# oncosec™

**Powerful, Tumor-agnostic Immunotherapy Treatment**


**VLA:** INTRODUCING THE NEW
VISCERAL LESION APPLICATOR

**PITCH DECK**
2019

# OncoSec's Current Immunotherapy Platform

With our current applicator, we've seen **systemic** responses in both the treated and untreated tumors after applying our therapies to cutaneous and subcutaneous tumors.

Many tumors, "especially cold tumors," do not respond to conventional therapies (chemo, checkpoint inhibitors, TACE, embolization, ablation). **There is an industry rush to find replacement or augmenting therapies.**

**Using the tumor as a gateway to the immune system**, intratumoral plasmid-based IL-12, delivered via electroporation, can generate local and systemic immune responses that effectively converts immunologically cold tumors to hot tumors.

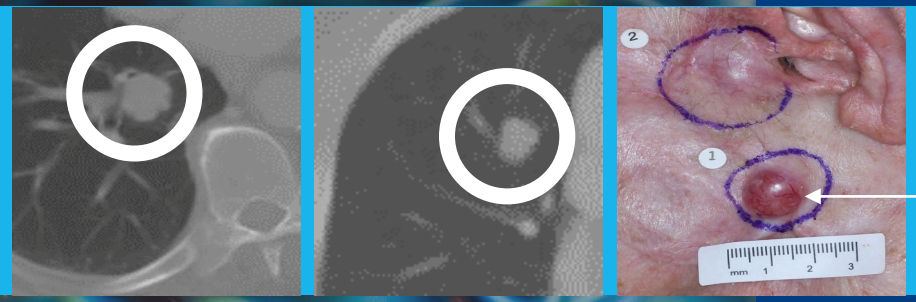
Our current **proprietary novel applicator** and generator allows for electroporation of IL-12 into cells across many tumor types.

CASE STUDY

# What TAVO, Combined with CPIs, is Capable Of

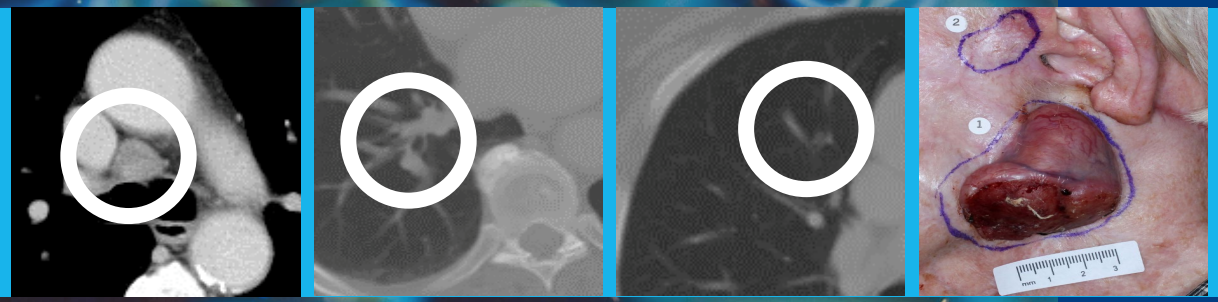
**Regression of untreated mediastinal node and parenchymal lung metastases**

**BASELINE**



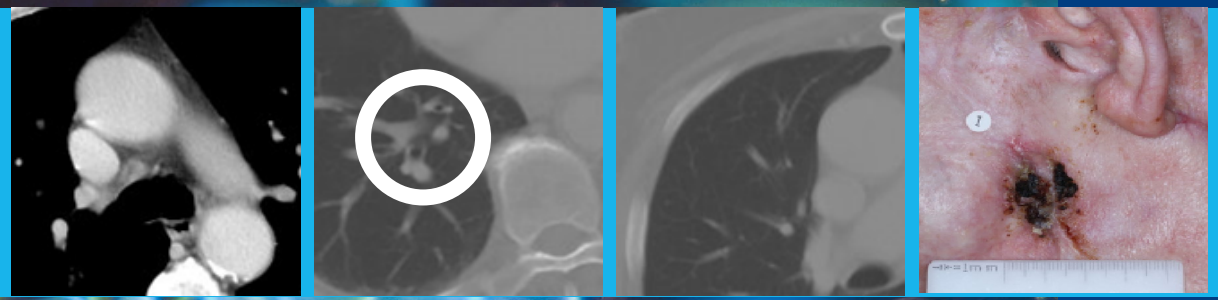
TREATED LESION

**12** WEEKS



**RESPONSE:** TUMOR FLARE, NECROSIS

**24** WEEKS



**REGRESSION OF ALL LESIONS** INCLUDING UNTREATED VISCERAL LESIONS IN LUNGS AND DISTAL LYMPH NODES

TODAY, PRACTITIONERS NEED

# Urgent Treatment Options for Patients with Visceral Lesions

## LIVER CANCER

**42k** 42K+ patients were diagnosed with liver cancer in 2018

The majority of diagnoses are in advanced stages of the disease not amenable to curative resection

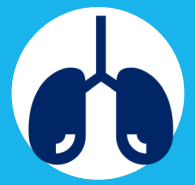
**30k** In 2018, 30K+ patients succumbed to liver cancer, despite decades of therapy advancements

## GASTROINTESTINAL CANCER

**55k** 55K+ patients were diagnosed with pancreatic cancer in 2018

**90%** A staggering 90% of pancreatic cancer cases are diagnosed at a stage when curative resection is not possible

**44k** 44K patients died from this malignancy in 2018



## LUNG CANCER

**2M** 2M patients were diagnosed with lung cancer in 2018

**16%** Only 16% of lung cancer cases are diagnosed at an early stage. Distant tumors (spread to other organs) drastically reduce the survival rate

**154k** 154K Americans are expected to die from lung cancer in 2018 (25 percent of all cancer deaths)

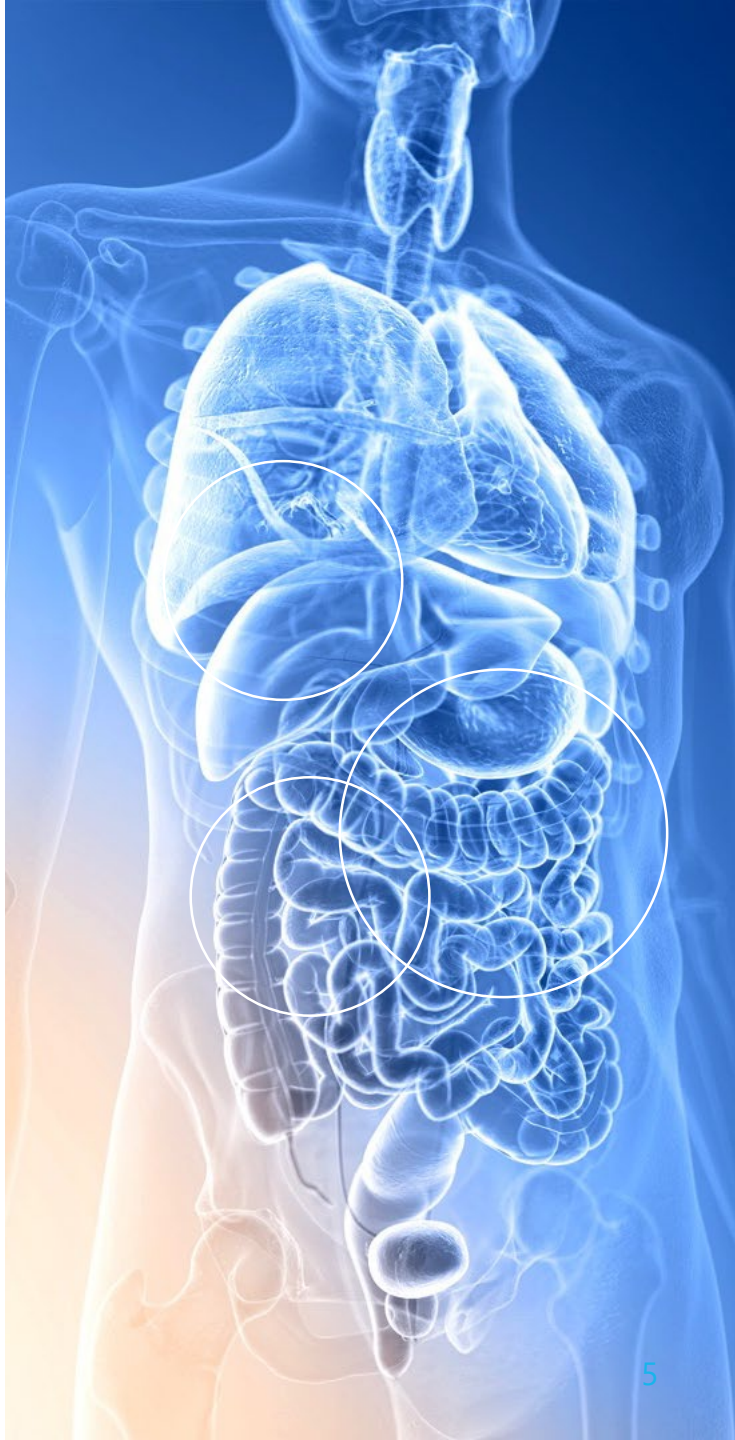
SOURCE: WCRF.ORG/DIETANDCANCER/CANCER-TRENDS/LUNG-CANCER-STATISTICS
LUNG.ORG/LUNG-HEALTH-AND-DISEASES/LUNG-DISEASE-LOOKUP/LUNG-CANCER/RESOURCE-LIBRARY/LUNG-CANCER-FACT-SHEET

PRACTITIONERS HAVE ASKED US TO DEVELOP A DEVICE THAT

# Delivers the Same Powerful Therapy to Visceral Lesions

Tumors located inside the body, including gastrointestinal (GI) tumors, pancreatic tumors, and liver (e.g. HCC) tumors have unique challenges:

- OFTEN DIAGNOSED LATE WHEN TREATMENT OPTIONS ARE LIMITED
- CURRENT OPTIONS TO CHANGE TUMORS FROM 'COLD' TO 'HOT' DO NOT DRIVE STRONG SYSTEMIC RESPONSES
- ABLATIVE SOLUTIONS ARE NOT HIGHLY EFFECTIVE; CANCER RECURS ELSEWHERE
- CURRENT LIMITATIONS: ONCOSEC'S CUTANEOUS/SUBCUTANEOUS DEVICE CAN ONLY REACH LESIONS 1.5-2CM DEEP



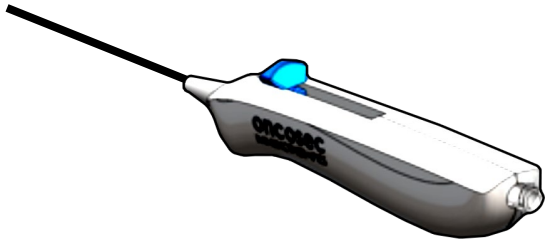
# The Power of TAVO for Visceral Lesions

Based on encouraging and consistent data and a clear unmet demand, we designed a platform to reach visceral lesions.

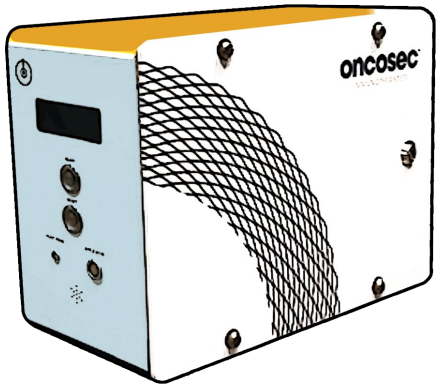
INTRODUCING THE

## **VLA:** Visceral Lesion Applicator

Flexible catheter-based applicator




A more rigid trocar-based applicator




Lower voltage Apollo generator

**CAN BE USED WITH**

Endoscope

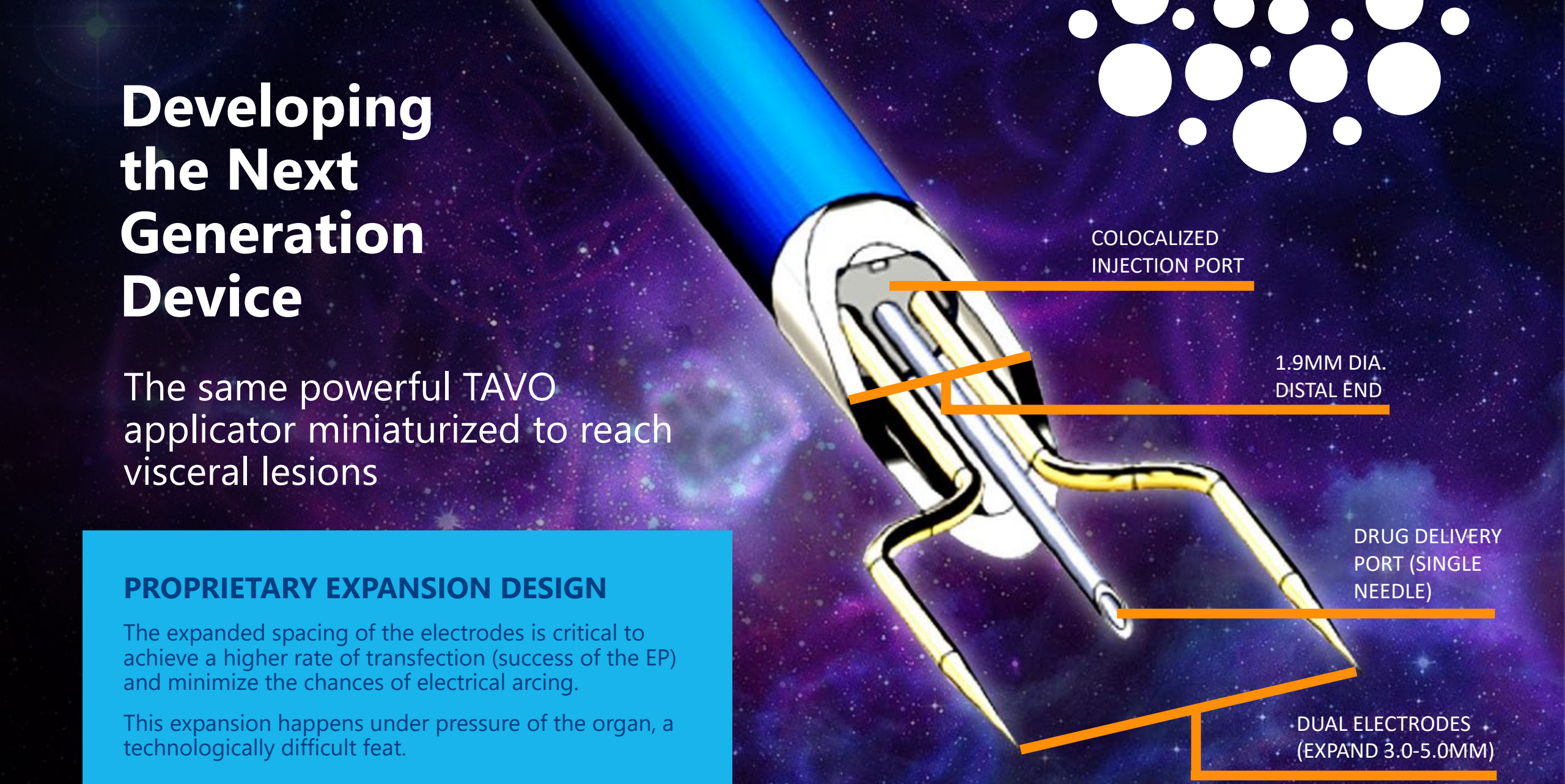
Bronchoscope

Trocar

Cystoscope

# Developing the Next Generation Device

The same powerful TAVO applicator miniaturized to reach visceral lesions



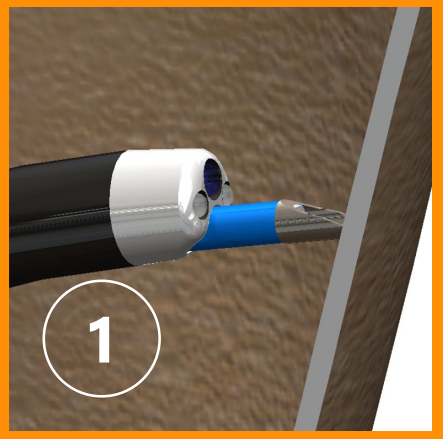

## PROPRIETARY EXPANSION DESIGN

The expanded spacing of the electrodes is critical to achieve a higher rate of transfection (success of the EP) and minimize the chances of electrical arcing.

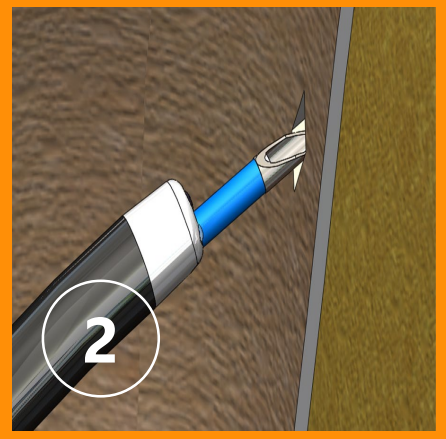
This expansion happens under pressure of the organ, a technologically difficult feat.

# The Flexible Catheter Applicator

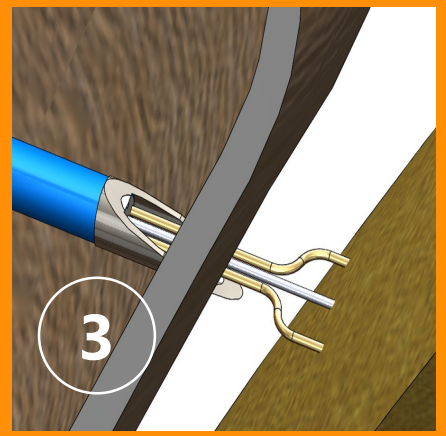
The catheter-based applicator includes a flexible body that, with a diameter of 1.9mm, is sized for passage through currently available endoscopes, cystoscopes, and bronchoscopes.



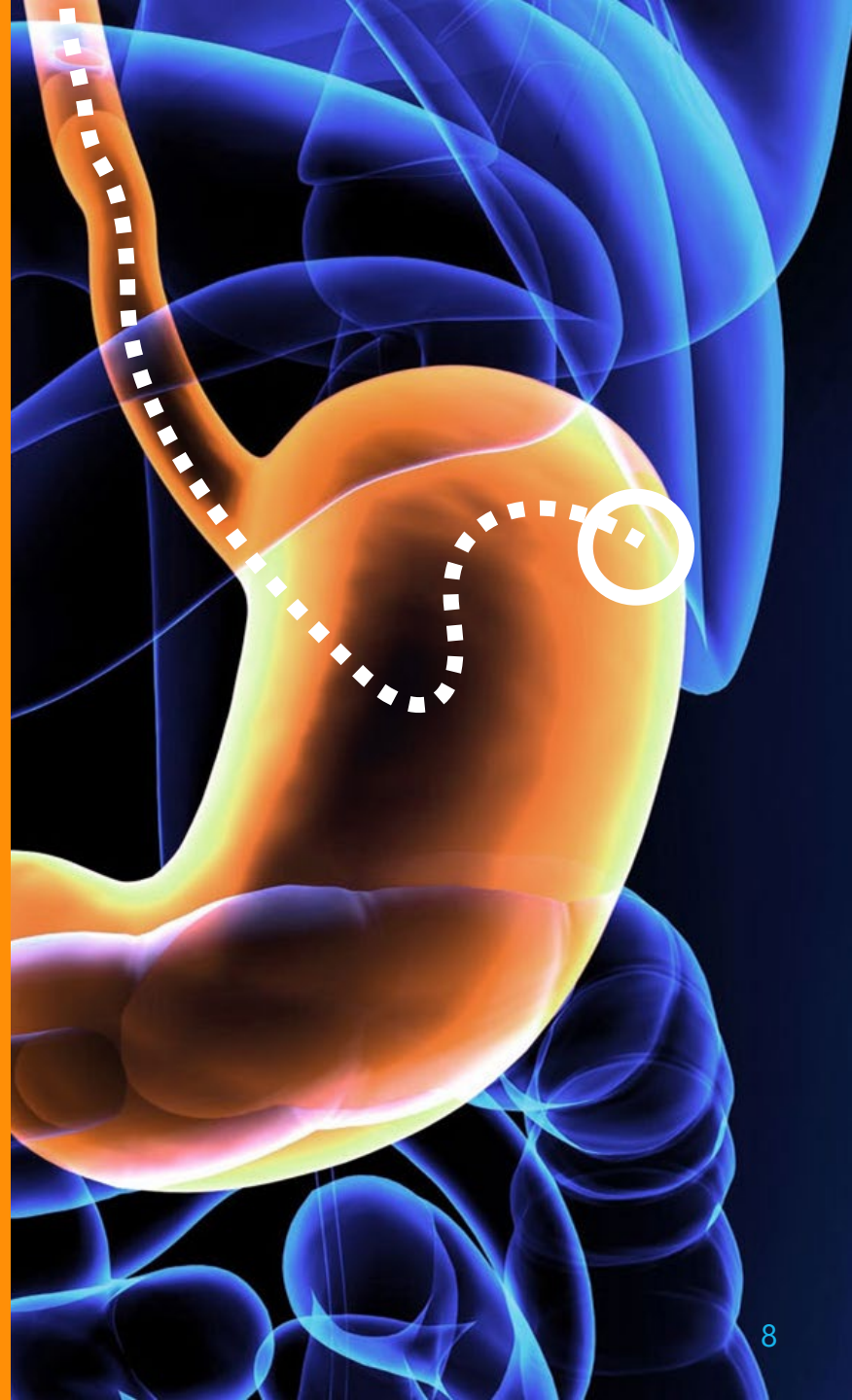

NAVIGATE TO THE ORGAN / LOCATION




ENTERS THE ORGAN BY PUNCHING THROUGH THE ORGAN WALL

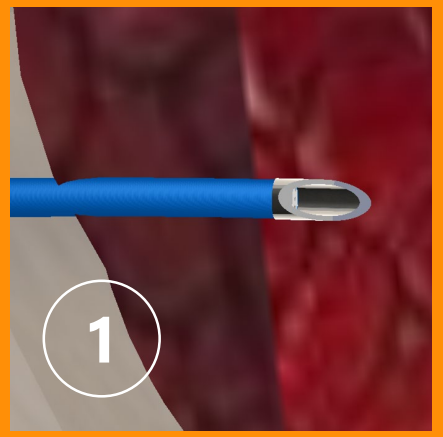



NEEDLE AND ELECTRODES DEPLOYED, PLASMID ADMINISTERED, ELECTROPORATION OCCURS

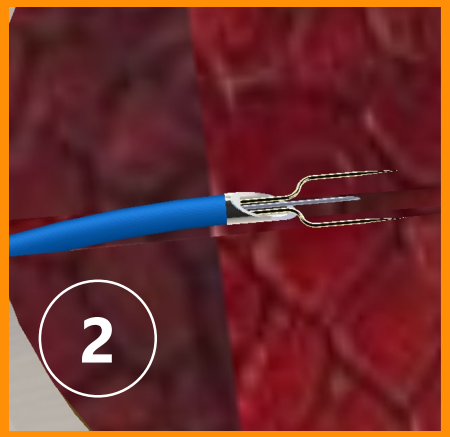


# Rigid Trocar-based Applicator

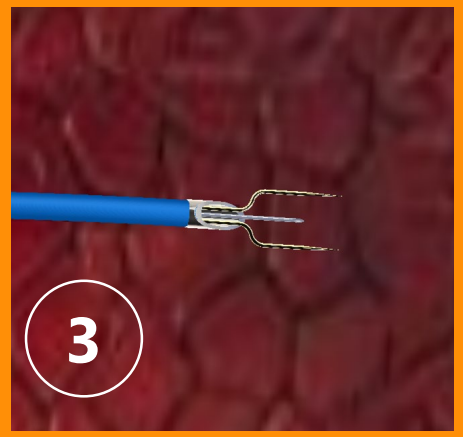
The trocar-based applicator accesses a visceral tumor using a minimally invasive transcutaneous approach under CT or ultrasound guidance.



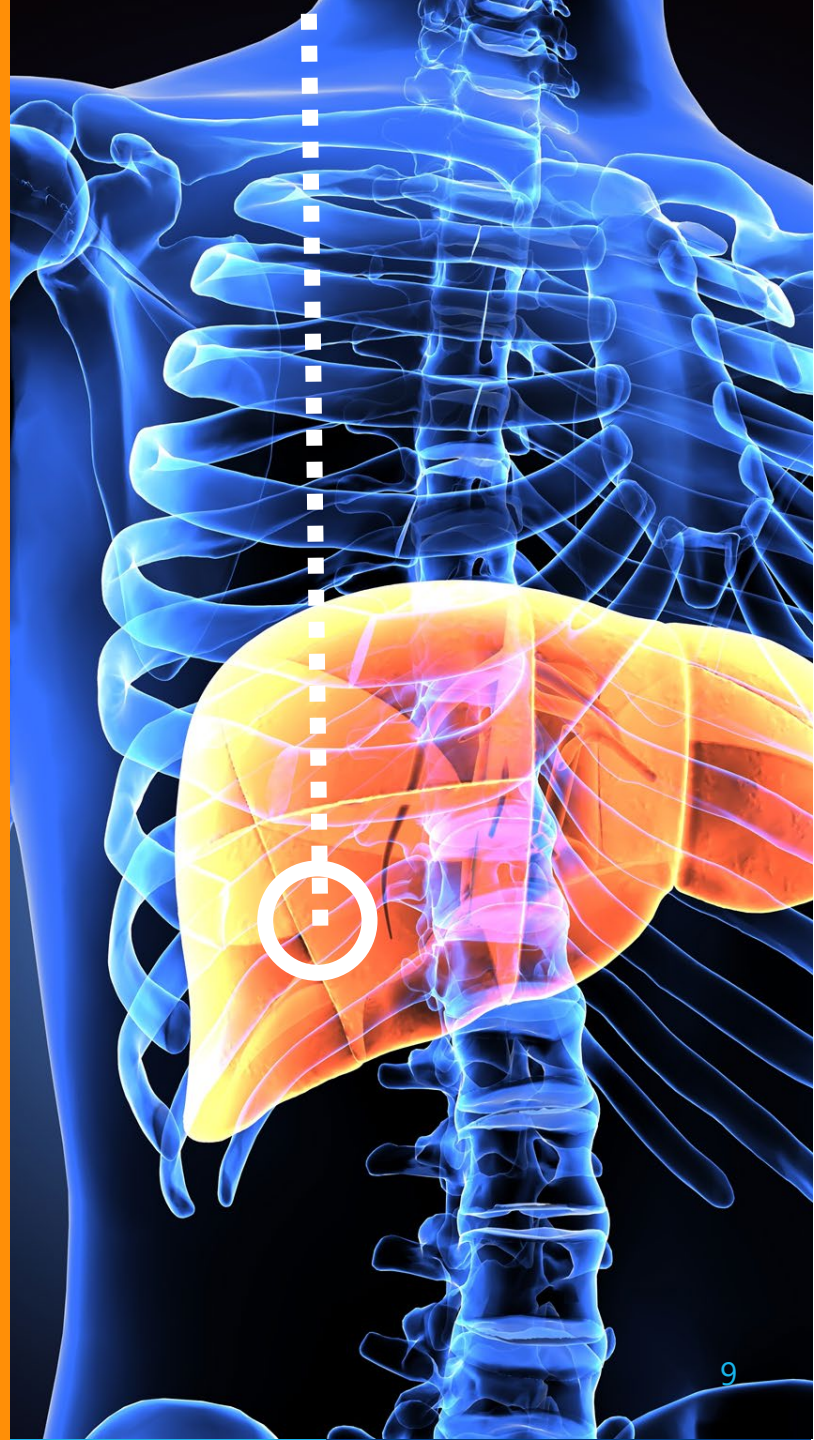

ENTERS THE ORGAN




**NEEDLE AND ELECTRODES EXPANDED**
THERAPEUTIC AGENT ADMINISTERED




**ELECTROPORATION OCCURS**
CELL MEMBRANES BECOME POROUS AND TAKE UP THE THERAPEUTIC AGENT



## APPLICATOR DEVELOPMENT STATUS

# Several live, large animal studies have been performed with the VLA

- **Design control Phase I complete. Molded component design, material selection in process. Product design evaluation in process.**
- **Preclinical prototypes of both rigid trocar-based and flexible catheter applicators are in functional evaluation.**
- **Product proof of concept complete. Applicators have successfully reached and deployed in lung, liver, pancreas, bladder, and bone in a live pig.**

**Estimated completion 3Q2020**

# The New Low Voltage Apollo Generator will be used with the Visceral Lesion Applicators

**PRE-CLINICAL GENERATOR COMPLETE**
In use by Oncosec research team and outside institutions

**CLINICAL GENERATOR IS BUILT**
In software development and design verification phase at Minnetronix (Estimated completion end of 2020)

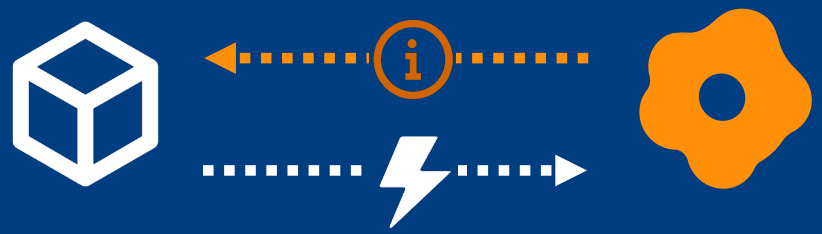
| | RANGE | ACCURACY |
|---|---|---|
| PULSE AMPLITUDE | 10V-300V | 5% |
| CONSTANT CURRENT LIMIT | 4A | 20% |
| PULSE LENGTH | 100US – 10MS | 5% |
| PULSE INTERVAL | 300MS – 10S | 5% |

**Increased Transfection Efficiency**

Lower voltage with longer duration pulses results in improved expression

# TRACE Technology Built In

## THE NEWEST GENERATOR COMES WITH THE ABILITY TO USE TRACE TECHNOLOGY



Generator receives information on impedance from the tissue, relays it back to the generator which is able to modulate the current

TRACE

**T**ISSUE-BASED
**R**EAL-TIME
**A**DAPTIVE
**C**ONTROL
**E**LECTROPORATION

## BENEFIT = MORE CONTROL

Different Cells Types Work Differently

Different Tumors Have Different Reactions

This next generation functionality will give us the ability to tailor and optimize the delivery in real-time

# A Focus on Safety Features

Throughout development we've been hyper-focused on the safety and consistent functioning of the applicators and generator.

## GENERATOR

### Always The Right Current

Continuous feedback system monitors energy delivery

Auto shut down in cases where voltage exceeds specified threshold

Provides feedback to clinician on correct tissue placement

## APPLICATOR

### Always Deployed Safely

Embedded and deployable electrodes within applicator to prevent accidental needle sticks

EP initiated by covered foot switch only, preventing accidental initiation

Expansion mechanism highly tested against failure to expand or electrode loss

Single use, sterile device

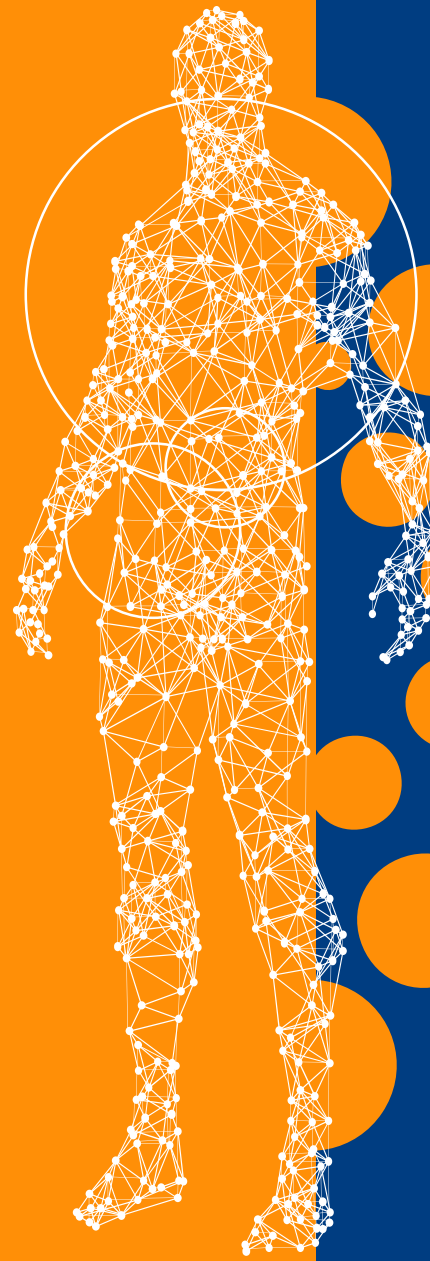
# THE VLA IS ABLE TO DELIVER TARGETED IMMUNOTHERAPIES, WHICH HAVE THE POTENTIAL TO ACT IN CONCERT WITH EXISTING THERAPIES TO DRIVE ENHANCED RESPONSES IN IMMUNOLOGICALLY COLD TUMORS.

ABLATION

CHEMO

TACE

SYSTEMIC IMMUNOTHERAPY



## POTENTIAL DUAL REGULATORY PATHWAY PROVIDES FOR NEARER TERM APPROVAL OF STANDALONE DEVICE (VLA) AND CONCURRENT COMBINATION IND WITH VLA + TAVO (OR NEXT-GEN PLASMID)

**Parallel device filing** will be used in order to get faster accessibility to doctors, quicker clinical deployment, and more timely profitability.

1. **STANDALONE Device Approval**
   IDE → PMA clearance
2. **COMBINATION**
   IND for VLA + TAVO

## BENEFITS

Faster pathway to clinic

Faster marketing authorization = Quicker time to revenue

Increase access to physicians through sales force

# Key Milestones in Our Path to Market

# Established Biotech Leaders
## WITH A TRACK RECORD OF SUCCESS

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# Thank You

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IMMUNOTHERAPIES

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