

# Annual General Meeting CEO Presentation Stephen Doyle



**QBiotics Group**

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# Introduction Stephen Doyle, CEO & Managing Director



# Special mentions



Vale  
Dr Sue Foden



Special thanks to  
Dr Victoria Gordon



Special thanks to Andrew  
Denver and Prof Bruce Robinson



# Key achievements

## Team:

- **Board appointments:** Mark Fladrich and David Phillips
- **Leadership:** Stephen Doyle CEO & Managing Director (post period)

## Development, Human:

### Tigilanol tiglate

- **FDA Orphan Drug Designation:** for the treatment of soft tissue sarcoma
- **Phase IIa Soft Tissue Sarcoma:** patient recruitment completed in US (QB460H07); preliminary data presented at European Society for Medical Oncology and Connective Tissue Oncology Society (post period)
- **Phase I/IIa Head and Neck Squamous Cell Carcinoma:** dose escalation trial in Australia and India (QB46-H03) met primary endpoints. Further trial sites added (QB46C-H08).
- **Preclinical Study:** published in The Journal for ImmunoTherapy of Cancer

### EBC-1013

- **Phase I Safety Trial:** recruitment commenced for venous leg ulcer trial in Australia

## Veterinary programme:

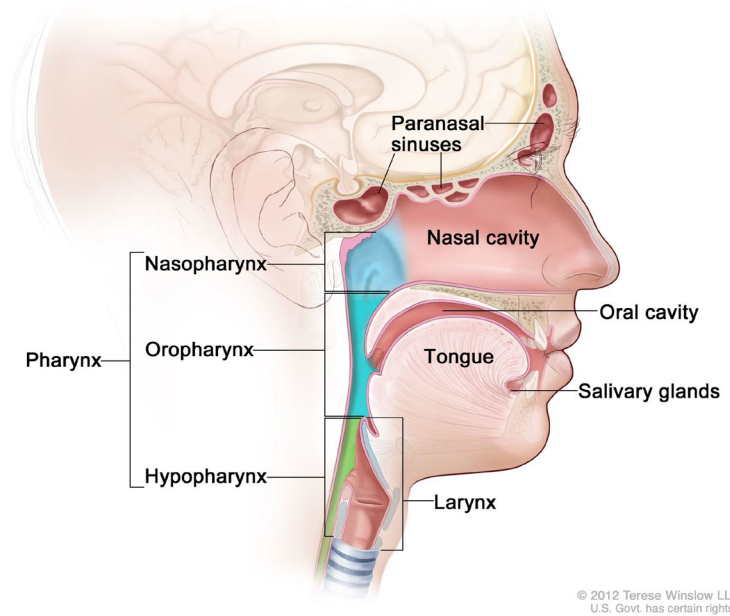
- **Commercial:** Stelfonta<sup>®</sup> exceeds 20,000 dogs treated globally

A close-up photograph of a microscope's objective lens and eyepiece, with a hand holding a petri dish containing a blue-stained sample. The background is a soft-focus laboratory setting. A large white circle is overlaid on the left side of the image, containing the text.

# Human oncology development

Tigilanol Tiglate – Head and Neck (HNSCC) and  
Soft Tissue Sarcoma (STS) Programs

# Head and Neck is a common cancer which remains is a high unmet need



- Head and neck cancer is the 7<sup>th</sup> most common cancer
- ~ **932,000** new cases globally in 2020<sup>1</sup>
- Extending overall survival remains a major unmet need

## Opportunity

- HNSCC market ~\$US2.1B in 2020<sup>2</sup>
- CAGR of 9.8%
- Sales of \$5.2 B by 2030
- No intratumoural product is approved
- Opportunity to preserve organ function & improve cosmetic outcomes
- Combination with Standard of Care

1. Globocan 2020.

2. Global Data. 8MM includes US, 5EU (France, Germany, Italy, Spain, and the UK), Japan, and urban China

CAGR: Compounded Annual Growth Rate

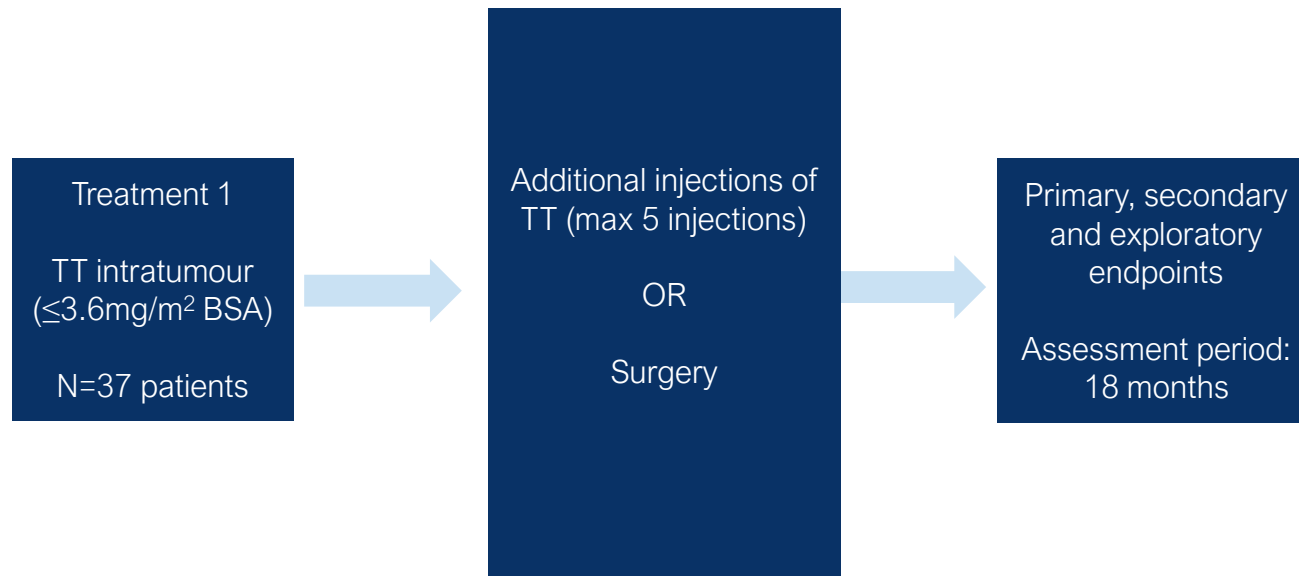
Image reference: National Cancer Institute

# Phase II open label study: recruitment underway

Multi center, single arm, open label, Phase II study assessing efficacy of tigilanol tiglate in various head and neck cancer malignancies

- Adults with advanced and/or metastatic head and neck cancer
- Lesion(s) volume measured by ultrasound (+CT or MRI)

QB46C-H08, NCT05608876



## Primary endpoint

- Tumour ablation rate

## Secondary endpoint

- AE's and SAE's- safety and tolerability
- Local recurrence rate
- Progression free survival (RECIST v1.1)

## Exploratory

- General cancer QoL
- Head and neck QoL
- Wound healing
- ORR (RECIST v1.1 and itRECIST)
- Immune infiltration in surgical/ biopsy specimens
- PBMC's

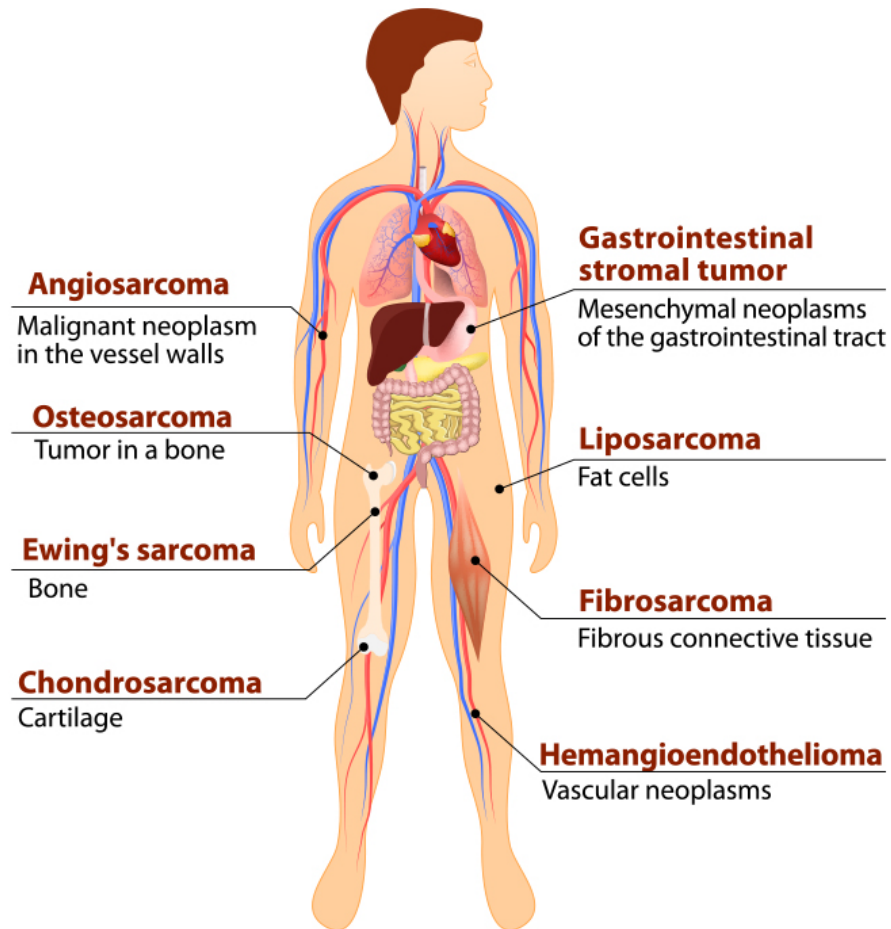


# H08 trial update

- This international study is continuing with 7 sites open
- 16 patients have been recruited
- Clinical Advisory Board, September 2024:
  - Analyse initial patient observations and based on results determine the minimal number of patients required to assess effect of TT in Head and Neck Cancer
- Protocol amendment underway – revised timeline to be announced

# About Soft Tissue Sarcoma: a heterogenous cancer with high unmet need

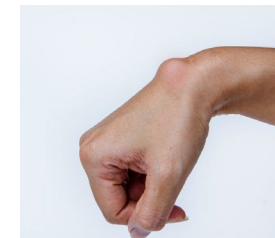
80-100 Histologically diverse subtypes



~124,573 new cases annually across 16 major markets<sup>1</sup>



Incidence is increasing at 0.5% per year



~75% of STS cases: in the extremities such as arms and legs

Trunk wall and retroperitoneum account for 10% cases

Patient segmentation at diagnosis:

70% patients have localised/ resectable disease

- Out of these, 75% of resected progress to advanced/ unresectable disease

30% are initially diagnosed with unresectable, advanced metastatic disease

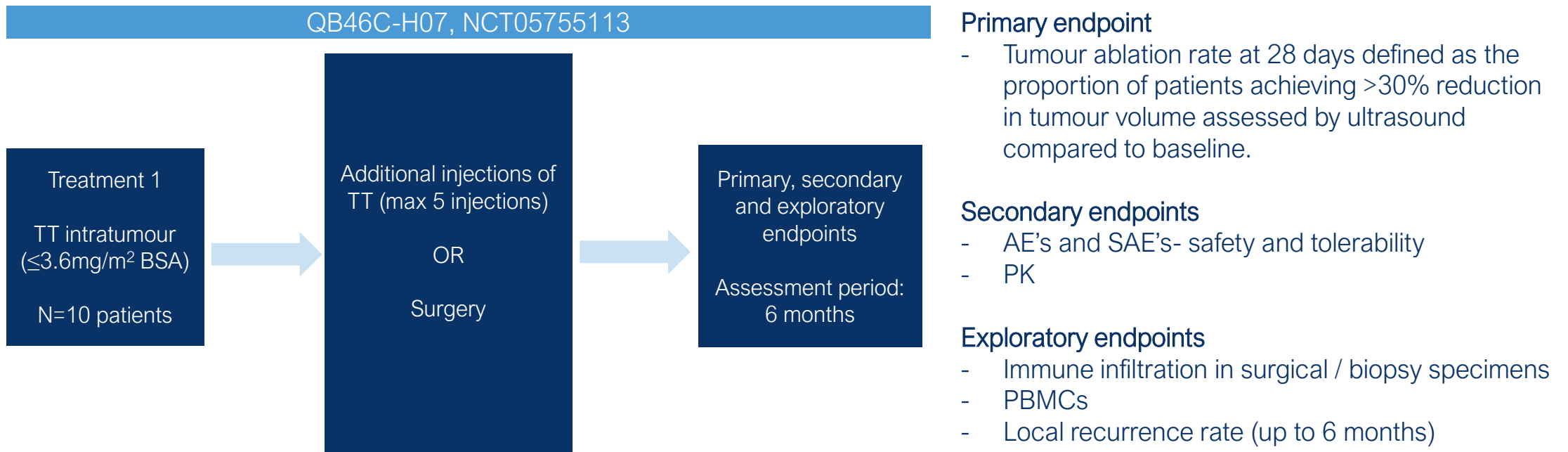
1. Global Data 2022

Image references: Surgical associates of North Texas, RT answers, Mayo clinic

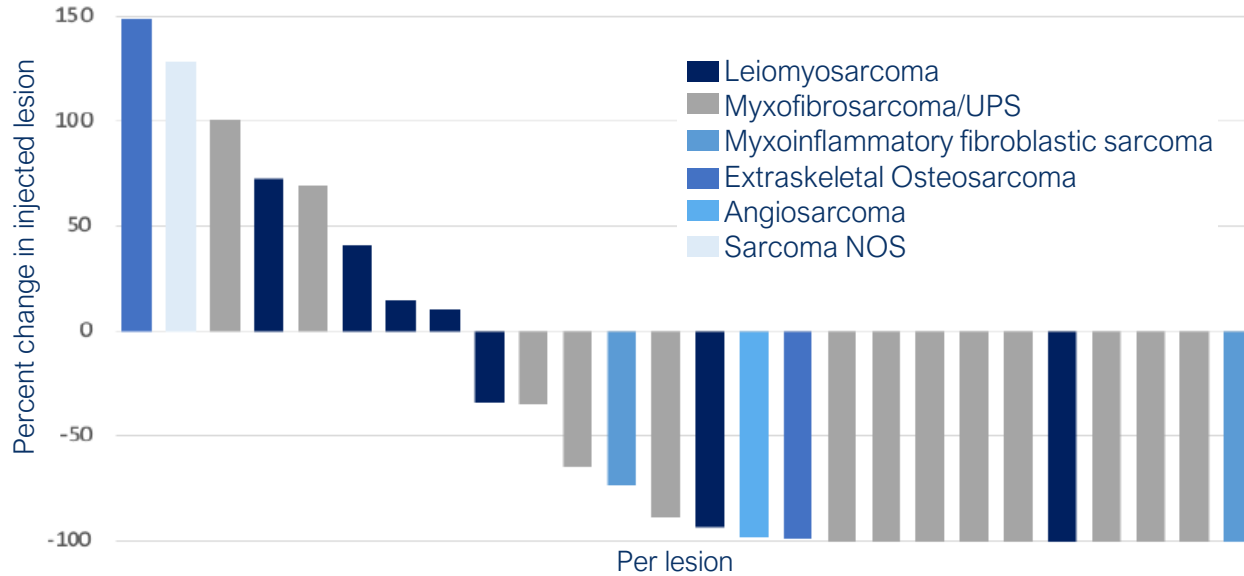
# Phase IIa trial in human STS completed recruitment

Single centre, single arm, open label, Phase IIa study assessing preliminary efficacy of tigilanol tiglate in STS patients conducted at Memorial Sloan Kettering Cancer Center

- Adults with advanced and/or metastatic STS with tumours accessible for injection with ECOG PS  $\leq$  2
- Lesion(s) volume measured by ultrasound (+CT or MRI)



# Promising early efficacy: 10 tumours with CR



The drug was well tolerated

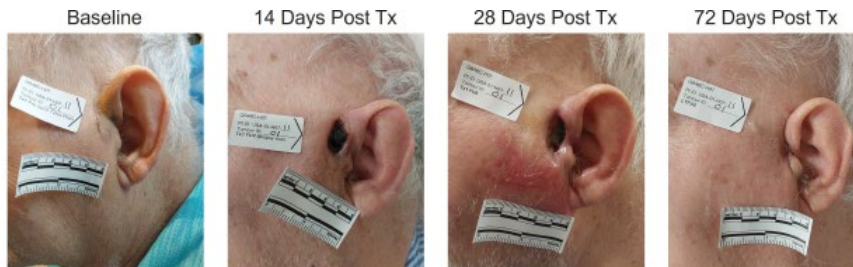
Injected tumour responses were observed across numerous STS histologic types, exceeding the primary endpoint for a promising response

Response rates at 4 weeks:

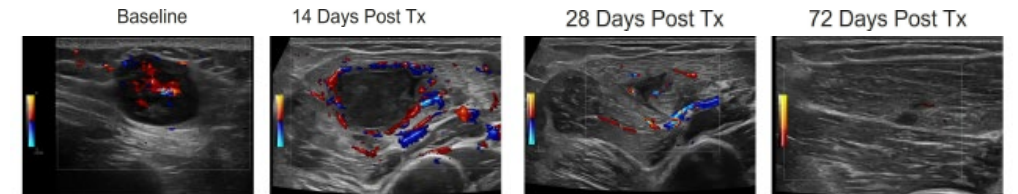
In each injected lesion:  
10 CRs, 8 PRs, 2 SD, 6 PD for each tumour

In injected lesion(s) per patient:  
7 out of 10 patients had response  $\geq 30\%$

Patient with cutaneous angiosarcoma:



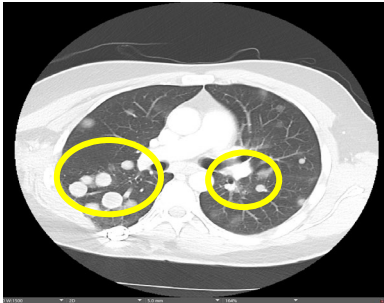
Patient with intramuscular leiomyosarcoma:



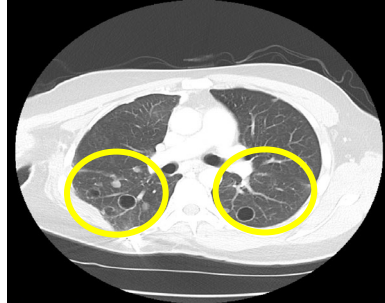
# Subsequent responses to systemic therapy observed in previously non-responsive STS patients

3 patients with pre-existing metastatic sarcoma that were initially non-responsive to systemic therapy, proceeded from tigilanol tiglate to subsequent systemic therapy

Patient 1:  
myxofibrosarcoma  
treated with  
gemcitabine/  
docetaxel/PD-1  
inhibition as 4th  
line

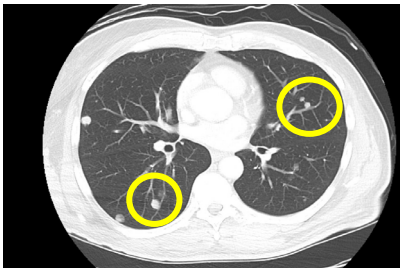


Post TT: lung metastatic



Post 4th line gemcitabine/  
docetaxel/PD-1

Patient 2:  
myxofibrosarcoma  
treated with  
gemcitabine/docet  
axel inhibition as  
2nd line



Post TT: lung metastatic



Post gemcitabine  
/docetaxel 2nd line chemo

## QBiotics Phase IIa Soft Tissue Sarcoma trial extended, following positive data presented at CTOS

BRISBANE, 19 November 2024.

- Data from Phase IIa clinical trial (QB46C-H07) evaluating QBiotics' small molecule, tigilanol tiglate (TT) in patients with advanced Soft Tissue Sarcoma (STS) presented at the Connective Tissue Oncology Society (CTOS) Annual Meeting (San Diego, CA: 13-16 November 2024).
- This new data follows presentation of preliminary data at the European Society for Medical Oncology (ESMO) conference 2024 (Spain, September 2024), which highlighted that TT appeared safe for patients with STS, with early indications of efficacy.
- CTOS presentation includes additional observations made by the investigators showing that patients with metastatic STS disease who were originally non-responsive to systemic therapies began to respond to systemic therapy after treatment with TT.
- These new trial discoveries have led QBiotics to extend the study. Ethics approval has been granted for this extension, and QBiotics is preparing to initiate the extension arm in Q1 2025.

A close-up photograph of a hand holding a petri dish under a microscope. The petri dish contains a blue agar medium with some brownish spots. The microscope is a light-colored compound microscope. The background is a soft-focus laboratory setting. A large white circle is overlaid on the left side of the image, containing the text.

# Human Wound Healing Development

EBC-1013 for wound healing

# EBC-1013 for chronic and acute wounds and burns

6.5 million

US chronic wounds p.a.<sup>1</sup>

14-29 million

globally p.a.<sup>2</sup>



Driven by ageing and increasing incidence of diabetes and obesity



Current treatments - advanced wound dressings and medical devices, only one wound healing pharmaceutical product Regranex (Becaplermin) approved in US



Significant unmet need: 10% of chronic wounds do not heal



Large failure rate; objective clinical endpoint = complete wound closure at 84 days

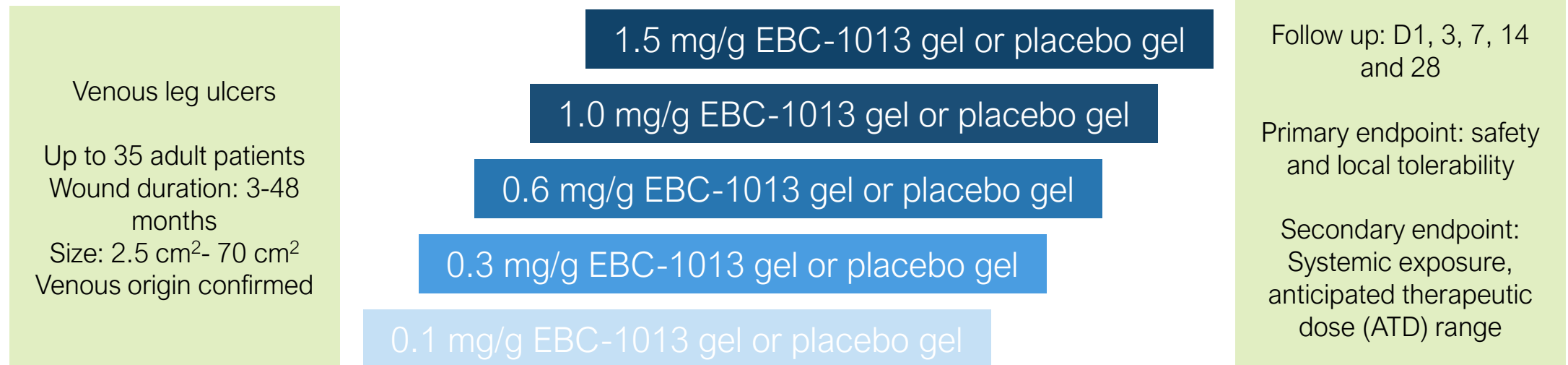
1. Hurlow et al, Defying the Recalcitrant Wound, Woundsource.com, Sponsored by ConvaTec.

2. Nussbaum et al, An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health, 2018 Jan;21(1):27-32.

# Phase I study recruiting patients across escalating doses of EBC-1013

A phase I first-in-human multi-centre dose escalation study to assess the safety and tolerability of EBC-1013 Gel in participants with venous leg ulcers.

Single application of EBC-1013 gel or placebo at ascending doses





# EBC-1013 – wound healing

- Initially planned to commence in the UK
  - Problems with NHS resourcing and recruitment
- Trial moved to Australia and initiated in June 2024 with more than 60pts pre-screened
- Issues identified early on:
  - Two rounds of review with sites to change the inclusion / exclusion
  - Criteria added to broaden available patient population
- The trial is open for recruitment in Australia across 2 sites
- Identified a Clinical Research Centre with a GP referral network to open additional locations

# Veterinarian Program

STELFONTA®

# STELFONTA® and our veterinary oncology programme

- Treated more than 20,000 dogs with STELFONTA®
- Despite pet owners preferring STELFONTA® over surgery for treating their dogs' mast cell tumours, many veterinarians remain hesitant to move away from the familiarity of surgery
- Actively collaborating with our marketing and distribution partner to educate veterinarians on the benefits of non-surgical mast cell tumour removal
- Sales of STELFONTA®, our veterinary oncology pharmaceutical are not yet reaching full potential

# Building Confidence to Prescribe STELFONTA®




**STELFONTA®**  
(tiglanol tiglate injection)

**dvm flex**

Join me for **Free**  
**RACE-Approved CE.**

Become a certified  
**STELFONTA®**  
Superstar!



## Official STELFONTA® Certification

- Continuous Education Approved
- Community of Certified Veterinarians
- Centres of Excellence




**STELFONTA®**

**CLINICAL CASE: REBA**  
9-year-old English Staffordshire Bull Terrier  
Two cutaneous MCTs treated concurrently at Reedy Creek Vet, QLD

Signalment	Tumour location
Name: Reba Breed: English Staffordshire Bull Terrier Age: 9 years old Weight: 18.2kg	Cutaneous MCT on chest wall & upper thigh
 Complete response achieved with one treatment	Treatment: chest
	Tumour dimensions: 1.7cm x 1.2cm x 0.5cm Tumour volume: 0.51cm <sup>3</sup> Stelfonta dose: 0.39mL
	Treatment: thigh
	Tumour dimensions: 1.6cm x 1.5cm x 0.4cm Tumour volume: 0.48cm <sup>3</sup> Stelfonta dose: 0.28mL

**Chest**



## Testimonials & 1:1 Support


- Email campaigns, Podcasts & Clinician discussions
- Feature testimonials – local clinics
- Technical guidance for all first treatments



[Stelfonta Consult Room Guide](#) | [Stelfonta Cytology Poster](#) | [Stelfonta Digital Clinicians' Case Book](#) | [Stelfonta Dosing Guide](#) | [Stelfonta: Tips for Pain Management](#) | [Stelfonta Pet Owner Leaflet](#) | [Stelfonta Pet Owner Treatment Diary](#) | [Stelfonta Practical Aspects](#) | [Stelfonta Vet Brochure](#) | [Stelfonta: Tips for Wound Management](#) | [Virbac Wound Article - Surgery or Stelfonta](#)

**ONCOLOGY VIDEOS**

**STELFONTA®: MODE OF ACTION** | **STELFONTA® - A GUIDE FOR OWNERS**



## Ease of treatment education

- Addressing barriers such as cytological grading & wound
- Remove 'non-resectable' label restriction

# Green Light from an Independent Audit of STELFONTA®

Veterinary specialist business consultant

In-depth analysis of STELFONTA® globally:

- ✓ Insights led strategy
- ✓ Marketing initiatives
- ✓ Educational tools
- ✓ Collaboration with marketing and distribution partner, Virbac



*“The performance of STELFONTA...whilst disappointing, is probably not an industry outlier”.*

# Robust clinical pipeline in human disease, supported by validation in veterinary programmes

Human disease programmes									
Drug candidate	Therapeutic Area	Indication	Discovery	Preclinical	Phase I	Phase II	Phase IIb/III	Approval	Programme updates
Tigilinol tiglate (TT)	Oncology	Soft tissue sarcoma (STS)					FDA: Orphan Drug Designation granted	QB46C-H07: Phase IIa Preliminary data at ESMO 2024 Full results in Q1 CY2025	
		Head & neck cancers (H&NC)							QB46C-H08: Phase IIa Recruiting
EBC-1013	Wound healing	Venous leg ulcers						QB1013C-H201- Phase I Recruiting	
Several leads	Novel antibiotics							Lead optimization	
	Anti-inflammatory							Lead optimization	

Veterinary programmes						
Drug/ Drug candidate	Therapeutic Area	Indication	Clinical		Approval	Programme updates
STELFONTA®		Canine: mast cell tumours				Marketed EU, USA, UK, AU
Tigilinol tiglate (TT)	Oncology	Canine: soft tissue sarcoma, oral melanoma				Recruiting
		Equine: sarcoid, melanoma				Sarcoids reporting, melanoma recruiting
EBC-1013	Wound healing	Equine & canine: acute & chronic wounds				Recruiting

# QBiotics Senior Management Team

- Strong management team with skills to execute on our corporate and clinical plans
- Diverse skills and background
- Currently recruiting for a Chief Medical Officer



# QBiotech: financial overview and upcoming milestones



\$194M Capital raised to date



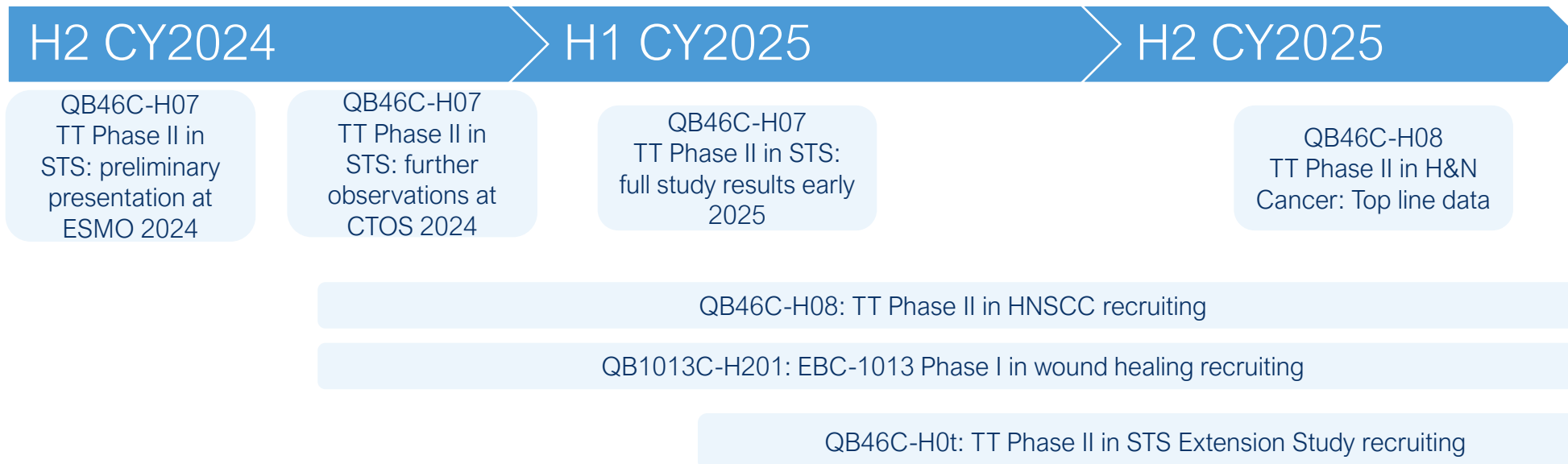
\$43.5M Current cash at bank<sup>1</sup>



\$60.3M R&D tax incentive refunds and government grants received to date



\$3.9M Average quarterly operating expense<sup>2</sup>



<sup>1</sup> As of 30 June 2024

<sup>2</sup> Average cash burn rate per quarter from 1 July 2023 to 30 June 2024



# Priorities

## Product development and commercialization

- Accelerated Clinical Development Plan leading to a registration and path to market for TT in STS
- Attract commercial partners to realize the value of TT
- Accelerate wound healing program for EBC-1013
- Challenge Stelfonta sales and marketing initiatives

## Move the company to next stage of growth

- Attract institutional investment / biotech specialist
- Preserve cash and full review of our additional programs

## People

- As we move to a new phase of growth - expand and attract new talent



**QBiotics  
Group**

