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): **January 11, 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 January 12, 2022, Eagle Pharmaceuticals, Inc., or the Company, will present the attached presentation of the Company's products and product candidates at the 40th Annual J.P. Morgan Healthcare Conference, taking place virtually January 10-13, 2022.

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 January 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: January 11, 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 securities laws. Forward-looking statements are statements that are not historical facts. Words and phrases such as "anticipated," "forward," "will," "would," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," "guidance," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, the Company's ability to obtain and maintain regulatory approval of its products and product candidates; the Company's clinical development plan for its product candidates, including the number and timing of development initiatives or new indications for the Company's product candidates and the anticipated development expenses for such development plans; the potential therapeutic and clinical benefits of the Company's product candidates; the Company's timing and ability to enroll patients in upcoming clinical trials; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company's product candidates, including Landiolol and its fulvestrant product; the timing, progress and success of the Company's potential launch of any products, including vasopressin and PEMFEXY; the ability of the Company to successfully commercialize its product candidates, including vasopressin and PEMFEXY; the ability of vasopressin to benefit providers and patients as an alternative to Vasostrict; the period of marketing exclusivity for any of the Company's products or product candidates, including vasopressin; the potential market opportunity for any of the Company's products; the ability of the Company to obtain and maintain coverage and adequate reimbursement for its products; the success of the Company's collaborations with its strategic partners and the timing and results of these partners' preclinical studies and clinical trials, including the Company's collaborations with its licensing partners SymBio, Combioxin SA and AOP Orphan Pharmaceuticals GmbH; the future commercial success of its product candidates, if approved, related to such licensing agreements, and anticipated royalty and milestone revenue and potential market opportunity for such product candidates; the ability of the Company's executive team to execute on the Company's strategy and to utilize its cash and other assets to increase shareholder value; expectations regarding the Company's future growth and its ability to generate significant cash in the future; the Company's ability to effectively manage and control expenses in line with its budget; the Company's timing and ability to repurchase additional shares of the Company's common stock, if any, under its Share Repurchase Program; and the ability of the Company's product candidates to deliver value to stockholders. All of such statements are subject to certain 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 from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks and uncertainties include, but are not limited to: the impacts of the ongoing COVID-19 pandemic, including interruptions or other adverse effects on clinical trials and delays in regulatory review or further disruption or delay of any pending or future litigation; whether the Company will incur unforeseen expenses or liabilities or other market factors; delay in or failure to obtain regulatory approval of the Company's product candidates and successful compliance with FDA, European Medicines Agency and other governmental regulations applicable to product approvals; whether the Company will successfully implement its development plan for its product candidates, including its fulvestrant product; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of its products or that may have an impact on any of its products; successful compliance with the FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions, including the potential adverse effects of public health issues, including the COVID-19 pandemic, on economic activity and the performance of the financial markets generally; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; the risks inherent in drug development and in conducting clinical trials, including that preliminary results from clinical trials are not necessarily predictive of future clinical trial results; and those risks and uncertainties identified in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission (the "SEC") on March 5, 2021, as updated by the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2021, June 30, 2021 and September 30, 2021 filed with the SEC on May 10, 2021, August 9, 2021 and November 9, 2021, respectively, and its other subsequent filings with the SEC. Readers are 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 extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof.

Eagle Overview:

A Mainstream Pharmaceutical Company Specializing in Oncology + Acute Care

Specialty Pharma Company

Pharmaceutical Company Specializing in Acute Care & Oncology

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Eagle Pharmaceuticals Financial Position, Portfolio & Pipeline

Strong Financial Position

Share Buybacks
$230M or 24%*

Net Working Capital
of **$123.3M****

Total Cash and Cash
Equivalents **$99.7M****

No net debt supports opportunistic
approach to transactions

*As of 12/31/21
**As of 9/30/21

Current Portfolio	Upcoming Launches	Product Pipeline
Bendeka®	Vasopressin	Landiolol
Ryanodex®	Pemfexy™	SM-88***
Belrapzo®		CAL02
Treakisym® Symbio Japan		Fulvestrant

***Strategic collaboration with Tyme Technologies

EAGLE PHARMACEUTICALS

Near Term Business Highlights

- **Vasopressin:**
  - Shipping to commence on Monday, January 17, 2022, with 180 days of marketing exclusivity.
  - An important product for Eagle, as Vasostrict® U.S. sales totaled $890 million for the LTM ended September 30, 2021.
- **PEMFEXY™:**
  - On February 1, 2022, the Company will launch PEMFEXY, a ready-to-use liquid with a unique J-code.
  - Eagle has been building inventory and believes this is a significant opportunity, as the Alimta® U.S. market totaled $1.2 billion for the LTM ended September 30, 2021.
- **TREAKISYM:**
  - Eagle's bendamustine franchise continues to grow, with the Japan launch of TREAKISYM ready-to-dilute ("RTD") formulation.
  - Together with a potential approval of the rapid infusion ("RI") (50ml) liquid formulation, this could generate approximately $20 million of combined royalty and milestone revenue in 2022.
- **Fulvestrant:**
  - Based on discussions with FDA, Eagle will commence human pilot studies of its fulvestrant product candidate for the treatment of HR+/HER- advanced breast cancer shortly.
- **Landiolol:**
  - Eagle is on track to submit an NDA in the first half of 2022, seeking approval of Landiolol, a novel therapeutic, for the short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter.
- **CAL02:**
  - Eagle is preparing to begin clinical trials for CAL02, a novel approach to the treatment of severe bacterial pneumonia, later this year.

EAGLE PHARMACEUTICALS

CNS/Metabolic

Critical Care Pipeline Opportunities

Vasopressin

Vasopressin Overview

Vasopressin injection is FDA-approved to increase blood pressure in adults with vasodilatory shock (e.g., post- cardiotomy or sepsis) **who remain hypotensive despite fluids and catecholamines.**

- Currently Endo/Par markets VASOSTRICT® (vasopressin)
- U.S. sales totaled $890 million for the LTM ended September 30, 2021*
- Eagle is first-to-file an ANDA referencing VASOSTRICT® for the 20 units per ml presentation
- Commercial launch on January 17th 2022
  180-day market exclusivity
- Successful vasopressin patent trial; Court held Eagle's proposed vasopressin product does not infringe any of the patents Par asserted against the Company

*Source: Endo International plc

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CNS/Metabolic

Critical Care Pipeline Opportunities

CAL02 and Landiolol

CAL02 Overview

CAL02 (drug product): Specific mixture of re-engineered empty liposomes solely composed of sphingomyelin and cholesterol capable of capturing and neutralizing a broad spectrum of virulence effectors.

- Novel first-in-class antitoxin agent in development for combination use with antibiotics for the treatment of severe pneumonia
- Proposed injectable treatment for severely infected patients
- Applying for Qualified Infectious Disease Product Designation under the GAIN Act

CAL02 – Novel, First-in-Class Antitoxin Agent

Mechanism of Action

Address the downstream effects of bacterial Virulence Effectors/ Pore Forming Toxins through competitive inhibition

- Binds to virulence effector molecules secreted by infecting bacteria, prohibiting host tissue cell binding
- Acts as an extracellular "sink" for these toxins
- Potential to attenuate pore forming toxin related effects including host tissue damage, immune dysregulation, and inflammation that contribute to increase disease severity

Lead Indication

Severe Community Acquired Pneumonia

- Significant morbidity and mortality despite advances in direct acting antibacterials
- Addresses significant medical need and burden on health care systems

Differentiated Advantages

- Potential to be used as adjuvant therapy with any traditional antibacterial [therapy agnostic]
- Potential to be used against any bacteria that produces pore forming toxins [bacteria agnostic]
- Potential to carry less risk of antibacterial resistance development

Development Program somewhat de-risked for phase of development

- FTIH proof of concept study showed tolerability as well as trends toward efficacy
- Positive regulatory interactions with FDA and EMA – may be eligible for special designations and review processes
- Scalable manufacturing process

Anticipate that development costs through interim results will total approximately $35 million

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CAL02: Therapeutic Benefit & Unique Potential

Potential to become first line empirical therapy*

- Excellent **safety** profile
- Does not prompt any new **resistance**
- Unique **broad-spectrum** activity
- **No impact** on flora
- **Non**-immunogenic
- Biologically **neutral**

Offers a unique therapeutic benefit to critically ill patients

Positive trends over placebo in efficacy parameters*+

- Reduction of mortality risk+
- Potentially faster and complete recovery of organ function +
- Shorter duration of mechanical ventilation
- Immediate decrease in inflammatory biomarkers (e.g. IL-6)
- Shorter ICU length of stay +

+ statistically significant

THE LANCET
Infectious Diseases

Comment

Pletz et al. Lancet Infect Dis 2019 19(6):564-565

One step closer to precision medicine for infectious diseases

"A medical breakthrough"

CAL02 represents a milestone"

"Potentially suitable for adjunctive empirical treatment"

Addressing a significant unmet medical need

A straightforward and innovative approach

A potentially unique therapeutic benefit to critically ill patients

Already achieved critical de-risking milestones

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Landiolol: Beta-1 Adrenergic Blocker; Leading Hospital Emergency Use Product

- Signed licensing agreement for U.S. commercial rights from AOP Orphan Pharmaceuticals (AOP) in August 2021
- Eagle will facilitate regulatory pathway for U.S. approval based on existing data from Japanese and European studies with no additional clinical work expected
- Approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias
- Studies for additional indications, including sepsis and other cardioprotective indications, have begun in Europe, with the potential to be pursued in the U.S.
- Eagle will support seeking approval of Landiolol for short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter in the U.S.
- Enrollment of study in pediatric patients with supraventricular tachycardia is underway in Europe and will serve as the basis for initial pediatric study plans for a future FDA submission
- Anticipate filing NDA in Q1 2022, with expected ten-month review, based on well-defined feedback from FDA provided during AOP's Type C meeting
- Expect five years of new chemical entity exclusivity

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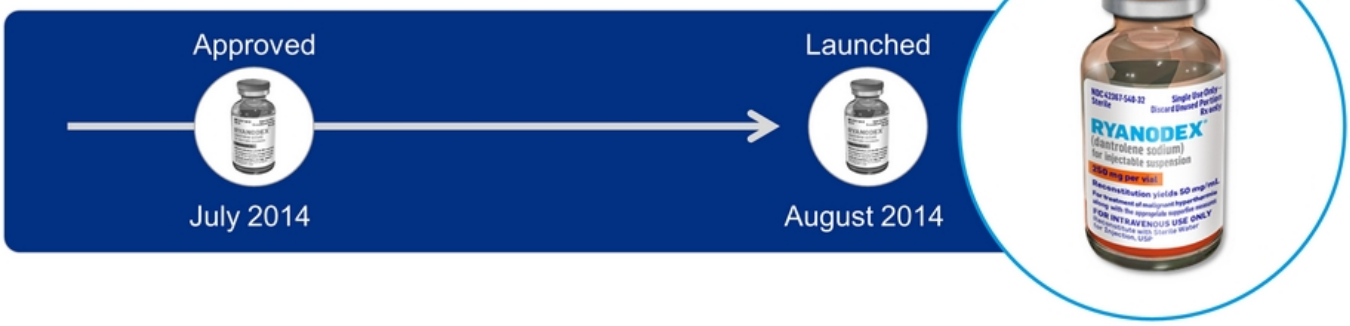
CNS/Metabolic

Critical Care Pipeline Opportunities

RYANODEX®

RYANODEX® (dantrolene sodium) injectable suspension

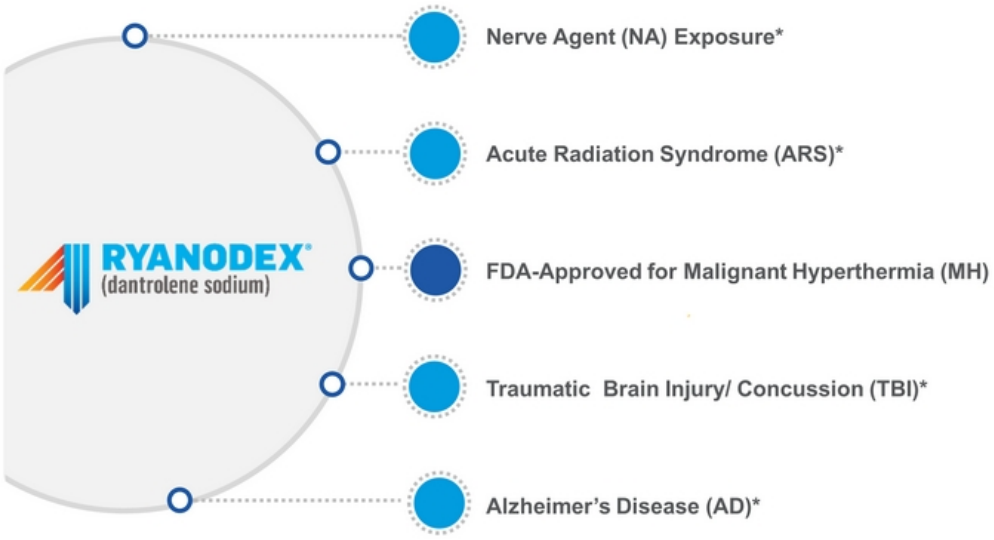
Breakthrough formulation



Currently indicated for the treatment of malignant hyperthermia (MH) in conjunction with appropriate supportive measures, and for the prevention of MH in patients at high risk

RYANODEX®: Building a Successful Franchise

New indications under development*



Ten U.S. patents issued to date, expiring between 2022 and 2025

EAGLE PHARMACEUTICALS

Oncology

Pipeline Opportunities

PEMFEXY™

Eagle's PEMFEXY™ is FDA-Approved for:

- Nonsquamous Non-Small Cell Lung Cancer in combination with cisplatin for initial treatment or locally in combination for advanced or metastatic disease
- Nonsquamous Non-Small Cell Lung Cancer maintenance, when disease has not progressed after four cycles of platinum-based first-line chemotherapy
- Nonsquamous Non-Small Cell Lung Cancer after prior chemotherapy as a single agent for locally advanced or metastatic disease

- Mesothelioma in combination with cisplatin for malignant pleural mesothelioma when disease is unresectable.

ALIMTA® (Eli Lilly) - PEMFEXY™ (Eagle)

Currently marketed by **Lilly as ALIMTA®** (pemetrexed)
100mg and 500mg powder single dose vials

- U.S. market totaled $1.2 billion for the LTM ended September 30, 2021*

Eagle first to market 505(b)(2) PEMFEXY™ (pemetrexed)

500mg liquid multi-dose vial

- Granted unique J-code by CMS
- Launch planned **February 1st 2022**
- Generic entrants blocked until May 24, 2022

*Source: Eli Lilly and Company

Eagle's Differentiated PEMFEXY™ (pemetrexed):

Other pemetrexed

Other pemetrexed formulations are **single-dose powder,** which require reconstitution

Some patients may need 2-3 vials; time-consuming for pharmacist/nurse and **wastage occurs frequently** because they are not multi-dose vials

Eagle's formulation

Eagle's formulation is available in a **500mg liquid** ready-to-dilute **multi-dose vial**

PEMFEXY™ **eliminates the reconstitution process wastage and helps prevent medication errors.** The vial **can be reused** under refrigeration for 28 days.

EAGLE PHARMACEUTICALS

Oncology

Pipeline Opportunities

EA-114 (Fulvestrant)

EA-114: Our Fulvestrant Product Candidate for HR+/HER2- Advanced Breast Cancer

Impact of Advanced Breast Cancer

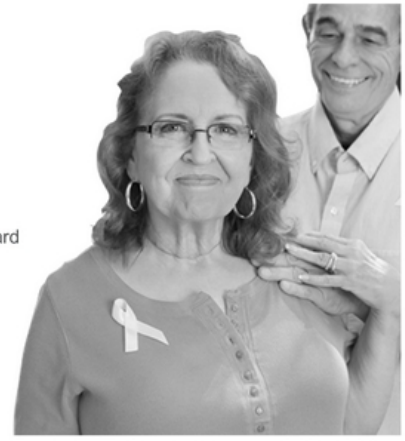
~75% of breast cancers are HR+[1]

~30% of patients first diagnosed with early-stage disease eventually develop metastatic disease[2]

27% five-year survival for patients in U.S. with metastatic breast cancer[3]

An Unmet Need

- Eagle's 600-subject PK trial yielded ~18,000 data points, which we mined for insights
- For fulvestrant to work, it needs to bind to and block the estrogen receptor (ER)
- Not everyone treated with fulvestrant achieves the desired result – a substantial number of women with advanced HR+/HER2- breast cancer receiving standard treatment experience early disease progression
- Currently, low ER inhibition is an important factor resulting in suboptimal treatment, which may lead to faster progression of the disease
- Our research suggests Eagle's product could substantially improve the clinical outcomes for these post-menopausal metastatic breast cancer patients



1. Keen JC, Davidson NE. The biology of breast carcinoma. Cancer 2003;97:825–33. DOI: 10.1002/cncr.11126
2. Zhao H, et al. Incidence and prognostic factors of patients with synchronous liver metastases upon initial diagnosis of breast cancer: a population-based study. Dove Press. 27 September 2018. DOI https://doi.org/10.2147/CMAR.S178395.
3. Howlader N, et al (eds). SEER Cancer Statistics Review, 1975-2016, National Cancer Institute, Bethesda, MD, https://seer.cancer. gov/csr/1975_2016/, based on November 2018 SEER data submission, posted to the SEER website, April 2019.

Existing Product Partnerships

SymBio

- SymBio received approval of TREAKISYM Ready-To-Dilute ("RTD") bendamustine formulation and launched in January 2021
- SymBio is currently conducting a clinical trial for a rapid infusion bendamustine product and pursuing additional indications
- Eagle earns tiered royalties on net sales of licensed products and $20-$25mm from combined royalty and milestone revenue in 2022

TYME SM-88

- In 2020 Eagle and TYME entered into a share purchase agreement and a co-promotion agreement for SM-88
- SM-88 is a novel investigational agent in a Phase II/III trial for pancreatic cancer
- For SM-88 Eagle shall earn 15% of U.S. net sales and will be responsible for 25% of the promotional effort
- Tyme may buy out Eagle's rights at any time under the co-promotion agreement for $200mm

Inflection Points

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Eagle Pharmaceuticals Summary

Experienced Organization	Mainstream pharmaceutical company with over 40 representatives calling into Hospital & Oncologists
Commercial Expansion	Commercial infrastructure in place and positioned to take on additional assets
Financial Position	Strong financial position supports opportunistic approach to transactions

Well positioned to capitalize on near-term opportunities

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Thank You!

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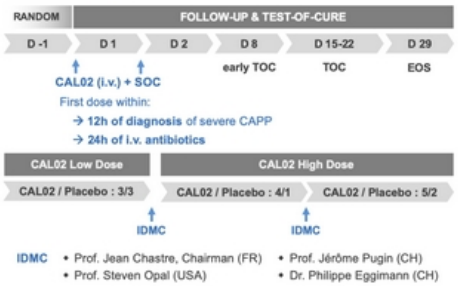
CAL02 Clinical Data

First-In Human Study Results

- **Randomized, double-blind, placebo-controlled**
- **3 arms / 19 patients:**
  - CAL02 Low dose (4 mg/kg) + Standard of Care
  - CAL02 High dose (16 mg/kg) + Standard of Care
  - Placebo (saline) + Standard of Care
- **2 IV administration 24h apart**
- **Severe CAPP: At least 1 major criteria** (mechanical ventilation/ vasopressors) **or 3 minor criteria**
- **Primary objective: Safety & Tolerability**
- **Secondary objective : Efficacy & Pharmacodynamics**



Baseline characteristics

Disease severity of the study population corresponded to that expected from the inclusion/ exclusion criteria

Severity at baseline:

- Mean APACHE II Score: 21.5 (95% CI 19.3-23.7)
- 58% in Septic Shock
- >40% under Invasive Mechanical Ventilation

No differences between treatment groups considered to have a substantial effect on safety and efficacy outcomes

Safety outcomes / TEAEs

CAL02 showed **the same safety profile as placebo** (saline)

- AE occurred in 12 (85%) of 14 patients in the CAL02 groups combined and in all 5 (100%) patients in the placebo group.
- SAE occurred in 4 (29%) of 14 patients in the CAL02 groups combined and 2 (40%) of 5 patients in the placebo group
- 1 AE (mild increase in the triglycerides) in a patient in the CAL02 High dose group was reported as related to study drug. However, the analysis of the changes in triglyceride in the CAL02 groups compared with the placebo group revealed no correction with CAL02.
- No AEs were liked to local tolerability events.

THE LANCET
Infectious Diseases
Articles

Laterre et al. Lancet Infect Dis 2019 19(6):629-630

CAL02, a novel antitoxin liposomal agent, in severe pneumococcal pneumonia: a first-in-human, double-blind, placebo-controlled, randomized trial

Efficacy Outcomes

	Low-dose CAL02 (n=3)	High-dose CAL02 (n=10)	Placebo (n=5)
Cured at early test of cure (day 8)	0	5 (56%)*	1 (20%)
Cured at test of cure (between days 15–22)	2 (100%)*	10 (100%)	5 (100%)
Median time to cure (days)	15·0 (14 to 16)†	8·0 (6 to 16)	10·0 (7 to 14)
All-cause mortality	1 (33%)	1 (10%)	1 (20%)
Relative change in Sequential Organ Failure Assessment score from baseline to day 8	–65·9% (–34·7 to –97·1)	–64·7% (–46·3 to –83·1)	–29·2% (–12·8 to –45·5)
Relative change in Acute Physiology and Chronic Health Evaluation II score from baseline to day 8	–59·9% (–34·0 to –85·8)	–60·4% (–45·3 to –75·5)	–22·1% (–15·5 to –28·7)
Relative change in PaO_2/FiO_2 from baseline to day 8	153·1 %(116·2 to 189·9)	78·4% (7·4 to 149·3)	58·5% (–27·5 to 137·9)
Median duration of invasive mechanical ventilation (days)†	12·0 (5 to 19)†	4·5 (4 to 14)	12·0 (11 to 56)
28-day ventilation-free days (days)	16·5 (1·8 to 31·2)†	25·1 (22·0 to 28·2)†	17·8 (7·7 to 27·9)
Median duration of intensive care unit stay (days)	15·0 (9 to 21)†	5·0 (2 to 15)	12·0 (6 to 56)
Median duration of stay in hospital (days)	33·0 (12 to 54)†	13·0 (4 to 28)†	21·0 (6 to 56)

Data are n (%), median (range), or mean (95% CI). PaO_2/FiO_2=partial pressure of oxygen in the blood/fraction of inspired oxygen. *One patient was missing for the assessment (because of death). †One patient censored because of death.

Overview of primary and secondary efficacy endpoints in CAL02 and placebo treatment groups (as-treated population)

CAL02 Competitive Advantages

Limitations of current approaches
(approved / in development)

Limited use
- Restrictions imposed by stewardship measures and purchasers, as antibiotics are inevitably linked to the emergence of new resistances

Slow and laborious market penetration
- Based on non-inferiority results
- Last-resort treatments
- Increasingly competitive space

Limited scope of application
- Action dedicated against resistant mechanism
- New mechanisms ultimately facing resistance issues
- Monoclonal antibodies targeting a single toxin
- Agents targeting a downstream specific pathway or cytokine dedicated to target patients already in shock

- **Potentially will not drive resistance; fills a significant medical gap**
- **Offers physicians a new treatment; potential to dramatically improve outcomes**
- **Combines with any treatment** (antibacterial agnostic)
- **May lead to a tremendous economy on cost of care; broad-spectrum** (used irrespective of pathogen identification or hemoculture or resistance to antibacterials)
- **Broad therapeutic impact**
- **Potential for expedited regulatory pathway to approval**

CAL02 Phase 2 Clinical Development Plan

Development Costs through Interim Results

Deal Signing Milestone	$10M
Phase I – Drug-Drug Interaction	$1M
P2B/3 Multicenter Global Study – Part 1 Through Interim Analysis Results	$21M
Clinical Trial Materials	$3M

Total = $35M

Key Next Steps

1. IND Filing
2. Start P2B/3 Multicenter Global Study – Part 1
3. P2B/3 Multicenter Global Study – Part 1
4. Interim Analysis Results

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