

Making Fridge-Free Vaccines A Reality



Stablepharma™
The Fridge Free Vaccine Company

Committed to Launching World's First Fridge-Free Vaccines

Q3 2023

Confidential

Stablepharma is seeking pre-IPO bridge funding in advance of an IPO in 2024

Seeking funding to bring fridge-free vaccines to market and ...



Series A Close

Since closing Series A in October 2022, Stablepharma has:

- Taken commercial exclusivity of two vaccine products
- Published peer-reviewed article in Vaccine (Elsevier)
- Made significant progress on product development and GMP manufacturing
- Held initial MHRA and EMA regulatory discussions
- Signed CDAs with major pharmaceutical companies to progress partnership discussions

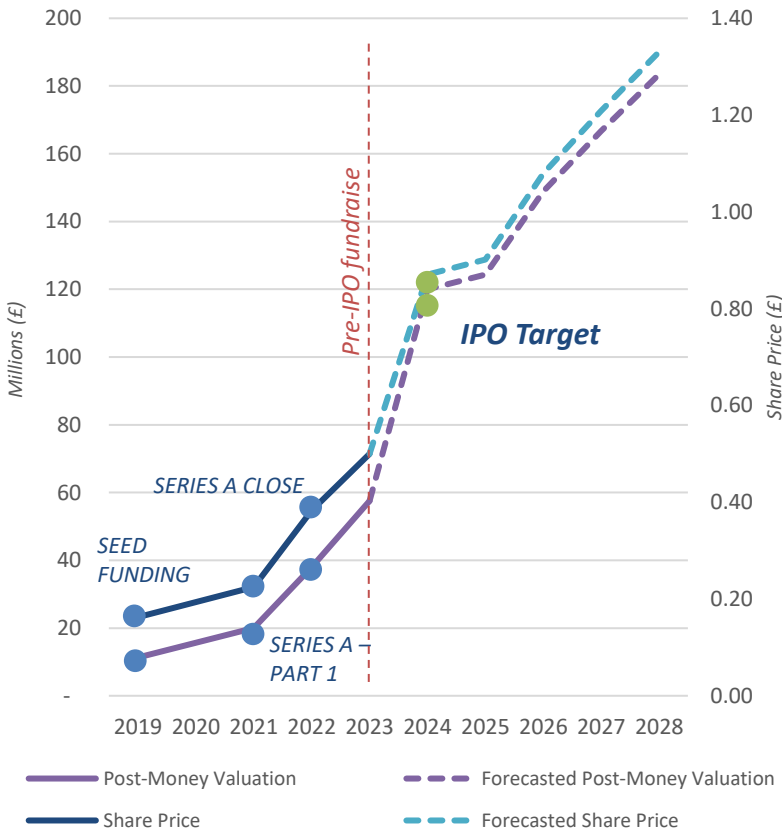


Pre-IPO bridge / IPO

£5-10 million Bridges the path to the commercialisation process

£15-20 million Completes the commercialisation process and brings the two fridge-free products to market

... to build on the significant value creation since the first seed funding round in 2019^(a)



Note: (a) Post-money valuation forecast is calculated based on the NPV of the core products less a 30% discount



Our vision

“Every 20 seconds a child dies from a vaccine preventable disease”

Bill & Melinda Gates Foundation

**Our vision is to save lives
and reduce global
wastage by making
fridge-free vaccines a
reality**






A healthcare worker in blue scrubs and a light blue surgical mask is administering a vaccine to a patient in a green shirt. The worker is wearing blue gloves and holding a syringe. The patient is also wearing a light blue surgical mask. In the background, another healthcare worker in blue scrubs is visible, and a sign with a biohazard symbol is partially visible on the left.

We are converting established vaccines to fridge-free forms and bringing them to market

Stablepharma are experts at creating fridge-free formulations of medicines through a combination of in-house expertise and patented technologies



Storage and transport of vaccines and other pharmaceutical products in a fridge or freezer can be expensive, wasteful, risky and damaging to the environment⁽¹⁾

Challenges	Stablepharma has eliminated several challenges across the development and commercialisation process	
Scientific	Established proof-of-concept <i>in vivo</i> and <i>in vitro</i> – thermostable at +45°C for 12 months	
Regulatory	Clear regulatory path established with MHRA and EMA	
Clinical trials	Small trial needed for approval – time and capital efficient approach	
Commercial	Commercial rights to two reformulated vaccines – exclusive supply agreements signed	
Scalability	GMP manufacturing process established with Thermo Fisher Scientific	

Our solution addresses current cost, waste and environmental vaccine challenges



Challenges

Cost



\$400M per annum spent on cold-chain requirements⁽³⁾

Waste



Up to 50% of vaccines are wasted globally each year⁽¹⁾

Short shelf life of vaccines leading to wastage

ESG



Cold-chain significantly contributes to global carbon footprint

StablevaX™

Eliminates the need for cold-chain storage and transport

Stabilisation reduces risk of ineffective vaccines due to extreme temperatures

StablevaX vaccines can be stored for extended periods of time at room temperature

Reduces CO₂ footprint of the cold-chain

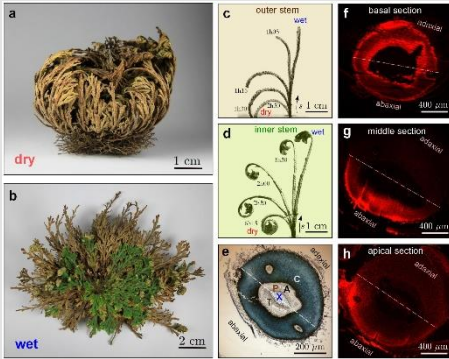
Sources: (1) WHO, 2005 (2) Vaccine, 2021 (3) IQVIA, 2023

Our solution solves different challenges in each target market



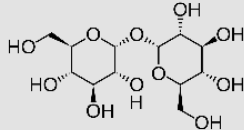
	High-income countries	Middle- and low-income countries
Potential regions	Europe, North America, Middle-East, Asia-Pacific	Africa, South America
Key focus of markets	<ul style="list-style-type: none"> • Cost to healthcare systems • Wastage • Sustainability • Convenience and reliability 	<ul style="list-style-type: none"> • Access • Pharmaceutical supply chain
Potential benefits from our solution	<ul style="list-style-type: none"> • Decrease need for refrigeration space in small community and regional primary care practices • Reduces wastage due to expiry with extended shelf-life of product • Minimises environmental impact of cold-chain transportation related to vaccines • Positive impact on overall health budget 	<ul style="list-style-type: none"> • Eliminates the need for costly transportation and storage in regions with limited cold-chain supply structures/equipment • Improves ability of healthcare professionals to reach and deliver immunisation programmes or ad-hoc wound care

Our StablevaX™ platform utilises sugar glass structures to preserve vaccines and their thermostability



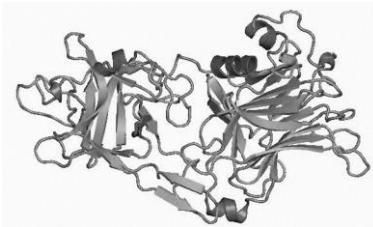
Hydro-responsive resurrection plant employing trehalose to go into suspended animation

The resurrection plant can survive for extended periods of time without water as a result of its ability to produce trehalose.



Trehalose structure

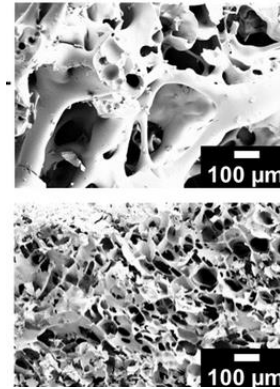
Trehalose is able to protect the plant as it dries out and enables the plant to grow when water becomes available.



Tetanospasmin structure

Vaccine structures are prone to denaturing and unfolding at extreme temperatures rendering them ineffective

StablevaX™



Sugar glass structures

Stablepharma uses sugar glass structures and other excipients to reformulate existing vaccines into thermostable products

- ✓ Inert nature of sugar glass structures does not interact with vaccine
- ✓ Stable at extreme temperatures yet highly soluble
- ✓ 60+ vaccines can be stabilised using this technology

Our StablevaX™ platform can be deployed in several formats

StablevaX™ can be applied to form a portfolio of different products that are adapted to healthcare professional and patient needs

Products will be initially developed in vial format to accelerate commercial potential. No modification is required to the current industrial manufacturing process to produce the lyophilised vials.

Vial with diluent

Single-dose vial with rapidly dissolving fridge-free formulation, accompanied by diluent, such as water for injection (WFI)

Syringe formulations will be developed post-vial launch. Some modification is required to the current industrial manufacturing process.

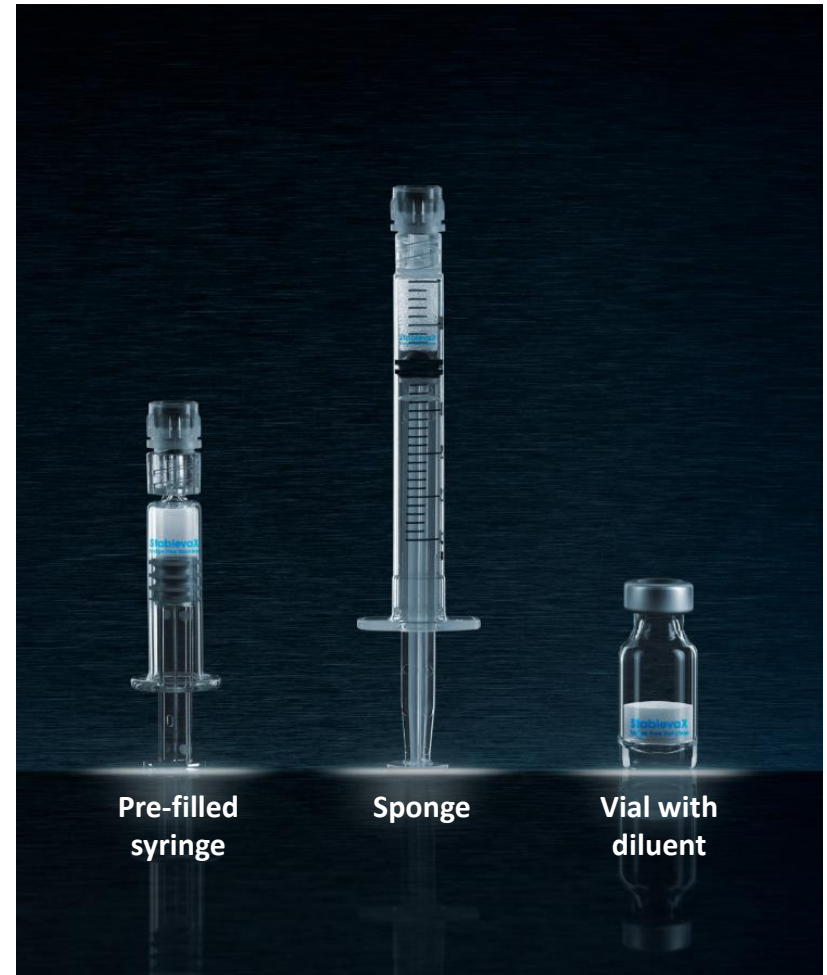


Pre-filled Syringe (PFS)

Pre-dosed syringe with rapidly dissolving fridge-free formulation, accompanied by diluent

Sponge

Matrix that contains single-dose of vaccine



A pipeline of products and technologies have progressed from research into development

Product Candidate	Programme	Stablepharma Rights	Upcoming Milestones	Development Progress				
				Research (Formulation Optimisation)	Proof-of-Concept (Potency & Stability Assays)	Pre-Clinical	Clinical Development	Marketed
SPVX02	Tetanus diphtheria (Td)	Global	Clinical trials					
SPVX06	Tetanus (TT)	Global	Animal potency challenge tests					
	mRNA/LNP Technology	Global	In-Vitro Thermostability Experiments					

We are pursuing a dual commercial go-to-market path

LAUNCHING PRODUCTS

Model 1: Value Creation Through Life-Cycle Management

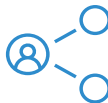
Take rights of established specialty vaccines and launch fridge-free versions



Establish partnership agreement with bulk vaccine partner and CMO



Manufacture and package reformulated vaccine kit



Distribute direct to customers or key partner via licensing agreements

Programmes

SPVX02 (Td)
SPVX06 (TT)

Revenue stream
Direct ownership & Sales

TECHNOLOGY PARTNERSHIPS

Model 2: Develop technologies in partnership with big pharma

Establish research collaborations to utilise the StablevaX technology



Establish and patent thermostable process



Enter into research collaboration with big pharma companies



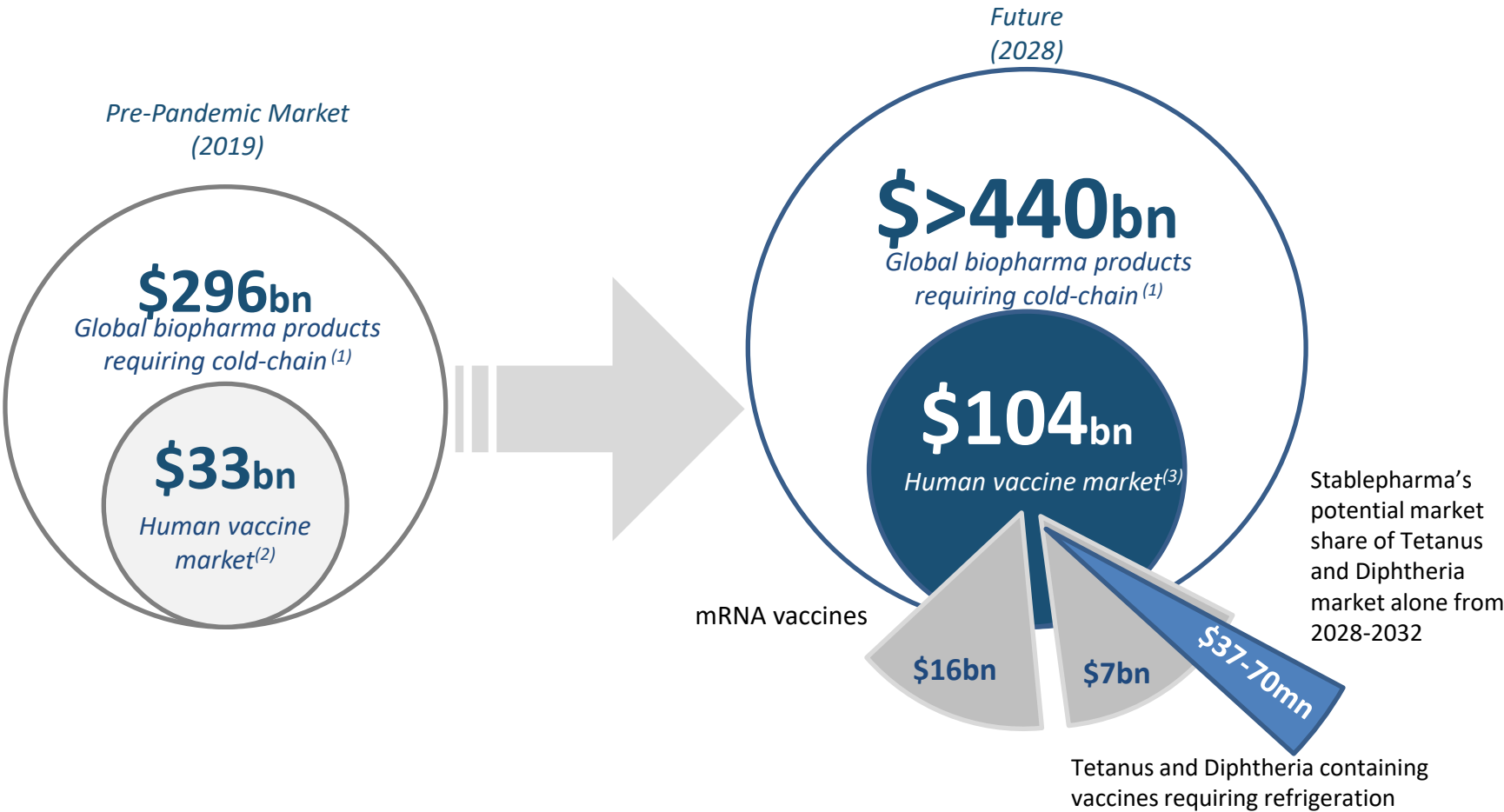
Transfer technology to manufacturers via licensing agreement

Programmes

mRNA/LsNP

Revenue stream
Royalties and milestone payments

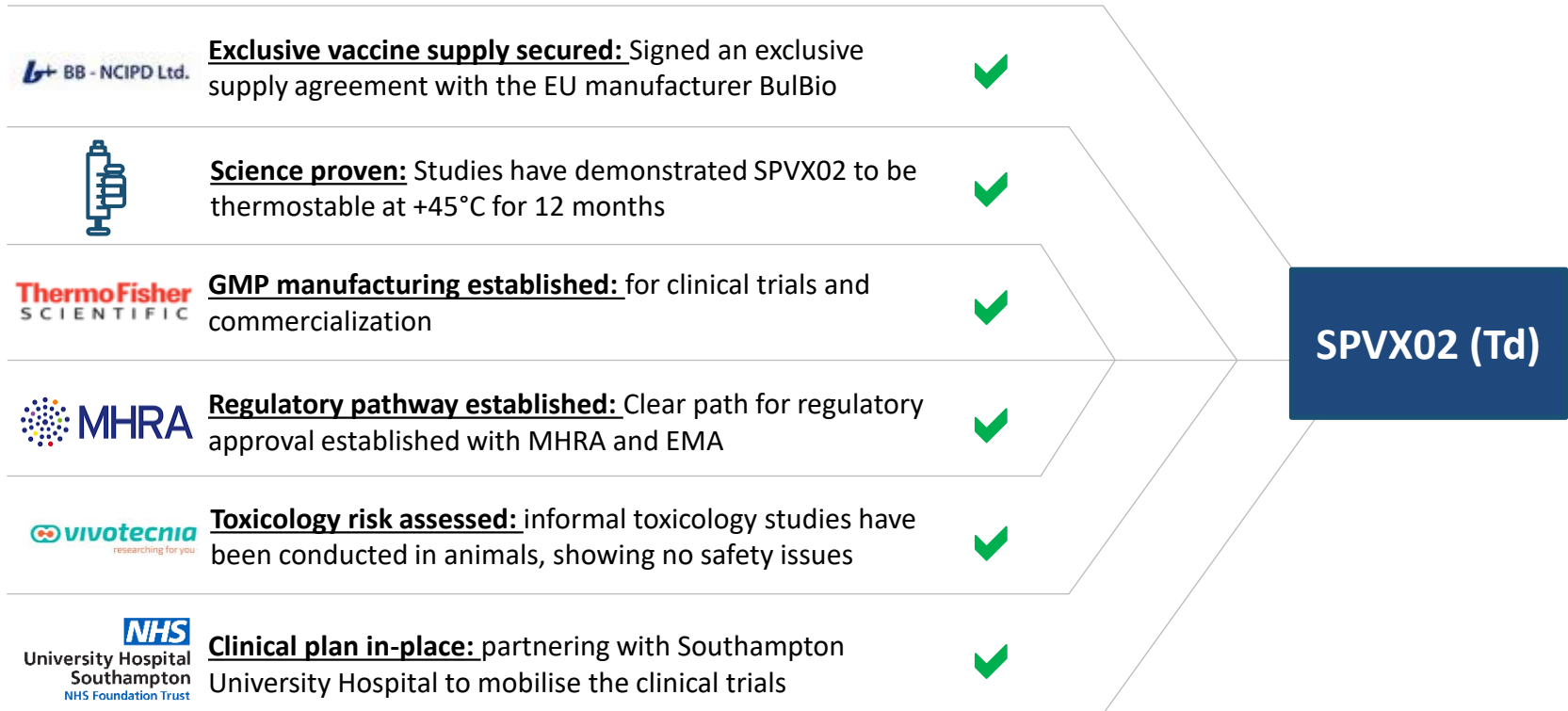
The dual approach will enable us to capture a substantial global market opportunity



Sources: (1) Statista (2) WHO MI4A Public Database, 2022 (3) Statista (3) Financial Times, 2021 (4) WHO, 2019 (5) Logistics Insider (6) Allied Market Research (7) Nature

SPVX02 for Tetanus diphtheria (Td) well on track to launch in 2025

Stablepharma have made significant progress on developing SPVX02



We have significant advantages against current competition

Stablepharma has clear competitive advantage with the commercial ownership of two vaccines, low-cost base (no phase 3 required) and adherence to WHO guidelines

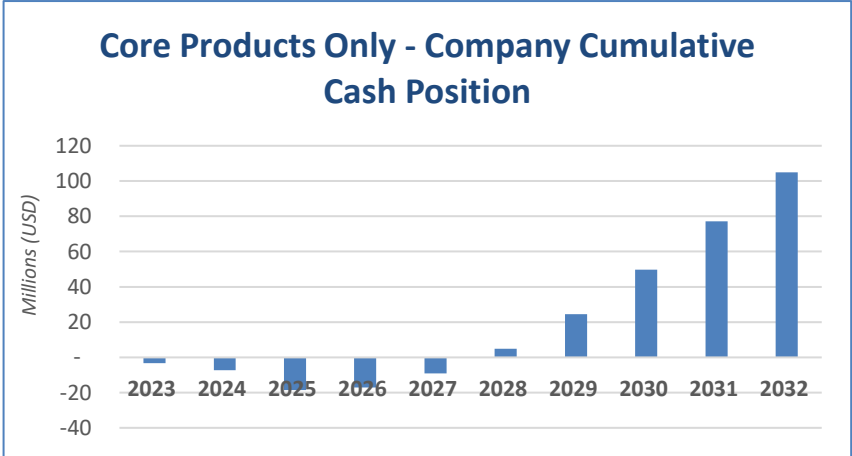
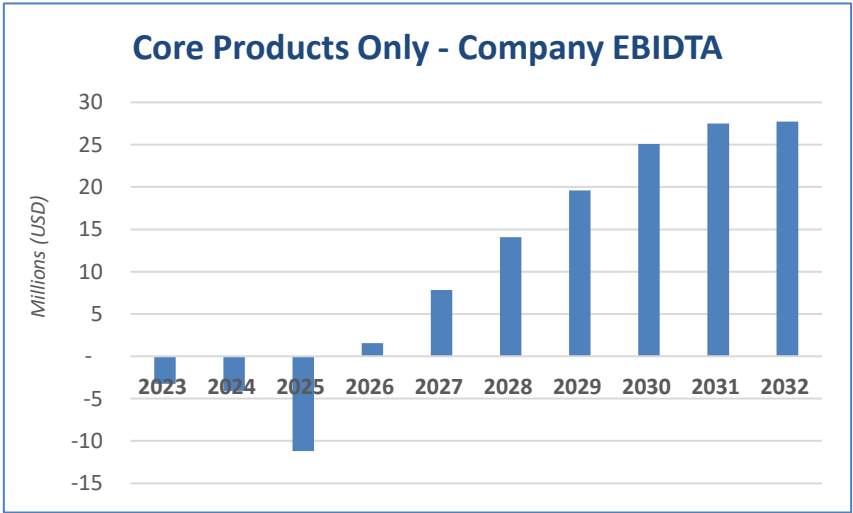
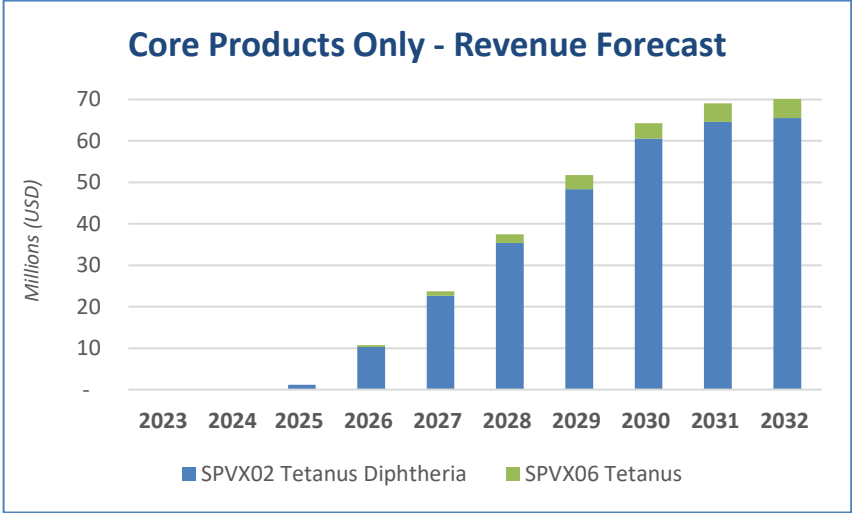


		Microneedle patches		Oral	Implants	Biotech reformulation			
	 Stablepharma StablevaX™	 Micron Biomedical	 VAXESS technologies MIMIX	 iosBio OraPro	 aVaxziPen	 LEUKOCARE	 Nova Laboratories Ltd Hydris	 Vitris	 Areacor
Ownership of vaccine commercial rights	✓	?	✓	?	✗	?	✗	✗	✗
Clinical trial ready	✓	?	✓	?	✗	?	✗	✗	✓
No Phase 3 Requirement	✓	✗	✗	✗	✗	✗	✗	✗	✗
Follows current WHO vaccine guidance	✓	✗	✗	✗	✗	?	?	?	✓
Commercial scalability	✓	?	?	?	?	?	?	?	?

Sources: (1) [Vaxess](#) (2) [iosBIO](#) (3) [Enesi Pharma](#) (4) [NovaLabs](#) (5) [Areacor](#) (6) [Micron Biomedical](#) (7) [Leukocare](#)



Our Core Financials include revenue from SPVX02 & SPVX06 only and demonstrate attractive, low-risk financial returns^(a)



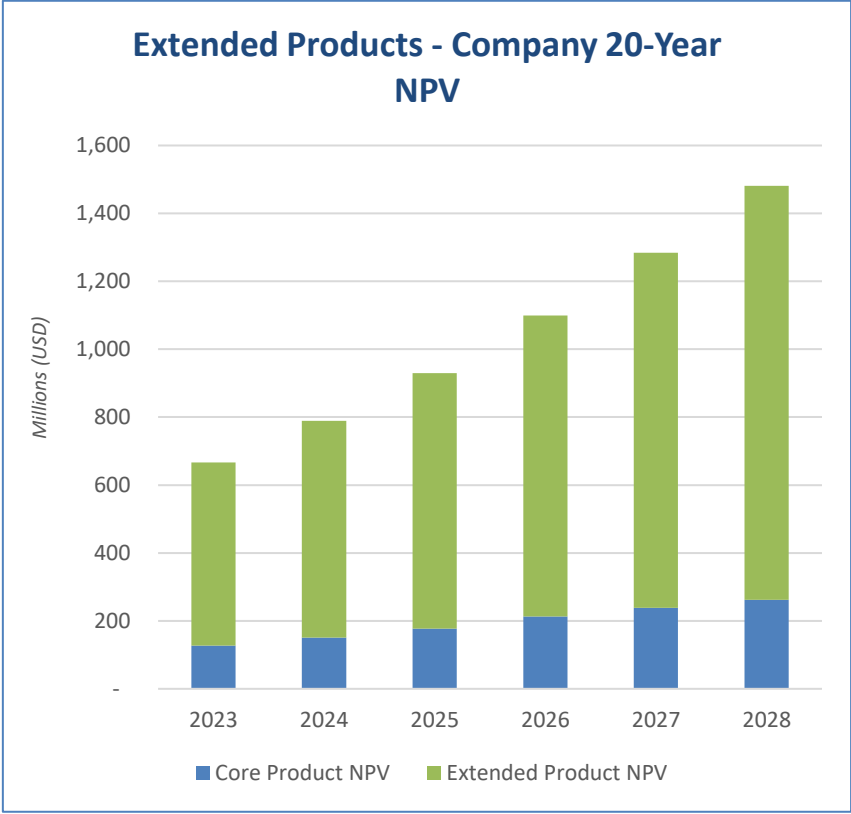
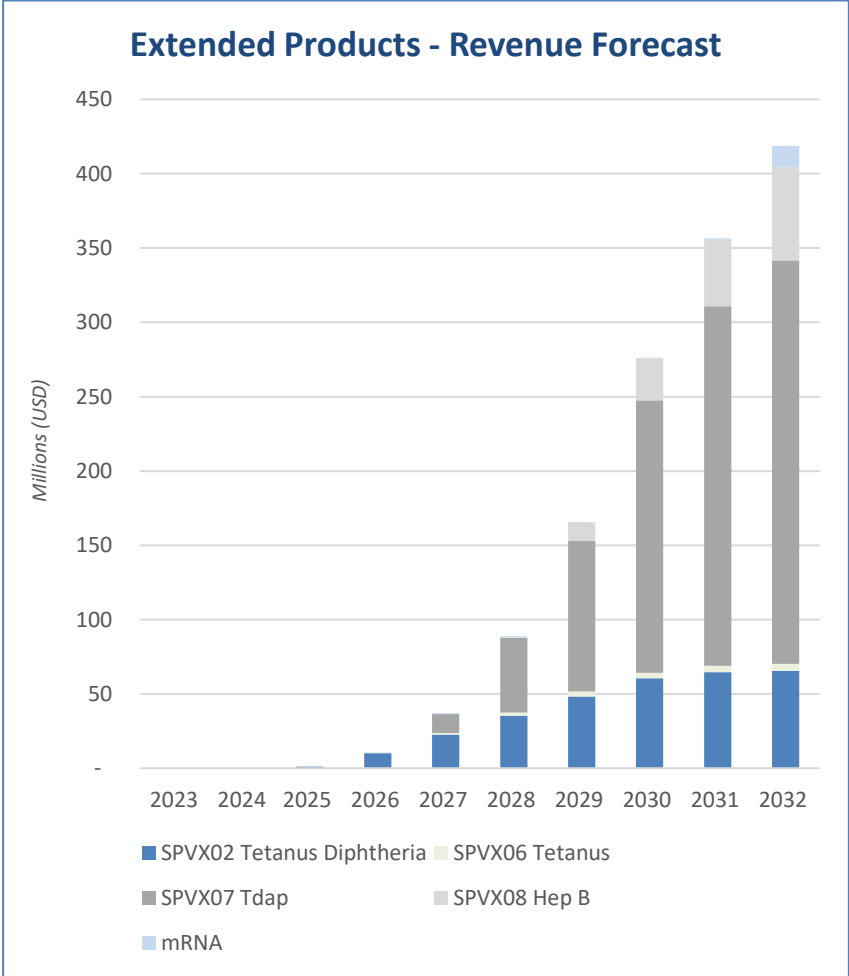
Core Products Only - NPV (20 Year) Progression

20-Year NPV from Start Year	
2023	\$127,087,011
2024	\$150,532,894
2025	\$177,586,678
2026	\$212,715,193
2027	\$238,088,735
2028	\$262,049,625

Note: (a) The core financials are shown in tabular form in the Appendix



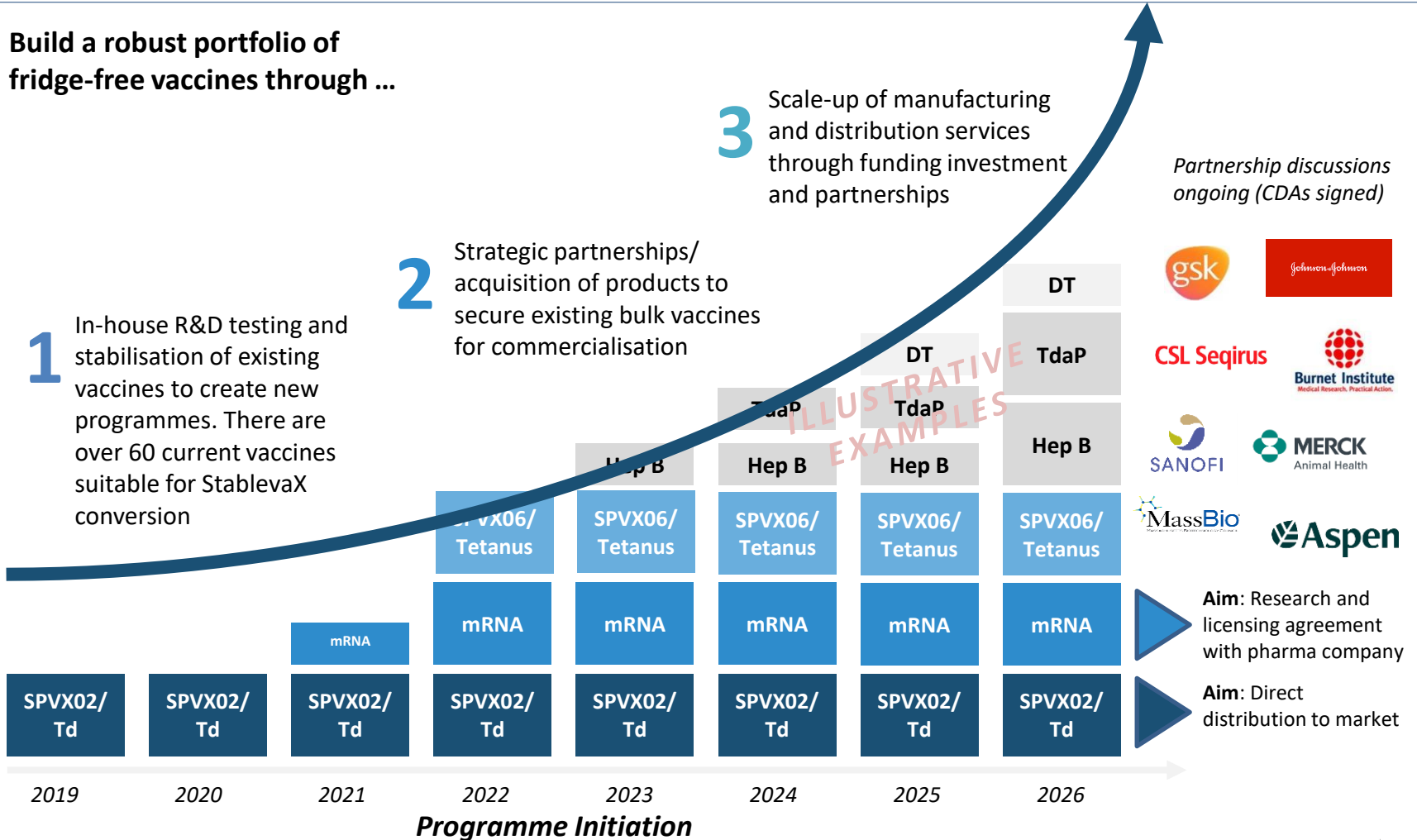
Our Extended Financials include SPVX07, SPVX08 and mRNA Partnership Revenue, showing significant upside potential



The Extended Financials are intended to be illustrative and are dependent on closing deals for the supply of Tdap and HepB vaccines, and striking mRNA partnership deals.

We are building a fridge-free portfolio in partnership with established pharmaceutical manufacturers

Build a robust portfolio of fridge-free vaccines through ...



We are an international team across UK and Spain

Management Team (United Kingdom)



Ozgur Tuncer
CEO and Executive Director



Dr Bruce Roser
Chairman and Founder



Nick Child
VP and Co-Founder



Charlie Goddard
COO and Director



Neil Mayall
CFO and Director



Laura Murphy
Head of Communications



Michelle Hennessy
Finance Controller



Anh Go
Strategy and Corporate Dev. Lead



Shankar Seetharaman
Head of Quality and CMC



Richard Amaee
Programme Manager



Lorena Carmona Rodriguez
Senior Scientist

R&D Centre of Excellence (Spain)



Dr Arcadio García de Castro
Chief Scientific Officer



Juana de la Torre Arrietas
Senior R&D Manager

Advisory Board



Prof Alan Boyd
FRSB FFLM FRCP
FFPM FMedSci
Regulatory Expert



Prof Saul Faust
BMA, MBBS, FRCPCH,
PhD, FHEA
University Hospital of Southampton



Dr Gunther Faber
Ex. VP Sub-Saharan Africa for GSK



Robert Shepard
Shareholder Director

We are seeking pre-IPO bridge funding in advance of an IPO in 2024

Round	Seed	Series A		Pre-IPO bridge	IPO
	Q2 2019	Q2 2021	Q3 2022	2023	2024
Amount	Target Raise: £700k Actual Raise: £1.3m <i>(oversubscribed)</i>	Target Raise: £2m Actual Raise: £2m <i>(oversubscribed)</i>	Target Raise: £3m+ Actual Raise: £3.2m	Target Raise: £5-10m	Target Raise: £15-20m
	Total Series A total raise of max: £5.2m				
Pre-money valuation	£10million	£18million	£30million	Target of £50million	Target of >£100million
Post-money valuation	£11.3million	£20million	£33.2million/ £38million (fully diluted)		

Pre-IPO bridge funding will enable Stablepharma to:

SPVX02 (Td)
SPVX06 (TT)

- Complete human comparative trials of SPVX02 (3-month trial with 48 healthy adults)
- Progress regulatory approval of SPVX02 with MHRA and EMA
- Perform pre-clinical trial testing for SPVX06
- Commence clinical trials

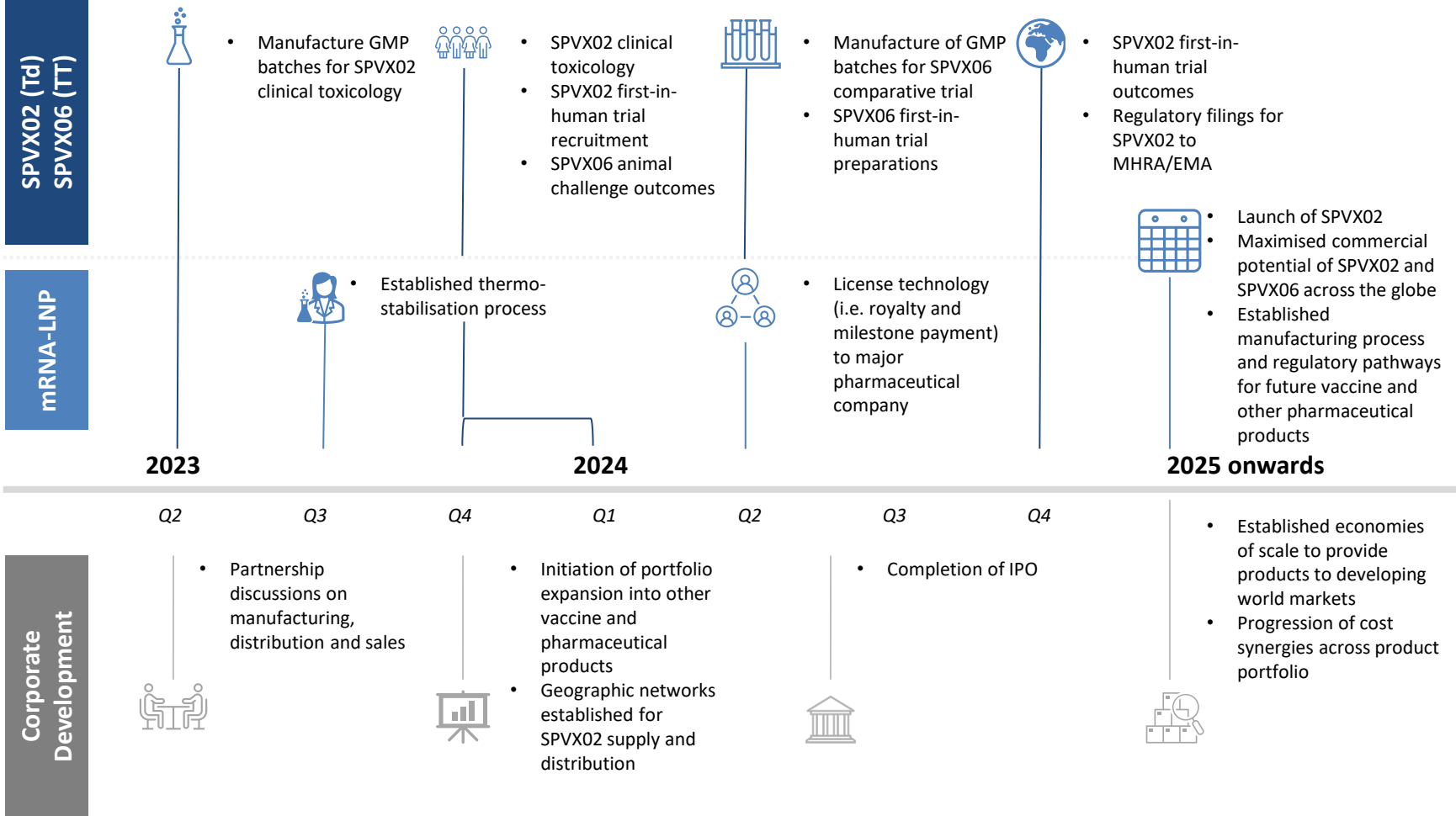
mRNA-LNP

- Progress mRNA R&D in collaboration with external partners (expected to be partially funded by partners)
- Sign a research collaboration with first pharmaceutical company

Corporate Development

- Prepare for IPO in 2024. IPO will raise a further £15-£20m required for full commercialisation and manufacture of SPVX02 and SPVX06

We have a clear execution and commercialisation timeline



Appendix: Core Financials (SPVX02 and SPVX06 Only)

	1	2	3	4	5	6	7	8	9	10
	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
1. Core Product Contribution										
1.1 SPVX02 Tetanus Diphtheria										
1.1.1 Revenues	0	0	1,180,191	10,300,000	22,658,119	35,348,820	48,379,679	60,518,050	64,600,752	65,480,357
1.1.2 Development Costs	(1,211,063)	(1,292,284)	(2,454,421)	(125,158)	(145,874)	0	0	0	0	0
1.1.3 Ongoing Costs	0	0	(3,906,363)	(349,027)	(7,548,647)	(11,382,282)	(15,421,270)	(18,960,319)	(19,988,817)	(20,262,370)
1.1 SPVX02 Financial Contribution	(1,211,063)	(1,292,284)	(5,180,593)	9,825,815	14,963,598	23,966,538	32,958,409	41,557,731	44,611,935	45,217,987
1.2 SPVX06 Tetanus										
1.2.1 Revenues	0	0	0	444,238	1,053,619	2,128,311	3,383,792	3,739,618	4,477,362	4,768,480
1.2.2 Development Costs	0	(121,250)	(2,148,780)	(1,823,370)	(539,404)	(125,158)	(145,874)	0	0	0
1.2.3 Ongoing Costs	0	0	0	(313,048)	(871,080)	(1,759,582)	(2,909,289)	(3,430,295)	(3,958,123)	(4,374,055)
1.2 SPVX06 Financial Contribution	0	(121,250)	(2,148,780)	(1,692,181)	(356,865)	243,571	328,629	309,323	519,238	394,425
2. Central Costs										
2.1 Spain R&D Centre of Excellence										
2.1.1 Premises and Staff	(414,567)	(569,393)	(681,464)	(718,489)	(757,661)	(799,116)	(839,072)	(881,025)	(925,077)	(971,330)
2.1.2 Consumables and Other Costs	(60,215)	(66,237)	(72,860)	(80,146)	(88,161)	(96,977)	(101,826)	(106,917)	(112,263)	(117,876)
2.1 Spain R&D Centre of Excellence Total Costs	(474,782)	(635,629)	(754,324)	(798,635)	(845,822)	(896,093)	(940,898)	(987,942)	(1,037,340)	(1,089,207)
2.2 UK Team										
2.2.1 Premises and Staff	(1,562,688)	(2,041,735)	(2,258,933)	(2,485,713)	(2,614,399)	(2,754,779)	(2,889,086)	(3,034,827)	(3,182,966)	(3,343,466)
2.2.2 Central SG&A costs and Other	0	0	(861,881)	(3,284,348)	(3,293,192)	(6,470,014)	(9,856,633)	(12,750,301)	(13,420,515)	(13,449,804)
2.2 UK Team Total Costs	(1,562,688)	(2,041,735)	(3,120,814)	(5,770,061)	(5,907,590)	(9,224,792)	(12,745,719)	(15,785,128)	(16,603,481)	(16,793,270)
EBITDA of Core Financials (SPVX02 and SPVX06)	(3,248,533)	(4,090,899)	(11,204,511)	1,564,938	7,853,321	14,089,223	19,600,421	25,093,983	27,490,352	27,729,936
Cumulative Cash Position Core Financials	(3,248,533)	(7,339,432)	(18,543,943)	(16,979,005)	(9,125,684)	4,963,539	24,563,960	49,657,943	77,148,296	104,878,231

All figures in USD

Appendix: Key Financial Assumptions

Financials shown are projections and are based on the following assumptions:

SPVX02 (Td)

- Price per dose assumed to be between \$11.98 to \$19.11 USD depending on region
- Peak market share between 20%-30% depending on region
- Rest of World (RoW) revenue forecast only incorporated eight high-income countries (HIC) and does not incorporate any middle-income or low-income countries

SPVX06 (TT)

- Price per dose assumed to be between \$5.28 to \$11.92 USD depending on region
- Peak market share around 15% depending on region
- RoW forecast only incorporates eight HIC

Extended Financials Including SPVX07 (Tdap), SPVX08 (Hep B) and mRNA

- Figures presented are illustrative and dependent on ability to close partnership deals

Data Sources

- (1) [Statista](#) (2) [WHO MI4A Public Database, 2022](#) (3) [Statista](#) (3) [Financial Times, 2021](#)
(4) [WHO, 2019](#) (5) [Logistics Insider](#) (6) [Allied Market Research](#) (7) [IQVIA, 2023](#)

Contacts

Özgür Tuncer

CEO & Executive Director
E: otuncer@stablepharma.com

Nick Child

VP & Co-Founder
E: nchild@stablepharma.com

Neil Mayall

CFO
E: nmayall@stablepharma.com

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Stablepharma Ltd - The Fridge-Free Vaccine Company,
committed to launching the world's first fridge-free vaccines.



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