Pioneering personalized medicine in epigenetics

ORYZON

JUNTA GENERAL DE ACCIONISTAS

MADX: ORY

29 de Junio de 2022

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An Epigenetic champion determined to bring new therapies to the patients

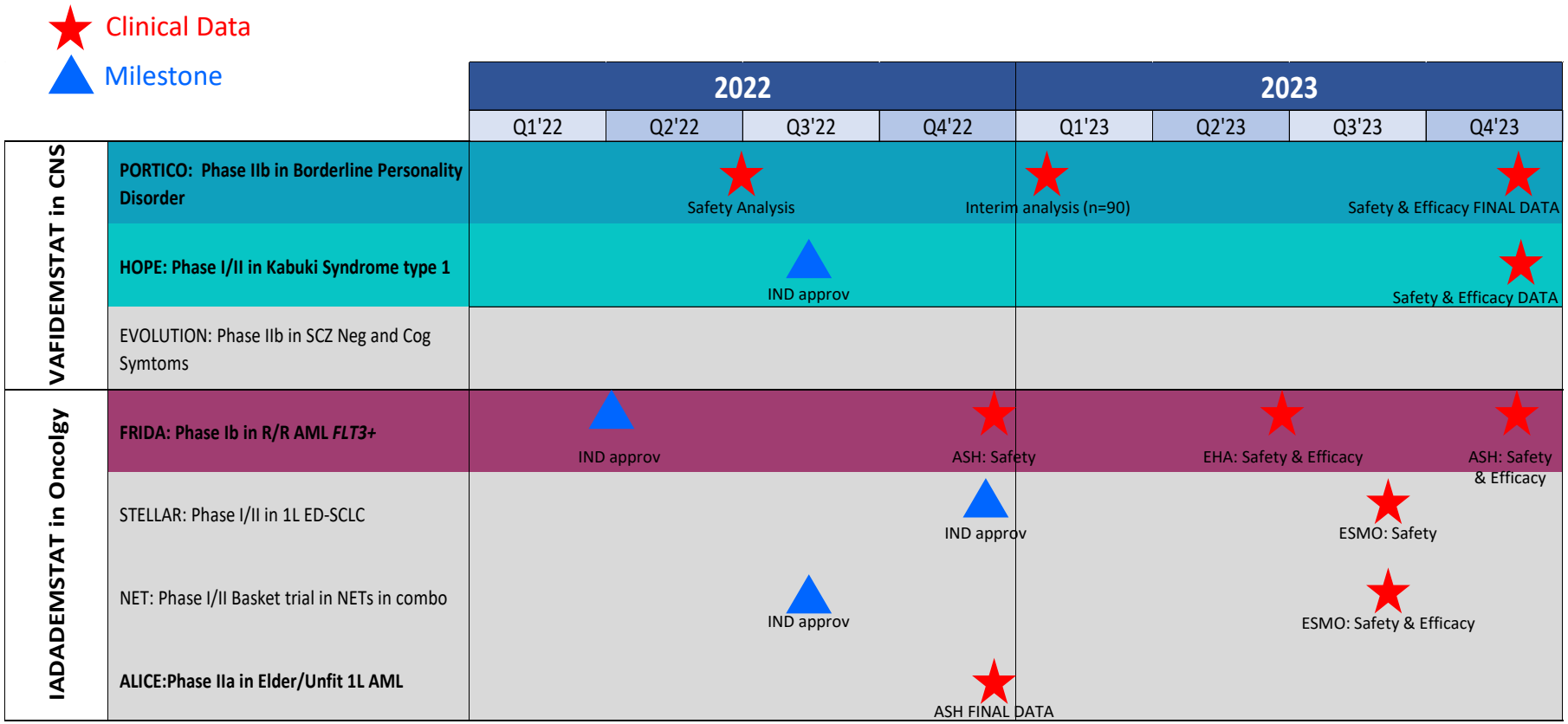
Jun 2021-Jun 2022

2021-2022 a challenging period for the global economy

- A clinical strategy focused on registration in CNS and Oncology
- A US oriented strategy with a first-in-class US team
- Regulatory advances in US with INDs and ODD
- Adapting to an increasingly adverse market condition
- Securing additional Funds to guarantee operations

2022-23 Company Milestones & Principal investment thesis

- With multiple complementary resources we expect to extend our runway till 1Q2024.
- Focus is now execution and setting an optimal long-run corporate strategy reinforcing the BD angle.
- The company continues its preps to get listed in NASDAQ:
  - Legal disclosures
  - Account conciliation to US-GAAP
  - Resolutions of GSM to issue ADRs



ORYZON has an ambitious epigenetic program in Oncology

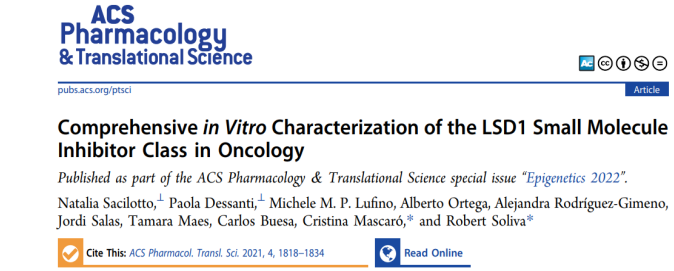
IADADEMSTAT
A Phase II LSD1 inhibitor in Oncology

Orphan Drug Designation granted for AML and SCLC

Iadademstat: first and potentially best-in-class LSD1 inhibitor in AML

The asset

- **The most potent (nM) oral inhibitor of the lysine histone demethylase LSD1 in clinical development**


ACS Pharmacology & Translational Science

pubs.acs.org/ptsci Article

Comprehensive *in Vitro* Characterization of the LSD1 Small Molecule Inhibitor Class in Oncology

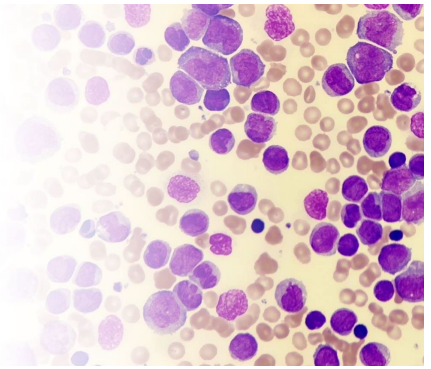
Published as part of the ACS Pharmacology & Translational Science special issue "Epigenetics 2022".

Natalia Sacilotto,[⊥] Paola Dessanti,[⊥] Michele M. P. Lufino, Alberto Ortega, Alejandra Rodríguez-Gimeno, Jordi Salas, Tamara Maes, Carlos Buesa, Cristina Mascaró,* and Robert Soliva*

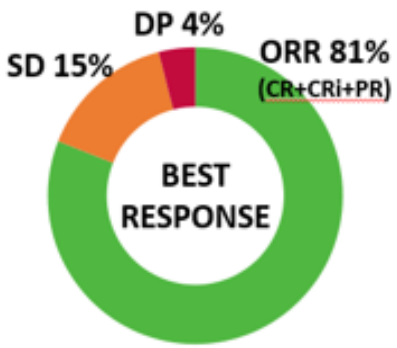
Cite This: *ACS Pharmacol. Transl. Sci.* 2021, 4, 1818−1834 Read Online

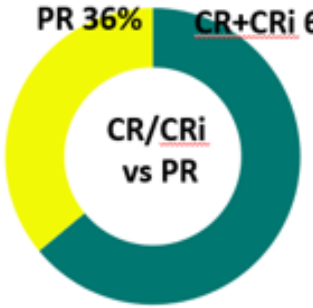
Mechanism of Action

- **LSD1 is required for leukemic stem cell survival and blocking leukemic cell differentiation**
- **Iadademstat prevents leukemic stem cell survival and promotes rapid differentiation/death of leukemia cells**



Key Clinical Data in ALICE





EHA 2022

ALICE, an AML Phase II trial with LSD1i in combination with azacitidine in unfit patients

- Multicenter, single arm & open label study
- 36 patients enrolled (LPI 10/2021)
- **Primary endpoint:** Safety and tolerability of the combo
- **Secondary endpoints:** Response; time to response; duration of response; overall survival

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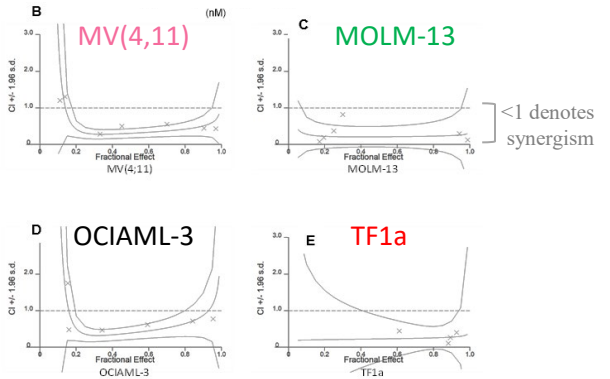
Corporate Strategy: a Phase Ib trial in R/R AML as a foundation stone for an accelerated development

IND Approved

FRIDA:

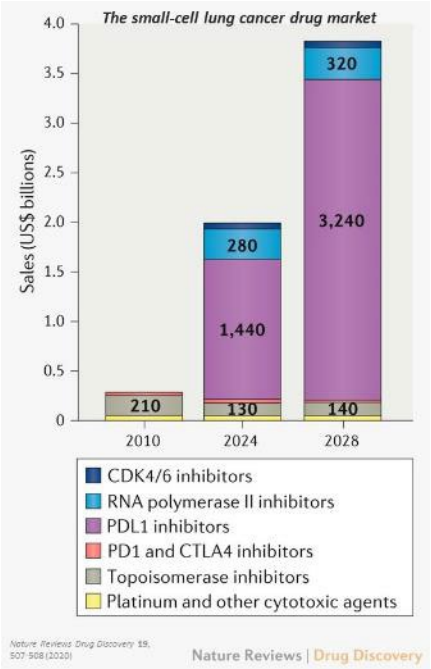
A Phase Ib in FLT3 mut+ R/R AML patients combining iadademstat and gilteritinib (Xospata®)



(B-E) In vitro synergistic effects combining iadademstat with gilteritinib in AML cell lines (Company internal data)

- R/R AML is an underserved population: **Majority of AML patients relapse after 1L treatment and require further treatment.** FLT3 is the most common mutation in AML (**30-40%**)
- 2L R/R FLT3mut+ patients are now treated with **gilteritinib,** yet it remains a subpopulation with **high medical need (mEFS 2.8 months & CR+CRi 34%)**
- **FRIDA, a strong rationale**: High preclinical synergy observed in vitro between iadademstat and gilteritinib
  - Primary objectives: evaluate safety/tolerability, and determine the RP2D of the combination
  - Secondary objective: evaluate efficacy of the combination (CR rate, DoR, MRD)
  - Up to 50 patients
  - IND approved March 2022 / FPI 2H2022
  - Agreement with FDA to discuss next steps for pivotal trial development after this Phase Ib

A Market opportunity



Collaborative PoC basket trial in neuroendocrine tumors (NETs) with iadademstat

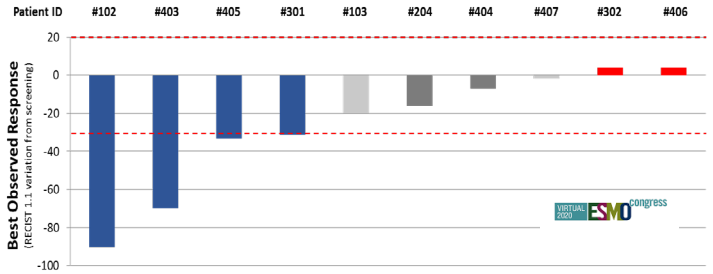
FOX CHASE CANCER CENTER
TEMPLE HEALTH

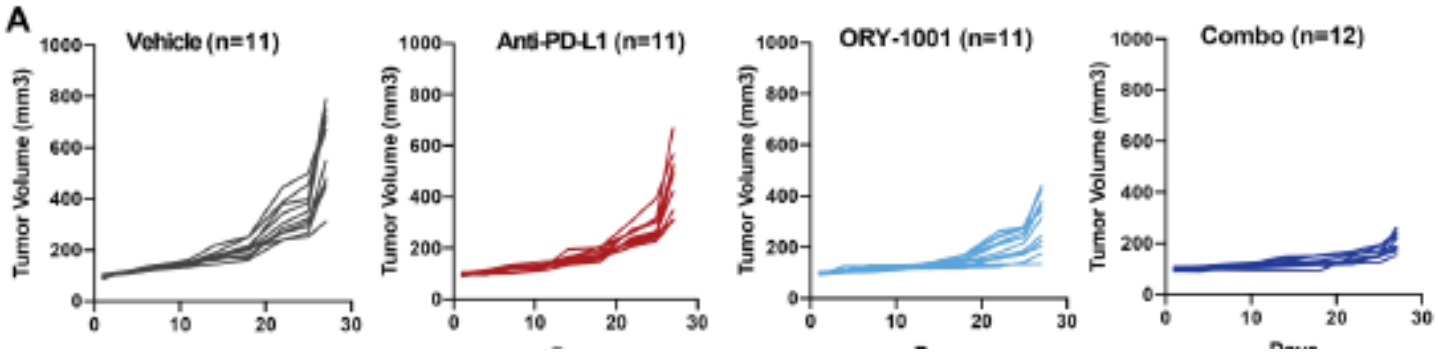
A Phase Ib/II study of iadademstat in combination with synergistic agents in platinum R/R SCLC and extrapulmonary high grade neuroendocrine carcinomas

- **Label expansion opportunity**
- **High unmet medical need: Treatment of platinum relapsed (<6 mos)**
- **Low hanging fruit: NETs has dismal outcomes** ranging from ORR 5% (extrapulmonary) to ~20-30% in SCLC; and PFS 3 to 4 months respectively
- **Strong rationale** for combination of iadademstat with nonTCP-inducing synergistic agents in several tumors
- IND submission 2H2022 / FPI 2H2022

STELLAR: a future Phase Ib/II trial in 1L ED-SCLC with potential for accelerated development

A Proof of Concept (CLEPSIDRA)





Memorial Sloan Kettering Cancer Center

Targeting LSD1 rescues MHC class I antigen presentation and overcomes PD-L1 blockade resistance in small cell lung cancer. Nguyen EM et al., J Thorac Oncol. 2022 DOI:https://doi.org/10.1016/j.jtho.2022.05.014

FOX CHASE CANCER CENTER
TEMPLE HEALTH

STELLAR:
A randomized controlled Phase Ib/II study of iadademstat plus a checkpoint inhibitor in 1L patients with metastatic SCLC

- **High unmet medical need** and a relative low bar for improving efficacy due to the modest efficacy improvements (**2 months OS increment with recent approval of ICI in combo with chemotherapy**) shown in the IMPower-133, CASPIAN and Keynote-604 trials in 1L SCLC

STELLAR can potentially support an accelerated approval if a significant clinical benefit in the population is demonstrated over the efficacy of SoC treatment

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ORYZON, the only company developing epigenetic drugs in CNS

VAFIDEMSTAT
A Phase II LSD1 inhibitor for CNS diseases

CNS disorders: a field evolving towards Precision Medicine

LSD1 is key for the function of the CNS and is involved in multifactorial CNS disorders and monogenic syndromes

Large multifactorial indications

- Unknown origins
- Still diagnosed by predominant symptoms
- Confounding comorbidities
- May include genetically better defined subpopulations
- Large market opportunities

Small/rare monogenic indications

- Molecular diagnosis
- Allows smart drug design based on MoA
- Fast Market Approval conceivable
- Small markets but premium price
- May expand label to similar indications

Vafidemstat may be developed in both indications based on different formulations and commercial channels

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Vafidemstat: an LSD1 inhibitor to treat large multifactorial CNS indications including borderline personality disorder (BPD) and schizophrenia (SCZ)

The Asset

- **A potent (nM) oral inhibitor of the lysine histone demethylase LSD1 with high BBB penetration, optimized for CNS disorders**

FiM: 110 volunteers:

87 treated with vafidemstat and 23 with placebo

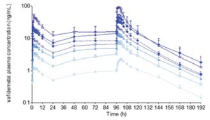
Safe

No differences between placebo and vafidemstat-treated patients

Brain Penetrant

An optimal CSF : plasma ratio of 0.9

Oral, once a day

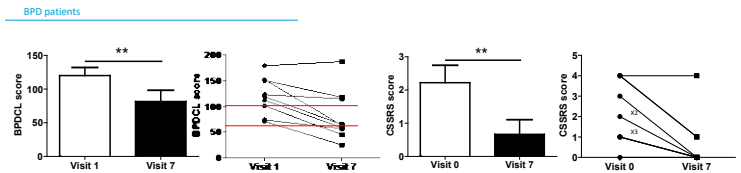


PK data supports once daily dosing in both adult and elder subjects

Key Clinical Data

- **+300 subjects treated** with vafidemstat
- **Safety and effectiveness demonstrated as a single agent**
- REIMAGINE trial (basket trial in BPD, ASD and ADHD).
  - **Statistically significant improvements in aggression** in each of the three disease groups, as well as in aggregate
  - **Improvements** also observed in **overall patient functioning**, particularly in BPD patients

A Proof of Concept (REIMAGINE)



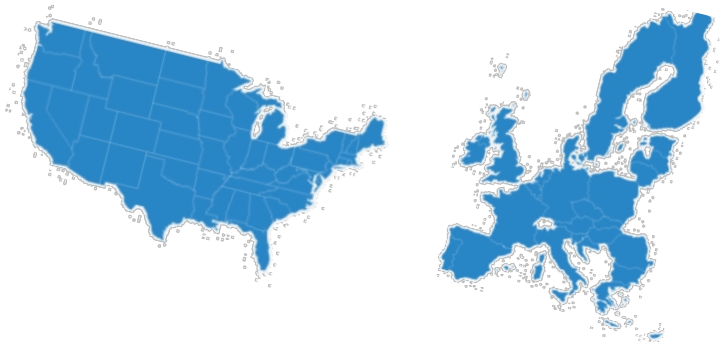
Overall improvement in BPDCL scale to diagnosis threshold level Supporting general treatment of the disease

28th European Congress of Psychiatry, EPA 2020

Borderline personality disorder: a snapshot

A Prevalent & impairing disease

9 million in US & EU



Two main types of symptoms

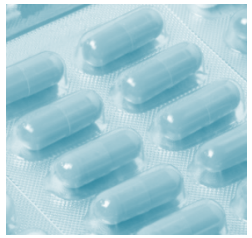
Unstable-extreme interpersonal relationships

+

Aggression & self-aggression

No approved drugs yet

Patients in off-label antipsychotics



Vafi improves these symptoms in PC models

Expected Market Value in 2027

US$ ~3 billion

Highest Revenue Drug Category: Anti-psychotics followed by anti-depressants

Aggregated sells: ~ 1 Billion

Very low competition

0 Phase III trials

2 Phase II trials

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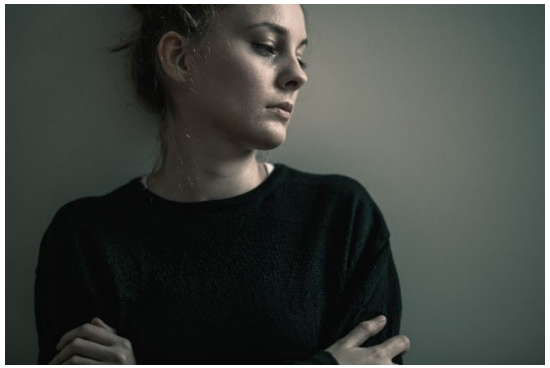
Ongoing Study: a Phase IIb in Borderline Personality Disorder

PORTICO:

An adaptative randomized double blind Phase IIb trial with vafidemstat in Borderline Personality Disorder patients



- BPD is a **serious psychiatric condition** affecting 1.6% in the general population. Prevalence is 9 million people in US and EU
- BPD patients often experience emotional instability, impulsivity, irrational beliefs and distorted perception, and intense but unstable relationships with others
- **High unmet need**: no drugs specifically approved for BPD. 1.4 million patients in US are being treated with off-label anti-psychotics
- **PORTICO** will enroll approximately 156 patients
- Two primary independent endpoints:
  - Overall clinical BPD improvement, and
  - Improvement in aggression
- Actively enrolling in EU and US

An interim analysis (90 patients) is anticipated by the 4Q2022-1Q2023. Assuming current accrual expects:

Final read out 4Q 2023

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EVOLUTION an ongoing PoC Schizophrenia study with vafidemstat

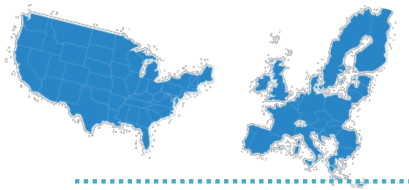
EVOLUTION:
An adaptative randomized double blind Phase IIb trial with vafidemstat in schizophrenia patients

- Double blind, placebo controlled adaptive trial design (n=100)
- Vafidemstat as add-on to SoC. 6 months of treatment
- Primary endpoints: efficacy to address SCZ Negative and cognitive symptoms
- Actively recruiting patients in EU

- Prevalence SCZ and related psychotic disorders in the US range between 0.25% and 0.64%. Prevalence is around 5 million people in US and EU
- SCZ patients experience: ***Psychotic symptoms*** including hallucinations, delusions, abnormal thinking and disorganized speech; ***Negative symptoms*** include loss of motivation, disinterest or lack of enjoyment in daily activities, social withdrawal and difficulty showing emotions. ***Cognitive symptoms*** include problems in attention, concentration, and memory
- **No current approved treatments for the cognitive impairment or the negative symptoms of SCZ**
- LSD1i restores phenotypes in various SCZ mice models

A Prevalent & impairing disease
20 millio ww.

~5 million in US & EU

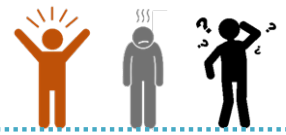


Market Value in 2021

US$ ~8 billion

Three main types of symptoms

Positive or Negative
+
Cognitive Impairment

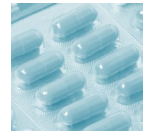


Highest Revenue Drug Category: long-acting injectable (LAI) antipsychotics

Single Best seller:
+ $ 3 Billion

No approved drugs yet for

Negative symptoms (60%)
Cognitive Impairment (70%)



Vafi improves these symptoms in PC models

Moderate competition

14 Phase III trials
12 Phase II trials

ORYZON is pioneering personalized medicine in CNS

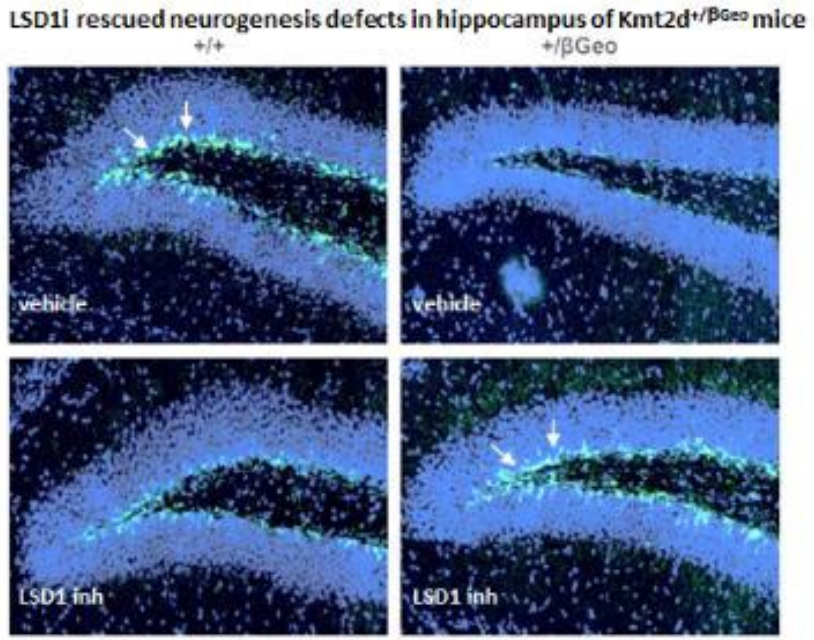
VAFIDEMSTAT
A Phase II LSD1 inhibitor for CNS diseases

Vafidemstat: an LSD1 inhibitor targeting genetically defined neurodevelopmental syndromes, e.g. Kabuki

KABUKI syndrome a possible fast Route to Market

- Initial clinical development program focused on new study **HOPE** for patients with Kabuki syndrome (KS) type1 with possible registration merits
- **Approx. 6,000+ pts with KS type 1 will be eligible for HOPE, with a significant market potential.** Application to larger pediatric population to follow rapidly as safety and efficacy are demonstrated.
- Additional well-established genetically-defined diseases emerging **as possible label extensions**

A Proof of Concept



*Modified from Zhang et al, Molecular Therapy: Methods & Clinical Development, Vol. 20, 779-791 (March 2021)

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Corporate Strategy: a Phase Ib/II trial in Kabuki syndrome patients with registrational potential

In pre-IND discussions with the FDA

HOPE:
An adaptative randomized double blind Phase I/II trial with vafidemstat in KS Type 1 patients

- KS is a **congenital, rare, multisystem disorder** characterized by multiple multiorganic abnormalities including intellectual disability
- **Strong preclinical rationale exist for inhibiting LSD1 in KS**
- Phase Ib objectives: evaluate safety/tolerability, and determine the RP2D
- Phase II objective: evaluate efficacy of vafidemstat at the RP2D in KS Type1 patients
- ~50 patients
- IND 2H2022 /FPI 2H2022
- Recruitment expected in 12-15 months

Trans-Atlantic management team with proven drug development and operational capabilities

Carlos Buesa
PhD
CEO

Molecular Biologist, entrepreneur and founder of Oryzon and Board Former Director of 6 biotech companies. Former Director of INVEREADY SEED CAPITAL and of INVEREADY BIOTECH

Douglas Faller
MD, PhD
Global CMO

MD from Harvard. PhD from MIT. Professor Harvard Med, Brigham&Womens, Boston Children's, Dana-Farber. Founder and Director of Boston University Cancer Center. Grunebaum Professor for Cancer Research. Founder and CMO of several public Biotech Companies. Exec. Medical Director at Takeda Pharmaceuticals.

Michael Ropacki
MD
CMO for CNS

Dr. Ropacki held a SVP of Clinical Development role at MedAvante-ProPhase. Previously he served as GMA Leader, Head of Late-Stage Development for Alzheimer's, and as a Dir of Clinical Development in Neurosciences, at Janssen

Saikat Nandi
PhD
Global CBO

PhD from Oxford, UK. Visiting Scientist at CSHL, NY. Investment executive with 15+ years of buy- and sell-side experience in healthcare & finance industries. Managed public & private investments totaling more than $1B. Portfolio Manager at AIG.

Jordi Xaus
PhD
CSO

Immunologist. Postdocs at Burnham Institute and Genentech. 20 years industry experience at Puleva Biotech SA as Head of the Immunology Department and at Palau Pharma SA as CSO. Since 2021 he serves as CSO at Oryzon

Ana Limon
PhD
SVP Clinical Development & Medical Affairs

Molecular Biologist. Scientist at DFCI. 16 years biotech/pharma experience in drug development with GMA and leadership management positions in Oncology at Amgen, Millennium, Takeda and Deciphera

Sonia Gutierrez
MS
Chief of Clinical Operations

Pharmacist with 20+ years of experience in the clinical research and operations area at international pharma and biotech companies (Synthelabo, Pharmacia-Upjohn, Sanofi, Lundbeck and Regeneron), on the fields of psychiatry, neurology, pain and oncology

ORYZON Research and Clinical Deveelopment leverages on collaborations with prestigious international Institutions

2021-22 a Period with Financial Markets in Distress

Unprecedented systemic crisis

- **Covid-19 Pandemics and Omicron waves**
- **Supply chains disruptions**
- **Energy Price**
- **Inflation rates**
- **Slower growth**
- **ECB/FED rate hikes**
- **War in Ukraine**
- **Food / Cereal Crisis**

For first time the Biotech Sector has been specially affected by the negative market sentiment

Biotech Traded Up Last Week

The XBI closed at 71.2 on Friday (unchanged from a week ago). In contrast, Torreya's comprehensive measure of the aggregate value of biotech was up 4.1% - impacted by change in Turning Point's value.

Biotech Stocks Down Last Week

Return: May 28, to June 3, 2022

Nasdaq Biotech Index: -2.5%
Arca XBI ETF: +0.2%
Torreya Global Biotech (EV): +4.1%*
S&P 500: -1.2%

Return: Jan 1 to June 3, 2022

Nasdaq Biotech Index: -21.7%
Arca XBI ETF: -36.4%
Torreya Global Biotech: -50.8%**
S&P 500: -13.8%

VIX Down a Smidge

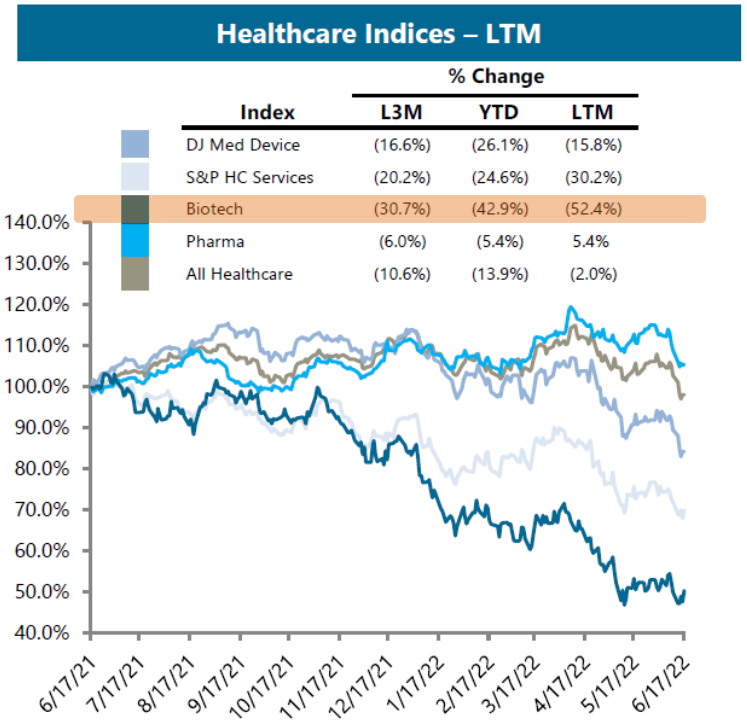
Jan 3: 16.6%
Mar 11: 30.8%
April 15: 22.7%
April 29: 33.4%
May 7: 30.2%
May 20: 29.4%
May 27: 25.7%
June 3: 24.9%

10-Year Treasury Yield Up a Bit

Jan 3: 1.63%
Feb 25: 1.98%
Apr 29: 2.94%
May 7: 3.12%
May 20: 2.78%
May 27: 2.74%
June 3: 2.88%

XBI Index, April 1, 2021 to June 3, 2022

Source: S&P Capital IQ, Google and Torreya analysis



BTIG Healthcare ECM Dashboard: June 17, 2022

* Change by enterprise value. The market cap equivalent was +2.5% for the week (higher than the XBI).

** Drop by enterprise value. The market cap equivalent is -40% for the year.

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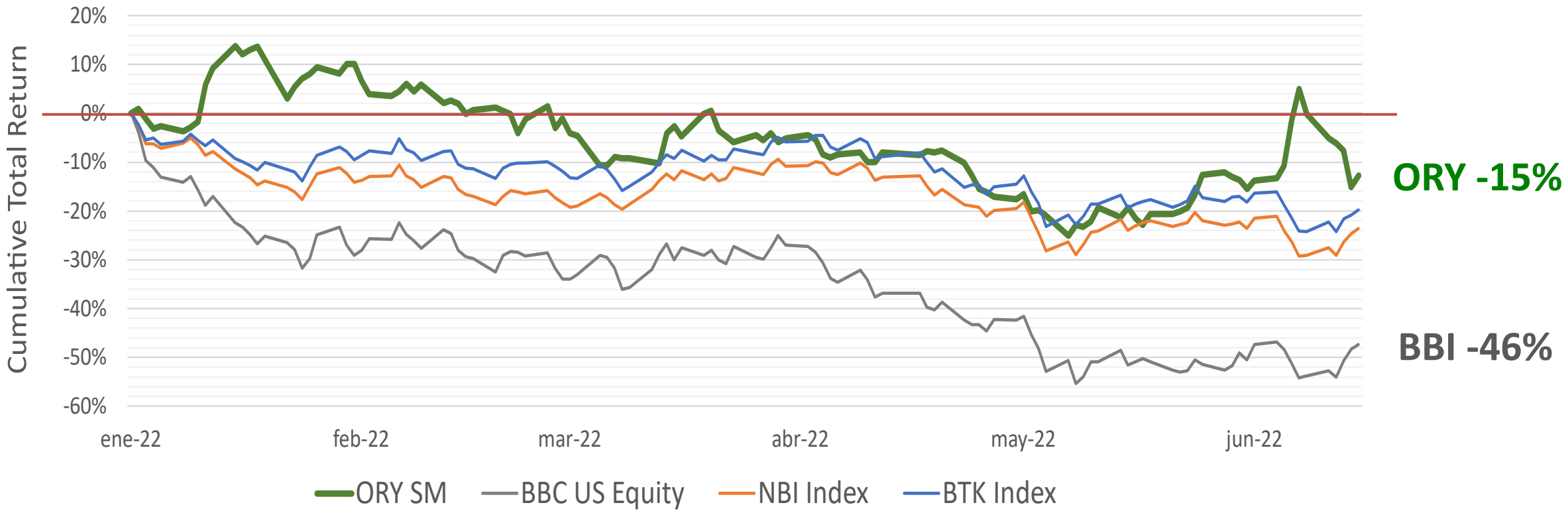
In a very adverse market, Oryzon has performed better than its US peers in Nasdaq

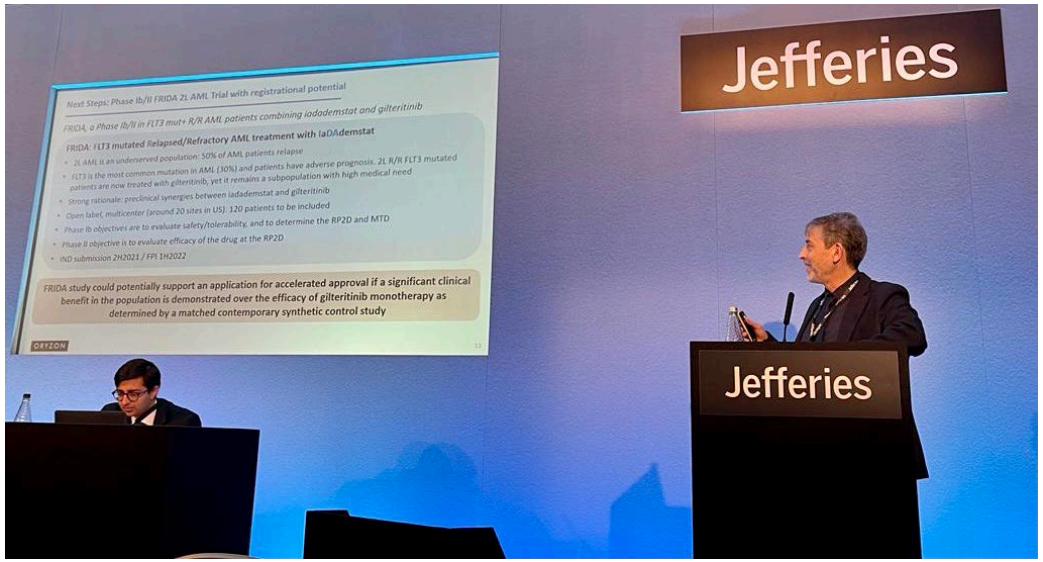


BBC US Equity - The Bioshares Biotechnology Clinical Trials Index (Nasdaq: BBC) comprised solely of pure-play biotechnology companies with an asset in Phase 1 to Phase 3 clinical trials and is therefore representative of the performance of the biotechnology companies with no approved products. Most biotechnology indexes include non-biotech companies and are dominated by large companies with approved products. The BBC should also reflect the volatility of clinical-stage companies, which is typically greater than those with approved products.

In a very adverse market, Oryzon has still performed better than its US peers in Nasdaq

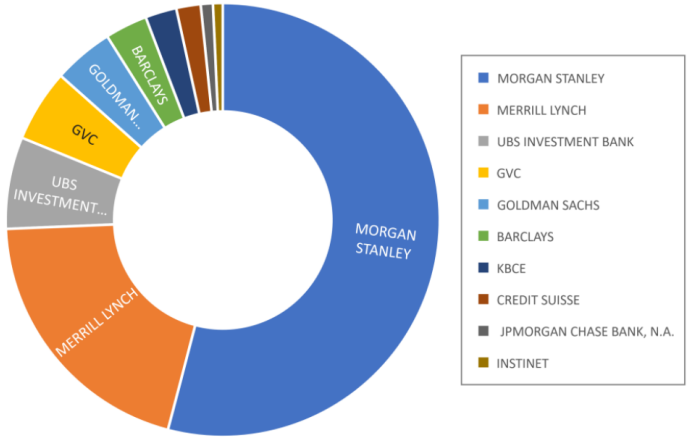
- Good progress of the clinical programs with positive results
- Good regulatory news with FDA approvals of ODD and INDs
- Intense communication campaign in the media in Spain
- Intense Relation with International investors
- A careful cash consumption

As a consequence of an intense international IR campaign, a relevant part of the daily trading is originated internationally

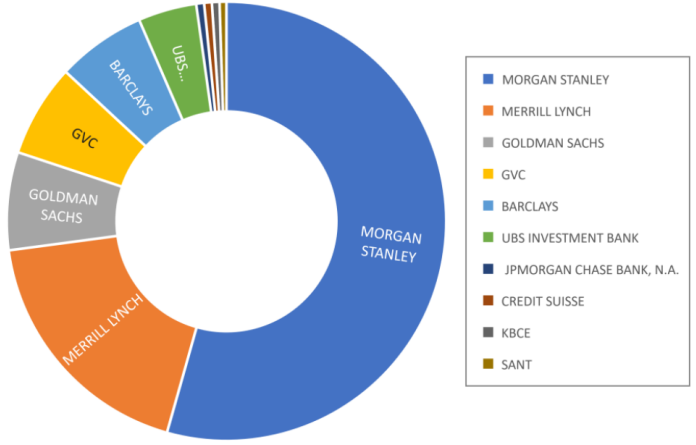


Last 12 Months*			
1	MSCO	7,055,316	39.3%
2	MLCO	3,437,559	19.2%
3	GVC	2,585,623	14.4%
4	BCAP	1,440,760	8.0%
5	UBS	929,816	5.2%
6	GS	674,414	3.8%
7	JPMS	361,932	2.0%
8	FIDE	289,467	1.6%
9	SANT	243,788	1.4%
10	INCA	217,810	1.2%

Last 30 Days Brokerage Volume Distribution



Last 90 Days Brokerage Volume Distribution



* Charts only display top 10 brokers; as of 05/02/2022

Source: Bloomberg

The Company continues its preparations to get listed in Nasdaq

- **The company has invested €1.3 Million in 2021 in**
  - **Legal Preps for the disclosures needed to list the company in Nasdaq**
  - **Auditing Preps to reconciliate the Spanish GAAPs with the US-GAAPs (PCOBs)**
- **Today in this GSM, we propose to authorize the Board to issue ADS (American Depositary Shares) securities to list in Nasdaq**
- **With these preps the company is ready to list in Nasdaq when the appropriate market conditions occur**

ORYZON

A unique dual EPIGENETIC proposition in CNS and ONCOLOGY

- A validated approach with multiple shots on goal
- One and only epigenetic company in CNS
- 2 Phase II programs
- Differentiated pipeline of first- and potentially best-in-class LSD1 therapies
- Derisked: Safety proven in 400+ subjects dosed

Value Creation in 2022-23

Multiple inflection points

- Final data for 1L AML PoC ALICE
- Read-out Phase IIb in BPD
- Kabuki Syndrome Phase I/II trial start in 2022
- 1L ED-SCLC and 2L AML trials start in 2022 with potential to support accelerated development
- Additional trial initiations in Oncology & CNS

PARTE III

INFORME SOBRE LA MARCHA

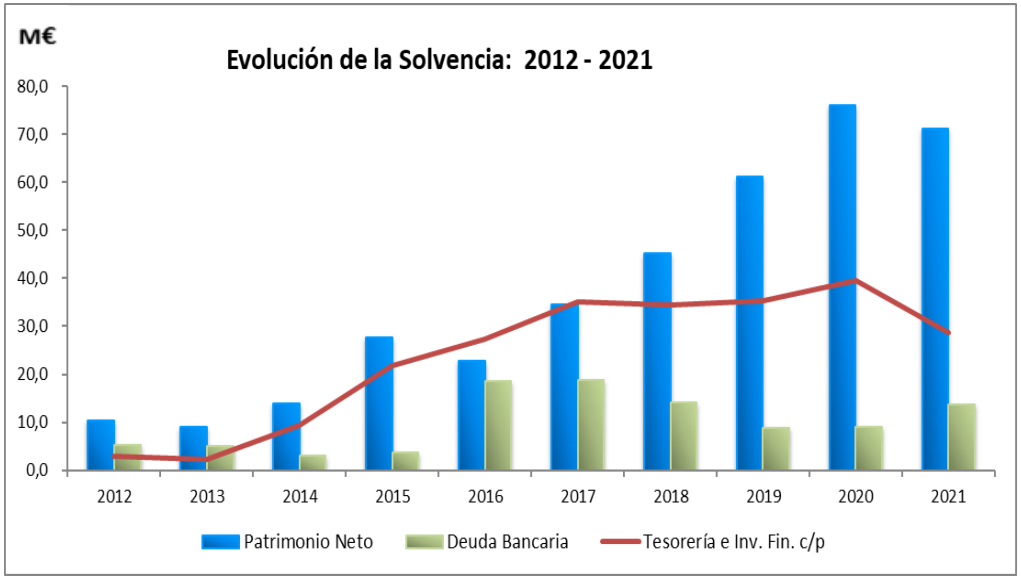
GENERAL DE LA COMPAÑÍA

HITOS FINANCIEROS

Evolución de la solvencia financiera (2012-2021)

Patrimonio Neto → 71,2 M€
Tesorería e inv. financieras c/p → 28,7 M€
Endeudamiento financiero → 17,7 M€

Patrimonio Neto → 75%
Recursos permanentes → 91%
Exigible a corto plazo → 9%



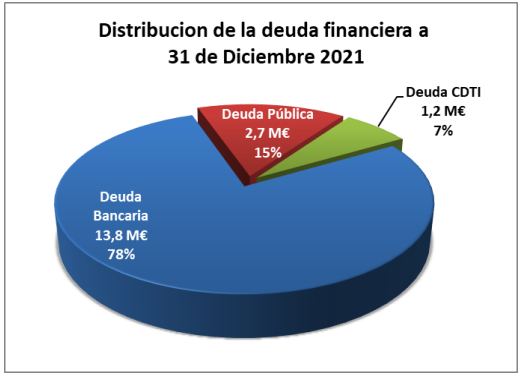
Millones / €	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Patrimonio Neto	10,3	9,0	13,9	27,6	22,7	34,4	45,1	61,1	75,9	71,3
Tesorería e Inv. Fin. c/p	2,8	2,2	9,3	21,7	27,3	35,2	34,5	35,3	39,6	28,7
Deuda Bancaria	5,3	4,9	3,1	3,6	18,5	18,9	14,1	8,9	9,1	13,8
Deuda Pública	3,0	4,8	5,0	4,6	4,0	3,9	3,4	3,8	3,0	2,7
Deuda CDTI	1,0	1,0	1,0	0,8	0,7	0,6	0,7	0,6	1,5	1,2

FINANCIACION BANCARIA:

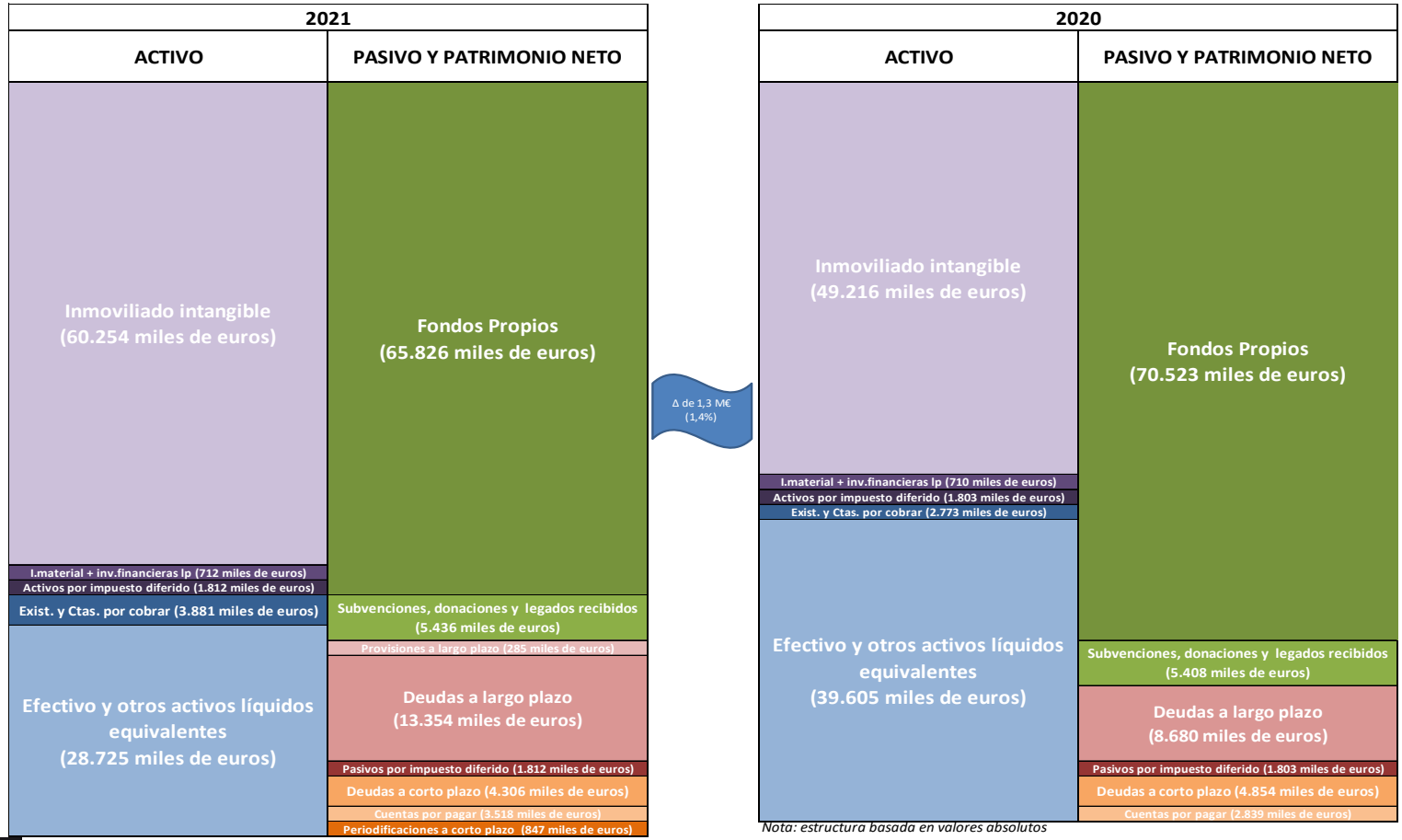
- 78 % de participación en la deuda financiera
- 13,8M€ de financiación viva
- Sin garantías ni avales

FINANCIACION PUBLICA

- 22% de participación en la deuda financiera
- 3,9M€ de financiación viva



Evolución del Balance



Nota: estructura basada en valores absolutos

Estados Financieros – Ejercicio 2021 - Resultado

	Resultado 2021	Resultado Actividades No Recurrentes 2021	Resultado Actividades Ordinarias 2021	Resultado 2020	Variación
INGRESOS					
Ingresos por Subvenciones	168	-	168	100	68
Ingresos por capitalización	10.615	-	10.615	9.521	1.094
GASTOS					
I&D	-9.676	967	-8.709	-7.666	-1.043
Personal	-3.782	-	-3.782	-3.540	-242
Gastos Generales	-4.188	1.309	-2.879	-2.558	-321
Amortización	-148	-	-148	-150	2
Financieros	-169	-	-169	-485	316
Impuesto Sociedades	2.493	-	2.493	1.379	1.114
RESULTADO NETO	**-4.687**	**2.276**	**-2.411**	**-3.399**	**988**

Inversión I+D (capitalizado + No capitalizado)
+ 3,1 ORY 1001- Iadademstat
+ 4,7 ORY 2001- Vafidemstat
+ 1,0 ORY 2001- Vafidemstat (ESCAPE)
+ 0,9 ORY 3001 y Otras act. en fases tempranas

Actividades de desarrollo no capitalizada para contribuir en la lucha contra COVID-19 en el ensayo clínico ESCAPE

Coste preparación salida NASDAQ (actividades jurídicas preparatorias de cumplimiento regulatorio y auditorias bajo normativa PCAOB)

Diferencias de cambio de Bº neto generado por los cambios de cotización del USD sobre los saldos bancarios

Mayor Cash back por deducciones fiscales I+D en el Impuesto sobre sociedades respecto a 2020

Nota: *Información expresada en Miles de Euros.*

Estado de Cambios en el Patrimonio Neto

PATRIMONIO NETO A 31.12.2020	**75.931**
Resultado del ejercicio	-4.687
Subvenciones (Neto de efecto fiscal)	28
Otras variaciones del patrimonio neto	-10
PATRIMONIO NETO A 31.12.2021	**71.262**

Nota: *Información expresada en Miles de Euros.*

Estado de Flujos de Efectivo

	TOTAL	ACTIVIDADES DE EXPLOTACIÓN Y TIPOS DE CAMBIO	ACTIVIDADES DE INVERSIÓN	ACTIVIDADES DE FINANCIACIÓN
TESORERÍA A 31.12.2020	**39.605**			
Cash In				
Grant Kabuki	847			847
Subvenciones	9			9
Préstamos	7.960			7.960
Desinversión Financiera	43			43
Variaciones de tipo de cambio	348	348		
Cash back	1.297	1.297		
Cash Out				
Préstamos	-3.837			-3.837
CAPEX	-11.767		-11.767	
Costes financieros netos	-253	-253		
Gastos Ordinarios	-5.527	-5.527		
TESORERÍA A 31.12.2021	**28.725**	**-4.135**	**-11.767**	**5.022**

Nota: *Información expresada en Miles de Euros.*

Pioneering personalized medicine in epigenetics