

Acacia Pharma Group plc

May 2021

Delivering innovative products to
enhance surgical patients' recovery

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Acacia Pharma Group – in Summary

BARHEMSYS® – FDA approved for PONV, launched late 2020

- Broad label for prevention and treatment of Post-Operative Nausea and Vomiting (PONV)
- Only agent approved for ‘Rescue’ of ~16m patients p.a. in US with PONV after generic antiemetics fail¹
- PONV “rescue” is an estimated \$2.7 billion annual total addressable market²

BYFAVO™ – In-licensed, FDA approved for procedural sedation, launched Jan 2021

- Indicated for procedural sedation in adults – launch benefitting from shared value proposition
- Key target: 40m procedures a year in US, including 25m GI procedures³
- Estimated >\$1.5 billion annual total addressable market⁴

Commercialization began in 2H 2020 and showing good progress

- Strong sales, marketing, medical affairs, commercial operations teams in place
- Sales team deployed against ~900 initial targeted hospital accounts since mid-October
- Drug shortages and surgery backlog creating pent-up demand (heightened by Covid)

¹ Calculations based on available procedural data, applied Compound Annual Growth Rate and quantitative market research responses as follows: National Hospital Discharge Survey, 2006; National Survey of Ambulatory Surgery, 2006 (as revised in 2009); Source Healthcare; NCHS 2005; Life Science Strategy Group, LLC Market Research; Apfel et al., 2004. ² Based on the calculations in (1) multiplied by the number of doses per patient at a WAC price of \$85 per 10mg dose. ³ iData Research, US Market Report Procedure Numbers for Gastrointestinal Endoscopic Devices February 2019; American Society of Anesthesiologists, Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018; and Quantitative Market Research prepared by The Link Group for Cosmo Technologies (March 2019). ⁴ Based on the calculation in (4) multiplied by the number of doses per patient at a WAC price of \$39 per dose.

Leadership Team with Experience to Deliver the Vision

Mike Bolinder
CEO



- Joined 2015, became CEO 1 August 2019
- 18 years in pharma sales & marketing
- Relevant commercial experience with OFIRMEV® at Cadence/Mallinckrodt



Gary Gemignani
CFO



- Joined as CFO January 2020
- 30+ years finance experience in healthcare
- Relevant CFO experience in early commercial stage pharma



Dr Gabriel Fox
CMO



- Joined as CMO 2008
- 24 years in pharmaceutical medicine
- Relevant development and medical-marketing experience in repurposed drugs



We have been able to make significant progress in a very challenging operational environment caused by the global pandemic

“ The OR accounts for up to 65% of hospital profit margin, so this missing volume is cutting deeply into cash flow and net income. ”
– Becker’s Hospital Review¹

COVID-19 impact on hospitals and surgical centers

- Non-essential surgeries cancelled creating a significant backlog
- Physical access to hospital decision-makers even more restricted

Hospital profits have suffered and need to be restored quickly

- Surgeries and procedures are major contributors to hospital profits
- Providers need to dramatically increase throughput to regain lost profits

We believe our products and team are ideally positioned to help

- BARHEMSYS and BYFAVO can help improve patient throughput – both are now even more relevant and of greater interest to customers due to COVID
- Our strong relationships are helping us gain access to key decision-makers

¹ How to rebuild surgical revenue after COVID-19, **Becker’s Hospital Review**, accessed via <https://www.beckershospitalreview.com/strategy/how-to-rebuild-surgical-revenue-after-covid-19-even-if-you-just-lost-60-of-your-or-volume.html>



BARHEMSYS®

(amisulpride for injection)

**The first and only FDA-approved
product for PONV rescue treatment¹**

¹ FDA labels for other recommended treatments do not include treatment after failed prophylaxis. Treatment agents recommended by Society for Ambulatory Anesthesiology Consensus Guidelines (2014). Habib et al (2019): no agent has previously been shown in a prospective trial to be more effective than a placebo for treating PONV for patients who have failed prophylaxis.



BARHEMSYS® and the PONV Commercial Opportunity

BARHEMSYS Addresses the major unmet need in PONV

- BARHEMSYS is the **only FDA-approved drug for PONV rescue** after failed prophylaxis¹
- Dopamine D₂/D₃ antagonist with **broad, differentiated label**
- Offers significant **economic savings** to hospital vs current standard of care

Large US market opportunity in PONV²

- Estimated ~65m eligible surgeries annually, ~49m patients receive preventative antiemetics⁴
- Estimated **~16m patients still develop PONV and need rescue treatment**³
- **Total addressable PONV rescue market estimated at ~\$2.7 billion/year**⁴

Concentrated market, addressable by small direct sales force

- Estimated 80% of surgeries carried out in ~1,200 hospitals⁵
- 30 sales territories address accounts with greatest immediate opportunity
- **Sales team began customer engagement in mid-October**

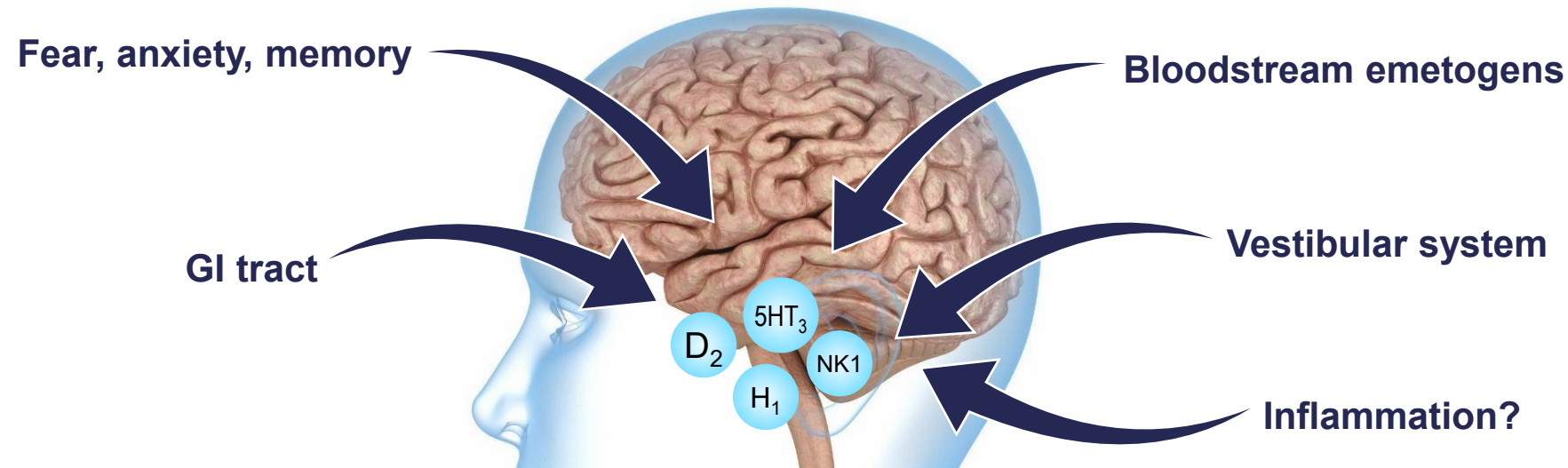
High gross profit, secure supply chain and worldwide rights

- **Cost of goods ~10% of sale price**
- Substantial product inventory to minimize supply risk
- **Worldwide rights and exploring out-licensing opportunities in OUS markets**

1 FDA labels for other recommended treatments do not include treatment after failed prophylaxis, 2 This is the belief of the Company. 3 Company market size estimates based upon: 2006 National Hospital Discharge Survey; National Survey of Ambulatory Surgery, 2006 (as revised in 2009); LSSG Quantitative Research November 2014; Apfel, NEJM 2004. Calculations based on available procedural data, applied Compound Annual Growth Rate and quantitative market research responses. 4 Based upon WAC price of \$85 per 10mg rescue dose with, on average, 2 rescue doses per patient, and the above estimates. 5 Symphony Health, Source Non Retail, August 2017 - July 2018.

Nausea and Vomiting is a Complex Process

Managed by combinations of antiemetics targeting multiple mechanisms



Multiple pathways, including:

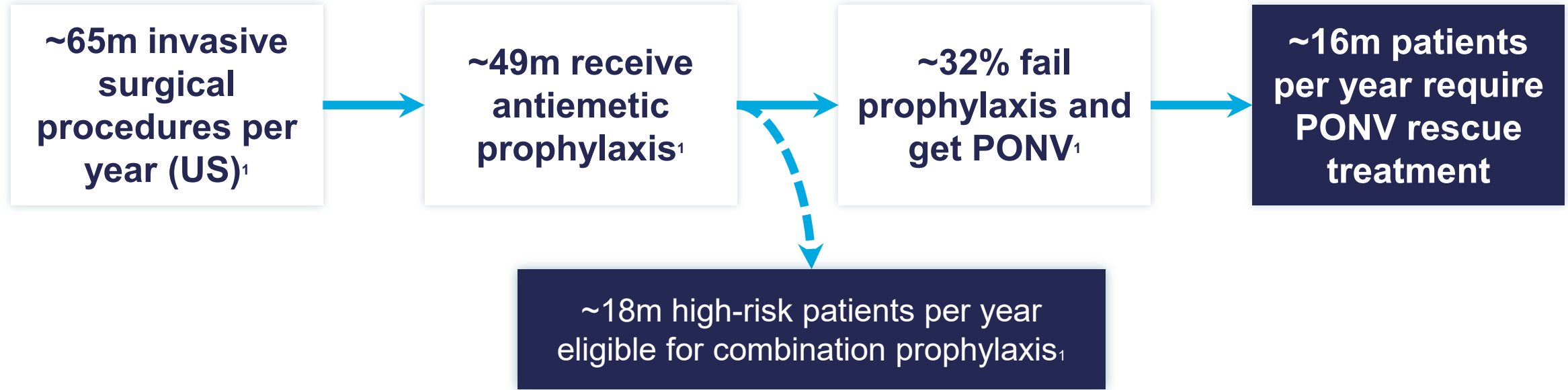
- Serotonin (5-HT₃)
- **Dopamine (D₂)**
- Histamine
- NK1

Current standard of care for PONV prophylaxis¹:

5-HT₃ antagonist
(e.g. ondansetron)
± corticosteroid

Despite this >30% of surgical patients still get PONV²

Targeting PONV Rescue Market



Total estimated addressable market in PONV rescue \approx \$2.7B per year

Secondary market in combination prophylaxis in highest-risk patients, estimated to be worth \$765M per year²

1 Company market size estimates based upon: 2006 National Hospital Discharge Survey; National Survey of Ambulatory Surgery, 2006 (as revised in 2009); LSSG Quantitative Research November 2014; Apfel et al, 2004. Calculations based on available procedural data, applied Compound Annual Growth Rate and quantitative market research responses. 2 Based on WAC price of \$85 per 10 mg rescue dose and average 2 rescue doses per patient; \$42.50 per 5 mg prophylaxis dose.

BARHEMSYS[®] is the Only FDA-Approved Product for PONV Rescue

“ When PONV prophylaxis has failed, patients should receive antiemetic treatment from a different pharmacological class to the PONV prophylaxis ”
– Consensus Guidelines¹

Antiemetic	Can't redose	Efficacy issues	Safety issues	Current share of rescue patients ⁴
Ondansetron	X ₁			69%
Dexamethasone	X ₁	X ₂		19%
Metoclopramide		X ₁	X ₁	19%
Promethazine			X ₁	11%
BARHEMSYS	✓ ₃	✓ ₃	✓ ₃	INTENT TO PRESCRIBE⁴ 61%

BARHEMSYS® – Compelling Clinical and Commercial Proposition

Only FDA-approved product for PONV rescue¹

- Only drug proven in randomized clinical trial to work in PONV rescue²
- Excellent safety profile demonstrated in clinical studies
- Also demonstrated to be effective for prevention

Throughput and health economic benefits

- 35-minute reduction in PACU stay
- 6-hour reduction in hospital stay
- Offers significant economic savings to hospital vs current standard of care

Convenient, easy to use, high margin product

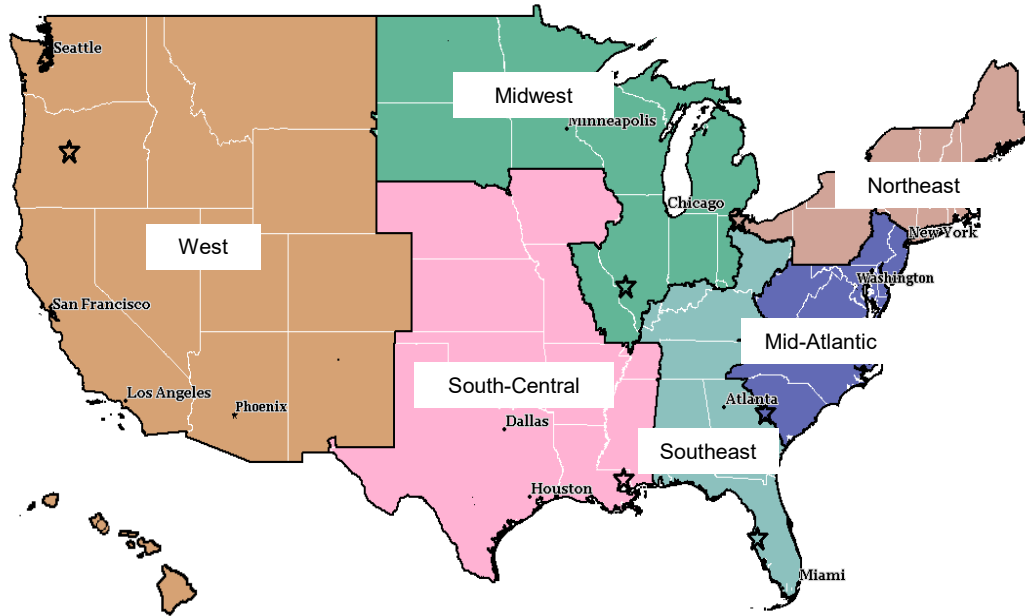
- 5-year room temperature shelf-life
- Fits in auto-dispensing (Pyxis™) machines
- Cost of goods ~10% of sale price

Helps post-COVID pressure to get through surgical backlog

- Shorter time in PACU (recovery room) allows increased surgical throughput
- Better efficacy and safety means better recovery and patient experience



Highly Experienced Commercial Team is Driving Formulary Adoption



Team has direct experience successfully launching OFIRMEV into same market to same key customers

Field Force Design

- 1 SVP of Field Commercial Teams
- 1 National Accounts Group Leader
- 1 National MSL Group Leader
- 6 Sales Regions each with:
 - 1 RBD
 - 1 MSL
 - 1 National Account Director
 - 5 Hospital Territory Managers

Commercial Leadership Team

28+

Years avg
industry

60+

Launches

Sales Leadership Team

22

Years avg
industry

18+

Years
hospital

National Accounts Team

24

Years avg
industry

21+

Years
hospital

Medical Science Liaison Team

22

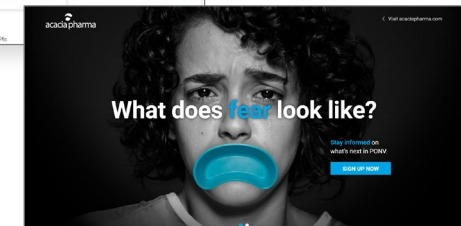
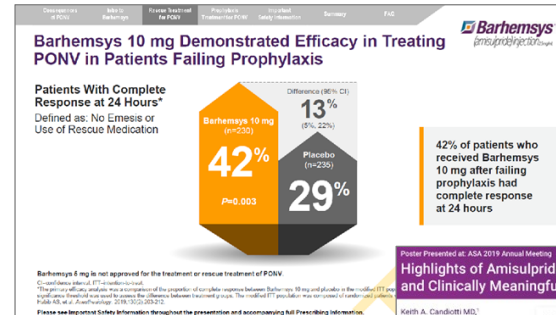
Years avg
industry

10+

Years as
MSL

BARHEMSYS - Robust Commercial Engagement Creating Traction

- Robust WorseThanPain/ Disease state campaign highlighting unmet need in PONV (worsethanpain.com)
- Medical congress engagements: ~ 750 symposia attendees and 700+ leads generated
- Peer-to-peer programs: 70+ programs with ~750 attendees (live, virtual and on demand) since launch
- All promotional materials available both physically and digitally to meet customers needs
- Digital brand engagements in the most trusted anesthesia publications with 89% readership (51K members)



Formulary Reviews of BARHEMSYS Began 2H 2020

Post-COVID pressures improve our access to key decision-makers

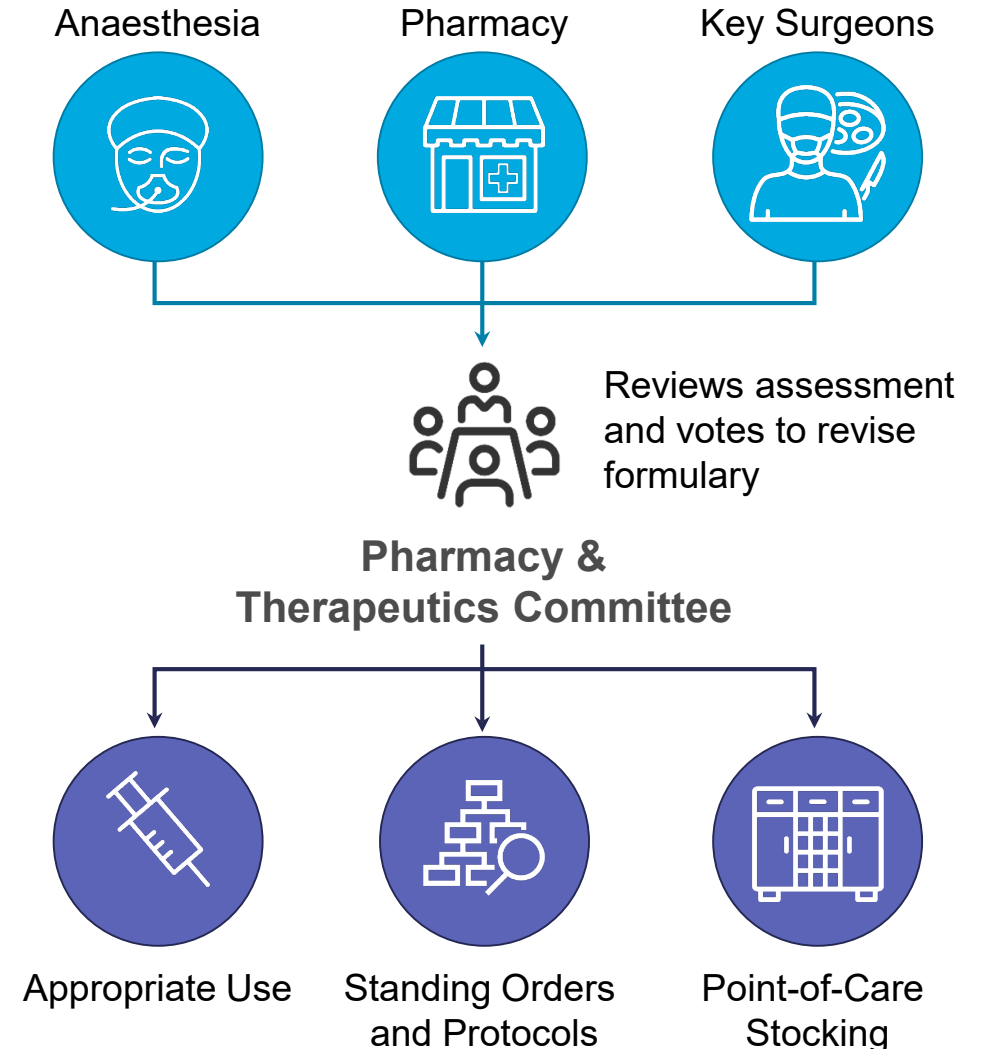
- Surgery backlogs are major issues for US hospitals
- Value of BARHEMSYS and BYFAVO in improving throughput facilitates our access to key decision-makers

Demonstrate unmet need, appropriate use & health economic benefit

- Highlight current unmet needs with existing products
- Educate on efficacy and safety data for our products
- BARHEMSYS and BYFAVO can provide economic savings to hospital vs current standard of care

Formulary adoption and pull-through

- P&T Committee approval typically takes 9-12 months on average
- Protocols, standing orders and point-of-care supplies drive sales pull-through





BYFAVO™

(remimazolam) for injection

Rapid onset/offset procedural
sedative with favorable safety profile

Procedural Sedation Market Opportunity



~40 million¹

procedures each year
requiring sedation



~25 million

GI procedures performed
each year²



>80%

GI procedures have sedation administered
by an anesthesia provider³



>6 million

Interventional
Radiology⁴



~4 million

Ophthalmic
Procedures⁵



~1 million

Bronchoscopy⁶



~1.5 million

Cosmetic/
Plastic Surgery⁷

Total addressable market in procedural sedation >\$1.5B/year⁸

1 Calculations based on available procedural data, applied Compound Annual Growth Rate and quantitative market research responses. 40 million includes other opportunities: CC (MHA National) EP (dicardiology), Dental (areadentist), Plastic Surgery (American Society of Plastic Surgeons), ECT (MHA National). 2 iData Research, US Market Report Procedure Numbers for Gastrointestinal Endoscopies Nov 2016; CDC website. 3 Quantitative Market Research prepared by The Link Group for Cosmo Technologies (March 2019). 4 Report on interventional Radiology November/December 2007. 5 American Medical Association 2011. 6 iData Bronchoscopy 2019 report. 7 American Society of Plastic Surgeons 2018. 8 Based on the calculation in iData Research, US Market Report Procedure Numbers for Gastrointestinal Endoscopic Devices February 2019; American Society of Anesthesiologists, Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018; and Quantitative Market Research prepared by The Link Group for Cosmo Technologies (March 2019) multiplied by the number of doses per patient at a WAC price of \$39 per dose.

BYFAVO Addresses Unmet Need in Procedural Sedation

Propofol

*fast acting but
significant safety issues^{1,2}*

- Rapid onset and offset anesthetic with narrow therapeutic index¹
- **Dose-related cardiorespiratory depression**, pain at injection site¹
- Non-linear dosing effects due to individual variability⁴
- **Needs continuous monitoring by anesthesiologist, no reversal agent²**
- Lipid formulation susceptible to bacterial contamination⁴

Midazolam

*better safety profile but
longer onset and recovery^{1,2}*

- Benzodiazepine sedative, reversible by flumazenil¹
- **Slower onset and offset^{2,3}**
- Metabolized by cytochrome system; individual variability affects sedation¹
- Active metabolite can accumulate and cause prolonged sedation²
- **Risk of respiratory depression¹**

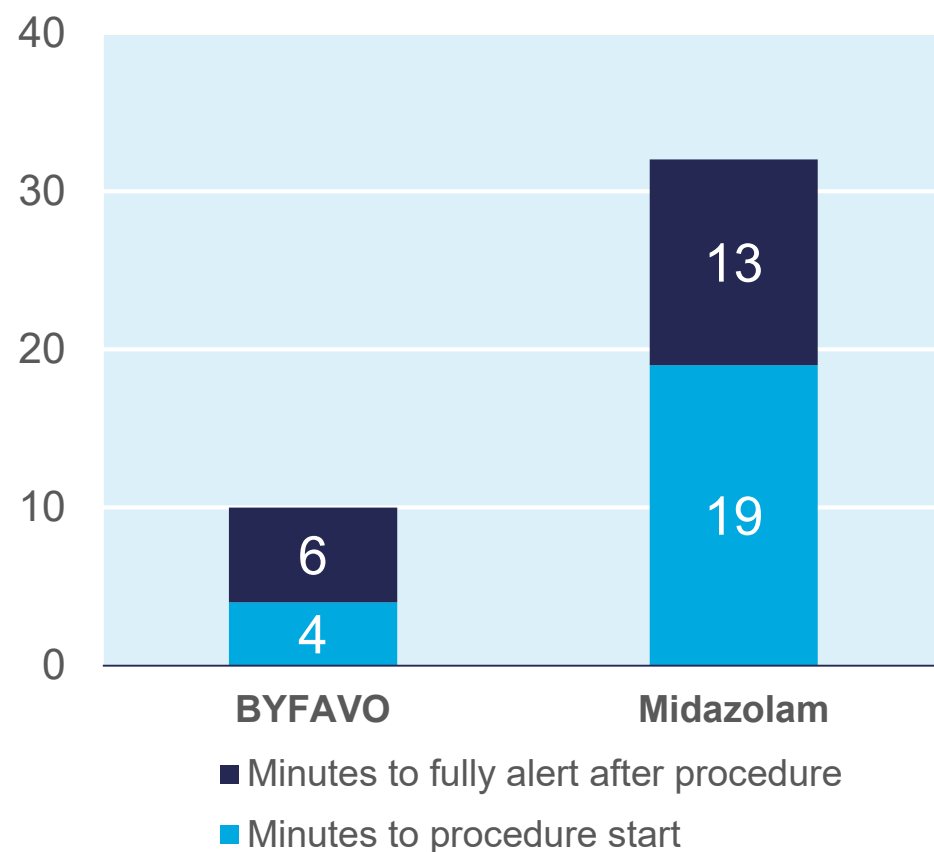
BYFAVO

*fast acting AND favorable
safety profile^{1,2}*

- **Rapid onset/offset^{1,2,3}**
benzodiazepine
- Rapid biotransformation into inactive metabolites via non-specific tissue esterases – not dependent on liver enzymes¹
- **Predictable behavior, no pharmacokinetic drug interactions⁵**
- **Reliable sedation, reliable safety profile¹**
- Reversible by flumazenil¹

Rapid Onset/Offset with a Favorable Safety Profile¹

Average Procedure Timings¹



Key Adverse Events¹

	BYFAVO	Midazolam
Any adverse event	74%	91%
Vascular disorders	62%	81%
Cardiac disorders	18%	26%
Respiratory disorders	4%	6%

BYFAVO™ – Compelling Clinical and Commercial Proposition

Approved with a broad label

- Indicated for **procedural sedation in adults** in procedures lasting 30 mins or less
- Substantial clinical data package shows **compelling efficacy and safety** in colonoscopies and bronchoscopies, including least fit patients

Throughput and health economic benefits

- Rapid onset/offset enables shorter procedure times and greater patient throughput for hospitals and surgical centers compared to other recommended treatments

Commercial synergy with BARHEMSYS

- Target prescribers: **anesthesiologists and proceduralists in hospitals and ambulatory surgery centers**

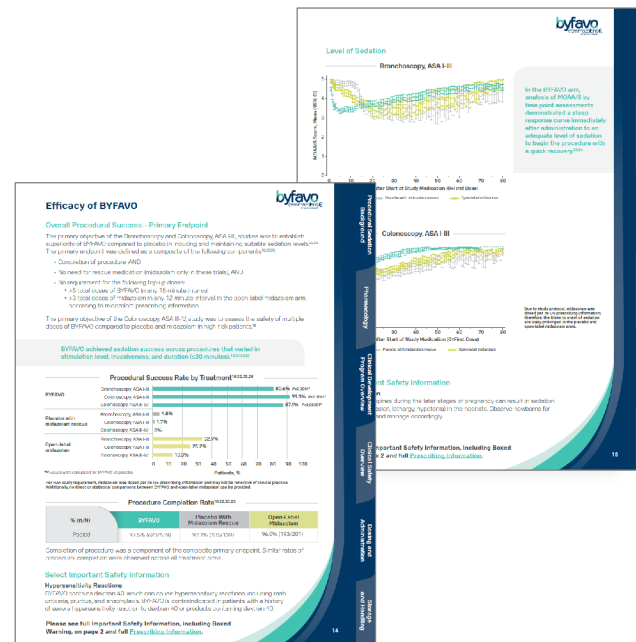
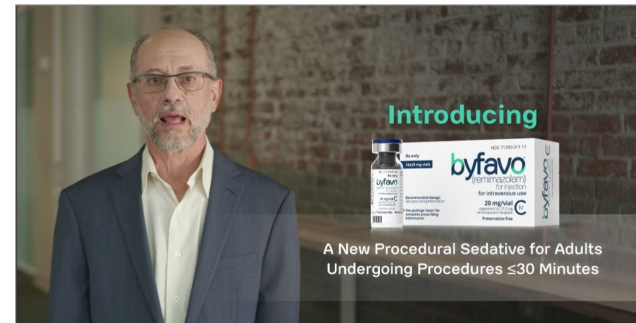
Helps post-COVID pressure to alleviate procedural backlog

- **Shorter procedure times allow increased procedural volumes**
- Both midazolam and propofol currently on FDA drug shortages list



BYFAVO - Launching the First New Sedative in the US for 20 years

- Promotional programming (National satellite) roll out, featuring anesthesia investigator, and live peer to peer in Q2
- Full congress plan across Anesthesia, Pharmacy, and including key GI and Pulm congresses
 - Medical congress engagements: ~ 120+ symposia attendees and 400+ booth leads generated
 - Anesthesia, GI and Pulm conferences the remainder of 2021 include symposia and booth engagements
- All promotional materials available in both digital and physical format
- Non-personal promotional efforts, including direct mail are being initiated
 - Direct email, banner ads, paid search and expanded web site



byfavo
remimazolam C

A Short-Acting Sedative for Procedures 30 Minutes or Less

An Intentionally Designed Benzodiazepine

Chemical structure diagram showing the conversion of remimazolam to its active form.

Indication

For sedation of patients undergoing procedures lasting 30 minutes or less.

Contraindications

Severe hepatic impairment, severe respiratory impairment, severe hypotension, severe hypoxemia, severe hypothermia, severe hypotension, severe hypoxemia, severe hypothermia.

Warnings

Respiratory depression, hypotension, hypoxemia, hypothermia, hypotension, hypoxemia, hypothermia.

Important Safety Information

Respiratory depression, hypotension, hypoxemia, hypothermia, hypotension, hypoxemia, hypothermia.

Dosing and Administration

Recommended Dosage for Procedural Sedation

Induction	Maintenance (as needed)
For Adult Patients	Administer 5 mg intravenously over a 1-minute time period.
For ASA III and IV Patients	Administer 2.5 mg intravenously over 1 minute based on the general condition of the patient.

Preparation and Administration

Once removed from packaging, protect vials from light. To reconstitute BYFAVO for injection:

- Add 8.2 mL sterile 0.9% NaCl Injection, USP to the vial.
- Direct the stream of solution toward the wall of the vial.
- Gently swirl the vial (do not shake) until the contents are fully dissolved.

The reconstituted product will deliver a final concentration of 2.5 mg/mL. Reconstituted BYFAVO can be stored in the vial for up to 8 hours under controlled room temperature at 20°C to 25°C (68°F to 77°F). Discard any unused portion.

Important Safety Information

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION AND RISK OF CONCOMITANT USE WITH OPIOID ANALGESICS

Please see full Boxed Warning on the next page.



Financials

Acacia Pharma Group – Financial Summary

Listed on Euronext Brussels exchange

- IPO in March 2018
- ~99.7m shares outstanding
- ~80% free float

Cash position

- Cash balance as of December 31, 2020 was \$46.7m
- Equity financing in February 2021 with gross proceeds of €27m (~\$33m)

Debt

- Recently repaid the outstanding Hercules loan
- Cosmo ~€25m outstanding loan

Summary

In Summary

Our products address **unmet medical needs** in therapeutic areas with **large total addressable market opportunities** (~\$2.7B in PONV rescue, >\$1.5B in procedural sedation)

The team is making **tremendous commercial progress** despite a very challenging operating environment due to the global pandemic

We have seen a **great response from customers in the early stages of launch adding our products to formulary** with positive customer feedback on both products so far

While the environment remains very dynamic, **we believe we should be able to benefit from a relaxation of restrictions and a rebound in procedural volumes in the second half of this year**

We believe we have **the right team, with the right experience** to continue to drive the successful commercial launch for both products this year

Q & A