



# Acacia Pharma Group plc 2018 Results Presentation

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# Highlights

## BARHEMSYS™ A new option in PONV

- Differentiated antiemetic mechanism (dopamine D<sub>2</sub>/D<sub>3</sub>)
- Clinically proven in 4 pivotal PONV trials
- First drug approved for rescue treatment, if approved
- **PDUFA DATE: 5 MAY 2019**

## Significant market opportunity in PONV

- ~65m surgical patient a year in the US eligible for an antiemetic
- ~49m patients a year receive an antiemetic
- ~16m patients develop PONV despite prophylaxis and require rescue treatment
- ~18m high-risk patients eligible for combination prophylaxis

## Building efficient US commercial capability

- Initially 60 reps can target 1,600 US hospitals representing ~80% of surgical procedures
- Key personnel already recruited to enable effective US launch
- Own global marketing rights – upside potential from ex-US partnerships

## Strong product protection

- Market exclusivity in US – minimum 5 years
- Initial patent term to 2031 with likely patent extension
- Additional patent applications filed – potential term to 2038

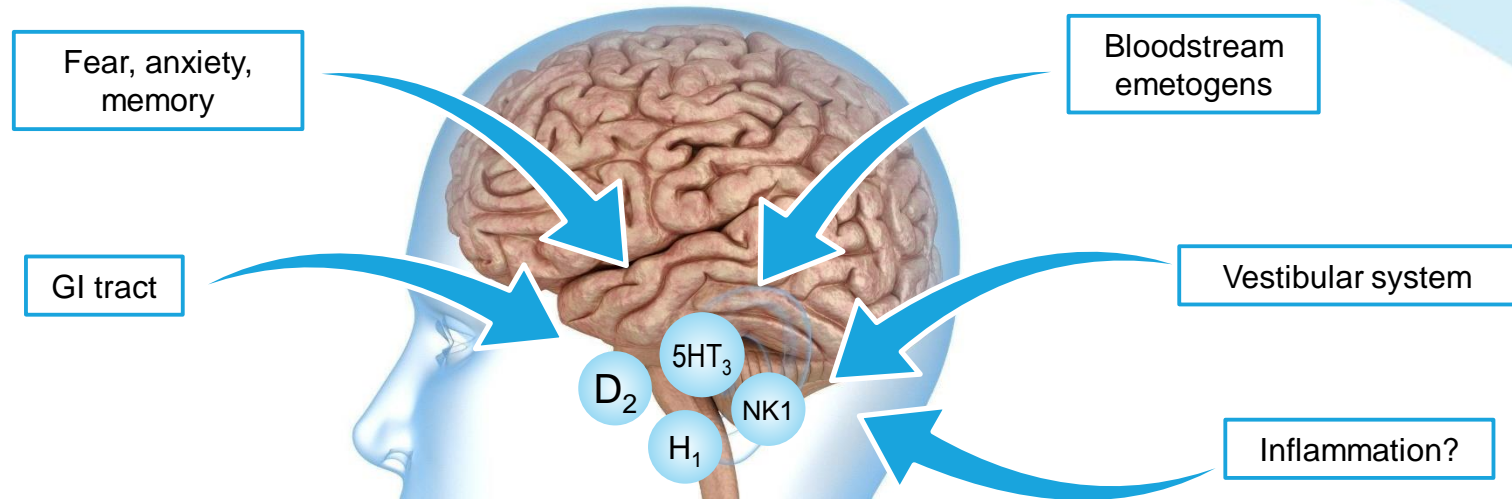
## 2018 operational highlights

- IPO and listing on Euronext Brussels raised net proceeds of £34.1m in March
  - Key to funding pre-commercial activities and finalising development work
- US infrastructure established in preparation for commercialising BARHEMSYS™, pending regulatory approval
  - 35 highly experienced sales, marketing, regulatory and operations professionals in place
  - Platform key to support direct sales force of 60 (increasing to 100), upon launch
- Revised target PDUFA review date of 5 May 2019 for BARHEMSYS NDA
  - Unique label sought addressing two key needs – rescue treatment and combination prophylaxis
  - Complete Response Letter received 5 October 2018 – deficiencies at pre-approval inspection at API supplier, no issues cited over safety or efficacy
  - Rapid re-submission (5 November) and acceptance
  - **Continue to plan for launch 1H2019**
- Positive Phase 3 trial results published in leading peer-reviewed journals
  - Additional safety study adds supportive data
- Board strengthened with appointments of Dr John Brown and Edward Borkowski

## Financial highlights

- Loss after tax of £15.5m (2017: £6.2m) with increases reflecting costs relating to Euronext listing and preparations for the commercialisation of BARHEMSYS™ in the US:
  - R&D expenses (£2.3m higher at £3.8m)
  - G&A expenses (£2.8m higher at £4.3m)
  - Sales and marketing costs (£6.9m higher at £6.9m)
- IPO raised net proceeds of £34.1m in March 2018
- New \$30m term loan facility secured with Hercules Technology Growth Capital
  - \$10m drawn in June 2018 and existing Silicon Valley Bank loan (£5.2m) repaid
- Strong cash position at year end of £29.4m (2017: £3.1m)

# Nausea & vomiting is a complex process managed with combinations of antiemetics



- Multiple pathways involved, including:
  - Serotonin ( $5-HT_3$ )
  - Dopamine ( $D_2$ )
  - Inflammatory mediators
  - Substance P ( $NK1$ )

- Previous gold standard in PONV was  $D_2$  antagonist droperidol, now rarely used due to safety issues

- Current standard-of-care:  $5-HT_3s \pm$  corticosteroids
- $NK1s$  added in CINV

- Despite this
  - ~One third of surgical patients still get PONV
  - Up to 50% of cancer patients get CINV

Dopamine blockade is a key mechanism, but no longer served by current antiemetics

# An effective and safe 3<sup>rd</sup> antiemetic mechanism is required

## PREVENTION

Assess risk factors: Female, Prior history, Non-smoker, Opioid pain control			
Prophylaxis	Low risk (0/1)	Medium risk (2)	High risk (3 or 4)
	No antiemetic “Wait & see” and treat if needed	Give one antiemetic	Give multiple antiemetics from different mechanisms of action

~90% of patients get 5-HT<sub>3</sub>, ~80% 2<sup>nd</sup> drug get steroid, options very limited when 3<sup>rd</sup> drug needed

## TREATMENT

Approximately 30% of surgical patients still get PONV even after prophylaxis		
Treatment	No prophylaxis given	Prophylaxis given but patient suffers PONV
	Treat with any available antiemetic	Treat using an antiemetic from a mechanism that has not been given prophylactically

Can't use 5-HT<sub>3</sub> in 90%, can't use steroids too slow  
Rescue options extremely limited a 3<sup>rd</sup> drug is acutely needed

## High incidence of PONV, increasing hospital costs and reducing income potential

Common complication of surgery (30-80%)

Increases morbidity and is a driver for ERAS protocols to improve mobilisation

25%

increase in length of stay

Increases hospital costs

Unanticipated & extended in-patient hospital stays and extended time in PACU

~\$2,300

per day

Distressing to patients

Patient satisfaction linked to income and used as a marketing tool

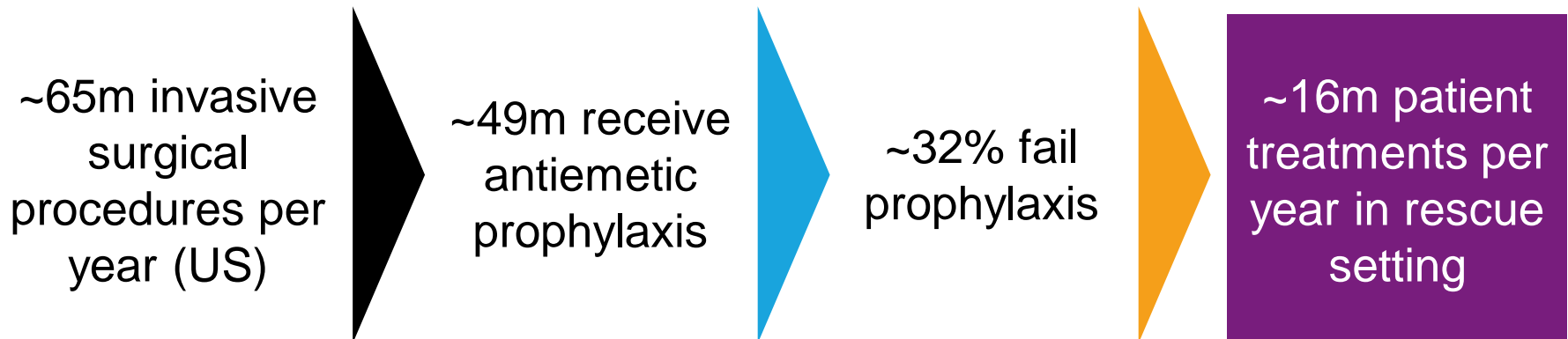
1st

over pain

Better PONV management can therefore reduce hospital costs and optimise hospital income



## Key market segment of PONV, rescue treatment, is not being adequately addressed



Patients currently receive 2 rescue doses giving a total addressable rescue market of up to ~32 million doses

## No drugs currently indicated for rescue treatment

- “When rescue therapy is required, the antiemetic should be chosen from a **different therapeutic class** than the drugs used for prophylaxis” (Consensus Guidelines)
- 90% of US prophylaxis includes a 5-HT<sub>3</sub> antagonist

And yet...

- 69% rescue patients receive a 5-HT<sub>3</sub> (against guidelines, contrary to label) and
- **No drug currently indicated for rescue treatment of PONV**
- **No drug shown to be effective for rescue in controlled clinical trials**

Major unmet need for effective, safe antiemetic (not 5-HT<sub>3</sub> or steroid) for rescue treatment

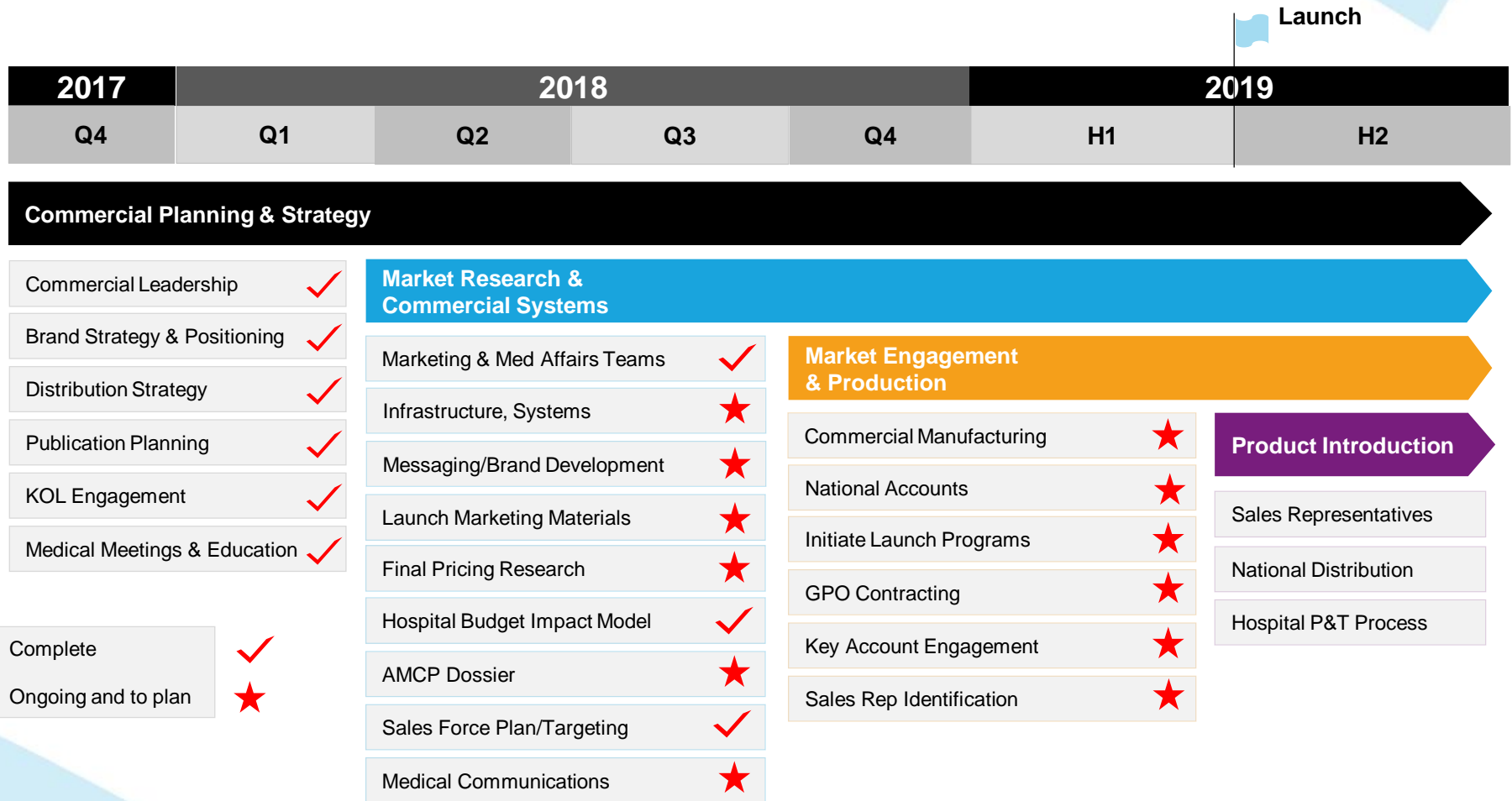
## BARHEMSYS™ clinical and regulatory overview

- FDA issued a Complete Response Letter 5 October 2018
  - No issues cited with respect to BARHEMSYS safety or efficacy or proposed label
  - Sole issue related to deficiencies at Contract Manufacturer of API
  - Following submission of CAPA by manufacturer, NDA re-submitted 5 November
  - **PDUFA date 5 May 2019**
- Broad and unique proposed label
  - Treatment of established PONV (including after failed 5-HT<sub>3</sub> prophylaxis) with 10 mg single dose
  - Prophylaxis of PONV (alone or in combination) with 5 mg single dose
- Comprehensive and robust NDA package of 8 clinical trials (North America, Europe)
  - **Two positive pivotal studies in PONV rescue/treatment plus two positive pivotal studies in PONV prophylaxis**
  - Two further supportive prophylaxis studies, thorough QT study: below FDA threshold of concern, clinical pharmacology study with radio-labelled drug
- Extensive safety and efficacy database
  - More than 3,000 patients enrolled, ~2,000 received BARHEMSYS

 **Barhemsys**<sup>™</sup>  
(amisulpride) injection 2.5mg/mL

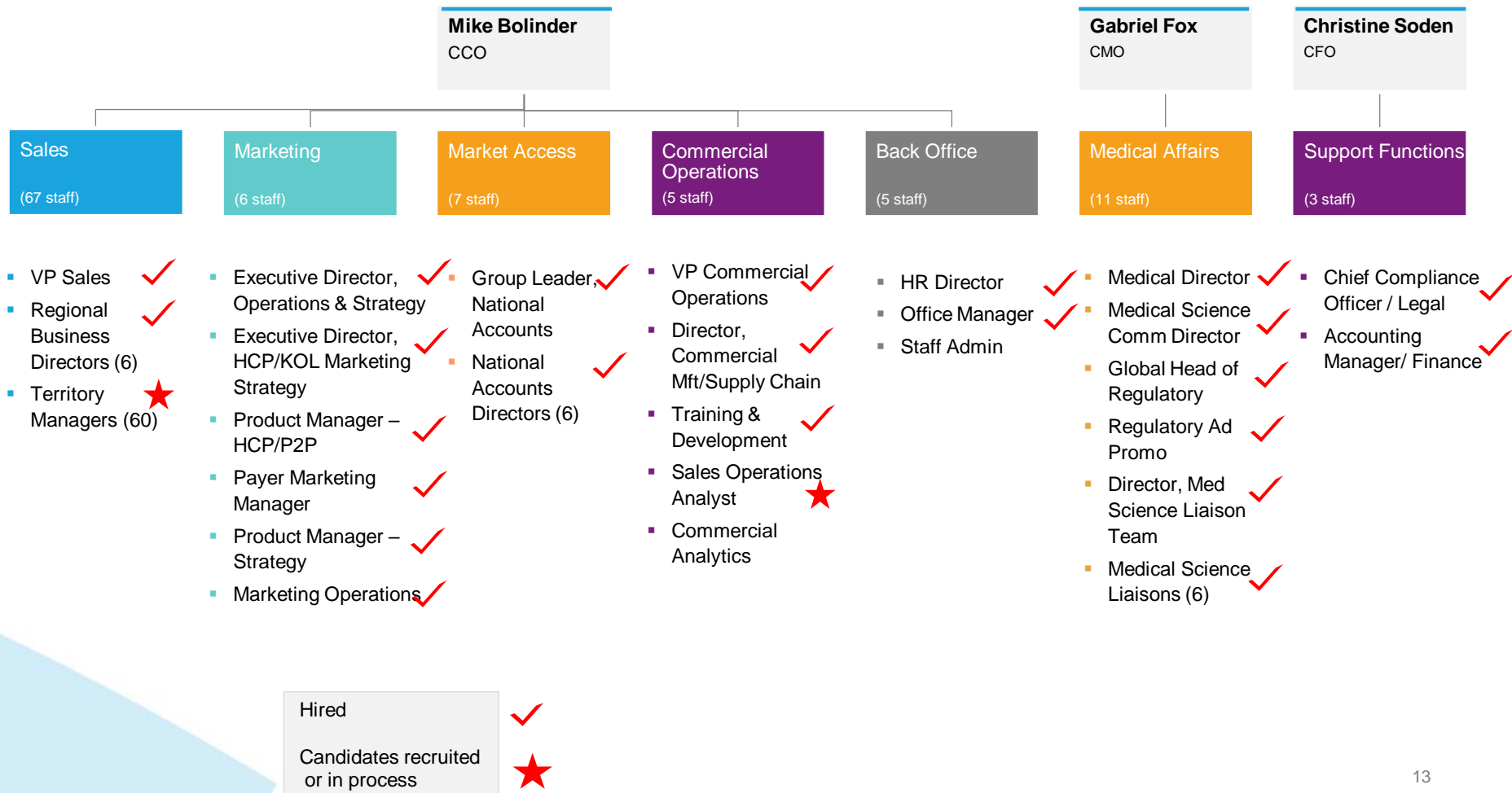


# BARHEMSYS US launch readiness plan

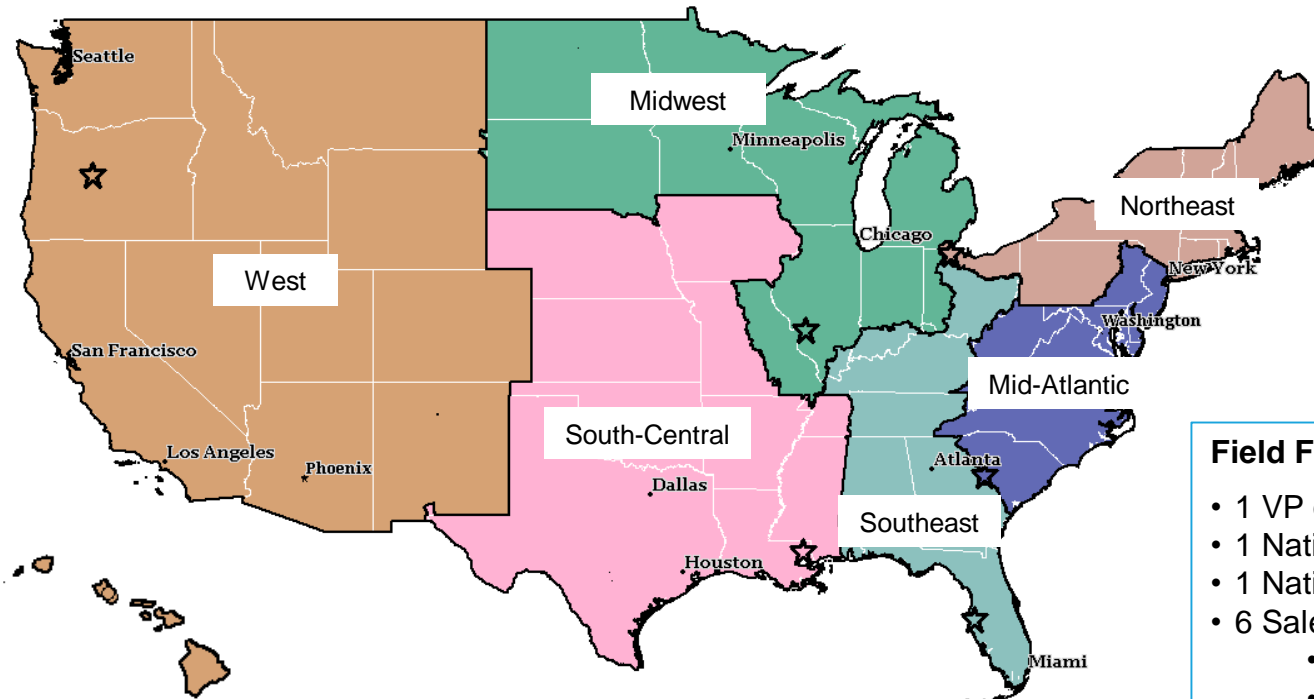


Key launch workstreams completed and ongoing

# US team hiring on track for launch and mostly completed with exception of the sales force



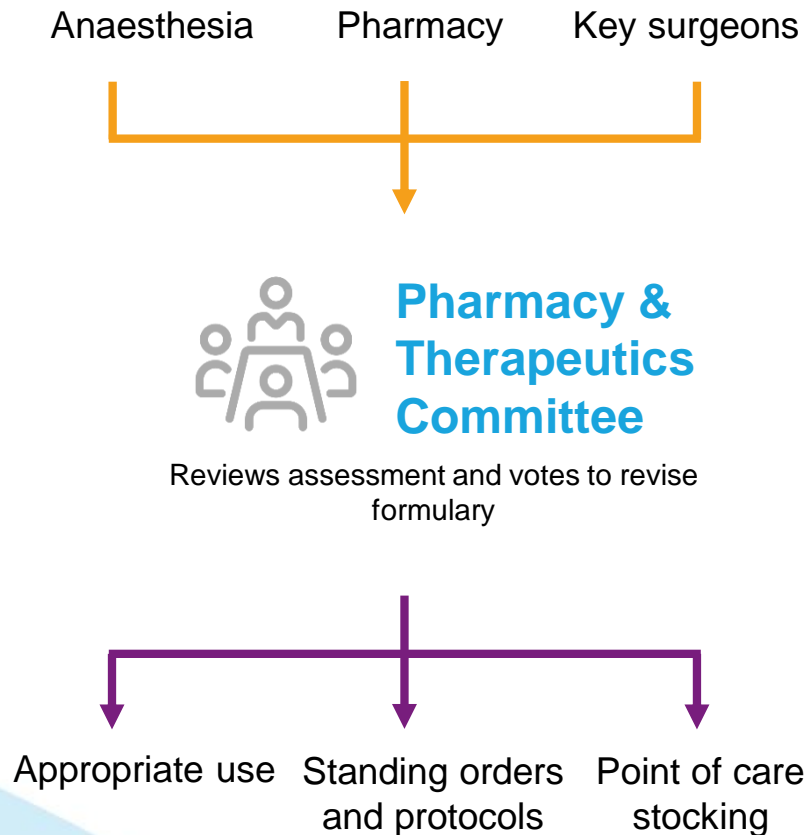
# Planned US field force deployment



## Field Force Design

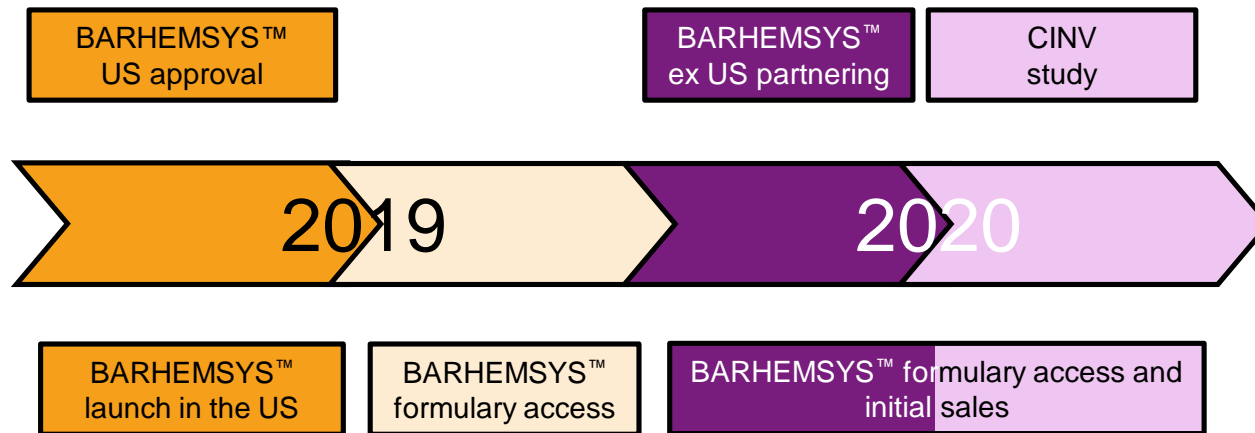
- 1 VP of Sales
- 1 National Accounts Group Leader
- 1 National MSL Group Leader
- 6 Sales Regions each with:
  - 1 RBD
  - 1 MSL
  - 1 National Account Director
  - 10 Hospital Territory Managers

## Plan for formulary access and pull through



- Real unmet need
  - No drug approved for rescue treatment
- Paid for through capitated fixed fee for surgical procedure - “the DRG”
- Key to demonstrate pharmacoeconomic benefit
- Key to have appropriate restrictions on use
  - Use following failed standard of care
- Price for access on >80% of hospital formularies

## Significant near-term news flow







Questions?