UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 31, 2022**

Eagle Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36306**	**20-8179278**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

50 Tice Boulevard, Suite 315 **Woodcliff Lake, NJ** (Address of principal executive offices)	**07677** (Zip Code)

Registrant's telephone number, including area code: **(201) 326-5300**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock (par value $0.001 per share)	EGRX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On March 31, 2022, Eagle Pharmaceuticals, Inc., or the Company, released an investor presentation relating to the Company's proposed transaction to acquire Acacia Pharma Group plc, as well as products and product candidates updates. The Company will refer to the presentation during its previously announced investor conference call taking place on March 31, 2022, at 8:30am ET, and the presentation may be used from time to time in meetings with investors.

A copy of the above-referenced presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The information furnished pursuant to Item 7.01 of this current report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing. The furnishing of the information in this Current Report on Form 8-K is not intended to, and does not, constitute a determination or admission by the Company that the information in this Current Report on Form 8-K is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Presentation of the Company, dated March 31, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 31, 2022

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Scott Tarriff
Chief Executive Officer

Exhibit 99.1

Forward-Looking Statements

This presentation contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other se
Forward-looking statements are statements that are not historical facts. Words and phrases such as “anticipated,” “forward,” “will,” “would,” “may,” “remain,” “p
“expected,” “believe,” “plan,” “near future,” “belief,” “guidance,” and similar expressions are intended to identify forward-looking statements. These statements
limited to, statements regarding future events such as: the expected structure, anticipated synergies, terms, timing and closing of the transaction with Acacia
strategic fit of BARHEMSYS and BYFAVO with Eagle’s specialized hospital-based salesforce; statements regarding the estimated addressable market size fo
BYFAVO, Landiolol and other products or product candidates; Eagle’s marketing, product development, partnering and growth strategy, including relating to t
of BARHEMSYS and BYFAVO, and the ability of Acacia’s technology and know-how to help Eagle achieve its strategy; the ability of Eagle to expand the appl
products; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company’s product candidates, including Landiolo
BARHEMSYS, BYFAVO and Landiolol to address unmet clinical needs; the ability of BARHEMSYS to offer significant economic savings to hospitals and amb
ability of BYFAVO to offer potential health economic benefits and enable shorter procedure times and greater patient throughput; the potential market opportu
products or product candidates, including for BARHEMSYS, BYFAVO or Landiolol; expected patient volumes; the ability of the proposed transaction to create
and the ability of the Company’s executive team to execute on the Company’s strategy and build stockholder value; expectations regarding the Company’s fu
ability to generate significant cash in the future; and the ability of the Company’s product candidates to deliver value to stockholders. All of such statements ar
risks and uncertainties, many of which are difficult to predict and generally beyond the Company’s control, that could cause actual results to differ materially fr
in, or implied or projected by, the forward-looking information and statements. Such risks and uncertainties include, but are not limited to: the risk that the Com
with Acacia is not consummated or that the benefits of the transaction are not realized; the impacts of the COVID-19 pandemic and geopolitical events such a
Ukraine, including disruption or impact in the sales of the Company's marketed products, interruptions or other adverse effects to clinical trials, delays in regul
manufacturing and supply chain interruptions, adverse effects on healthcare systems, disruption in the operations of the Company's third party partners and d
global economy, and the overall impact of the COVID-19 pandemic or other events on the Company's business, financial condition and results of operations;
Company will incur unforeseen expenses or liabilities or other market factors; whether the Company will successfully implement its development plan for its p
delay in or failure to obtain regulatory approval of the Company's or its partners’ product candidates; whether the Company can successfully market and comm
candidates; the success of the Company's relationships with its partners; the availability and pricing of third party sourced products and materials; the outcom
involving any of its products or that may have an impact on any of the Company’s products; successful compliance with the FDA and other governmental regu
product approvals, manufacturing facilities, products and/or businesses; general economic conditions, including the potential adverse effects of public health i
COVID-19 pandemic and geopolitical events, on economic activity and the performance of the financial markets generally; the strength and enforceability of t
intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition
into the market; the risks inherent in the early stages of drug development and in conducting clinical trials; the outcome of Acacia’s shareholder vote, the High
closing conditions; and factors in addition to the foregoing that may impact the Company’s financial projects and guidance, including among other things, any
development transactions, acquisitions, restructurings or legal settlements, in addition to any unanticipated factors, that may cause the Company’s actual resu
materially differ from its projections and guidance; and those risks and uncertainties identified in the “Risk Factors” section of the Company's Annual Report o
year ended December 31, 2021, filed with the Securities and Exchange Commission (the “SEC”) on March 8, 2022, and its other subsequent filings with the S
cautioned not to place undue reliance on the forward-looking statements contained in this presentation, which speak only as of the date hereof. Except to the
law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof.

Agenda

	Topic	Presenter
1	Eagle Strategic Update	Scott Tarriff & Brian Cahill
2	BARHEMSYS® & BYFAVO® Overview	Michael Moran & Michael Greenberg
3	Landiolol Overview	Michael Moran & Michael Greenberg
4	Q&A	

EAGLE PHARMACEUTICALS

Eagle's Strategy is to Evolve into:

A Diversified, Branded Pharmaceutical Company with Assets in Oncology + A

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Proposed Acacia Transaction Rationale

Eagle's proposed acquisition of Acacia is a significant step in our journey to become a leading pharmaceutical company focused on innovative hospital and oncology products

- ✓ Opportunity for Eagle's highly skilled hospital-based salesforc and promote BARHEMSYS and BYFAVO, and to leverage lor relationships to realize the full potential of these assets, assur successful closing of proposed transaction
- ✓ Commercial stage, NCE products with long patent duration w complementary and diversified revenue streams to Eagle
- ✓ Strong financial position enables Eagle to invest in this opport potential significant value creation
- ✓ Anticipated compelling peak commercial opportunity in both F products:
  - BARHEMSYS is the only FDA-approved drug for PONV re offers potentially significant savings to hospitals versus the standard of care
  - BYFAVO addresses an unmet need in procedural sedation fast-acting and favorable safety profile versus other current

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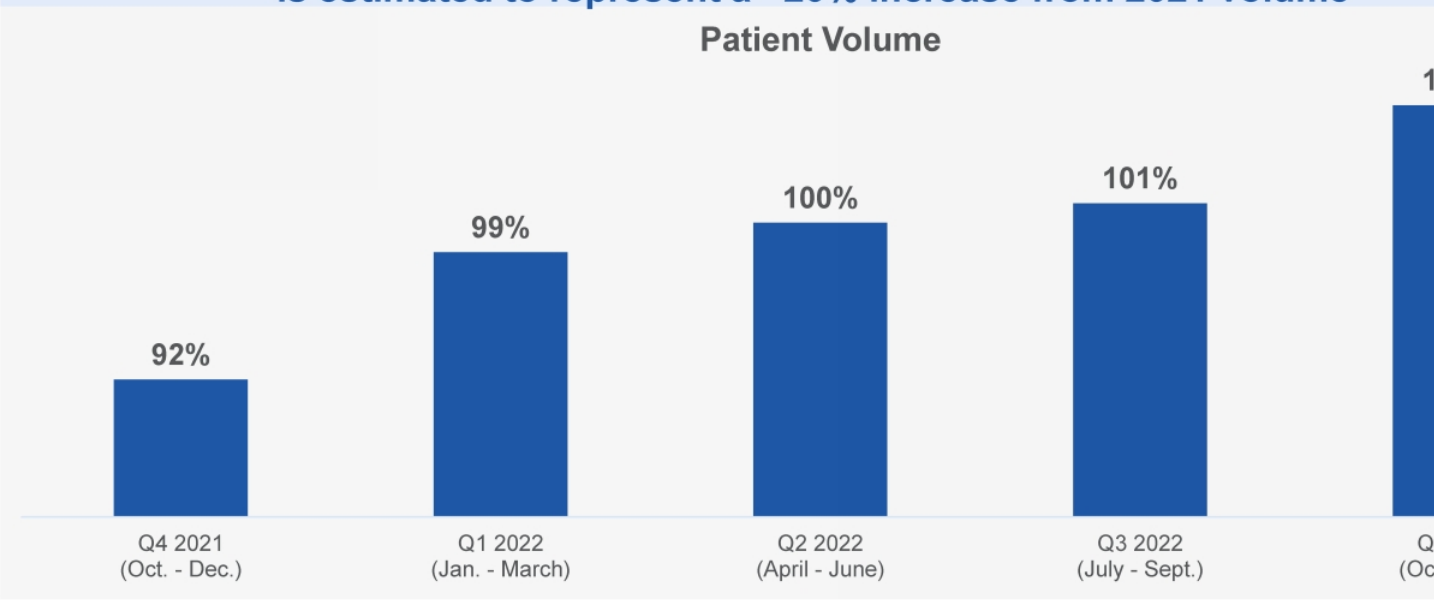
Hospital Patient Volume is Slowly Returning with Physicians Expe
Volumes to Exceed Pre-COVID Levels in the 2nd Half of 2022

100% of pre-COVID patient volume during 2022 is estimated to represent a ~20% increase from 2021 volume[1]



1 Provided by The Alexander Group (AGI), March 21, 2022

*Based on responses

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Eagle Pharmaceuticals Financial Position, Portfolio & Pipe

Strong Financial Position

As of 12/31/2021

Share Buybacks
$230M or 24%

Net Working Capital
of **$98.2M**

Total Cash and Cash
Equivalents **$97.7M**

Current Portfolio	Proposed Transaction
BENDEKA®	BARHEMSYS®
RYANODEX®	BYFAVO®
BELRAPZO®	
TREAKISYM® Symbio Japan	
Recently Launched	
Vasopressin	
Pemfexy™	

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**Strategic collaborati

Proposed Transaction Details

Transaction Terms

- 75% cash, 25% stock transaction, values Acacia at approximately €94.7 million ($104 million)
- Acacia shareholders would receive total consideration of €0.90 per share in exchange for each Aca share consisting of the following:
  - Cash consideration of €0.68 per share, funded by existing cash resources
  - 0.0049 shares of Eagle common stock
- Eagle would guarantee Acacia's €25 million outstanding term loan at closing

Estimated Ownership at Closing

- Existing Eagle shareholders: 96.2%
- Acacia shareholders: 3.8%

Voting Agreements

- Certain Acacia directors, executive officers and major shareholders, representing approximately 5(outstanding ordinary shares, have entered into irrevocable undertakings to vote in favor of the tran

Anticipated Timing

- Transaction expected to close late Q2 2022, subject to closing conditions including, among others, requisite approval of Acacia's shareholders and the sanction of the High Court of England and Wal 2022, which date may be extended by mutual agreement of the parties*

*There is no assurance that the proposed transaction will be consummated on the proposed terms or timing or at all

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Additional Financial Information

- Transaction expected to be earnings accretive in 2024
- Eagle plans to continue Acacia's post marketing commitme for Phase IV pediatric studies on BARHEMSYS and BYFAVC
- Acacia net operating losses expected to provide cash tax sl
- Ex-US IP may provide future favorable effective tax rate

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BARHEMSYS® and BYFAVO® Overview

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BARHEMSYS®

(amisulpride for injection)

The first and only FDA-approved product for PONV rescue treatment[1]

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 a 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.

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BARHEMSYS® and Potential PONV Commercial Opportuni

BARHEMSYS addresses the major unmet need in PONV[2]	• BARHEMSYS is the **only FDA-approved drug for PONV rescue** after failed propl • Selective dopamine D_2/D_3 antagonist with **broad, differentiated label**
Large but concentrated US estimated addressable market in PONV[2]	• ~70m surgical patients annually in the US receive prophylactic treatments, ~10m br cases annually in the US[3] • **Total addressable prophylactic antiemetic market estimated at ~$2.3 billion/ye** • Estimated 80% of surgeries carried out in ~1,200 hospitals annually in the US[4]
Established supply chain & worldwide rights[2]	• Substantial product inventory to help minimize supply risk • EU marketing authorization application filed, review process expected to be compl • **Worldwide rights would allow for potential exploration into future out-licensir opportunities outside US**
Can help with COVID surgical backlogs[2]	• Non-essential surgery cancellations create significant backlogs • **Shorter time in PACU (recovery room) can help increase surgical throug**

1 FDA labels for other recommended treatments do not include treatment after failed prophylaxis, 2 This is the belief of the Company. 3 Based on market research performed by or for Eagle .
4 Symphony Health, Source Non Retail, August 2017 - July 2018 estimates.

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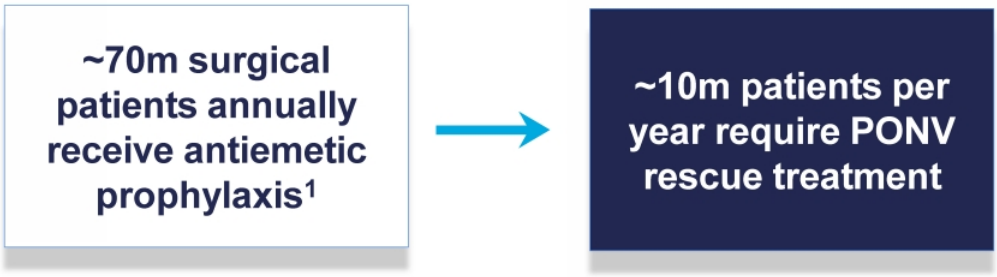
Targeting PONV Rescue Market in the US



Total estimated addressable market in PONV rescue ≈ $0.7B p

1 Based on market research performed by or for Eagle.

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 Guidelines[1]

Antiemetic	Can't redose	Efficacy issues	Safety issues	Curren rescue
Ondansetron	✗[1]			6
Dexamethasone	✗[1]	✗[2]		1
Metoclopramide		✗[1]	✗[1]	1
Promethazine			✗[1]	1
BARHEMSYS[4]	✓[3]	✓[3]	✓[3]	INTENT T 6

1 Fourth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting. 2 Wang et al (2000). 3 BARHEMSYS label prescribing information. 4 LSSG quantitative market research among 152 anesthesiolo Question referred to "Product X" with a description matching the profile of BARHEMSYS. Note: current shares totals > 100% as responses included some combination therapy.

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BARHEMSYS – Compelling Commercial Potential

Significant unmet need

- Nausea more so than vomiting, worse than pain
- Consensus Guidelines: "When PONV prophylaxis has failed, patients antiemetic treatment from a different pharmacological class to the PO

Only FDA-approved product for PONV rescue[2]

- Only drug proven in randomized clinical trial to work in PONV rescue[3]
- Excellent safety profile demonstrated in clinical studies
- Also demonstrated to be effective for prevention

Potential throughput and health economic benefits

- Is non-sedating – a common complaint of standard antiemeticagents
- Opportunity to reduce PACU and overall hospital stays
- Potential to offer significant economic savings to hospital vs current sta

1 Fourth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting; 2 FDA labels for other recommended treatments do not include treatment after failed prophylaxis. Treatment agents recomme 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 failed prophylaxis. 3 FDA labels for other recommended treatments do not include treatment after failed prophylaxis.

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BYFAVO®

(remimazolam) for injection

Rapid onset/offset procedural sedative with favorable safety profile

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Procedural Sedation US Potential Addressable Market

~40 million[1]

procedures each year requiring sedation

~25 million

GI procedures performed each year[2]

>80%

GI procedures have sedation adr an anesthesia provide

>6 million

Interventional Radiology[4]

~4 million

Ophthalmic Procedures[5]

~1 million

Bronchoscopy[6]

~1.5 millio

Cosmetic/ Plasti Surgery[7]

Total potential addressable market in procedural sedation >$0.4B/year[8]

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), De (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 prepa 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 20 performed by or for Eagle

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BYFAVO Addresses Unmet Need in Procedural Sedation

Propofol	Midazolam	BYFAVO
fast acting but noted safety issues[1,2]	*established safety profile but longer onset and recovery*[1,2]	*fast acting AN established safety p*
• Rapid onset and offset anesthetic with narrow therapeutic index[1]	• Benzodiazepine sedative, reversible by flumazenil[1]	• **Rapid onset/offset**[1,] benzodiazepine
• **Dose-related cardiorespiratory depression**, pain at injection site[1]	• **Slower onset and offset**[2,3]	• Rapid biotransformat inactive metabolites specific tissue estera dependent on liver e
• Non-linear dosing effects due to individual variability[4]	• Metabolized by cytochrome system; individual variability affects sedation[1]	• **Predictable behavic pharmacokinetic dr interactions**[5]
• **Needs continuous monitoring by anesthesiologist, no reversal agent**[2]	• Active metabolite can accumulate and cause prolonged sedation[2]	• **Reliable sedation, r safety profile**[1]
• Lipid formulation susceptible to bacterial contamination[4]	• **Risk of respiratory depression**[1]	• Reversible by flumaz

1 Colao J, et al. *J Anesth Clin Res*. 2016; 7:690. 2 Whizar-Lugo V, et al. *J Anesth Crit Care*. 2016; 4(6): 00166. 3 Rex DK et al. Gastrointest Endosc. 2018 Sep;88(3):427-437. 4 Prescribing lab for Propofol. 5 Prescribing label for BYFAVO.

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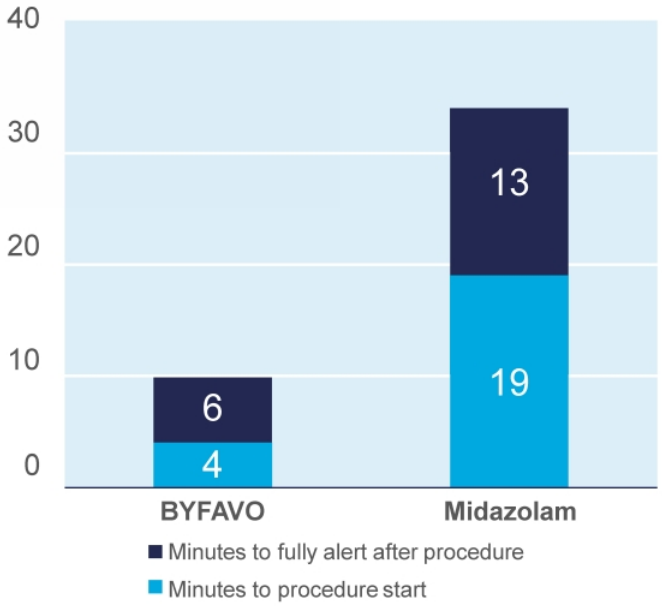
Rapid Onset/Offset with a Favorable Safety Profile[1]

Average Procedure Timings[1]



Key Adverse Events[1]

	BYFAVO	Mid
Any adverse event	**74%**	
Vascular disorders	62%	
Cardiac disorders	18%	
Respiratory disorders	4%	

1 Rex DK et al. Gastrointest Endosc. 2018 Sep;88(3):427-437.

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BYFAVO – Compelling Commercial Proposition

Clear unmet need

- No innovation in the sedation space for 20+ years
- Customers seeking fast onset, titratable and rapid recovery for quick discharge
- Shorter procedure times allow increased procedural volumes

Broad label & health economic benefits

- Indicated for procedural sedation in adults in procedures lasting 30 mins or less
- Substantial clinical data package demonstrated efficacy and safety in colonoscopies and bronchoscopies, including challenging patients
- Enables shorter procedure times and greater patient throughput

Commercial synergy with BARHEMSYS

- Target prescribers: anesthesia providers and proceduralists in hospitals and ambulatory surgery centers

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Landiolol

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Landiolol – Investigational Drug Candidate in the US - Ke

- **Ultra-short acting cardioselective β1-blocker**
- **Rapid control**
  - Supraventricular tachycardia
  - Ventricular rate
- **Simple intravenous dosing**
- **Multiple use settings**
  - Critical/Intensive Care
  - Perioperative
  - Emergency Department

- **Safety and efficacy qualified by for approved marketing authorizations**
  - European Union
  - Japan
- **Derisked 505(b)(2) opportunity**
- **Key competitors**
  - β-blockers
  - Amiodarone

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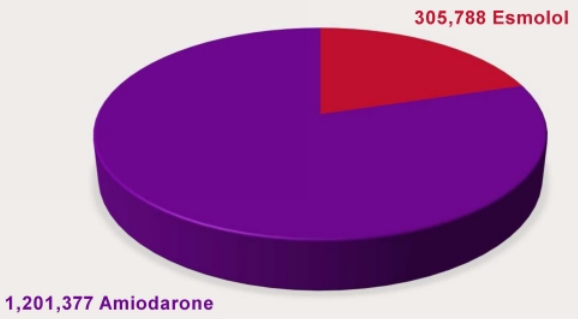
US Potential Addressable Market Considerations

Patient Treated with Amiodarone and Esmolol in 2018

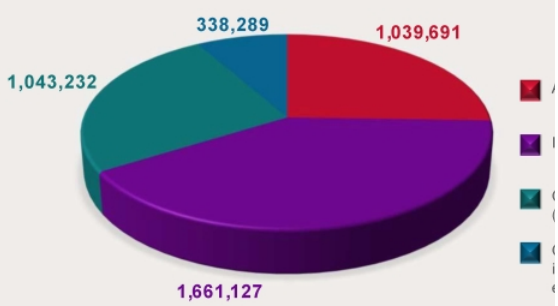


Considering 6 ampoules of 150mg Amiodarone for one single infusion course
Considering 1 bag of 2500mg Esmolol for one single infusion course

- US market corresponds to **1.5 million treated patients** based on 2018 Afib treatment data

Every 4th adult over 40 years has a lifetime risk of atrial fibrillation
Expected prevalence of 12.1 million in 2030 expected[1]

Diagnosis and # of Interventions USA*



*Calculated based on Austrian data using a treatment factor
factor established on PCI interventions in Austria vs USA of

1 Torio, Celeste M. Ph.D.,M.P.H., Moore, Brian J. Ph.D., "National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2013", HCUP, May 2016,
Fingar, Kathryn R. Ph.D., Stocks, Carol Ph.D., R.N., Weiss, Audrey J. Ph.D., Steiner, Claudia A. M.D., M.P.H., "Most Frequent Operating Room Procedures Performed in U.S. Hospitals, 2003-2012, HCUP, December 2
Muhlberger V, Kaltenbach L, Kobel C, Pachinger O, Austrian Journal of Cadiology 2014, 21 (3-4), 76-80

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Summary on Landiolol Potential Addressable Market

- **Landiolol, if approved by the FDA, is expected to get its volume sales from current Esmolol and Amiodarone (injectables) markets**
- **Esmolol market (all injectables)**
  - Esmolol annual market size in the US was estimated to be ~$80M. This constitutes branded (Brevibloc) Esmolol of $43M and generic Esmolol of $37M[1]
- **Amiodarone market**
  - Amiodarone annual market size in the US was estimated to be ~$107M. This includes both branded (Pacerone, Cordarone and Nexterone) and generics.
  - Only 6.8% of this market (~$7.3M) is injectable.
- **The total estimated size of the US addressable market for landiolol per year is ~$90M which constitutes[1]:**
  - Esmolol: $80M
  - Amiodarone (injectable): $7.3M
  - Sotalol: $2.9M

1 Premier data (2017 - 2020) from Fpane
Torio, Celeste M. Ph.D.,M.P.H., Moore, Brian J. Ph.D., "National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2013", HCUP, May 2016,
Fingar, Kathryn R. Ph.D., Stocks, Carol Ph.D., R.N., Weiss, Audrey J. Ph.D., Steiner, Claudia A. M.D., M.P.H., "Most Frequent Operating Room Procedures Performed in U.S. Hospitals, 2003-2012, HCUP, December 2
Muhlberger V, Kaltenbach L, Kobel C, Pachinger O, Austrian Journal of Cadiology 2014, 21 (3-4), 76-80

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Landiolol Potentially Addresses an Important Unmet Clinical Ne

- **Plan to file NDA in May 2022**
- **Seeking approval of landiolol for use in patients in whom it is necessary to safely and rapidly reduce heart rate**
  - Including where it is important to limit effect on blood pressure and inotropy (e.g., pts in sepsis, pts with heart failure)
- **Current therapeutic options for these patients are limited**

Comorbidities are common in this

HEART FAILURE

RENA IMPAIRM

HEPATIC DYSFUNCTION

RESPIRA DISEA

Landiolol Features from Clinical Data Expected to be in tl

Rapid onset of action (≤1 min) and short duration of action (10-15 min)[1]

Limited effect on blood pressure due to pure S-enantiomer molecular structure[2]

Minimal negative inotropic action due to limited effect on the refractory period o potential in cardiomyocytes[3]

1. Krumpl G, et al. *Eur J Clin Pharmacol.* 2017;73(4):417-428. 2. McKee JS, et al. *Anesthesiology.* 2014;121(6):1184-1193. 3. Shibata S, et al. *J Pharmacol Sci.* 2012;118(2):255-265.

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Landiolol Features from Clinical Data Expected to be in tl

Low volume of distribution (0.3-0.4 L/kg) leading to less distribution to tissues a fewer possible toxicities[1,2]

Compatible in patients with respiratory disease (eg, asthma, COPD) due to high cardioselectivity (β1/β2-selectivity = 255:1) among β1 blockers[1,3]

Metabolized in the plasma (CYP450 is not involved) and eliminated primarily in urine[1]

- No dose adjustment is necessary in renal impairment and careful dosing is recommended in patients with hepatic impairme due to limited data[1,4]

COPD, chronic obstructive pulmonary disease; CYP450, cytochrome P450

1. Landiolol. Summary of Product Characteristics, current version. 2. Krumpl G, et al. *J Cardiovasc Pharmacol.* 2018;71(3):137-146. 3. Balik M, et al. Eur Heart J Suppl. 2018;20(A):A10-A14.

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Landiolol – Compelling Commercial Proposition

– Potential to expand β-blocker market

– Anticipated health economic benefits

– Aligns with Eagle's hospital-based sales force

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Question & Answer

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Appendix

EAGLE PHARMACEUTICALS

BARHEMSYS Indications and ISI

Indication

BARHEMSYS is a selective dopamine-2 (D_2) and dopamine-3 (D_3) receptor antagonist indicated in adults for:

- prevention of postoperative nausea and vomiting (PONV), either alone or in combination with an antiemetic of a different class
- treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis

Important Safety Information

Contraindication

- BARHEMSYS is contraindicated in patients with known hypersensitivity to amisulpride.

QT Prolongation

- BARHEMSYS causes dose- and concentration-dependent prolongation of the QT interval. The recommended dosage is 5 mg or 10 mg as a single intravenous (IV) dose infused over 1 to 2 minutes.
- Avoid BARHEMSYS in patients with congenital long QT syndrome and in patients taking droperidol.
- Electrocardiogram (ECG) monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders, electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval.

Adverse Reactions

- Common adverse reactions reported in ≥ 2% of adult patients who received BARHEMSYS 5 mg (N=748) and at a higher rate than placebo (N=741) in clinical trials for the prevention of PONV were: chills (4% vs. 3%), hypokalemia (4% vs. 2%), procedural hypotension (3% vs. 2%), and abdominal distention (2% vs. 1%).
- Serum prolactin concentrations were measured in one prophylaxis study where 5% (9/176) of BARHEMSYS-treated patients had increased blood prolactin reported as an adverse reaction compared with 1% (1/166) of placebo-treated patients.
- The most common adverse reaction, reported in ≥ 2% of adult patients who received BARHEMSYS 10 mg (N=418) and at a higher rate than placebo (N=416), in clinical trials for the treatment of PONV was infusion site pain (6% vs. 4%).

Use in Specific Populations

Lactation

Amisulpride is present in human milk. There are no reports of adverse effects on the breastfed child and no information on the effects of amisulpride on milk production.

BARHEMSYS may result in an increase in serum prolactin levels, which may lead to a reversible increase in maternal milk production. In a clinical trial, serum prolactin concentrations in females (n=112) increased from a mean of 10 ng/mL at baseline to 32 ng/mL after BARHEMSYS treatment and from 10 ng/mL to 19 ng/mL in males (n=61). No clinical consequences due to elevated prolactin levels were reported.

To minimize exposure to a breastfed infant, lactating women may consider interrupting breastfeeding and pumping and discarding breast milk for 48 hours after receiving a dose of BARHEMSYS.

EAGLE PHARMACEUTICALS

Important Safety Information

Use in Specific Populations

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness were observed between these patients and younger patients experience has not identified differences in responses between the elderly and younger patients, but greater individuals cannot be ruled out.

Renal Impairment

Avoid BARHEMSYS in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] < 3 pharmacokinetics of amisulpride in patients with severe renal impairment have not been adequately studied i known to be substantially excreted by the kidneys, and patients with severe renal impairment may have incre increased risk of adverse reactions.

No dosage adjustment is necessary in patients with mild to moderate renal impairment (eGFR ≥ 30 mL/min/1

Drug Interactions

- BARHEMSYS causes dose- and concentration-dependent QT prolongation. To avoid potential additiv BARHEMSYS in patients taking droperidol.
- ECG monitoring is recommended in patients taking other drugs known to prolong the QT interval (e.g.
- Reciprocal antagonism of effects occurs between dopamine agonists (e.g., levodopa) and BARHEMSY BARHEMSYS.

Please click to access full Prescribing Information.

BYFAVO Indication and ISI

Indication

BYFAVO is a benzodiazepine indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

Important Safety Information

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION AND RISKS FROM CONCOMITANT USE WITH OPIOID ANALGESICS AND OTHER SEDATIVE-HYPNOTICS

Personnel and Equipment for Monitoring and Resuscitation

- Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO.
- Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation.
- BYFAVO has been associated with hypoxia, bradycardia, and hypotension. Continuously monitor vital signs during sedation and during the recovery period.
- Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO.

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of benzodiazepines, including BYFAVO, and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of intravenous BYFAVO can be accentuated by concomitantly administered CNS depressant medications, including other benzodiazepines and propofol. Continuously monitor patients for respiratory depression and depth of sedation.

Contraindication

BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Personnel and Equipment for Monitoring and Resuscitation

Clinically notable hypoxia, bradycardia, and hypotension were observed in Phase 3 studies of BYFAVO. Continuously monitor vital signs during sedation and through the recovery period. Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO. Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation. Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO. Consider the potential for worsened cardiorespiratory depression prior to using BYFAVO concomitantly with other drugs that have the same potential (eg, opioid analgesics or other sedative-hypnotics). Administer supplemental oxygen to sedated patients through the recovery period. A benzodiazepine reversal agent (flumazenil) should be immediately available during administration of BYFAVO.

Important Safety Information

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of BYFAVO and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of IV BYFAVO can be accentuated when administered with other CNS depressant medications (eg, other benzodiazepines and propofol). Titrate the dose of BYFAVO when administered with opioid analgesics and sedative-hypnotics to the desired clinical response. Continuously monitor sedated patients for hypotension, airway obstruction, hypoventilation, apnea, and oxygen desaturation. These cardiorespiratory effects may be more likely to occur in patients with obstructive sleep apnea, the elderly, and ASA III or IV patients.

EAGLE PHARMACEUTICALS

Important Safety Information

Hypersensitivity Reactions

BYFAVO contains dextran 40, which can cause hypersensitivity reactions, including rash, urticaria, pruritus, a
contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products contain

Neonatal Sedation

Use of benzodiazepines during the later stages of pregnancy can result in sedation (respiratory depression, l
neonate. Observe newborns for signs of sedation and manage accordingly.

Pediatric Neurotoxicity

Published animal studies demonstrate that anesthetic and sedation drugs that block NMDA receptors and/or
increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for l
significance of this is not clear. However, the window of vulnerability to these changes is believed to correlate
trimester of gestation through the first several months of life but may extend out to approximately 3 years of
Anesthetic and sedation drugs are a necessary part of the care of children needing surgery, other procedures
delayed, and no specific medications have been shown to be safer than any other. Decisions regarding the ti
requiring anesthesia should take into consideration the benefits of the procedure weighed against the potenti

Adverse Reactions

The most common adverse reactions reported in >10% of patients (N=630) receiving BYFAVO 5-30 mg (tota
colonoscopy (two studies) or bronchoscopy (one study) were: hypotension, hypertension, diastolic hypertens
hypoxia, and diastolic hypotension.

Use in Specific Populations

Pregnancy

There are no data on the specific effects of BYFAVO on pregnancy. Benzodiazepines cross the placenta and
depression and sedation in neonates. Monitor neonates exposed to benzodiazepines during pregnancy and l
respiratory depression.

Lactation

Monitor infants exposed to BYFAVO through breast milk for sedation, respiratory depression, and feeding pr
consider interrupting breastfeeding and pumping and discarding breast milk during treatment and for 5 hours

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. BYFAVO should not be used in pati

Geriatric Use

No overall differences in safety or effectiveness were observed between these subjects and younger subjects
for greater sensitivity (eg, faster onset, oversedation, confusion) in some older individuals. Administer supple
to achieve the level of sedation required and monitor all patients closely for cardiorespiratory complications.

Hepatic Impairment

In patients with severe hepatic impairment, the dose of BYFAVO should be carefully titrated to effect. Depen
patient, lower frequency of supplemental doses may be needed to achieve the level of sedation required for
should be monitored for sedation-related cardiorespiratory complications.

Abuse and Dependence

BYFAVO is a federally controlled substance (CIV) because it contains remimazolam which has the potential
dependence.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch or call 1-800-FDA-1088