nekaterih držav, tehnični podatki za substance v cepivih, uradne strani neprofitnih organizacij, uradne študije, patenti, novice iz glavnih medijev,...)!*

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»Naši kandidati za izdelke lahko povzročijo resne neželene dogodke ali neželene stranske učinke, ki lahko odložijo ali preprečijo odobritev trženja ali, če je odobritev sprejeta, zahtevajo, da se umaknejo s trga, zahtevajo vključitev varnostnih opozoril ali kako drugače omejijo njihovo prodajo.«.....	39
»V našem poslu uporabljamo nevarne kemikalije. Morebitni zahtevki v zvezi z nepravilnim ravnanjem, skladiščenjem ali odstranjevanjem teh kemikalij bi nas lahko prizadeli ter bili zamudni in dragi.«.....	39
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## UVOD

Kot boste lahko videli v tej krajši prezentaciji je v njej trden dokaz o povezanosti cepiv in vojske ter tudi digitalizacije (Digitalizacijo smo podrobneje opisali v 1. delu).

Ker je v tem času (jeseni) povsem možno, da se imajo namen lotiti rezervnega scenarija »opičjih koz« smo vzeli pod drobnogled patente in vojaške povezave izdelovalcev cepiva za opičje koze. Isto kot pri COVIDU ugotavljamo, da so bile prvotne recepture **razvite v vojaških inštitucijah** (z njihovo podporo oz. mentorstvom). Nekatere od teh inštitucij pa so specializirane za razvoj **kemičnega in biološkega orožja, nikoli pa niso izdelovale ali razvijale zdravil in so v vrhu vojaških struktur oboroženih sil ZDA.**

Odkrite sestavine (kemikalije) v vseh dosedanjih cepivih dokazujejo ravno to, da so podtahnjene sestavine z zelo toksičnimi lastnostmi, ki jih pa dokumentacija o »cepivih« prikriva. To je dokazljivo, ker so tehnični listi o sestavinah v »cepivih« pogosto revidirani in v vsaki naslednji verziji tehničnega lista so črtane ali omiljene navedbe o toksičnosti. Primerjava vseh revizij pove vse!

Informacije, ki jih farmacevti objavljajo investitorjem so šele tisto, kar je za jemati bolj resno, nam, raji pa trosijo pravljice o virusih, učinkovitosti cepiv, preprečevanju okužb... Torej, v letnih poročilih farmacevtskih korporacij najdemo njihove iskrene izjave, da se zavedajo škodljivosti svojih cepiv in da ne vejo, če bodo zaradi stranskih učinkov kdaj dobila pravo odobritev.

# PRVO POGLAVJE: VOJAŠKE POVEZAVE

## Naslov novice: »Številke nacionalne zaloge, dodeljene kritičnim medicinskim protiukrepom za borce«

Vir:

<https://www.jpeocbrnd.osd.mil/Media/News/Article/2590168/national-stock-numbers-assigned-to-critical-medical-countermeasures-for-the-war/>

Citati:

»Skupni vodja projekta za kemijsko, biološko, radiološko in jedrsko obrambo (JPM CBRN Medical) izvršilne pisarne združenega programa za kemijsko, biološko, radiološko in jedrsko obrambo ( JPEO-CBRND) je imel ključno vlogo pri lažšanju dodeljevanja številke nacionalne zaloge (NSN) štirim medicinskim protiukrepom (MCM) – razvitimi v partnerstvu med proizvajalci, JPM CBRN Medical in drugimi vladnimi agencijami ZDA – ki ščitijo pripadnike oboroženih sil naše države. NSN so bistveni del nacionalne logistične dobavne verige, ki se uporabljajo pri upravljanju, premikanju, shranjevanju in odlaganju materiala. Dodeljevanje NSN-jev je korak naprej pri dostavi teh izdelkov razporejenim silam, kar omogoča vnaprejšnjo namestitev medicinskih protiukrepov na strateških lokacijah po vsem svetu in zagotavlja pravočasen dostop do izdelkov v regijah, kjer se borci srečujejo z edinstvenimi grožnjami.«

»Štirje produkti vključujejo:

**JYNNEOS™** smallpox vaccine (NSN 6505-01-684-4091)

•Tecovirimat (**TPOXX®**) smallpox treatment (NSN 6505-01-684-9538)

•Heptavalent Botulism Anti-Toxin (**HBAT®**) (NSN 6505-01-684-9483)

•EVZIO® naloxone autoinjector (NSN 6505-01-684-9014)«

National Stock Numbers Assigned to Critical Medical Countermeasures for the Warfighter > JPEO-CBRND > News — Mozilla Firefox

National Stock Numbers Assigned to Critical Medical Countermeasures for the Warfighter

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Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense

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News

NEWS | Feb. 11, 2020

### National Stock Numbers Assigned to Critical Medical Countermeasures for the Warfighter

By Press Release

FORT DETRICK, Md. – The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense's (JPEO-CBRND) Joint Project Manager for Chemical, Biological, Radiological and Nuclear Medical (JPM CBRN Medical) played a critical role in facilitating the assignment of National Stock Numbers (NSNs) to four medical countermeasures (MCMs) developed under partnerships between manufacturers, the JPM CBRN Medical, and other U.S. government agencies – that protect our nation's service members. NSNs are an essential part of the national logistics supply chain.

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# warfighter

By Press Release

**FORT DETRICK, Md.** – The Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense's (JPEO-CBRND) Joint Project Manager for Chemical, Biological, Radiological and Nuclear Medical (JPM CBRN Medical) played a critical role in facilitating the assignment of National Stock Numbers (NSNs) to four medical countermeasures (MCMs) – developed under partnerships between manufacturers, the JPM CBRN Medical, and other U.S. government agencies – that protect our nation's service members. NSNs are an essential part of the national logistics supply chain used in managing, moving, storing, and disposing of material. Assigning NSNs is a step forward in delivering these products to deployed forces, allowing the MCMs to be prepositioned in strategic locations around the globe and ensuring timely access to the products in regions where warfighters encounter unique threats.

The four products include:

- JYNNEOS™ smallpox vaccine (NSN 6505-01-684-4091)
- Tecovirimat (TPOXX®) smallpox treatment (NSN 6505-01-684-9538)
- Heptavalent Botulism Anti-Toxin (HBAT®) (NSN 6505-01-684-9483)
- EVZIO® naloxone autoinjector (NSN 6505-01-684-9014)



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<https://www.jpeocbrnd.osd.mil/Media/News/Article/2590168/national-stock-numbers-assigned-to-critical-medical-countermeasures-for-the-war/>

## Naslov novice: »Naložbe BARDA v pripravljenost so omogočile hiter odziv na izbruh opičjih koz v ZDA«

Vir:

<https://www.medicalcountermeasures.gov/stories/monkeypox/>

»Kot del naših prizadevanj za obravnavo potencialnega izrednega stanja črnih koz je BARDA podprla napredni razvoj, licenciranje FDA in začetno dobavo treh izdelkov, ki jih je FDA odobrila za zdravljenje črnih koz ter preprečevanje črnih in opičjih koz. To so protivirusni terapevtiki (TPOXX in TEMBEXA) za zdravljenje črnih koz in cepivo (JYNNEOS) za preprečevanje črnih in opičjih koz.«

## phe.gov – DoD integrated PORTFOLIO

### »BARDA Guiding Principles«, »Vodila BARDE«

Vir:

<https://www.phe.gov/about/barda/stratplan/Pages/barda-guiding-principles.aspx>

Citat iz zgornjega linka:

#### »Zagotavljanje integriranega portfelja z DOD

Poleg upravljanja posebnih programov v okviru zgoraj poudarjenega prizadevanja je BARDA v sodelovanju s svojimi partnerji HHS in Ministrstvom za obrambo prevzela integriran pristop k soupravljanju nacionalnega skupnega portfelja razvojnih programov medicinskih protiukrepov za CRBN grožnje. Splošni cilj je optimizirati uporabo virov za naslavljanje širokega nabora pogostih groženj in zahtev z večjo učinkovitostjo in uspešnostjo. Čeprav imata **Ministrstvo za obrambo in HHS** vsako določene edinstvene zahteve zaradi svojih različnih misij in osredotočenosti, **obstaja veliko področij podobnih zahtev za izdelke ali zmogljivosti, kjer bodo viri in informacije ustrezno razdeljeni, da se optimizirajo naložbe in preprečijo nepotrebne redundance. Ta celostni pristop bo zagotovil ravnotežje in popolnost v vseh agencijah, ki financirajo raziskave, razvoj in dobavo medicinskih protiukrepov za CRBN grožnje.**«

Tukaj se že nakazuje povezava medicine z vojsko.

## Članek O BARDA na Wikipediji

Vir:

[https://en.wikipedia.org/wiki/Biomedical\\_Advanced\\_Research\\_and\\_Development\\_Authority](https://en.wikipedia.org/wiki/Biomedical_Advanced_Research_and_Development_Authority)

Citat:

»»Uprava za napredne biomedicinske raziskave in razvoj (BARDA) je urad ameriškega ministrstva za zdravje in socialne zadeve (HHS), odgovoren za dobavo in razvoj medicinskih protiukrepov, predvsem proti bioterorizmu, vključno s kemičnimi, biološkimi, radiološkimi in jedrskimi (CBRN) grožnjami, pa tudi pandemični gripi in nastajajočim boleznim. BARDA je bila ustanovljena leta 2006 z Zakonom o pripravljenosti na pandemije in vse nevarnosti (PAHPA) in odgovarja Uradu pomočnika sekretarja za pripravljenost in odziv (ASPR). Urad upravlja projekt BioShield, ki financira raziskave, razvoj in kopičenje cepiv in zdravil, ki bi jih vlada lahko uporabila v izrednih razmerah na področju javnega zdravja, kot so kemični, biološki, radiološki ali jedrski (CBRN) napadi.««

## Odstavek »Advancing inovacion«:

### Citat:

»»PAHPA nalaga BARDA-i podporo inovacijam za zmanjšanje trajanja in stroškov razvoja in naprednih raziskav medicinskih protiukrepov in izdelkov. To naj bi dosegli z razvojem tehnologij, ki pomagajo pri naprednem razvoju protiukrepov, naložbami v raziskovalna orodja in tehnologije ter raziskavami za spodbujanje strateških pobud, vključno s hitro diagnostiko, protimikrobnimi zdravili širokega spektra in tehnologijami za proizvodnjo cepiv. PAHPA je zagotovil dodatna pooblastila za BARDA-o za spodbujanje inovacij s pomočjo industrije in partnerstev. ««

## Poglejmo za trenutek še članek o PAHPA na Wikipediji

Vir: [https://en.wikipedia.org/wiki/Pandemic\\_and\\_All-Hazards\\_Preparedness\\_Act](https://en.wikipedia.org/wiki/Pandemic_and_All-Hazards_Preparedness_Act)

### Citat:

»Dne 19. decembra 2006 je predsednik George W. Bush podpisal Zakon o pripravljenosti na pandemije in vse nevarnosti (PAHPA), zakon št. 109-417.

PAHPA. Zakon, ki sta ga v Parlamentu prvič predstavila predstavnik Mike Rogers (R-MI) in predstavnica Anna Eshoo (D-CA), je imel široke posledice za dejavnosti pripravljenosti in odzivanja Ministrstva za zdravje in socialne zadeve Združenih držav (HHS). Zakon je med drugim spremenil Zakon o javni zdravstveni službi, s katerim je na ministrstvu bil vzpostavljen novi pomočnik sekretarja za pripravljenost in odzivanje (ASPR); zagotovil nova pooblastila za številne programe, vključno z naprednim razvojem in usvajanjem medicinskih protiukrepov; in naložil oblikovanje štiriletne nacionalne strategije zdravstvene varnosti. «

## Vrnimo se na članek o BARDA, na odstavek »Advancing inovacion«

Vir: [https://en.wikipedia.org/wiki/Biomedical\\_Advanced\\_Research\\_and\\_Development\\_Authority](https://en.wikipedia.org/wiki/Biomedical_Advanced_Research_and_Development_Authority)

### Citat:

»Julija 2005 je na zaslišanjih pred Odborom za zdravje, izobraževanje, delo in pokojnine prva izvršna direktorica in direktorica centra, dr. med. Tara O'Toole, MPH, opozorila na vlogo centra kot »BioDARPA« ( tj. "biomedicinska DARPA").«

## Spletna stran [www.govinfo.gov](http://www.govinfo.gov) - prepis zaslišanij pred Odborom za zdravje, izobraževanje, delo in pokojnine

### Citat:

»Taktični, kratkoročni cilji

Razmislite o novih pristopih financiranja za podporo kratkoročnemu razvoju posebnih protiukrepov in za spodbujanje strateškega cilja pospeševanja razvoja zdravil in cepiv na splošno. Bolj podrobno, bi kongres lahko razmislil o:

Mehanizmi financiranja za podporo zgodnje razvojne faze protiukrepov („dolina smrti“).

Ustanovitev »BioDARPA«, ki bi vlagala v transformacijske bioraziskave. Takšne raziskave bi bile »projektne vodene« in povezane z opredeljenimi nacionalnimi potrebami.«

Vir: <https://www.govinfo.gov/content/pkg/CHRG-109shrg28743/html/CHRG-109shrg28743.htm>

## Članek o Tari O'Toole na Wikipediji

Vir: [https://en.wikipedia.org/wiki/Tara\\_O%27Toole](https://en.wikipedia.org/wiki/Tara_O%27Toole)

### Nekaj citatov:

»»Pred potrditvijo za podsekretarko (4. novembra 2009) je O'Toole ustanovila in bila glavna izvršna direktorica ter direktorica Centra za biološko varnost pri Medicinskem centru Univerze v Pittsburghu. Hkrati je bila profesorica medicine in javnega zdravja na Univerzi v Pittsburghu. S položaja podsekretarke je odstopila 23. septembra 2013. Od leta 2006 do 2007 je predsedovala upravnemu odboru Zveze ameriških znanstvenikov. Leta 2006 je bila imenovana v upravni odbor mednarodnega mrežnega sistema za popolno zgodnje odkrivanje bolezni fundacije Google. Od leta 2001 do 2003 je vodila Johns Hopkins Center for Civilian Biodefense Strategies.«

»»Vaje odzivanja na nesreče

O'Toole je najbolj znana po svojih vajah za odzivanje na nesreče. Bila je glavna avtorica in producentka Temne zime (2001) in Atlantske nevihte [2] (2005), ki sta simulirala prikriti izbruh črnih koz v Združenih državah. Številni strokovnjaki so pozdravili te vaje za objavo presenetljivih ranljivosti države, vključno s pomanjkanjem cepiva.[3] Kritiki so očitali, da so te vaje pretiravale z grožnjo bioterorizma, kar je povzročilo nepotrebno povečanje števila raziskovalnih laboratorijev.[4] ««

## Članek o Johns Hopkins Center for Health Security na Wikipediji

Vir: [https://en.wikipedia.org/wiki/Johns\\_Hopkins\\_Center\\_for\\_Health\\_Security](https://en.wikipedia.org/wiki/Johns_Hopkins_Center_for_Health_Security)

### Nekaj citatov:

»Center Johns Hopkins for Health Security (skrajšano CHS) je neodvisna, neprofitna organizacija Johns Hopkins Bloomberg Šole javnega zdravja. Center si prizadeva zaščititi zdravje ljudi pred epidemijami in pandemijami ter zagotavlja, da so skupnosti odporne na velike izzive. Center je tudi zaskrbljen zaradi biološkega orožja in posledic nastajajoče biotehnologije za biološko varnost.«

»Center za zdravstveno varnost daje strateška priporočila vladi Združenih držav, Svetovni zdravstveni organizaciji in Konvenciji ZN o biološkem orožju.««

### V članku je v odstavku »Funding« omenjen Open Philanthropy Project.

»»Leta 2002 je center prejel 1 milijon dolarjev donacije od ameriške zvezne vlade.[10] Pred letom 2017 je bil CHS močno odvisen od državnega financiranja.

Januarja 2017 je **Open Philanthropy Project** Centru za zdravstveno varnost dodelil 16 milijonov dolarjev za obdobje treh let. Septembra 2019 so bila dodeljena še ena nepovratna sredstva v višini 19,5 milijona dolarjev.««

Ali se spomnete vaje na Munchenski varnostni konferenci, ki je leta 2021 predvidela izbruh opičjih koz? Tudi NTI je bila podprta od Open Phylantrophy!

Vir: [https://www.nti.org/wp-content/uploads/2021/11/NTI\\_Paper\\_BIO-TTX\\_Final.pdf](https://www.nti.org/wp-content/uploads/2021/11/NTI_Paper_BIO-TTX_Final.pdf)

Citat iz zgornje povezave:

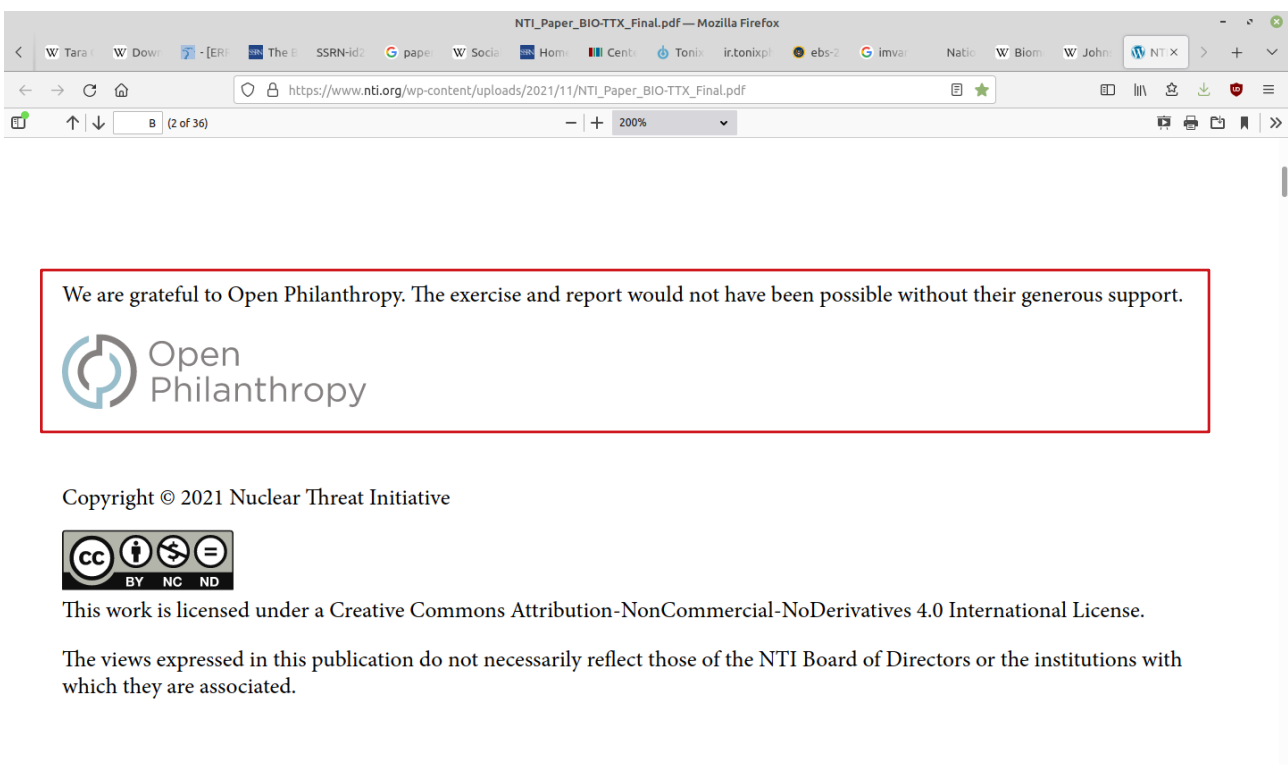
»Hvaležni smo Open Philanthropy. Vaja in poročilo ne bi bila mogoča brez njihove velikodušne podpore.«

## Dokument organizacije NTI iz leta 2021

Tudi v temu dokumentu je omenjen Open Philanthropy.



Vir: [https://www.nti.org/wp-content/uploads/2021/11/NTI\\_Paper\\_BIO-TTX\\_Final.pdf](https://www.nti.org/wp-content/uploads/2021/11/NTI_Paper_BIO-TTX_Final.pdf)



Vir: [https://www.nti.org/wp-content/uploads/2021/11/NTI\\_Paper\\_BIO-TTX\\_Final.pdf](https://www.nti.org/wp-content/uploads/2021/11/NTI_Paper_BIO-TTX_Final.pdf)

## Članek o Dark Winter na Wikipediji

Vir: [https://en.wikipedia.org/wiki/Operation\\_Dark\\_Winter](https://en.wikipedia.org/wiki/Operation_Dark_Winter)

Citat iz zgornje povezave:

»Operacija Dark Winter (Temna zima) je bilo kodno ime za simulacijo bioterorističnega napada na visoki ravni, izvedeno 22. in 23. junija 2001. Zasnovana je bila za izvedbo navidezne različice prikritega in razširjenega napada črnih koz na Združene države. [Tara O'Toole](#) in [Tom Inglesby](#) iz Johns Hopkins Center for Civilian Biodefense Strategies (CCBS)/Center for Strategic and International Studies (CSIS) ter [Randy Larsen](#) in [Mark DeMier](#) iz Analytic Services so bili glavni oblikovalci, avtorji in nadzorniki Projekta Temna zima. «

### Še posebej je zanimiv naslednji odstavek o medijih in vplivu na množice:

»»Ravnanje z mediji bo velik takojšnji izziv za vse ravni oblasti. Dark Winter je razkril, da bosta upravljanje informacij in komunikacija (npr. učinkovito ravnanje s tiskom, komunikacija z državljani, vzdrževanje informacijskih tokov, potrebnih za poveljevanje in nadzor na vseh institucionalnih ravneh) ključni element pri obvladovanju kriz/posledic. Udeležence je na primer skrbelo, da ne bi bilo mogoče prisilno uvesti cepljenja ali omejitev potovanja za velike skupine prebivalstva brez njihovega splošnega sodelovanja. Da bi pridobili to sodelovanje, so predsednik in drugi voditelji v Temni zimi prepoznali pomen prepričevanja svojih volivcev, da je razdeljevanje cepiva in drugih redkih virov pravično, da so ukrepi za zajezitev bolezni v splošno dobro družbe, , da so bili sprejeti vsi možni ukrepi za preprečitev nadaljnega širjenja bolezni in da je vlada kljub razraščajoči se epidemiji ohranila trdni nadzor.««

Če bi imela oblast dobre namene, ji ne bi bilo potrebno prepričevati ljudi, da dela v njihovo splošno dobro, kot to piše tukaj.

Lahko bi se reklo, da ta odstavek vbistvu govori o sedanjih dogodkih v zvezi z mediji, kljub temu, da je bil napisan veliko pred letom 2020.

### Članek z naslovom »Shining Light on “Dark Winter”« iz aprila 2002, ki govori o Dark Winter je dostopen na naslednji strani:

<https://academic.oup.com/cid/article/34/7/972/316999?login=false>

Citat iz zgornje povezave:

»Več mednarodnih meja je zaprtih za trgovino in potnike iz ZDA. Pomanjkanje hrane se v prizadetih državah pojavi zaradi težav s potovanji in zaprtja trgovin. Poročali so o občasnem nasilju nad manjšinami, za katere se zdi, da so arabskega porekla. Ni trdnih sledi o tem, kdo bi lahko zagrešil ta napad. Odziv vlade na epidemijo je bil kritiziran. Mediji nadaljujejo s 24-urnim poročanjem o krizi. Na internetu in v medijih se začnejo pojavljati napačne informacije o izbruhu črnih koz, vključno z lažnimi poročili o zdravilih za črne koze. Šole so zaprte po vsej državi. V prizadetih državah so javna zbiranja omejena. Nekatere države omejujejo potovanja in nebitvena srečanja. Ministrstvo za zdravje in socialne storitve ustanovi nacionalni informacijski center. Tri ameriške farmacevtske družbe se strinjajo, da bodo proizvedle novo cepivo s hitrostjo 6 milijonov odmerkov na mesec, s prvimi dobavami v 5 tednih. Rusija ponuja 4 milijone odmerkov cepiva.«

## Johns Hopkins CHS v svojem članku omenja JPEO, DARPO in In-Q-Tel:

### Naslov novice:

»Center Johns Hopkins za zdravstveno varnost poziva k financiranju novih pobud za hiter razvoj medicinskih protiukrepov za nove nalezljive bolezni v mesecih in ne letih«

»April 30, 2020 «

Vir: <https://www.centerforhealthsecurity.org/news/center-news/2020/2020-04-30-covid-19-proposal.html>

Citat iz zgornje povezave:

»Center za zdravstveno varnost poziva k novi namenski strategiji in programu Virus 201, za doseg tega cilja pa je treba zagotoviti financiranje prek HHS Biomedical Advanced Research and Development Authority (BARDA) in DOD Joint Programme Executive Office for Chemical and Biological Defense (JPEO). Ta strategija ne bi smela konkurirati ali kanibalizirati drugih pomembnih prizadevanj za razvoj medicinskih protiukrepov, osredotočenih na posebne znane grožnje, in bi morala vključevati druge inovativne agencije, kot sta DARPA in In-Q-Tel.«

### Članek na Wikipediji o In-Q-Tel

Vir: <https://en.wikipedia.org/wiki/In-Q-Tel>

Citat iz zgornje povezave:

»In-Q-Tel (IQT), prej Peleus in In-Q-It, je ameriško neprofitno podjetje tveganega kapitala s sedežem v Arlingtonu v Virginiji. Vlada v visokotehnološka podjetja, da bi [Centralna obveščevalna agencija in druge obveščevalne agencije](#) ohranile opremo z najnovejšo informacijsko tehnologijo v podporo obveščevalnim zmogljivostim Združenih držav.[4] Ime "In-Q-Tel" je namerno sklicevanje na Q, fikcijskega izumitelja, ki dobavlja tehnologijo Jamesu Bondu.[5] «

**Že v prejšnjemu delu (Reanalogizavija 1) smo omenjali patent US 11107588B2.**

**Poglejmo si ga še enkrat!**

Vir: <https://patentimages.storage.googleapis.com/68/80/73/6a17a66e9ec8c5/US11107588.pdf>

Citat iz zgornje povezave:

»Vidik nekaterih izvedb izuma se nanaša za spodbujanje uporabnikov k uporabi namenske aplikacije/programske opreme za **sledenje stikom** (in opcijsko identificiranje potencialnih superrazširjevalcev anonimizirano ali ne) z zagotavljanjem cepljenja in/ali profilaktičnega zdravljenja najprej tistim posameznikom, ki uporabljajo namensko programsko opremo. V nekaterih različicah so posamezniki, ki uporabljajo namensko programsko opremo, tisti posamezniki, ki prispevajo k splošni koristi prebivalstva, zato so jim zagotovljena cepljenja in/ali profilaktično zdravljenje pred ostalimi.«

**Postavlja se vprašanje: Zakaj bi centralna obveščevalna agencija imela eno od glavnih vklog med pandemijo?**

Ali bi bilo možno, da sledenje stikom opravlja obveščevalna služba? Za naše zdravje?

Ali zaradi česa drugega?

## Novica na strani [www.niaid.nih.gov](http://www.niaid.nih.gov) govori tudi o cepivu JYNNEOS

Vir: <https://www.niaid.nih.gov/diseases-conditions/smallpox-vaccine>

Citat iz zgornje povezave:

»Po obetavnih rezultatih kliničnih preskušanj je bil MVA-BN prenesen na Upravo za napredne biomedicinske raziskave in razvoj (BARDA) za napredni razvoj. Leta 2013 sta Kanada in Evropska unija odobrili cepivo (pod trgovskima imenoma IMVAMUNE in IMVANEX) za uporabo pri splošni populaciji, vključno z ljudmi z oslabiljenim imunskim sistemom ali atopičnim dermatitisom. Od avgusta 2014 je bilo 24 milijonov odmerkov dostavljenih ameriškim strateškim nacionalnim zalogam (SNS) za uporabo med temi skupinami. BARDA je podprla tudi velika klinična preskušanja cepiva 3. faze. Na podlagi obetavnih podatkov iz teh študij je FDA septembra 2019 odobrila MVA-BN (zdaj imenovan JYNNEOS). NIAID je podprl tudi projekt za razvoj freeze-dried ali liofilizirane različice cepiva. V primerjavi s trenutno tekočo formulacijo je liofilizirana različica stabilnejša z daljšim rokom uporabnosti. NIAID je ta projekt prenesel na Upravo za napredne biomedicinske raziskave in razvoj Ministrstva za zdravje in socialne zadeve ZDA (BARDA) za nadaljnji razvoj«

### Naslov novice: »Bavarian Nordic bo proizvedel prve liofilizirane odmerke cepiva proti črnim kozam potem, ko je vlada ZDA uveljavila pogodbeno opcijo«

BARDA financira Bavaria Nordic:

BARDA 539 MILLION Award! Novica je iz **May 18, 2022!**

Vir: <https://www.bavarian-nordic.com/investor/news/news.aspx?news=6569>

Nekaj citatov:

»Bavarian Nordic bo proizvedel prve liofilizirane odmerke cepiva proti črnim kozam potem, ko je vlada ZDA uveljavila pogodbeno opcijo«

»Od leta 2009 BARDA podpira razvoj liofilizirane različice cepiva z daljšim rokom uporabnosti za nadomestitev zalog in leta 2017 je podjetju podelila desetletno pogodbo v vrednosti 539 milijonov USD za dobavo liofiliziranih cepiv. Del te pogodbe (37 milijonov USD) je financiral študijo 3. faze. Poleg tega je Bavarian Nordic v skladu s to pogodbo proizvedel cepivo v velikih količinah v vrednosti 253 milijonov USD, ki bo dodano obstoječi zalogi cepiva, proizvedenega po prejšnjih naročilih, kar skupaj pomeni približno 13 milijonov odmerkov za prihodnjo dostavo. Večji del pogodbe (299 milijonov USD) pa bo realiziran z dobavo liofiliziranih odmerkov, ki bodo proizvedeni v novem obratu družbe.«

## Naslov novice iz leta 2014: »Bavarian Nordic-ova MVA-BN Platforma za cepiva, ki jo je Ministrstvo za obrambo ZDA izbralo za razvoj novega cepiva«

DoD Award \$510894 Novica je iz leta 2014.

Vir: <https://www.bavarian-nordic.com/investor/news/news.aspx?news=3101>

### Nekaj citatov:

»Bavarian Nordic-ova MVA-BN Platforma za cepiva, ki jo je **Ministrstvo za obrambo ZDA izbralo za razvoj novega cepiva**«

»Po tej novi pogodbi v vrednosti 0,5 milijona USD bo Bavarian Nordic zasnoval, proizvedel in testiral rekombinantna cepiva proti Burkholderiji na osnovi MVA-BN. Če bo pogodba prinesla uspešen dokaz koncepta, lahko DTRA podpre nadaljnji razvoj cepiva z oddajo večje pogodbe.««

## Naslov novice iz leta 2018: »Bavarian Nordic napoveduje sodelovanje z ministrstvom za obrambo ZDA za boj proti virusu konjskega encefalitisa«

Vir: <https://www.bavarian-nordic.com/investor/news/news.aspx?news=5410>

### Nekaj citatov:

»Bavarian Nordic napoveduje **sodelovanje z ministrstvom za obrambo ZDA za boj proti virusu konjskega encefalitisa**«

»Sodelovanje v vrednosti do 36 milijonov dolarjev

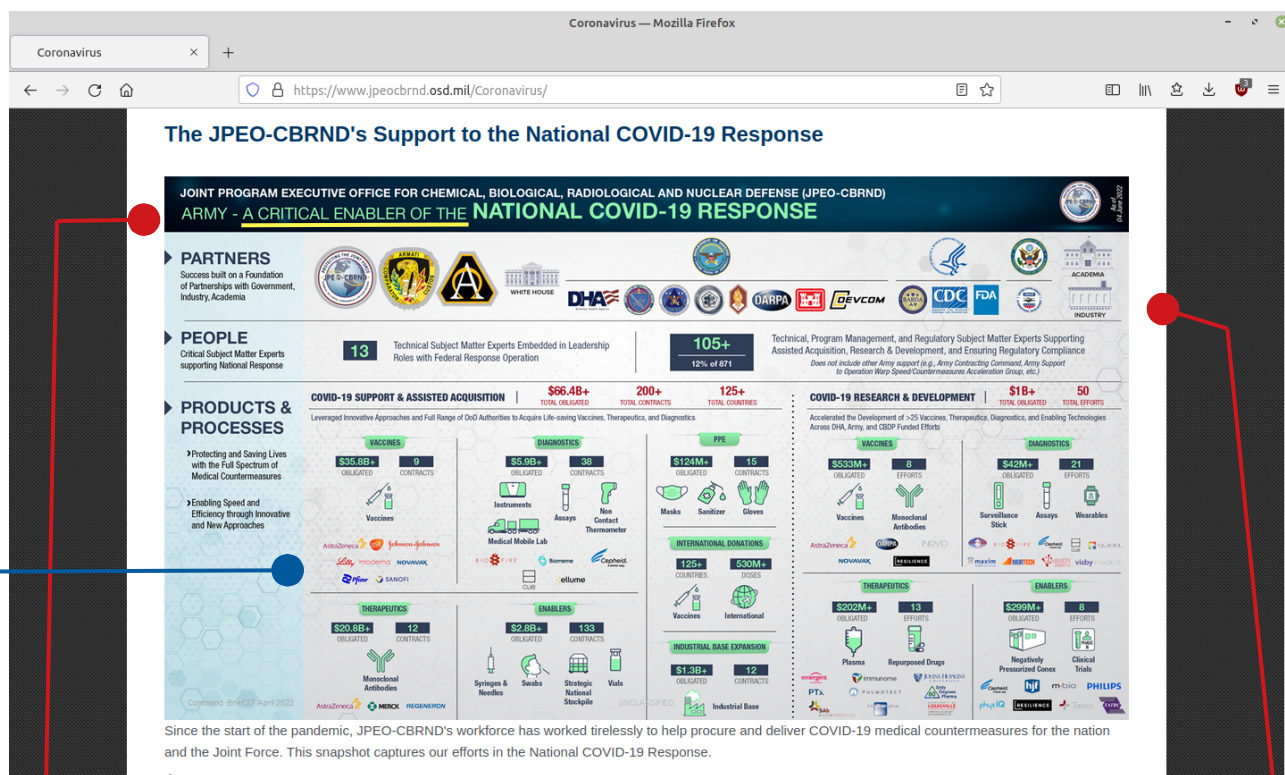
Multivalentno cepivo, zasnovano za zaščito ljudi pred vzhodnim, venezuelskim in zahodnim virusom konjskega encefalitisa

KOPENHAGEN, Danska, 16. marec 2018 – Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) je danes objavil podpis **novega zaveznitva z Ministrstvom za obrambo Združenih držav (DoD)** za razvoj profilaktičnega cepiva proti virusu konjskega encefalitisa – redka, a potencialno smrtonosna bolezen, ki jo prenašajo komarji. **S financiranjem Ministrstva za obrambo** bo Bavarian Nordic uporabil svojo lastniško platformo MVA-BN za razvoj cepiva proti različnim sevom virusa, za katerega trenutno ni na voljo preventivnega cepiva.«

Komentar:

Velike farmacevtske korporacije očitno vedno bolj direktno sklepajo partnerstva kar z ministrstvom za obrambo (in ne z ministrstvom za zdravstvo). Ali ni to že samo po sebi dovolj veliko znamenje, da tu ne gre za izdelavo zdravil?

# Vse je to vojska!



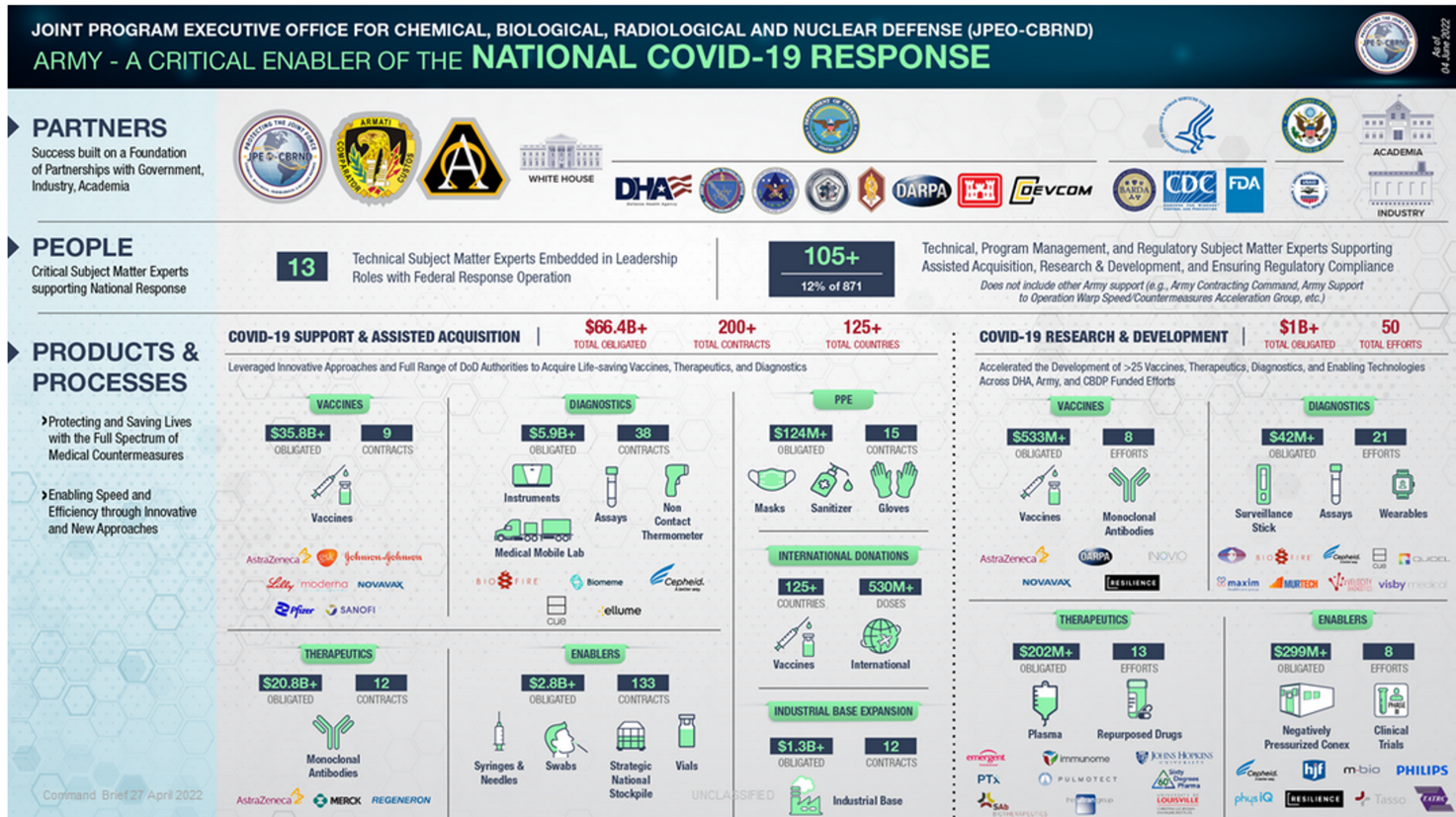
Kot piše tukaj: »VOJSKA: KRITIČNI OMOGOČEVALEC NACIONALNEGA COVID-19 ODZIVA«

Vir: <https://www.jpeocbrnd.osd.mil/Coronavirus/>

V VRHU INŠTITUCIJ, KI DELUJEJO POD POVELJSTVOM VOJSKE SO: Bela hiša, univerze, industrija, CDC, FDA, BARDA,...

NA SEZNAMU KORPORACIJ, KI DELUJEJO POD POVELJSTVOM VOJSKE SO GLEDE NA TOLE INFOGRAFIKO OČITNO TUDI: Pfizer, Moderna, Johnson&Johnson, Novavax, AstraZeneca,...

## The JPEO-CBRND's Support to the National COVID-19 Response




Since the start of the pandemic, JPEO-CBRND's workforce has worked tirelessly to help procure and deliver COVID-19 medical countermeasures for the nation and the Joint Force. This snapshot captures our efforts in the National COVID-19 Response.

Vir: <https://www.jpeocbrnd.osd.mil/Coronavirus/>

Coronavirus — Mozilla Firefox

Coronavirus

https://www.jpeocbrnd.osd.mil/Coronavirus/



### The JPEO's COVID-19 Support

Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)'s core focus areas contribute to building a more lethal force, a priority in the National Defense Strategy, and streamline JPEO-CBRND efforts to meet the Joint Service's needs in combating chemical, biological, radiological and nuclear (CBRN) threats.

JPEO-CBRND is supporting our interagency partners in their response to the COVID-19 pandemic, from helping develop detection, diagnosis, treatment, and vaccines for our Warfighters, to tools that increase situational awareness of the coronavirus, all thanks to our team effort with industry and academia.

### The JPEO-CBRND's Support to the National COVID-19 Response

Vir: <https://www.jpeocbrnd.osd.mil/Coronavirus/>

Coronavirus — Mozilla Firefox

SSRN-Hid: G pape W Socia BBS Homi Cent: Tonix ir.tonixpl ebs-2 imvar Natic W Biom W NTL Shini BAVAI BAVAI News Co: X

https://www.jpeocbrnd.osd.mil/Coronavirus/

# Support

Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)'s core focus areas contribute to building a more lethal force, a priority in the National Defense Strategy, and streamline JPEO-CBRND efforts to meet the Joint Service's needs in combating chemical, biological, radiological and nuclear (CBRN) threats.

Vir: <https://www.jpeocbrnd.osd.mil/Coronavirus/>

## Če citiramo iz posnetkov zaslona na prejšnjih dveh straneh:

“The JPEO-CBRND's Support to the National COVID-19 Response

Since the start of the pandemic, JPEO-CBRND's workforce has worked tirelessly to help procure and deliver COVID-19 medical countermeasures for the nation and the Joint Force. This snapshot captures our efforts in the National COVID-19 Response.”

»Podpora Izvršilne pisarne združenega programa za kemijsko, biološko, radiološko in jedrsko obrambo ( JPEO-CBRND) pri nacionalnemu odgovoru na Covid-19

**Odkar se je začela pandemija** je delovna sila Izvršilne pisarne združenega programa za kemijsko, biološko, radiološko in jedrsko obrambo ( JPEO-CBRND) **tesno sodelovala**, da bi pomagala dostaviti Covid-19 medicinske protiukrepe za narod in združene sile. Ta posnetek zajema vse naše napore pri nacionalnemu Covid-19 odgovoru.«

“Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND)'s core focus areas contribute to **building a more lethal force**, a priority in the National Defense Strategy, and streamline JPEO-CBRND efforts to meet the Joint Service's needs in combating chemical, biological, radiological and nuclear (CBRN) threats.”

»Glavna fokusna področja izvršilne pisarne združenega programa za kemijsko, biološko, radiološko in jedrsko obrambo ( JPEO-CBRND) prispevajo k grajenju bolj **smrtonosne sile**, ki je prioriteta nacionalne obrambne strategije, in racionaliziranju naporov JPEO-CBRND za doseganje potreb združenih služb v bojevanju proti kemičnim, biološkim, radiološkim in nuklearnim (CBRN) grožnjam.«

Vir: <https://www.jpeocbrnd.osd.mil/Coronavirus/>

**Mislino, da komentar ni potreben.**

# DRUGO POGLAVJE – SEC IZJAVE

## Spletna stran [www.sec.gov](http://www.sec.gov) : 2016 – Bavarian Nordic

Vir: [https://www.sec.gov/Archives/edgar/data/1576915/000104746916009636/a2227062zf-1a.htm#cg48201\\_risk\\_factors](https://www.sec.gov/Archives/edgar/data/1576915/000104746916009636/a2227062zf-1a.htm#cg48201_risk_factors)

F-1/A 1 a2227062zf-1a.htm F-1/A

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As filed with the Securities and Exchange Commission on January 11, 2016

Registration No. 333-208834

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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AMENDMENT NO. 1  
TO  
**FORM F-1**  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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**Bavarian Nordic A/S**  
(Exact name of Registrant as specified in its charter)

**Not Applicable**  
(Translation of Registrant's name into English)

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The chart below summarizes our active clinical development programs:

PRODUCT CANDIDATE	INDICATION	COMMERCIAL RIGHTS	PHASE 1	PHASE 2	PHASE 3	APPROVED	LOCATION OF CLINICAL TRIAL
<b>Infectious Disease Portfolio</b>							
<b>IMVAMUNE / IMVANEX</b> <i>(liquid frozen)</i>	Smallpox	Bavarian Nordic	Approved in Canada and the European Union				United States
	Smallpox	Bavarian Nordic	Phase 3 in the United States (non-inferiority)				United States
<b>IMVAMUNE</b> <i>(freeze dried)</i>	Smallpox	Bavarian Nordic	Phase 2 complete				United States
<b>MVA-BN Filo</b>	Ebola / Marburg	Janssen					United States
<b>MVA-BN RSV</b>	RSV	Bavarian Nordic	Fully enrolled				United States
<b>Cancer Immunotherapy Portfolio</b>							
<b>PROSTVAC</b>	mCRPC	BMS <sup>®</sup>	PROSPECT fully enrolled				Australia, Belgium, Canada, Denmark, Estonia, France, Germany, Iceland, Israel, Netherlands, Poland, Russia, Spain, United Kingdom and United States (including Puerto Rico)
	Localized Prostate Cancer	BMS <sup>®</sup>					United States

Isto cepivo je na enemu kontinentu v preizkušanju, medtem ko je sočasno na drugemu kontinentu že v redni uporabi??

	Localized Prostate Cancer	BMS <sup>(a)</sup>	[REDACTED]	United States
	Localized Prostate Cancer (neoadjuvant) <sup>(b)</sup>	BMS <sup>(a)</sup>	[REDACTED]	United States
	mCRPC	BMS <sup>(a)</sup>	+ XTANDI (enzalutamide)	United States
	Non-Metastatic Prostate Cancer	BMS <sup>(a)</sup>	+ XTANDI (enzalutamide)	United States
	Prostate Cancer	BMS <sup>(a)</sup>	+ ipilimumab	United States
<b>CV 301</b>	Bladder Cancer	Bavarian Nordic	[REDACTED]	United States
<b>MVA-BN Brachyury</b>	Solid Tumors	Bavarian Nordic	[REDACTED]	United States

(a) BMS holds an option to commercialize PROSTVAC globally, regardless of treatment setting  
 (b) Treatment given to shrink the tumor before the main treatment.

In addition to our clinical pipeline, we have multiple ongoing preclinical programs. These include multiple contracts with U.S. government agencies, including the NCI and the Biomedical Advanced Research and Development Authority, or BARDA. Through the Janssen collaboration, we are also exploring additional diseases and targets; specifically, MVA-BN is being actively evaluated in preclinical stages for the early treatment and prevention of human papillomavirus, or HPV, induced cancers. MVA-BN is also being evaluated for the treatment and prevention of two undisclosed infectious disease targets for the potential further expansion of the Janssen collaboration. We and Janssen are also developing the MVA-BN vaccine to target Marburg virus. We also continue to collaborate with the NCI and to develop our own proprietary immunotherapy programs.

We own and operate a fully integrated, highly scalable current Good Manufacturing Practices, or cGMP, commercial scale vaccine production facility in Kvistgaard, Denmark, which we believe reduces our dependency on sub-contractors. This facility has been inspected by the European Medicine Agency, or EMA, and the U.S. Food and Drug Administration, or FDA, without notice of any material deficiency. Our filling and finishing capabilities at this facility were established to support the commercial launch of PROSTVAC. Our ability to manufacture our live virus vaccines has been demonstrated by our production of 28 million doses of IMVAMUNE/IMVANEX for smallpox and more than 2 million doses of our MVA-BN Filo product candidate for Ebola to date.

Če prevedemo prvi odstavek iz posnetka zaslona na prejšnji strani:

»Poleg našega kliničnega načrta imamo več tekočih predkliničnih programov. Ti vkjučujejo številne pogodbe z vladnimi agencijami ZDA, vključno z NCI in Biomedicinsko napredno raziskovalno in razvojno upravo ali BARDA-o. S sodelovanjem z Janssen-om raziskujemo tudi dodatne bolezni in tarče; zlasti se MVA-BN aktivno ocenjuje v predkliničnih fazah za zgodnje zdravljenje in preprečevanje raka, ki ga povzroči humani papiloma virus ali HPV. MVA-BN se prav tako ocenjuje za zdravljenje in preprečevanje dveh nerazkritih tarč nalezljivih bolezni za morebitno nadaljnjo širitev sodelovanja Janssen. Z Janssenom razvijamo tudi cepivo MVA-BN za targetiranje virusa Marburg. Prav tako še naprej sodelujemo z NCI in razvijamo lastne programe imunoterapije.«

Opomba:

Spet smo na sledi tesnemu sodelovanju farmacije z vladnimi vojaškimi strukturami. (glej rdeče podčrtan tekst).

received, which may require us to adjust our operating plans.

### Risks Related to Our Products and Product Candidates

***Our product candidates will need to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the EMA, FDA and other similar regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of these product candidates.***

The European Commission (following review by the EMA) in Europe, the FDA in the United States and comparable regulatory authorities in other jurisdictions must approve new drug or biologic candidates before they can be marketed, promoted or sold in those territories. We must provide these regulatory authorities with data from nonclinical studies and clinical trials that demonstrate that our product candidates are safe and effective for a specific indication before they can be approved for commercial distribution. Our smallpox vaccine, marketed under the trade names IMVAMUNE and IMVANEX in Canada and the European Union, respectively, is our only approved product, and is not yet approved in the United States. Although not yet approved in the United States, we have also supplied 28 million doses of IMVAMUNE/IMVANEX to the U.S. government. The U.S. government stockpiles IMVAMUNE/IMVANEX in the event of an emergency outbreak of smallpox, which it would be able to distribute in such event under an EUA. We cannot assure you that our Phase 3 trials of IMVAMUNE/IMVANEX or PROSTVAC will be successful or that IMVAMUNE/IMVANEX will receive approval from the FDA or that any of our other product candidates will receive approval from the EMA or FDA or any other comparable regulatory authority.

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. For example, our ongoing Phase 3 trial of IMVAMUNE/IMVANEX is currently being conducted in collaboration with the U.S. government. The FDA has substantial control over the enrollment and other decisions regarding this trial and these decisions may cause delays or impact our ability to complete this trial to the satisfaction of the FDA or other regulatory authorities. The primary endpoint of the ongoing Phase 3 trial of PROSTVAC is event driven and it is therefore difficult to predict when OS data will be available to report. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a product candidate, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. An unfavorable outcome in one or more trials would be a major setback for our product candidates and for us. An unfavorable outcome in one or more trials may require us to delay, reduce the scope of or eliminate one or more product development programs, which could have a material adverse effect on our business and financial results.

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In connection with clinical testing and trials, we face a number of risks, including risks that:

- § a product candidate is ineffective, inferior to existing approved products for the same indications, unacceptably toxic or has unacceptable side effects;
- § patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- § extension studies on long-term tolerance could invalidate the use of our product;
- § the results may not confirm the positive results of earlier testing or trials;
- § the results may not meet the level of statistical significance required by the EMA, FDA or other regulatory agencies to establish the safety and efficacy of our product candidates for continued trial or marketing approval; and
- § our collaborators or contract research organizations, or CROs, are unable or unwilling to perform under their contracts.

The results of preclinical studies do not necessarily predict clinical success, and larger and later-stage clinical trials may not produce the same results as earlier-stage clinical trials. Our and our collaborators' clinical trials of our product candidates conducted to date have generated favorable safety and efficacy data. However, we may have different enrollment criteria in our future clinical trials. As a result, we may not observe a similarly favorable safety or efficacy profile as in our prior clinical trials. For example, while the results of the Phase 2 trials for PROSTVAC showed potential efficacy and acceptable safety results, our Phase 3 trials may fail to produce similar results. Additionally, our Phase 3 trial of IMVAMUNE/IMVANEX may fail to show positive safety and efficacy and we may not be successful in commercializing the vaccine in the United States. It is also possible that PROSTVAC may not demonstrate any clinical benefits either as monotherapy or in combination with other therapies. In addition, we cannot assure you that in the course of potential widespread use of any of our product candidates in future, we will not suffer setbacks in maintaining production quality or stability. In addition, clinical trials of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If we do not successfully complete preclinical and clinical development, we will be unable to market and sell our product candidates and generate additional revenue. Even if we successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before marketing applications may be submitted to the EMA or FDA, as applicable.

Furthermore, we sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings

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**Prevedimo obkroženi del:**

»V zvezi s kliničnimi testiranj in preskušanj se soočamo s številnimi tveganji, vključno s tveganji, da:

- je kandidat za izdelek neučinkovit, slabši od obstoječih odobrenih izdelkov za iste indikacije, nesprejemljivo strupen ali ima nesprejemljive stranske učinke;
- pacienti lahko umrejo ali utrpijo druge neželene učinke zaradi razlogov, ki so lahko ali pa tudi ne povezani s kandidatnim izdelkom, ki se preskuša;
- podaljšane študije o dolgoročni toleranci bi lahko razveljavile uporabo našega izdelka;
- rezultati morda ne potrjujejo pozitivnih rezultatov prejšnjih testiranj ali poskusov;
- rezultati morda ne bodo dosegli ravni statistične pomembnosti, ki jo zahtevajo EMA, FDA ali druge regulativne agencije za ugotavljanje varnosti in učinkovitosti naših izdelkov, kandidatov za nadaljnje preskušanje ali odobritev trženja; in
- naši sodelavci ali pogodbene raziskovalne organizacije ali CRO ne morejo ali nočejo opravljati svojih pogodb.«

objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, which may cause the timing of achievement of the milestones to vary considerably from our estimates. If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our product candidates may be delayed, we may not be entitled to receive certain contractual payments and it could have a material adverse effect on our business and financial results.

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**IMVAMUNE/IMVANEX, approved for sale in the European Union and Canada, has not yet been approved by the FDA and is supplied to the U.S. Strategic National Stockpile, or the SNS, as having fulfilled the requirements for the potential use following an EUA. There is no guarantee our Phase 3 trial of IMVAMUNE/IMVANEX will be successful or that the FDA will approve the vaccine for marketing.**

IMVAMUNE/IMVANEX is currently approved for sale only in the European Union and Canada. IMVAMUNE/IMVANEX may never receive approval from the FDA. There are several factors that may impact our ability to continue to sell IMVAMUNE/IMVANEX to the U.S. government and in other jurisdictions where it is approved for sale or obtain regulatory approval from the FDA or other regulatory authorities. These factors include our ability to successfully complete the Phase 3 trial currently being conducted at a U.S. military garrison in South Korea and the successful development of the freeze dried formulation of IMVAMUNE/IMVANEX. Our failure to successfully complete the Phase 3 trial or successfully develop the freeze dried formulation may prevent us from achieving certain milestones and receiving certain milestone payments under our contracts with BARDA and may result in a decline in orders of IMVAMUNE/IMVANEX from the U.S. and other governments.

**IMVAMUNE/IMVANEX or any of our product candidates for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products following approval.**

IMVAMUNE/IMVANEX or any of our product candidates for which we obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the EMA, FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the FDA requirement to implement a Risk Evaluation and Mitigation Strategy, if applicable, to ensure that the benefits of a drug or biological product outweigh its risks.

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## Prevedimo obkroženi odstavek:

**Str. 18:» Za IMVAMUNE/IMVANEX ali katerega koli od naših kandidatov za izdelek, za katerega pridobimo dovoljenje za trženje, bi lahko veljale omejitve po trženju ali umik s trga, lahko pa smo tudi kaznovani z znatnimi kaznimi, če ne izpolnimo zakonskih zahtev ali naletimo na nepričakovane težave z našimi izdelki po odobritvi. «**

regulatory approval from the FDA or other regulatory authorities. These factors include our ability to successfully complete the Phase 3 trial currently being conducted at a U.S. military garrison in South Korea and the successful development of the freeze dried formulation of IMVAMUNE/IMVANEX. Our failure to successfully complete the Phase 3 trial or successfully develop the freeze dried formulation may prevent us from achieving certain milestones and receiving certain milestone payments under our contracts with BARDA and may result in a decline in orders of IMVAMUNE/IMVANEX from the U.S. and other governments.

**IMVAMUNE/IMVANEX or any of our product candidates for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products following approval.**

IMVAMUNE/IMVANEX or any of our product candidates for which we obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the EMA, FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the FDA requirement to implement a Risk Evaluation and Mitigation Strategy, if applicable, to ensure that the benefits of a drug or biological product outweigh its risks.

The EMA and FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product, such as long term observational studies on natural exposure. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The EMA and FDA impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market any of our product candidates for which we receive marketing approval for only their approved indications, we may be subject to warnings or enforcement action for off-label marketing. Violation of the Federal Food Drug and Cosmetic Act, and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

**Although we obtained a special protocol assessment from the FDA for our ongoing Phase 3 trial of PROSTVAC, a special protocol assessment does not guarantee any particular outcome from regulatory review, including any regulatory approval.**

We have obtained an agreement with the FDA, following a special protocol assessment, or SPA, for the Phase 3 trial of PROSTVAC as monotherapy and in combination with GM-CSF for the

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Prevedimo del modro obkroženega odstavka na prejšnji strani:

Str 18: » EMA in FDA nalagata stroge omejitve pri komunikaciji proizvajalcev glede nenamenske uporabe in če ne tržimo nobenega od naših izdelkov, za katerega prejmemo dovoljenje za trženje, samo za njihove odobrene indikacije, bomo morda izpostavljeni opozorilom ali prisilnim ukrepom zaradi nenamenske uporabe. Kršitev Zveznega zakona o živilih in kozmetičnih izdelkih ter drugih zakonov, vključno z Zakonom o lažnih trditvah, ki se nanašajo na promocijo in oglaševanje zdravil na recept, lahko vodi do preiskav ali obtožb o kršitvah zveznih in državnih zakonov o goljufijah in zlorabah v zdravstvu ter zakonov, ki ščitijo državne potrošnike.«

# Spletna stran www.sec.gov : Emergent Biosolutions

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https://www.sec.gov/Archives/edgar/data/1367644/000136764421000033/ebs-20201231.htm

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 10-K

(Mark One)


ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to  
Commission file number: 001-33137

  
EMERGENT BIOSOLUTIONS INC.  
(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction of Incorporation or Organization)

14-1902018  
(IRS Employer Identification No.)

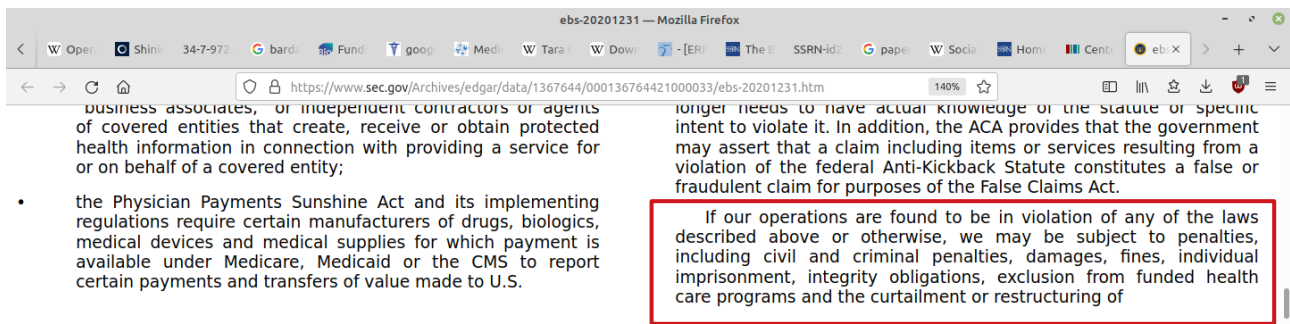
400 Professional Drive, Suite 400  
(Address of Principal Executive Offices)  
Gaithersburg MD 20879

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## Kaj proizvaja Emergent Biosolutions?

»BioThrax® (adsorbirano cepivo proti antraksu), RSDL® (Reactive Skin Decontamination Lotion Kit), BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)), Anthrasil® (Anthrax Immune Globulin intravensko (človeški)), VIGIV (intravenski imunski globulin proti vakciniji (človeški)), Trobigard® (atropin sulfat, obidoksim klorid), ACAM2000® (cepivo proti črnim kozam (vaccinia), živo), Vivotif® (cepivo proti tifusu, živo peroralno Ty21a), Vaxchora® (cepivo proti koleri, živo, peroralno), pršilo za nos NARCAN® (nalokson HCl) in vse blagovne znamke, izdelki, storitve in imena, logotipi in slogani so blagovne znamke ali registrirane blagovne znamke Emergent-a ali njegovih podružnic v Združenih državah Amerike ali drugih državah. Vse druge znamke, izdelki, storitve in imena funkcij ali blagovne znamke so last njihovih lastnikov.«

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our operations. Any such penalties could adversely affect our financial results. We continue to improve our corporate compliance program designed to ensure that our development, marketing, and sales of existing and future products and product candidates are in compliance with all applicable laws and regulations, but we cannot guarantee that this program will protect us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with health care laws and regulations will involve

- Limitations on our ability to continue certain operations;
- Decreased product demand; and
- Injury to our reputation.

Moreover, an adverse outcome, or the imposition of penalties or sanctions for failing to comply with the fraud and abuse and antitrust laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

*If we fail to comply with our obligations under U.S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines.*

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Prevedimo rdeče obkrožene dele:

**»Če se ugotovi, da je naše delovanje v nasprotju s katerim koli od zgoraj opisanih zakonov ali drugače, smo lahko kaznovani, vključno s kaznimi na podlagi civilnih in kazenskih predpisov, odškodninami, globami, zaporno kaznijo posameznika, obveznostmi integritete, izključitvijo iz financiranih programov zdravstvenega varstva in omejitev ali prestrukturiranje našega poslovanja. Takšne kazni bi lahko negativno vplivale na naše finančne rezultate. Še naprej izboljšujemo naš korporativni program skladnosti, ki je zasnovan tako, da zagotavlja, da so naš razvoj, trženje in prodaja obstoječih in prihodnjih izdelkov ter kandidatov za izdelke v skladu z vsemi veljavnimi zakoni in predpisi, vendar ne moremo zagotoviti, da nas bo ta program zaščitil pred vladnimi preiskavami ali drugimi dejanji ali tožbami, ki izhajajo iz neupoštevanja takih zakonov ali predpisov.«**

### **POZOR!!!**

**PAZLJIVO BERITE ZGORNJI ODSTAVEK, IZ NJEGA VAM JE LAHKO JASNO, DA SE FARMACEVTI PREKLETO DOBRO ZAVEDAJO, DA KRŠIJO VSE TISTE ZAKONE, KI NAS DRŽAVLJANE ŠČITIJO PRED ZLORABAMI TE ISTE FARMACIJE IN PRED VSEMI, KI NASTOPAJO V OZADJU VSEH TEH POSLOV.**

**VSE VEČKRAT JE V TEH OZADJIH PRAV VOJSKA.**

...consequently, Teva) have filed applications for generic versions of an intranasal naloxone spray based on NARCAN® Nasal Spray with the FDA and Health Canada. Teva has not launched its generic product in either jurisdiction, but may launch at risk, despite our patent infringement litigation (described in more detail below) that is currently proceeding against them. NARCAN® Nasal Spray also faces branded competition from other injectable naloxone, auto-injectors and improvised nasal kits, including Amphastar Pharmaceuticals, Inc.'s naloxone injection product and Kaléo's EVZIO™ (naloxone HCl injection) Auto-Injector and Teleflex Medical Inc's Intranasal Mucosal Atomization Device. NARCAN® Nasal Spray may face additional generic and branded competition in the future.

- **ACAM2000®.** ACAM2000® faces competition from JYNNEOS™, which is licensed by the FDA for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. JYNNEOS is also approved in Canada and in the European Union under the trade names IMVAMUNE and IMVANEX, respectively. ACAM2000 remains the primary smallpox vaccine stockpiled by the USG and offers key features for public health mass vaccination programs that are critical, including a single dose vaccination schedule and multi-dose vial presentation.
- **BAI®.** Our botulinum antitoxin immune globulin product is the only heptavalent therapeutic licensed by the FDA and Health Canada for the treatment of symptomatic botulism. Direct competition is currently limited.
- **VIGIV.** Our VIGIV product is the only therapeutic licensed by the FDA and Health Canada to address adverse events from smallpox vaccination with replicating virus smallpox vaccines. While direct competition in terms of the treatment of smallpox vaccination side effects is limited, SIGA has obtained FDA approval for TPOXX® (tecovirimat), an oral therapy for the treatment of smallpox disease TPOXX® is currently procured by the SNS. Chimerix is also developing brincidofovir, a nucleotide analog lipid conjugate for treatment of smallpox.
- **RSDL®.** In the United States, the RSDL Kit is the only medical device cleared by the FDA to remove or neutralize chemical warfare agents and T-2 toxin from the skin. Internationally, various Ministries of Defense have procured Fullers Earth, Dutch Powder and French Powder as a preparedness countermeasure for the decontamination of liquid chemical weapons from the skin.
- **Vivotif®.** Vivotif is the only FDA-approved oral typhoid vaccine. In the markets where Vivotif is licensed, it competes primarily with Sanofi Pasteur's Typhim VI® vaccine, an injectable polysaccharide typhoid vaccine.

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**V obkroženemu odstavku lahko preberemo naslednje:**  
**»JYNNEOS je odobren tudi v Kanadi in v Evropski uniji pod trgovskima imenoma IMVAMUNE oziroma IMVANEX.«**

### 3. Poglavje – KLINIČNE RAZISKAVE

## Naslov raziskave: »«MVA-BN Imvamune cepivo proti črnim kozam za zdravljenje bazaloceličnega karcinoma, ploščatoceličnega karcinoma»«

Vir: <https://www.clinicaltrials.gov/ct2/show/NCT04410874>

Imvamune Vaccine for the Treatment of Non-melanoma Skin Cancer - Full Text View - ClinicalTrials.gov — Mozilla Firefox

Condition or disease	Intervention/treatment	Phase
Non-melanoma Skin Cancer	Biological: Imvamune	Phase 1
Basal Cell Carcinoma		Phase 2
Squamous Cell Carcinoma		

Detailed Description:

One of the main ways cancer is able to develop is by hiding or evading our immune system which usually detects and kills potential tumor cells. Once cancer has developed the ability to evade the immune system it can continue to grow and become a tumor. One potential strategy currently being researched, called immunotherapy, uses viruses to stimulate an immune response which attacks the tumor.

Imvamune is a live, non-replicating virus used in Canada to vaccinate adults and children against smallpox. It is safe to use in immunosuppressed patients because the virus is unable to replicate and spread past the first infected cell. This makes the Imvamune vaccine a viable candidate for immunotherapy in immunosuppressed patients who are at a much higher (up to 60x) risk of developing non-melanoma skin cancers.

**Study Design** Go to

Study Type: Interventional (Clinical Trial)  
Estimated Enrollment: 45 participants  
Allocation: N/A  
Intervention Model: Sequential Assignment  
Masking: None (Open Label)  
Primary Purpose: Treatment  
Official Title: MVA-BN Imvamune Smallpox Vaccine Virus for Treatment of Basal Cell Carcinoma, Squamous Cell Carcinomas  
Actual Study Start Date: November 16, 2020  
Estimated Primary Completion Date: November 2022  
**Estimated Study Completion Date: July 2023**

Resource links provided by the National Library of Medicine  
MedlinePlus related topics: [Skin Cancer](#) [Smallpox](#) [Vaccines](#) NIH | NLM

??Rak??

**Datum konca študije: Julij 2023«**

# Naslov raziskave: »Študija za oceno varnosti in farmakokinetike TPOXX® pri oralni administraciji za 28 dni«

Vir: <https://www.clinicaltrials.gov/ct2/show/NCT04957485>

Study to Assess the Safety and Pharmacokinetics of TPOXX® When Administered Orally for 28 Days - Full Text View - ClinicalTrials.gov — Mozilla Firefox

https://www.clinicaltrials.gov/ct2/show/NCT04957485

**Brief Summary:**  
This study is designed to evaluate the immunogenicity profile of JYNNEOS® when 2 doses are administered subcutaneously (SC) 4 weeks apart; and potential immunological interference while concomitantly administering TPOXX or placebo orally twice daily (BID) for 28 days.

Condition or disease	Intervention/treatment	Phase
Smallpox	Biological: JYNNEOS + TPOXX Biological: JYNNEOS + TPOXX PLACEBO	Phase 2

**Expanded Access:** An investigational treatment associated with this study is available outside the clinical trial. [More info ...](#)

**Detailed Description:**  
This is a Phase 2, open-label (JYNNEOS), double-blind (TPOXX and placebo), multicenter, randomized, placebo-controlled, drug-vaccine interaction study to examine whether administering TPOXX with JYNNEOS concomitantly affects JYNNEOS immunogenicity in healthy adult subjects. A total of 100 subjects (approximately 50 subjects per treatment group), ages 18 to 42, inclusive, will be enrolled and randomly assigned to 1 of 2 treatment groups.

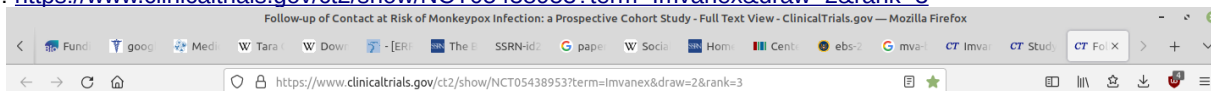
**Study Design** Go to

**Study Type:** Interventional (Clinical Trial)  
**Estimated Enrollment:** 100 participants  
**Allocation:** Randomized  
**Intervention Model:** Parallel Assignment  
**Masking:** Double (Participant, Investigator)  
**Masking Description:** double-blind randomized  
**Primary Purpose:** Treatment  
**Official Title:** A Phase 1, Open-Label (JYNNEOS®), Double-Blind (TPOXX® And Placebo), Multicenter, Randomized, Placebo-Controlled, Drug-Vaccine Interaction Study To Evaluate the Impact of TPOXX on JYNNEOS Immunogenicity  
**Actual Study Start Date:** January 5, 2022  
**Estimated Primary Completion Date:** July 31, 2022  
**Estimated Study Completion Date:** October 31, 2022

»Datum konca študije: Oktober 2022«

# Naslov raziskave: »Spremljanje stika s tveganjem okužbe z opičjimi kozami: prospektivna kohortna študija (MonkeyVax)«

Vir: <https://www.clinicaltrials.gov/ct2/show/NCT05438953?term=Imvanex&draw=2&rank=3>



## Brief Summary:

Since one month (first case confirmed the 05/06/2022), some cases of non-imported were reported by Portuguese and British authorities then in several European countries, the US and the Canada. The 05/19/2022, a first case of Monkeypox was confirmed in France. The 06/01/2022, "Santé Publique France" (SPF) declared 33 confirmed cases of Monkeypox without a direct interaction with people returning from endemic area. No deaths are currently recorded.

Currently, data on efficiency of modified vaccinia Ankara virus (MVA) used in post-exposure prophylaxis are few. The Centers for Disease Control and Prevention (CDC) consider that 2 doses of MVA vaccine used in post-exposure vaccination do not prevent totally the infection but consider that one rapid vaccination of high-risk contacts could reduce the severity of symptoms.

In order to clarify clinical impact and safety of PEV, it is proposed to set up a national cohort including contacts cases falling within the indications for vaccination, i.e. seen within 14 days of last contact.

The purpose of this study is to estimate the failure rate of a PEV by the MVA vaccine in Monkeypox contact case participants at risk after one dose.

Condition or disease	Intervention/treatment	Phase
Monkey Pox Monkey Diseases	Biological: Vaccination with MVA vaccine ( <b>IMVANEX®</b> and JYNNEOS®)	Not Applicable

## Detailed Description:

Post-exposure vaccination (PVE) has demonstrated its interest in different situations, in particular rabies, tetanus or hepatitis B, as recalled in the report "Guide for post-exposure immunization: vaccination and immunoglobulin" of the High Committee for Public Health in 2016.

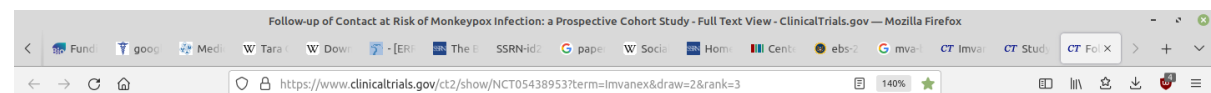
For Monkeypox, the PEV was used in 2018 and 2019 in UK, when several import cases were discovered. In 2018, 3 cases were diagnosed and 154 contact cases identified (including 147 healthcare professionals). In total, 131 people have accepted the PEV (including 126 healthcare professionals) and 1 single case among healthcare professionals, having been exposed for 6 to 7 days. In 2019, following an imported case, 17/18 contacts (including children) accepted EPV. No secondary cases or serious adverse effects have been reported.

Several countries have recommended EPV as part of Monkeypox. In France, the Haute Autorité de Santé (HAS) recommends the implementation of a reactive vaccine strategy in post-exposure with the 3rd generation vaccine administered in 2 doses spaced 28 days apart, the first dose being ideally administered within 4 days after the risky contact and at most 14 days after the risky contact. Currently, data on the efficacy of the MVA vaccine used in post-exposure prophylaxis are few. The Centers for Disease Control and Prevention considers it unlikely that 2 doses of MVA vaccine used in PEV will completely prevent infection but believes that rapid vaccination of at-risk contacts could reduce the severity of symptoms.

In France, the definitions for identifying contact persons are :

### 1. Contact at risk:

- o Anyone who has had unprotected direct physical contact, i.e. without wearing surgical masks and FFP2, without using hygiaphones and vis-à-vis direct physical contact, without wearing waterproof




- o A positive result in generic qPCR of the genus Orthopoxvirus, in a person presenting recent risks of exposure to the MKPXV virus in the 3 weeks preceding the onset of the signs (returning from a trip to an endemic zone or where the virus is circulating or at-risk contact of a person returning from a trip to an endemic zone or where the virus is circulating, contact person at risk of a probable or confirmed case).

In order to specify the clinical interest and the safety of an PEV, it is proposed to set up a national cohort including contact cases falling within the indications for vaccination, i.e. seen within 14 days after the last contact.

## Study Design

Go to

Study Type  : Interventional (Clinical Trial)

Estimated Enrollment  : 226 participants

Allocation: Non-Randomized

Intervention Model: Parallel Assignment

Masking: None (Open Label)

Primary Purpose: Prevention

Official Title: Follow-up of Contact at Risk of Monkeypox Infection: a Prospective Cohort Study

Actual Study Start Date  : July 12, 2022

Estimated Primary Completion Date  : April 2023

Estimated Study Completion Date  : July 2023

Resource links provided by the National Library of Medicine



MedlinePlus related topics: [Vaccines](#)

Vir: <https://www.clinicaltrials.gov/ct2/show/NCT05438953?term=Imvanex&draw=2&rank=3>

»**IMVANEX + JYNNEOS**«

»Datum konca študije: Julij 2023«

Čakaj! Ali ni bilo cepivo Imvanex že odobreno? Poglejmo si na naslednji strani!

## Spletna stran agencije EMA: Imvanex

Vir: <https://www.ema.europa.eu/en/medicines/human/EPAR/imvanex#authorisation-details-section>

**Product details**

Name	Imvanex
Agency product number	EMEA/H/C/002596
Active substance	modified vaccinia Ankara - Bavarian Nordic (MVA-BN) virus
International non-proprietary name (INN) or common name	smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)
Therapeutic area (MeSH)	<ul style="list-style-type: none"><li>• Smallpox Vaccine</li><li>• Monkeypox virus</li></ul>
Anatomical therapeutic chemical (ATC) code	J07BX

Additional monitoring ▼ This medicine is under additional monitoring, meaning that it is monitored even more intensively than other medicines. For more information, see Medicines under [additional monitoring](#).

Exceptional circumstances ⓘ This medicine was authorised under exceptional circumstances, because the applicant was unable to provide comprehensive data on the efficacy and safety of the medicine under normal conditions of use. This can happen because the condition to be treated is rare or because collection of full information is not possible or is unethical. For more information, see [Pre-authorisation guidance](#).

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### Citat iz zgornje povezave:

»»To zdravilo je pridobilo dovoljenje za promet v izjemnih okoliščinah, ker **predlagatelj ni mogel zagotoviti celovitih podatkov o učinkovitosti in varnosti zdravila** pri običajnih pogojih uporabe. To se lahko zgodi, ker je stanje, ki ga je treba zdraviti, redko ali ker **zbiranje popolnih informacij** ni mogoče ali **je neetično**. Za več informacij glejte Navodila za predhodno avtorizacijo.««

Imvanex | European Medicines Agency — Mozilla Firefox

https://www.ema.europa.eu/en/medicines/human/EPAR/imvanex#authorisation-details-section

Exceptional circumstances ⓘ

This medicine was authorised under exceptional circumstances, because the applicant was unable to provide comprehensive data on the efficacy and safety of the medicine under normal conditions of use. This can happen because the condition to be treated is rare or because collection of full information is not possible or is unethical. For more information, see [Pre-authorisation guidance](#).

**Publication details**

Marketing-authorisation holder	Bavarian Nordic A/S
Revision	21
Date of issue of marketing authorisation valid throughout the European Union	31/07/2013
Contact address	Hejreskovvej 10 A Kvistgård, 3490 Denmark

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Vir: <https://www.ema.europa.eu/en/medicines/human/EPAR/imvanex#authorisation-details-section>

**Datum avtorizacije je torej: 31. 7. 2013.**

## 4. Poglavje – Nove platforme

139 cepiv v predkliničnemu preizkušanju

Enaka platforma za ne-Koronavirusna cepiva

139 candidate vaccines in preclinical evaluation

Platform	Type of candidate vaccine	Developer	Coronavirus target	Current stage of clinical evaluation/regulatory status-Coronavirus candidate	Same platform for non-Coronavirus candidates
DNA	DNA, engineered vaccine inserts compatible with multiple delivery systems	DIOSynVax Ltd/ University of Cambridge	SARS-CoV-2 and SarbecoCoronaviruses	Pre-Clinical	Same platform for non-Coronavirus candidates
DNA	DNA vaccine	Ege University	SARS-CoV2	Pre-Clinical	
DNA	DNA plasmid vaccine RBD&N	Scancell/University of Nottingham/ Nottingham Trent University	SARS-CoV2	Pre-Clinical	

Vir: <https://patentimages.storage.googleapis.com/68/80/73/6a17a66e9ec8c5/US11107588.pdf>

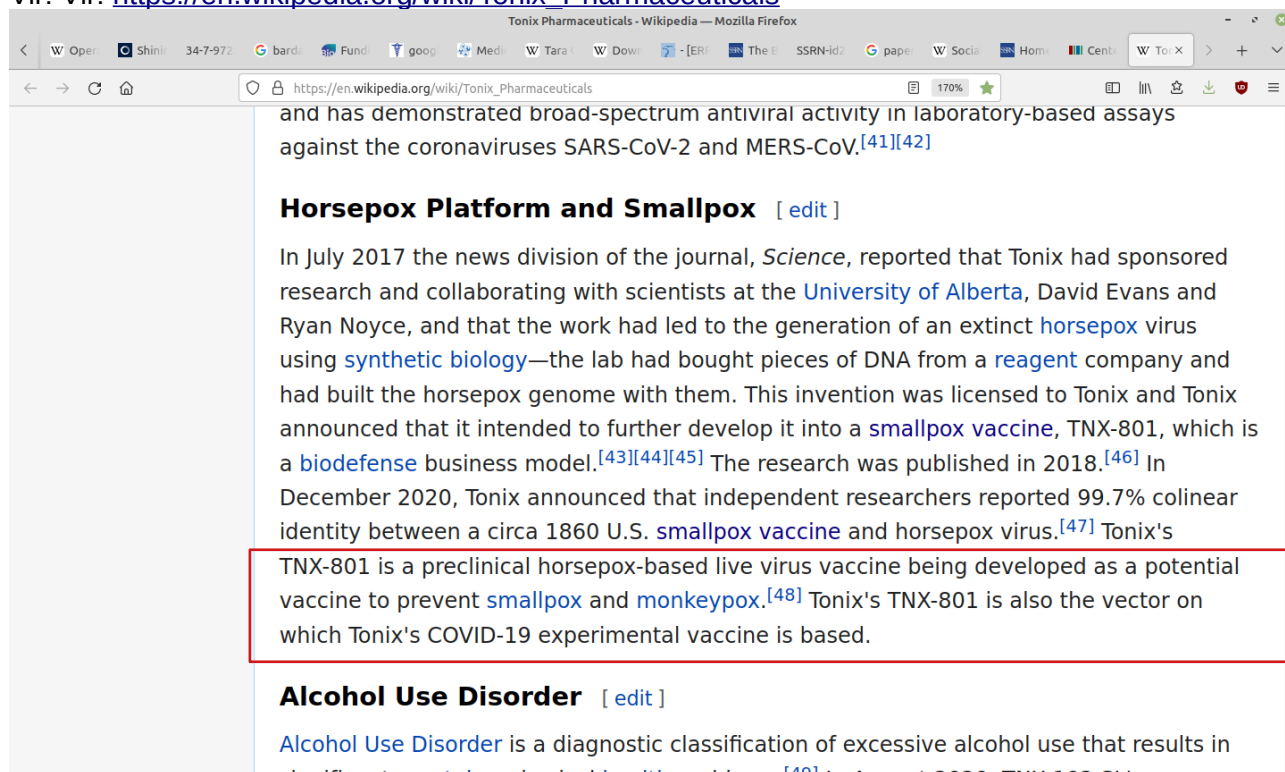
Platform	Type of candidate vaccine	Developer	Coronavirus target	Current stage of clinical evaluation/regulatory status-Coronavirus candidate	Same platform for non-Coronavirus candidates
Replicating Viral Vector	YF17D Vector	KU Leuven	SARS-CoV2	Pre-Clinical	Same platform for non-Coronavirus candidates
Replicating Viral Vector	Measles Vector	Cadila Healthcare Limited	SARS-CoV2	Pre-Clinical	
Replicating Viral Vector	Measles Vector	FBRI SRC VB VECTOR, Rospotrebnadzor, Koltsovo	SARS-CoV2	Pre-Clinical	
Replicating Viral Vector	Measles Virus (S, N targets)	DZIF - German Center for Infection Research/ CanVirex AG	SARS-CoV2	Pre-clinical	
Replicating Viral Vector	Horsepox vector expressing S protein	Tonix Pharma/Southern Research	SARS-CoV2	Pre-Clinical	
Replicating Viral Vector	Live viral vectored vaccine based on attenuated influenza virus backbone (intranasal)	BiOCAD and IEM	SARS-CoV2	Pre-Clinical	

Vir: <https://patentimages.storage.googleapis.com/68/80/73/6a17a66e9ec8c5/US11107588.pdf>

Patent US 11107588B2 smo že omenili v Reanalizaciji 1. Tokrat se bomo osredotočili na proizvajalca **Tonix Pharmaceuticals**.

## Članek na Wikipediji o Tonix Pharmaceuticals

Vir: Vir: [https://en.wikipedia.org/wiki/Tonix\\_Pharmaceuticals](https://en.wikipedia.org/wiki/Tonix_Pharmaceuticals)



and has demonstrated broad-spectrum antiviral activity in laboratory-based assays against the coronaviruses SARS-CoV-2 and MERS-CoV.<sup>[41][42]</sup>

### Horsepox Platform and Smallpox [ edit ]

In July 2017 the news division of the journal, *Science*, reported that Tonix had sponsored research and collaborating with scientists at the [University of Alberta](#), David Evans and Ryan Noyce, and that the work had led to the generation of an extinct [horsepox](#) virus using [synthetic biology](#)—the lab had bought pieces of DNA from a [reagent](#) company and had built the horsepox genome with them. This invention was licensed to Tonix and Tonix announced that it intended to further develop it into a [smallpox vaccine](#), TNX-801, which is a [biodefense](#) business model.<sup>[43][44][45]</sup> The research was published in 2018.<sup>[46]</sup> In December 2020, Tonix announced that independent researchers reported 99.7% colinear identity between a circa 1860 U.S. [smallpox vaccine](#) and horsepox virus.<sup>[47]</sup> Tonix's

TNX-801 is a preclinical horsepox-based live virus vaccine being developed as a potential vaccine to prevent [smallpox](#) and [monkeypox](#).<sup>[48]</sup> Tonix's TNX-801 is also the vector on which Tonix's COVID-19 experimental vaccine is based.

### Alcohol Use Disorder [ edit ]

[Alcohol Use Disorder](#) is a diagnostic classification of excessive alcohol use that results in significant mental or physical health problems.<sup>[49]</sup> In August 2020, TNX-102, a live

### Prevod:

»Tonixovo TNX-801 je predklinično živo virusno cepivo na osnovi horsepox, ki se razvija kot potencialno cepivo za preprečevanje črnih in opičjih koz. Tonixov TNX-801 je tudi vektor, na katerem temelji Tonixovo eksperimentalno cepivo proti COVID-19. «

# Tonix Pharmaceuticals glavna stran – novica o patentu - 1.junij 2022

June 01, 2022 7:00am EDT [Download as PDF](#)

*Strengthens Patent Portfolio Protecting Horsepox-Based Live Virus Vaccines*

*TNX-1840 and TNX-1850 are Potential RPV Vaccines Designed to Protect Against COVID-19*

*Confirms Leadership Position in Synthetic Biology*

*Statutory Term of New Patent Expected to Provide Exclusivity Until 2037*

CHATHAM, N.J., June 01, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, announced today that the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 11,345,896 to the Company on May 31, 2022. This patent, entitled "Synthetic Chimeric Poxviruses," includes claims covering synthetic horsepox virus, the basis for the Company's TNX-801<sup>1</sup> vaccine in development to protect against monkeypox and smallpox and for the Company's Recombinant Pox Virus (RPV) platform to protect against other pathogens, including SARS-CoV-2. This patent is expected to provide Tonix with U.S. market exclusivity until 2037, excluding any possible patent term extensions or patent term adjustments.

Vir: <https://ir.tonixpharma.com/news-events/press-releases/detail/1318/tonix-pharmaceuticals-announces-issuance-of-u-s-patent-for-tnx-801-smallpox-and-monkeypox-vaccine-and-recombinant-pox-virus-rpv-platform-technology>

## Citat:

»Tonix Pharmaceuticals napoveduje izdajo ameriškega patenta za cepivo TNX-801 proti črnim in opičjim kozam ter tehnologijo platforme rekombinantnega poksvirusa (RPV)«

## Tonix Pharmaceuticals: SEC statement

Vir: [https://ir.tonixpharma.com/sec-filings/all-sec-filings/content/0001387131-22-003640/tnxp-10k\\_123121.htm#tnxp10k123121b003](https://ir.tonixpharma.com/sec-filings/all-sec-filings/content/0001387131-22-003640/tnxp-10k_123121.htm#tnxp10k123121b003)

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https://ir.tonixpharma.com/sec-filings/all-sec-filings/content/0001387131-22-003640/tnxp-10k\_123121.htm#tnxp10k123121b003 180%

- We have a history of operating losses and may never generate revenues or achieve profitability.
- We expect our operating results to fluctuate, which may make it difficult to predict our future performance.
- Our product candidates are novel and still in development.
- We do not expect to generate any revenues from product sales in the foreseeable future, if at all.
- We are largely dependent on the success of our product candidates and cannot be certain that our product candidates will receive regulatory approval or be successfully commercialized.
- Clinical studies required for our product candidates are expensive and time-consuming, and their outcome is uncertain.

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- We are subject to extensive and costly government regulation.
- We have never submitted an NDA before, and may be unable to do so for our product candidates we are developing.
- Our product candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.
- We may be unable to meet our anticipated development and commercialization timelines for approval of any of our product candidates.
- Any breakthrough, fast track or orphan drug designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor assure FDA approval of our product candidates.
- Even if approved, our products may not be accepted by the market.
- We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.
- Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements. We may be unable to continue to operate without the threat of liquidation for

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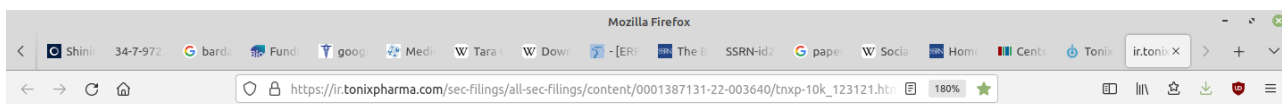
https://ir.tonixpharma.com/sec-filings/all-sec-filings/content/0001387131-22-003640/tnxp-10k\_123121.htm#tnxp10k123121b003 180%

- Coverage and adequate reimbursement may not be available for our current or any future drug candidates, which could make it difficult for us to sell profitably, if approved.
- Healthcare legislative reform measures may have a negative impact on our business and results of operations.
- If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.
- We face the risk of product liability claims and may not be able to obtain insurance.

47

- We use hazardous chemicals in our business. Potential claims relating to improper handling, storage or disposal of these chemicals could affect us and be time consuming and costly.
- If we retain collaborative partners and our partners do not satisfy their obligations, we will be unable to develop our partnered product candidates.
- We may be unsuccessful in obtaining a priority review voucher for material threat medical countermeasures.
- Government entities may take actions that directly or indirectly have the effect of limiting opportunities for our vaccines for COVID-19.
- If technology developed for the purposes of developing new medicines or vaccines can be applied to the creation or development of biological weapons, then our technology may be considered “dual use” technology and be subject to limitations on public disclosure or export.
- We face risks in connection with existing and future collaborations with respect to the development, manufacture, and commercialization of our product candidates.
- We face risks in connection with the testing, production and storage of our vaccine product candidates.
- An active trading market for our common stock may not be sustained.

Vir: [https://ir.tonixpharma.com/sec-filings/all-sec-filings/content/0001387131-22-003640/tnxp-10k\\_123121.htm#tnxp10k123121b003](https://ir.tonixpharma.com/sec-filings/all-sec-filings/content/0001387131-22-003640/tnxp-10k_123121.htm#tnxp10k123121b003)



Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against COVID-19, which may have the effect of increasing the number of competitors and/or providing advantages to competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share if we ultimately receive regulatory approval for our vaccines as a vaccine for COVID-19. COVID-19 vaccines may also be subject to government pricing controls, which could adversely affect the profitability of any COVID-19 vaccine we are able to develop and commercialize.

***If technology developed for the purposes of developing new medicines or vaccines can be applied to the creation or development of biological weapons, then our technology may be considered "dual use" technology and be subject to limitations on public disclosure or export.***

Our research and development of synthetic poxviruses is dedicated not only to creating tools that better protect public health but also to safeguarding any information with broad, dual-use potential that could be inappropriately applied. "Dual use research" is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat to public health, agricultural crops, or national security. Because variola, the agent that causes smallpox, is a pox virus, the technology we created could be considered dual use and could be subject to export control, for example under the Wassenaar Arrangement. Further, if federal authorities determine that our research is subject to institutional oversight, we will need to implement a risk-management plan developed in collaboration with the institutional review entity. Failure to comply with the plan may result in suspension, limitation, or termination of federal funding or loss of future federal funding opportunities for any of our research.

***We face risks in connection with existing and future collaborations with respect to the development, manufacture, and commercialization of our product candidates.***

We face a number of risks in connection with our current collaborations. Our collaboration agreements are subject to termination under

Vir: [https://ir.tonixpharma.com/sec-filings/all-sec-filings/content/0001387131-22-003640/tnxp-10k\\_123121.htm#tnxp10k123121b003](https://ir.tonixpharma.com/sec-filings/all-sec-filings/content/0001387131-22-003640/tnxp-10k_123121.htm#tnxp10k123121b003)

## **Prevod Izjav iz SEC poročila proizvajalca Tonix Pharmaceuticals:**

**»Naši kandidati za izdelke lahko povzročijo resne neželene dogodke ali neželene stranske učinke, ki lahko odložijo ali preprečijo odobritev trženja ali, če je odobritev sprejeta, zahtevajo, da se umaknejo s trga, zahtevajo vključitev varnostnih opozoril ali kako drugače omejijo njihovo prodajo.«**

**»V našem poslu uporabljamo nevarne kemikalije. Morebitni zahtevki v zvezi z nepravilnim ravnanjem, skladiščenjem ali odstranjevanjem teh kemikalij bi nas lahko prizadeli ter bili zamudni in dragi.«**

**»Če se tehnologija, razvita za namene razvoja novih zdravil ali cepiv, lahko uporabi za ustvarjanje ali razvoj biološkega orožja, potem se lahko naša tehnologija šteje za tehnologijo "dvojne uporabe" in za njo veljajo omejitve javnega razkritja ali izvoza.«**

**KROVNI DOKAZ, DA CEPIVA NE MOREJO IN NE SMEJO IMETI STATUSA ZDRAVILA, SAJ SO PO IZJAVI SAMEGA PROIZVAJALCA **BIOLOŠKO OROŽJE** IN ZAPADEJO POD TRETMAN »TEHNOLOGIJ DVOJNE RABE«. TEHNOLOGIJA DVOJNE RABE JE PO DEFINICIJI TISTA, KI SE UPORABLJA V CIVILNE IN **VOJAŠKE NAMENE**. ALI JE SPLOH POTREBNO ŠE KAJ DODATI?**

## ZAKLJUČEK

**Medicinske institucije niso niti približno tako organizirane in zmožne na nivoju države vzpostavljati strogi red pri izvajanju ukrepov, obveščanju, podajanju informacij, kaj šele, da bi ta strogi red na vseh nivojih vpeljale na celem kontinentu ali celo na celem svetu – hkrati, enotno, po istih pravilih, na isti način.**

**To se ni zgodilo nikoli do zdaj ne v Evropi, ne v ZDA ali kjerkoli drugje. Enako neverjetno hitro so se poenotile vlade vseh držav, vsi mediji vseh držav... Take navidezne enotnosti ni bilo nikoli v zgodovini nikjer po svetu. Celotne stranke znotraj ene države so začele enotno podpirati svoje trenutne vlade pri izvajanju ukrepov. Ponavadi se stranke niti pri eni stvari ne morejo tako hitro zmeniti za enoten nastop.**

**Očitno je šlo pri »koroni« takoj od začetka, marca 2020, za dobro usklajeno akcijo, vodeno iz enega centra. To pa je še najbolj podobno vojaškemu načinu vodenja akcij: en štab, enotna navodila vsem »podrejenim«, enotno informiranje javnosti, po enakem obrazcu, enako agresivno obveščanje, poplava informacij (beri: laži)...**

**In če so laži povsod enake, se lahko komu zazdi že skoraj kot resnica.**

**Iz vsega povedanega v tej predstavitvi pa lahko vidimo, da je na relaciji med ameriško državo (vlado) in proizvajalci cepiv nešteto inštitucij, ki imajo nalogo izvajati, podpirati ali vzpodbujati razvoj cepiv, ki imajo »svetovalno funkcijo« in so vpete v strukture znotraj ministrstva za obrambo.**

**Vse imajo navidez obrambno funkcijo, kot smo videli »za obrambo pred kemičnim, biološkim, radiološkim ali nuklearnim napadom.« Tukaj je vse polno leporečja, ampak, če pomislimo, vojska, ki je napadla Vietnam, je bila tudi pod poveljstvom Ministrstva za obrambo ZDA. In je tudi uradno obrambna. Saj ne obstajajo Ministrstva za napad!**

**Pri vojski nikoli ne veš, ali te bo ščitila, ali te bo jutri morda ta ista vojska napadla. In če vidimo, da imajo vse te agencije (DARPA, JPEO-CBRND, BARDA,...) opravka tudi z biološkimi in kemijskimi orožji, kako naj mirno spimo, če nam hočejo jutri na silo zapičiti v ramo svoj proizvod, ki so ga oni razvijali in »pospremili na tržišče«, sklepali partnerstva s farmacijo, direktnimi izdelovalci le-teh, jim donirali posebno visoka izplačila.**

**Ali mogoče zato, ker gre za visoko stopnjo »vojne tajne« in je cena takega posla toliko višja?**

**Skratka, v vsej zgodbi je – tako pri Kovid-u kot ostalih boleznih – preveč poslovnih subjektov, ki imajo direktnega opravka z biološkim in kemijskim orožjem pa tudi, če, uradno, v obrambni funkciji. In vse preveč teh subjektov je povezanih direktno z ameriško vojsko.**

**Kot smo videli, ameriške »obrambne sile« so nekoč krvavo napadle Vietnam, še bolj krvavo pa Hirošimo. Napadli so še veliko drugih destinacij po svetu.**

**To je njim, izgleda, v navadi. Večkrat se nekako »spozabijo«.**

## **SP NZ (Lk 8,16-17)**

»Nihče svetilke, potem, ko jo prižge, ne pokriva s posodo ali jo postavlja pod posteljo, ampak jo postavi na svetilnik, da tisti, ki vstopajo, vidijo luč.

Nič ni namreč skrito, kar se ne bi razodelo,  
in nič zakrito, kar se ne bi spoznalo in prišlo na dan«.