Pioneering Personalized Medicine in Epigenetics
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Company Highlights

- A clinical stage biopharmaceutical company developing innovative therapies in the field of Epigenetics
- Two molecules already with positive data in humans
- Large IP portfolio with technology fully developed in-house
- MADX: ORY — A publicly traded company on the Spanish Stock Exchange
- Integrated in the IBEX Small Cap Index

- Raised an aggregate of circa €85M (in 2015-2019)
- Cash runway expected till 2H2021
- One of the most LIQUID companies in the MicroCap group in the Spanish Stock Market
  - 45.7 M Shares outstanding. Fully diluted
  - +310,000 daily volume (Avg Traded Volume in 2019)
  - +78M shares negotiated in 2019 / ≈6 months for share full turnover

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**BALANCE SHEET DATA (AUDITED)**
(Amounts in thousands US $)

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<thead>
<tr>
<th></th>
<th>September 30th. 2019</th>
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<td>Cash and cash equivalents</td>
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<td>Total Assets</td>
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<tr>
<td>Total Stockholders' equity</td>
<td>67,595</td>
<td>39,314</td>
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1. Spanish GAAPs
Epigenetic Modifications: New Targets for Drug Development

- Heritable DNA modifications that do not alter the actual DNA sequence but change gene activity and expression
  - Histone modifications
  - DNA methylation
  - microRNAs...

- Histone modifying enzymes are “writers” or “erasers” - adding or removing epigenetic marks from histone tails

- Epigenetic dysfunctions are associated with aberrant gene expression and disease

- Epigenetic drugs can restore these transcriptional imbalances

Figure from Arrowsmith et al. Nature Reviews Drug Discovery volume 11 (2012)
Oryzon is pioneering epigenetics in CNS and active in oncology

A broad pipeline to address unmet medical needs with an attractive market opportunity

### CNS Market Need

**Aggression is a common feature in many psychiatric diseases. +50% in ADHD(***)**

**Global BPD market expected to grow to $2.6B in 2027**

**45 million people with AD worldwide; 20% shows aggressiveness**

**AD main disruptions: memory loss, aggression and apathy. AD global costs per annum of $605B**

### Oncology Market Need

**Global AML market of $990m in 2019. Room for new Combos according to KoLs**

**SCLC is a serious unmet medical need, with a MOS of 8–12 months and 5% 2-year OSR**

**Global SCLC market +300,000 patients/y. FDA approved label extension of Pembrol only 19% of ORR (****)**

**Projections of Rova-T when in Phase III were $5B peak sales/y**

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>STUDY*</th>
<th>RESEARCH</th>
<th>PRECLINICAL</th>
<th>PHASE I</th>
<th>PHASE II</th>
<th>PHASE IIB</th>
<th>PHASE III</th>
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<tr>
<td><strong>VAFIDEMSTAT (ORY-2001) - CNS optimized LSD1 inhibitor</strong></td>
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<td>Aggression in BPD</td>
<td>REIMAGINE / PORTICO (*)</td>
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<td>Aggression in ADHD</td>
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<td>Aggression in ASD</td>
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<td>Aggression in AD</td>
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<td>Multiple Sclerosis (RR &amp; SP)</td>
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<td><strong>IADADEMSTAT (ORY-1001) - selective LSD1 inhibitor</strong></td>
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<td>AML (Elderly Unfit)</td>
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<td>SCLC (First Line Relapsed)</td>
<td>CLEPSIDRA Combo w Platinum/Etoposide</td>
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<td><strong>ORY 3001 - selective LSD1 inhibitor</strong></td>
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**** Keynote study in 83 patients
VAFIDEMSTAT a Phase II Clinical Stage Compound with a broad developability in CNS diseases
Vafidemstat (ORY-2001): a “Neuron-fixer” ready for Phase IIb

- Vafidemstat is a small molecule LSD1 inhibitor optimized for CNS
- Excellent Pharmacology. High oral bioavailability
- Positive results in 7 different animal models and in in-vitro models
  - Cognition
  - Neuroprotection
  - Neuroinflammation
  - Social Withdrawal / Apathy
  - Aggression / Agitation
  - Others
- Epigenetic MoA that modulates neuroinflammation and expression of key plasticity neuronal genes
- Biomarkers identified
- Good Safety in humans in Phase I+II trials with +220 participants so far
- BBB penetrance and (indirect) human brain target engagement established
- Pharmacologically active in humans
Vafidemstat, and LSD1 inhibition, improves cognition

In Alzheimer’s SAMP8 model vafidemstat restores memory by the NORT model

In Huntington disease R6/1 model vafidemstat improves memory by the NORT model

In Schizophrenia SETD1a +/- model iadademstat (ORY-1001) improves working memory

In Psychosis & Schizophrenia NMDA receptor-hypofunction mice model T-448 (Takeda) LSD1 inhibitor improves memory

Vafidemstat Fully Restores Memory Measured by NORT in SAMP8 AD Model

Cognition and memory impairments are found in AD and dementias but also in Autism, Schizophrenia, Depression, Bipolar disorder and other psychiatric conditions
Vafidemstat Produces Significant Behavioural Changes

- **Vafidemstat Reduces Aggression in the Resident Intruder Test in the SAMP8 AD Mice model**

- **Vafidemstat Enhances Sociability in the Three-Chamber Test in SAMP8 AD Mice**

- **Vafidemstat Reduces Social Withdrawal in the Rat Isolation Model**
MoA: an upstream epigenetic mechanism producing a dual activity, antinflammatory and prosynaptic

LSD1 localizes in vivo to enhancers and promoters of confirmed CNS disease risk genes.
LSD1 binds to TFs that control IEG expression and stress in the PFC-amygdala axis, including SRF.

- Vafidemstat up-regulates genes associated with:
  - Cognition, notably memory and executive functioning
  - Neuroplasticity
- Vafidemstat potentiates the response capacity of IEGs to stress
- Vafidemstat reduces the expression of inflammatory genes including S100A9 and others

LSD1 inhibition rescues the axon branching deficits in the Setd1a-/-mice.

In invitro axon branching rescue assays ORY-1001 was 1000-fold more potent than TCP.
LSD1 inhibition rescues different phenotypes in genetic models of ASD and Schizophrenia

LSD1 inhibition also rescues the Shank3 ASD phenotype
Zhen Yan Oral Comm SFN-2019
SETD1A is a key schizophrenia (SCZ) susceptibility gene. Mutations in SETD1A increase the risk of SCZ by 35 times, as well as a number of other neurological disorders. SETD1A is part of the Set1/COMPASS complex, mediates mono-, di-, and tri-methylation of the lysine 4 on the histone H3 protein.

In addition to SETD1A, mutations in other subunits of Set1/COMPASS complex have been reported in SCZ and other neurodevelopmental disorders.

Mutant mice carrying a heterozygous loss-of-function mutation of the orthologous gene exhibit alterations in axonal branching and cortical synaptic dynamics, accompanied by specific deficits in working memory that recapitulate SCZ-related alterations.

SCZ patients carrying these mutations identified.

Increased interest by FDA and other regulators to explore a personalized medicine approach in these hard to treat populations.
Vafidemstat: Safety demonstrated in a Phase I study

Safe and well tolerated in a +100 healthy volunteers (young and elderly) Phase I (MAD+SAD) study

- No hematological impact at planned doses
- Efficiently crossed the BBB (70-90%)
- Oral PK - Half Life of 22h allowing once daily oral
- PK/PD data allowed definition of recommended Phase II doses

Safe and well tolerated so far in diverse Phase II studies

- Vafidemstat has been already administered to +220 volunteers and patients
- Phase IIs (MS, AD, ADHD, BPD and ASD patients) with no safety signals to date
- Longest exposure to date: 15 months
Vafidemstat: REIMAGINE - a Basket trial in aggression

**Endpoints**

Safety

Efficacy:

- Aggression / Agitation measured by CGI-S
- Aggression / Agitation measured by CGI-I
- Aggression / Agitation measured by NPI A/A 4 items
- Psychiatric status measured by NPI Global assessment (12 items)
- Change in specific disease scales

**Duration**

8 Weeks treatment + 4 weeks of follow up

<table>
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<tr>
<th>Cohorts to be recruited</th>
<th>6 patients</th>
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<td>Borderline Personality Disorder</td>
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<tr>
<td>Attention Deficit and Hyperactivity Disorder</td>
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<tr>
<td>Autism Spectrum Disorder</td>
<td>6 patients</td>
<td>Done – Data reported in April 2019</td>
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**Trial status: completed**

(LPO 22-oct-2019)
REIMAGINE the first proof of concept for vafidemstat in human patients

Reduced Aggressivity in patients of the three psychiatric indications: Borderline Personality Disorder (BPD), Attention Deficit and Hyperactivity Disorder (ADHD) and Autistic Spectrum Disorder (ASD) treated with vafidemstat

Secondary Endpoints: Efficacy

Also significant improvements in aggression evaluated using the Clinical Global Impression of Severity (CGI-S) and Improvement (CGI-I) scales

Data presented at CINP 2019
REIMAGINE the first proof of concept for vafidemstat in human patients

The significant improvements in the NPI global score and overall specific scales for BPD and ADHD suggest that vafidemstat has a **broader psychiatric effect beyond aggression**.
Vafidemstat: a new therapeutic option for aggression in Alzheimer’s disease

REIMAGINE-AD: A Phase IIa trial in Moderate and Severe AD

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- Safety
- Efficacy: Aggression / Agitation measured by NPI A/A 4 items, CMAI and CGI-A/A
- Memory status measured by MMSE
- Caregiver burden measured by changes in the Zarit Burden Interview (ZBI)

DATA expected in APRIL 2020
Next steps: PORTICO, a Phase IIb trial with vafidemstat in BPD to treat aggression

The company recognizes a significant development potential for vafidemstat in psychiatric indications

- Vafidemstat may be a disease modifying therapeutic option for BPD: reduces aggression and produces an overall improvement of the core features of the disease, with no sedation and no weight gain
- BPD prevalence ranges between 0.5%-1.4% of the total population (≤ 9.1M in US+EU5)
- The treatment of BPD is now based on psychotherapeutic interventions. No drugs currently approved for this condition
- A significant unmet medical need
- Global BPD Market, 2018-2027 (US$), $2.6B expected in 2027

PORTICO: a Phase IIb in BPD Under Preparation

- double blind, randomized, placebo-controlled, 16-week treatment period
- Spain, US and Europe TBD
- N=100
- Expected FPI: 1H2020
- Expected LPO: 2H 2021

- Additional Phase IIb in adult aggressive ADHD (ENTRANCE) and ASD (COLONNADE) under evaluation
- Contingent to positive data in REIMAGINE-AD, a Phase IIb in AD aggressive patients (GATEWAY) will be performed
An ambitious Phase II trial, ETHERAL: Epigenetic THERapy in ALzheimer’s Disease

Besides aggression, vafidemstat may provide also further benefits to AD patients

Phase IIa study to provide useful information to design future Phase II/III studies

✅ 150 Mild to Moderate AD patients (6+6 months)
✅ Primary Objective: Safety & Tolerability
✅ Secondary Objectives:
  ✗ Cognition/Agitation/Apathy/Depression/QoL
  ✗ Volumetric MRI
✅ Biomarker guided study (with 8 CSF Biomarkers)

Status as of Dec’19

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Status as of Dec’19

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Vafidemstat appears to be safe in AD patients: ETHERAL first data report

One of the main goals in ETHERAL is to establish safety of vafidemstat in long-term administration, at therapeutically relevant doses in a frail and elder AD population.

Vafidemstat treatment appears to be safe and well tolerated so far:

- Four SAEs were reported in three subjects suspected to be unlikely related to the treatment
- Platelet, neutrophils and other hematological parameters do not show clinically relevant variations due to vafidemstat treatment
- No abnormal and clinically significant liver enzymes levels or other laboratory findings have been reported-to-date

Biomarker and other functional evolution in ETHERAL (blind analysis) is compatible with an informative study

Baseline levels of pTAU and Abeta in ETHERAL are reflective of a clearly canonical Alzheimer population with active and progressing disease. S100A9 levels in CSF are elevated in these AD patients. S100A9 is a proinflammatory protein reported to be highly overexpressed in PFC in AD patients.
IADADEMSTAT a Phase II Clinical Stage Compound with a broad developability in oncology
LSD1 and cancer

- LSD1 is involved in different cancers and in **cancer stemness**
- High levels of LSD1 often correlate with more aggressive forms of cancer and/or bad prognosis
- Iademstat is a small molecule that selectively inhibits LSD1. Positive preclinical *in vivo* results in different xenograft models. Best in Class. Full characterization published in top-rank journal.

**Potential oncological indications:**

**Solid Tumors**
- Small Cell Lung Cancer
- Prostate cancer
- Colorectal cancer
- Bladder cancer
- Some breast cancers
- Merkel Cell Carcinoma

**HemONC**
- AML
- MDS
- Myelofibrosis
- Non Hodgkin Lymphoma

**Brain/rare Tumors**
- Medulloblastoma
- Glioblastoma

MoA well characterized in SCLC, AML and Medulloblastoma
Iadademstat (ORY-1001): a potent & selective differentiating agent: Summary

- Irreversible, highly selective, potent, small molecule LSD1 inhibitor. Covalently binds to FAD-cofactor of LSD1
- Orally bioavailable, good pharmacologic properties, ADME, PK
- Encouraging results in a FiM Acute Leukemia Phase I/IIa trial:
  - Administered to 41 Relapsed Refractory Acute Leukemia patients

Phase I/IIa acute leukemia – final data (Manuscript submitted)

- Safe and well tolerated: a meaningful candidate for combination with other agents
- Clear differentiating activity at molecular and cellular level
- Antileukemic activity observed in 29% of patients (12/41), including one CRi as proof of Biological concept
ALICE: An AML trial with LSD1i in Combination with azacitidine in the Elderly

A Phase IIa study to evaluate the safety, tolerability, dose finding and efficacy of iadademstat (ORY-1001) in combination with azacitidine in older patients with AML in first line therapy

- Single arm & Open label. Up to 36 patients to be enrolled. **Primary endpoint:** Safety and tolerability of the combo with hypomethylating agent Azacitidine. **Secondary endpoints:** Responses; time to responses; duration of response; and overall survival. Preliminary data for first 6 and 12 patients reported at **EHA-2019 & ASH-2019**

- Combination of iadademstat and azacitidine shows a good safety profile in elderly AML patients
- Preliminary signals of clinical efficacy are encouraging, with 75% of ORs (6/8 evaluable patients: 2 CR, 3 CRi and 1 PR)
- Rapid clinical responses (mean time to first response is currently 32 days)
- Preliminary rate of conversion to red cell Transfusion Independence (40%) is also encouraging
Iadademstat a therapeutic approach for SCLC with a well defined MoA

- LSD1 is a target well characterized in SCLC
- LSD1 inhibitors are effective in several in-vitro and in-vivo models of SCLC
- Characterized MoA
- Iadademstat produces complete and durable tumor regression in different chemoresistant PDX models
- Iadademstat is efficacious in combos with CbEt and other agents
- Identified and patented Biomarkers that are differential in sensitiveness to LSD1i
- Phase II trial ongoing in second line SCLC patients using these biomarkers to stratify patients and identify super-responders
Iadademstat is efficacious in monotherapy in some PDX-SCLC xenografts

- Response to iadademstat in PDX models of SCLC is variable, but some are very strong.

- FHSC04 model: derived from a SCLC patient who relapsed after first line therapy.

- 6/10 FHSC04 mice treated with iadademstat did not show relapse after 300 days.

iadademstat: SCLC - Phase II CLEPSIDRA - preliminary efficacy signals

CLEPSIDRA: A Combination trial of LSD1 and Etopo-Platinum in Small Cell Lung Cancer in biomarker-ID Relapsed patients

A Phase IIa study to assess the safety, tolerability, dose finding and efficacy of iademstat (ORY-1001) in combination with platinum-etoposide chemotherapy in patients with relapsed, extensive-stage disease small cell lung cancer who are positive to candidate predictive biomarkers

- Single arm
- Open label; 6 sites in Spain
- Up to 36 patients to be enrolled
- 4-6 cycles iademstat+platinum/etoposide, thereafter iademstat monotherapy (at investigators’ criteria)
- Primary endpoint: Safety and tolerability of the combo with platinum-etoposide therapy
- Secondary endpoints: RECIST responses; time to responses; duration of response; and overall survival

Biomarker analysis from a CLEPSIDRA patient
Iadademstat: SCLC - Phase II CLEPSIDRA - preliminary efficacy signals

**Preliminary Results**

- **75% response rate** (6/8 evaluable patients): 4 PRs and 2 long-term SD
- Current level of observed responses suggests that **patient selection by Biomarkers** may be effective to increase ratio of ORs

**Main toxicity observed in the combination with carboplatin-etoposide is hematological**

**Iadademstat alone is safe and shows no hematological, general or neuronal toxicity** in ED-SCLC patients, suggesting potential for monotherapy and other combos

**Iadademstat alone sustains further therapeutic benefit**
Anticipating a rich flow of science catalysts / clinical data (non-comprehensive selection)

**2020**
- **Vienna - April**
  - REIMAGINE-AD ETERHAL-EU 6m Interim-A
- **Athens - May**
  - ETERHAL-EU 6m Interim-B

**2021**
- **July - Amsterdam**
  - ETERHAL-EU 6m Interim-C
- **Boston - November**
  - ETERHAL-US 6m Interim-A

**2022**
- **Barcelona - March**
  - ETERHAL-US 6m Interim-B
- **Boston - June**
  - ETERHAL-EU+US 12m FINAL

Potential Conferences where data may be presented:
A-B-C Different data sets when the final analysis is not completed

CLEPSIDRA
ALICE

Vienna - April
Athens - May
July - Amsterdam
Boston - November
Barcelona - March
Boston - June
ORYZON – a unique investment opportunity in an epigenetic platform

✓ A differential proposition in **EPIGENETICS** drugs in **CNS and ONCOLOGY** around one of the most interesting targets in the field: **LSD1**
✓ **2 molecules** in **Phase II** with promising clinical signals of efficacy in patients
✓ **Pioneers in CNS epigenetics**
  ✓ Vafidemstat shows efficacy in psychiatric disorders (BPD, ADHD, ASD)
  ✓ **Phase IIb in Borderline personality disorder expected to start in 1H2020.** Additional trials in ADHD or ASD under evaluation
  ✓ Vafidemstat may be also clinically relevant in neurodegenerative disorders (Phase IIs in MS and AD ongoing)
  ✓ Trials in genetically defined patients under study
✓ **Most advanced** LSD1i (iadademstat) in **Oncology**
  ✓ **Positive preliminary efficacy results** reported in the ongoing Phase II trials in AML and SCLC
  ✓ **SCLC trial is a biomarker-guided** study to stratify responsive patients
  ✓ Options to get accelerated approval
✓ **Rich pipeline** of clinical **news** expected in the next 2-4 Qs. Clinical Operations in US started and under expansion
✓ **A cash efficient** company with a seasoned international management team
✓ **€135M market cap.** One of the most liquid stocks in the microcap group in MadridSEXC with **plans to get dual listed in NASDAQ**
✓ Perseverant **presence in the US market in the last 4 years.** Three successful PIPEs executed in 2017-19 led by US Investment Banks and with participation of US-EU-IL investors
Pioneering Personalized Medicine in EPIGENETICS