Corporate Overview

Bio€quity Europe 2022

16-18 May 2022, Milan, Italy

Non-Confidential
Forward-Looking Statement

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What is Spexis?

A new rare disease & oncology company

Initial rare disease focus: chronic respiratory disorders ("CRD"), a $15B global market

Lead CRD candidate ColiFin®: U.S. P3-ready; $300M+ market potential

Initial oncology focus: CXCR4/CXCR7 axis, a well-validated cancer target with rare disease potential as well

Powerful, proprietary & proven macrocycle platform as product pipeline generator & value driver

Significant validation of above via funding from Fosun Pharma, Cystic Fibrosis Foundation, PMI/Vectura, IMI & CARB-X

Leveraging >$400M historical investment; additional partnerships, strategic transactions & financings sought to facilitate growth
Spexis at a Glance:
Late Clinical-stage Biopharma Focused on Rare Diseases & Oncology

- Swiss stock exchange listed (SIX: SPEX)
- Formed December 2021 via merger of Enbiotix and Polyphor
- HQ: Allschwil, Switzerland (just next to Basel)
- Poised to dominate market for chronic lung infections in cystic fibrosis:
  - ColiFin®: approved/validated in EU; to enter P3 in U.S. in 2H2022;
  - Inhaled murepavadin (“iMPV”): novel mechanism-of-action in P1
  - Both programs significantly funded by CF Foundation; iMPV funded by IMI as well
  - Combined North American market potential US$ 500-700M
  - Other novel chronic respiratory disease long-term pipeline opportunities
- CXCR“X” inhibitor pipeline generated via proprietary macrocycle platform
  - Balixafortide: potentially best-in-class CXCR4 inhibitor; eight trials totaling ~485 subjects completed in solid tumor & heme-onc patients, including one P3;
  - Other candidates for resistant hematologic malignancy, rare disease, anti-inflammatory & anti-viral indications
## Spexis Executive Management & Board of Directors

### Highly Experienced Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeff Wager, MD</td>
<td>CEO</td>
<td>30 yrs VC &amp; CEO leadership; &gt;$2.5B in value created since 2000</td>
</tr>
<tr>
<td>Hernan Levett</td>
<td>CFO</td>
<td>25+ years financial leadership in pharma / biotech</td>
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<tr>
<td>Juergen Froehlich, MD</td>
<td>CMO</td>
<td>30+ yrs Chief Medical Officer &amp; senior reg affairs experience</td>
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<tr>
<td>Stephan Wehselau</td>
<td>COO</td>
<td>20+ years CEO &amp; CFO experience, ~$400M raised in career</td>
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<tr>
<td>Dennis Ausiello, MD</td>
<td>Director</td>
<td>17yrs Physician-in-Chief, MGH</td>
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<td>8 yrs lead director of the Pfizer board</td>
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<tr>
<td>Kuno Sommer, PhD</td>
<td>Director</td>
<td>Former CEO, Berna Biotech (acq. by J&amp;J)</td>
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<td></td>
<td></td>
<td>Chairman Bachem, Sunstar, Targimmune, more</td>
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<tr>
<td>Robert Clarke, PhD</td>
<td>Director</td>
<td>20+ yrs inhaled R &amp; D and CEO experience</td>
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<tr>
<td>Dan Hartman, MD</td>
<td>Director</td>
<td>25+yrs R &amp; D leadership; Head of $2B Gates malaria R &amp; D portfolio</td>
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<tr>
<td>Bernard Bollag, MBA</td>
<td>Director</td>
<td>Senior finance executive across corporate finance &amp; capital markets</td>
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</tbody>
</table>
# Spexis Pipeline: Multiple “Shots-On-Goal”

## Potential for Significant Value Generation

## Rare Disease

<table>
<thead>
<tr>
<th>Program</th>
<th>Research</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Partnership / Funding</th>
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<tbody>
<tr>
<td>ColiFin®</td>
<td>Chronic CF infections</td>
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<tr>
<td>Inhaled Murepavadin</td>
<td>Chronic CF infections</td>
<td>Non-CF bronchiectasis</td>
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<td>SPX-002</td>
<td>NTM</td>
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<tr>
<td>SPX-001</td>
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<td>LptA OMPTA</td>
<td>WHO Priority 1: CRE</td>
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## Immuno-oncology

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<tr>
<td>Balixafortide</td>
<td>Single agent/combo cancer Rx</td>
<td></td>
<td></td>
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<tr>
<td>New CXCR4 lead candidate (Undisclosed)</td>
<td>Rare disease indications</td>
<td></td>
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<tr>
<td></td>
<td>Solid tumors</td>
<td>Heme-onc.</td>
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</table>

- Pipeline Today
- Readiness if/when initiated
Rare Disease / Cystic Fibrosis (CF)

ColiFin®: Inhaled Colistin for CF

Inhaled Murepavadin for CF
Vicious Cycle of Progressive Lung Damage in CF Patients

- Infection
- Inflammation
- Impaired Mucus Clearance
- Lung Damage
ColiFin® & Inhaled Murepavadin (iMPV) for CF
Expanding the Clinical Pipeline For Cystic Fibrosis

Chronic lung infections: a major problem in CF even in post-CFTR modulator era

• CFTR modulator treatment → slowed disease progression leads to reduced mortality → more patients at all disease stages

• *P. aeruginosa* accounts for 2/3 of CF chronic lung infections – the leading cause of lung function decline & mortality in CF

• CF Foundation projects treatable CF patient population to increase over next 20 years

Spexis possesses two of the most potent inhaled CF antibiotics compared to those currently available

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<tr>
<th>MICs (mg/L) of 414 <em>P. aeruginosa</em> isolates from people with CF*</th>
<th>MIC&lt;sub&gt;50&lt;/sub&gt;</th>
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* Isolates collected between 2007-2018, mostly from The Netherlands and Spain.

Ref: Ekkelenkamp M. Report on in-vitro susceptibility of clinical isolates from cystic fibrosis and bronchiectasis patients against murepavadin (POL7080), part 1 of 2. The “inhaled Antibiotics in Bronchiectasis and Cystic Fibrosis” (iABC) consortium, 2018.
ColiFin®: Inhaled Colistin for CF
Phase 3 ready

• Ex-Europe rights licensed from PARI
• Already well proven in Europe:
  • On market for chronic lung infections in CF patients
• Phase 3 ready in U.S.:
  • FDA “Study May Proceed” letter received
  • Phase 3 design endorsed by CF Foundation’s Therapeutic Development Network
  • Fast Track designation received
• QIDP + Orphan Drug designation → 12 yrs market exclusivity
ColiFin®: Inhaled Colistin For CF
Adding EU-validated ColiFin® to U.S. treatment options

<table>
<thead>
<tr>
<th>ColiFin® Validated in EU</th>
<th>Leveraging EU Data to US &amp; RoW</th>
</tr>
</thead>
<tbody>
<tr>
<td>• EMA approved in 2010</td>
<td>• Positive FDA feedback on EU data &amp; clin-reg strategy: only 1 U.S. P3 trial for NDA submission</td>
</tr>
<tr>
<td>• &gt;15K patients dosed thus far</td>
<td>• P3:start projected 2-3Q22</td>
</tr>
<tr>
<td>• Strong efficacy, minimal serious adverse events</td>
<td>• KOLs say ColiFin® expected to become U.S. front-line Rx as in EU</td>
</tr>
<tr>
<td>• Front-line Rx for CF in EU</td>
<td>• U.S. CF iABXs priced 5-8x higher than in EU</td>
</tr>
<tr>
<td>• WW ex-Europe rights licensed to Spexis from PARI Pharma, world leader in nebulized drug delivery</td>
<td></td>
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</table>

EU CF Rx: 3 Major Antibiotics

<table>
<thead>
<tr>
<th>2 ABX rotation vs. Continuous Use</th>
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<tr>
<td>[Image of prescription bottles]</td>
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</table>
## ColiFin®: Favorable Profile vs. Current Standard Treatments

<table>
<thead>
<tr>
<th></th>
<th>TOBI®/Cayston®</th>
<th>ColiFin®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mechanism of Action</strong></td>
<td>Leads to resistance development</td>
<td>Difficult for <em>P. aeruginosa</em> to mutate around</td>
</tr>
<tr>
<td><strong>Resistance Development</strong></td>
<td>Increasing, up to 40% in some regions(^1,2)</td>
<td>Rarely exceeding ~5(^1,2)</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>TOBI has significant ototoxicity concerns</td>
<td>Latest EU post-marketing safety analyses show no reported drug-related oto-/neuro-/nephrotoxicities</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>Decreased efficacy over time</td>
<td>Front-line agent in Europe over TOBI®/Cayston®</td>
</tr>
<tr>
<td><strong>Dosing</strong></td>
<td>Continuous b.i.d./t.i.d. alternating therapy (“CAT”) (28d Rx on one, then switching to 28d on other)</td>
<td>Continuous (i.e., no CAT) b.i.d. dosing with P3 plans for q.d. dosing</td>
</tr>
<tr>
<td><strong>28d AWP Pricing</strong></td>
<td>Between ~$5400 – 11,000 (generics - branded)</td>
<td>Targeting ~$8,000</td>
</tr>
</tbody>
</table>

1. doi: 10.1128/AAC.01541-19  
2. doi: 10.1128/AAC.02483-20
The Colifin®
Market Opportunity

1. CF Foundation estimates ~12% of U.S. CF adults (~36% U.S. CF adults w/ moderate or advanced disease) currently treated w/ unapproved colistin (IV colistin solution used in generic nebulizers)
   - FDA strongly discourages this

2. @~$25K/yr/patient pricing (conservative), ColiFin® sales to only these patients = ~$100M/year

3. TOBI-like penetration to other treatable patients grows revenues to $250-300M/yr

4. Same scenario pre-TOBI/Cayston® approval: rapid switch by users of unapproved to approved product

~10,000 U.S. CF Adults w/ Moderate/Advanced Disease

- Immediately Capturable: 3.6K pts; ~$100M/yr
- After 3-4 Years on Market: 7.2K pts $250-300M/yr

~10,000 U.S. CF Adults w/ Moderate/Advanced Disease
ColiFin®: Phase 3 Ready in U.S.

- EU: approved for 2x daily (BID) or 3x daily (TID) dosing: 2 MIU per dose
- U.S.: FDA “Study May Proceed” letter based on BID dosing protocol
- Current medical practice moving to 1x daily (QD) dosing to reduce treatment burden
  - Poor adherence to approved BID (tobramycin) and TID (aztreonam)
  - QD use of inhaled tobramycin increasing
  - U.S.: increasing QD dosing for unapproved inhaled colistin use
- Nov 2021 Type C meeting: FDA acknowledged QD dosing utility but requested small trial with QD dosing regimen as part of P3 program
- Phase 3 program:
  - COPilot: 28d open label safety trial to investigate QD vs BID + 20wk follow up 24 weeks total; N=38; FPI expected June 2022
  - COPA: 28d Double-Blind Efficacy + 20wk open label safety 24 weeks total; N=480; FPI Dec 2022
Colifin® Phase 3 Program: COPILOT Pilot Safety Trial
QD vs BID dosing, open label

• **Primary Objective:** tolerability and safety of ColiFin®, comparing once daily (QD) with twice daily (BID)
  - Interim data (Day 42 analysis) intended to support switch from BID to QD dosing in COPA
• **Secondary Objectives:** Assessment of pulmonary function (ppFEV1), clinical events (number and severity of pulmonary exacerbations, hospitalizations) and additional antibacterial therapy
• **To be conducted at sites in central/eastern European countries; enrollment expected to initiate Jun-Jul ‘22

D 169: End of trial

D 42: Interim analysis

D 28: End of treatment

D1: 1:1 randomization QD vs. BID*

ColiFin®
4 MIU QD, n=19

ColiFin®
2 MIU BID, n=19

Screening:
Patients on stable inhaled Abx treatment

20 wk follow-up on “usual care”

* Stratification by current use of oral corticosteroids > or <= 10 mg QD or 20 mg QOD (prednisone or prednisolone equivalents)
Colifin® Phase 3 Program: COPA Pivotal Trial
Adults/Adolescents with CF + Chronic P. Aeruginosa Lung Infection

Screening: Patients on tobramycin, aztreonam or levofloxacin

Part A: 28d double-blind efficacy
- ColiFin n=360
- Placebo n=120
- D1: 3:1 randomization*
- D 28: Roll over

Part B: 20wk open label safety
- ColiFin® BID Rollover from ColiFin group; total n=300 completed
- Active Control (“usual care”) Rollover from placebo group; total n=100 completed
- D 169: End of treatment
- D 199: Safety follow-up (tel.); End of trial

- **Eligible: Therapy:** Continuous ColiFin® for 6 months vs. placebo + usual inhaled antibacterials
- **Primary endpoint:** Mean absolute diff. in ppFEV1** (of ≥3%) in change from baseline to Day 28
- **Key secondary endpoints throughout 6 months:** Difference in CFQ-R respiratory symptom score; evaluate exacerbation severity/duration; consistency of treatment response; microbiology in sputum: P aeruginosa density, resistance development (MIC)
- **Independent Data Monitoring Committee:** Interim efficacy analysis after 288 patients complete 28d days of treatment

* Stratification of randomization by age (<18, >18 yrs), pp FEV1 (<70%;>70%), prior PEx treated with systemic antibacterials in last 12 months, stable baseline use of CFTR modulators
** ppFEV1: Percent Predicted Forced Expiratory Volume in 1 second
Inhaled Murepavadin ("iMPV") for Cystic Fibrosis
Novel Class Therapeutic For a Rare Disease

• 9 clinical trials of IV MPV totaling 290 subjects have informed & de-risked the inhalation route
• Low systemic exposure upon inhalation mitigates nephrotoxicity risk
• High safety margin (5- to 10-fold above IV) in GLP tox studies
• Potent & selective activity against resistant *P. aeruginosa* of CF patients
• In P1: clinical development validated & supported by both IMI and CFF
• Market exclusivity through about 2036 via COM/additional IP; eligible for QIDP & orphan drug status
• Supported by EU innovative medicines initiative and Cystic Fibrosis Foundation

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# iMPV for Cystic Fibrosis

**P. aeruginosa** specific new class of inhaled antibiotic

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<th>Clinical Development</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
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<tbody>
<tr>
<td>Cystic Fibrosis</td>
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<tr>
<td>Ph 1a: SAD in HVs</td>
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<tr>
<td>Ph 1b: SAD in CF</td>
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<td>Ph 2: CF patients</td>
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**Targeted and Attractive Rare Disease Opportunity:**

- Attractive orphan market opportunity
- Peak CF sales 200-400m USD
- **Label expansion potential to nCFBE addresses >$1B market**

SAD: single ascending dose
iMPV for Cystic Fibrosis

Phase 1 Single Ascending Dose Trial

**Part A:** healthy subjects, single center, COMPLETED
- Double-blind
- Vs. placebo (pbo)
- Single ascending dose (SAD)
- Sentinel run-in phase
- Requested by MHRA
- **Objectives:** safety, tolerability, and pharmacokinetics of iMPV

**Part B:** healthy subjects, single center, START JUNE ‘22
- Double-blind
- SAD
- n=7 iMPV, n=2 pbo
- **Objectives:** safety, tolerability, and pharmacokinetics of iMPV
- **Cohort B3: dose predicted**

**Part C:** CF subjects, multi center, START NOV ‘22
- Double-blind
- SAD
- intrasubject
- n=8 iMPV, n=2 pbo
- **Objectives:** safety, tolerability and pharmacokinetics of iMPV in adult subjects with cystic fibrosis

SMG: Safety Monitoring Group; SAD: Single Ascending Dose
Spexis Macrocycle Platform
Balixafortide
Other CXCR“X” inhibitors
And more...
Spexis’ Macrocycle Platform
Broad Applicability, Extensively Evolved & Clinically Proven

• Result of >$400M of historical investment
• Validated with numerous pharma collaborations to date
• Two in-house candidates progressed through P3 thus far: study results informing potential new indications
• Extensive compound libraries, databases & IP
• Applicable to wide variety of extracellular & intracellular targets
• To fuel pipeline and generate corporate partnerships
Spexis’ Proprietary Macrocycle Platform ("MCP"):
Targets Difficult-to-Drug Extra-/Intracellular Targets

- Much of Spexis’ pipeline originates from its proprietary MCP
- Macrocycles: medium size, cyclic molecules occupying chemical space between small molecules and biologics

100 – 500 MW  
Small Molecules  
500 - 2'000 MW  
Spexis Macrocycles  
10’000 - 200’000 MW  
Biologics

Murepavadin  
Balixafortide  
New Candidates
MCP Introduction

Special Features of Macrocyccles

- **Clinically proven:** Macrocyccles have delivered important drugs & clinical stage compounds (e.g., cyclosporin A, eribulin, everolimus, etc.)

- **Protein-protein interactions (PPIs):** Can interact with protein interfaces of ~600-1'200 AZ & combine multiple & more distant interactions / hot spots

- **Conformational adaptation:** Protein surfaces dynamic; macrocyccles semi- rigid to provide balance of structural pre-organization & flexibility to mold to target surface & maximize binding → induced fit

- **Drug like properties & chimeric behavior:** Drug-like physicochemical and PK properties such as metabolic stability, cell permeability & oral bioavailability beyond rule of 5

- **Molecular glues:** can be combined with linkers & variety of payloads together with machine learning/informatic tools to tune desired cell component trafficking & phenotypic effects
MCP Introduction

Applications to Challenging Targets

- Novel and challenging targets extra- & intracellular
- Novel and challenging targets extracellular
- Validated targets currently addressed by small molecules; TPP: oral, inhaled
- Validated targets currently addressed by therapeutic proteins; TPP: oral
- Complex lung targets; TPP: inhaled
- Validated targets currently addressed by therapeutic proteins; TPP: parenteral

MF lead (oral)

MacroFinder

PEMFinder

POL7080 (Murepavadin)

POL6014
### Spexis’ Macrocycles in Practice:

**CXCR4 Inhibitors in Cancer: High Therapeutic Potential**

**CXCR4 is a key driver of cancer progression**

1. Immune suppression
2. Angiogenesis
3. Metastasis

**CXCR4 antagonist + Chemo**

- Immune cell activation
- Inhibited angiogenesis
- Reduced metastasis

**High therapeutic potential of CXCR4 inhibitors**

- **CXCR4**
  - overexpressed in most cancers
  - associated with poor prognosis
- **Validated target**:
  - Plerixafor on market since 2008 for stem cell mobilization
  - Other CXCR4 inhibitors in clinic for rare neutropenias and B-cell lymphomas
  - CXCR4 inhibitors efficacious in hematological malignancy models
  - CXCR4 inhibitor + SoC combination: enhanced response rates & reduced resistance
Balixafortide (BLX): Spexis’ Proprietary CXCR4 Inhibitor
Well Characterized, Well Tolerated, Multiple Therapeutic Opportunities

- Immunomodulatory, chemotherapy sensitizing, anti-angiogenic & anti-metastatic drug
- Extensively profiled in animal models of stem cell mobilization, solid tumors, hematological malignancies, inflammatory indications and rare diseases
- Positive PK data packages: population PK models, data in humans, monkey, dog and rodents
- Shown to overcome SoC drug resistance
- 485 patients administered BLX in 8 clinical trials thus far, with longest treatment duration of 16 months
- Well tolerated by i.v. route of administration; no limiting safety events identified at top dose given of 5.5mg/kg, MTD probably not achieved
- Applicable for various CXCR4-driven therapeutic indications & compatible with combination chemo & targeted therapies
Balixafortide + Eribulin:
Strong P2 PoC Results Across All Efficacy Parameters Supported Moving to P3

Balixafortide Proof of Concept\(^1\) – Improving treatment of advanced HER2 negative mBC\(^2\) (Open label, n=56)

**Overall Response Rate**
- Eribulin: 13%
- Balixafortide + Eribulin: 38%

**Clinical Benefit Rate**
- Eribulin: 28%
- Balixafortide + Eribulin: 63%

**Progression Free Survival**
- Eribulin: 3.6 months
- Balixafortide + Eribulin: 6.2 months

**Overall Survival**
- Low Dose (n=15): 0.5–2.0 mg/kg
- Medium Dose (n=15): 2.5–4.5 mg/kg
- High Dose (n=24): 5.5 mg/kg

Notes:
1. Reflects an indirect comparison
2. Metastatic Breast Cancer
3. “Embrace” Registration Trial for Eribulin Spexis trial – results from dose expansion cohort
4. Spexis trial
Phase 3 FORTRESS Study of Eribulin ± Balixafortide in Advanced BC (2019 – 2021)

Objectives:
- **Key primary endpoint:** Progression free survival (“PFS”) at 12 months after last patient randomized
- **Co-primary endpoint:** Objective Response Rate (“ORR”) at 6 months after last patient randomized

Patient Population:
- Locally recurrent or metastatic breast cancer (BC)
- HER2 negative, with any ER/PR
- Previously treated with 1–4 chemotherapeutic regimens for locally recurrent or metastatic BC
- Previously received an anthracycline and a taxane in either the adjuvant or metastatic setting, unless contra-indicated for safety reasons

Results:
- 3 positive DSMB decisions to continue trial without any modifications
- 3rd line+ patients: 344 / 320 recruited
- 2nd line patients: 88 / 64 recruited
- HER2- and HR+: 278 patients (64%) and Triple Negative: 154 (36%)
- **Outcomes:** no statistically significant difference in ORR or PFS between treatment arms observed

Forward Plan:
- FORTRESS study design & data analyses continuing to inform possible future trials
- Strategic decision on forward solid tumor and/or other development expected mid-2022
Expanding Shareholder Value

Value Inflection & Other Goals For 2022

• Chronic Respiratory Disease (CRD):
  • Initiate ColiFin® P3 trial
  • Complete inhaled murepavadin P1 trial and pursue P2 start ASAP thereafter
  • Evaluate EBX-001, EBX-002, and CXCR4 inhibitors for possible further CRD clinical development

• Oncology:
  • Complete BLX analyses for possible future clinical trials
  • Nominate heme-onc indication(s) for newly identified CXCR4 candidate based on preclinical PoC data overcoming resistance against SoC

• Business Development/Strategic Transactions
  • Further explore development possibilities under Fosun BLX alliance
  • Pursue strategic transactions targeting mid/late clinical stage products
  • Pursue additional partnerships/financings to support above
## Corporate Calendar & Important Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Est Date</th>
<th>Active Trials</th>
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</thead>
<tbody>
<tr>
<td>AGM</td>
<td>Apr 26 ’22</td>
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<tr>
<td>COPILOT 1st Patient In</td>
<td>June ’22</td>
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<tr>
<td>1H2022 Results</td>
<td>Sep ’22</td>
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<tr>
<td>QD vs. BID COPILOT Results</td>
<td>Sep-Oct ‘22</td>
<td>MPV P1a</td>
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<tr>
<td>iMPV Phase 1a Readout</td>
<td>Oct ‘22</td>
<td>MPV P1b</td>
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<td>iMPV Phase 1b 1st Patient In</td>
<td>Nov ’22</td>
<td>COPA</td>
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<tr>
<td>COPA 1st Patient In</td>
<td>Dec ‘22</td>
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<tr>
<td>FY 2022 Results</td>
<td>Mar ‘23</td>
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<tr>
<td>iMPV Phase 1b</td>
<td>Jun ‘23</td>
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<tr>
<td>H1 Results</td>
<td>Sep ‘23</td>
<td>P2</td>
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<tr>
<td>iMPV Phase 2</td>
<td>Q4 ’23</td>
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<tr>
<td>COPA Interim Efficacy Analysis</td>
<td>Q4 ’23</td>
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</tbody>
</table>

- Corporate Calendar
- Important Events
Summary of Key Messages

- New and unique rare disease and oncology company
- Initial rare disease focus: cystic fibrosis with two clinical candidates
  - ColiFin® starting Phase 3 mid-2022
  - Inhaled murepavadin ("iPMV") Phase 1 ongoing
- Proven macrocycle platform ("MCP") poised to build oncology & other rare disease pipeline and fuel corporate partnerships:
  - iMPV generated by MCP
  - Balixafortide: initial P3 study negative but other indications TBA
  - Novel CXCR”X”- active compounds under study with indications TBA
  - Highly leverageable towards other extracellular, intracellular & PPI targets
Thank you!

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