

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 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 10, 2023

**Biohaven Ltd.**

(Exact name of registrant as specified in its charter)

**British Virgin Islands**  
(State or other jurisdiction of incorporation)

**001-41477**  
(Commission File Number)

**Not applicable**  
(IRS Employer Identification No.)

**c/o Biohaven Pharmaceuticals, Inc.**  
**215 Church Street**  
**New Haven, Connecticut 06510**  
(Address of principal executive offices, including zip code)  
**(203) 404-0410**  
(Registrant's telephone number, including area code)  
**Not applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation 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 Shares, no par value	BHVN	New York Stock Exchange

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

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**

**Analyst and Investor Meetings**

On January 10, 2023, Biohaven Ltd. will be making an investor presentation (the "Presentation"). A copy of the Presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

<b>Exhibit Number*</b>	<b>Exhibit Description</b>
99.1	<a href="#">Investor Presentation, dated January 2023</a>
104	The cover page of this Current Report on Form 8-K formatted as Inline XBRL.

\* The XBRL instance document does not appear in the interactive data file because its XBRL tags are 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.

Date: January 10, 2023

**Biohaven Ltd.**

By: /s/ Matthew Buten  
Matthew Buten  
Chief Financial Officer

The Biohaven logo is displayed in a white rounded rectangle. The word "biohaven" is written in a lowercase, sans-serif font. "bio" is in green and "haven" is in blue.A circular logo with the text "BHVN LISTED NYSE" in a small, uppercase, sans-serif font.The background of the slide is a photograph of several hands of different ages and skin tones being held together in a supportive grip. The lighting is soft, highlighting the textures of the skin.

41st Annual J.P. Morgan Healthcare Conference  
**Vlad Coric, M.D., Chairman and Chief Executive Officer**  
January 10, 2023

# DAYS MATTER

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## Forward-Looking Statement

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This presentation includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements about Biohaven Ltd. (the “Company”) and our planned and ongoing trials for our BHV-2100, troriluzole, BHV-5500, BHV-1100, BHV-1200, Taldefgrobep Alfa, BHV-7000 and BHV-7010 development programs, the timing of and the availability of data from our clinical trials, the timing and our decisions to proceed with our planned regulatory filings, the timing of and our ability to obtain regulatory approvals for our product candidates, the clinical potential utility of our product candidates, alone and as compared to other existing potential treatment options, and the potential advancement of our early phase programs including ARM™, MATE™, MODE™, TRPM3, TDP-43, UC1MT and Kv7. The use of certain words, including “continue”, “plan”, “will”, “believe”, “may”, “expect”, “anticipate” and similar expressions, is intended to identify forward-looking statements. Investors are cautioned that any forward-looking statements, including statements regarding the future development, timing and potential marketing approval and commercialization of our development candidates, are not guarantees of future performance or results and involve substantial risks and uncertainties. Actual results, developments and events may differ materially from those in the forward-looking statements. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation. Additional important factors to be considered in connection with forward-looking statements are described in the Company’s filings with the Securities and Exchange Commission, including within the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”. This presentation also contains market data and other information based on industry publications, reports by market research firms or published independent sources. Some market data and information is also based on the Company’s good faith estimates, which are derived from management’s knowledge of its industry and such independent sources referred to above.

WE SUCCEEDED BY FOLLOWING THE  
THE SCIENCE  
FOR PATIENTS



**Nurtec**<sup>®</sup> ODT  
(rimegepant)

orally disintegrating tablets 75 mg



Pfizer  
Acquisition of  
CGRP Platform

**\$13B**



Through state-of-the-art drug discovery and passionate scientists  
— LARRY

With a powerful R&D engine  
— JAVIER

With a commitment to transforming patients' lives  
— KATRINA

We never forget patients need us.  
— JEREMY

Because we are passionate about the work we do everyday  
— FRANCINE

OUR EMPLOYEES KNOW  
WE WILL DO IT AGAIN.

## HIGH VALUE PLATFORMS

Pursuing novel paths of science to transform the treatment of neurological and neuropsychiatric diseases

## INNOVATIVE PORTFOLIO

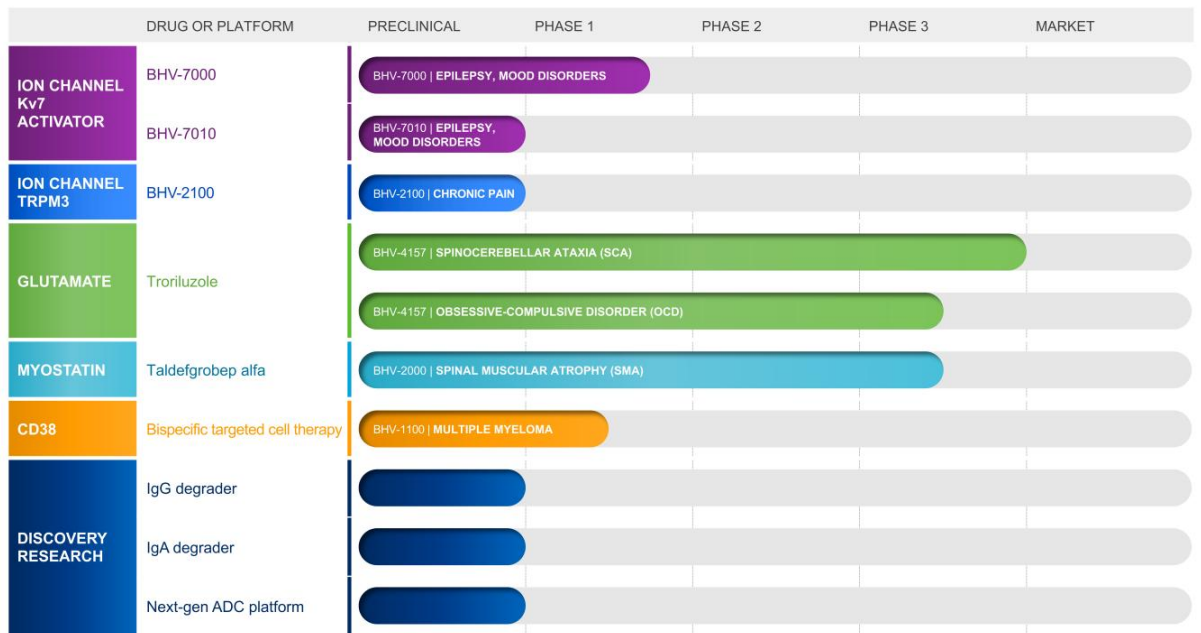
A broad therapeutic portfolio addressing patient needs with intention.

## PROVEN BUSINESS FORMULA

Formula for continued growth built upon past success of experienced team and a resilient focus on creating value for patients and shareholders

# BIOHAVEN TODAY





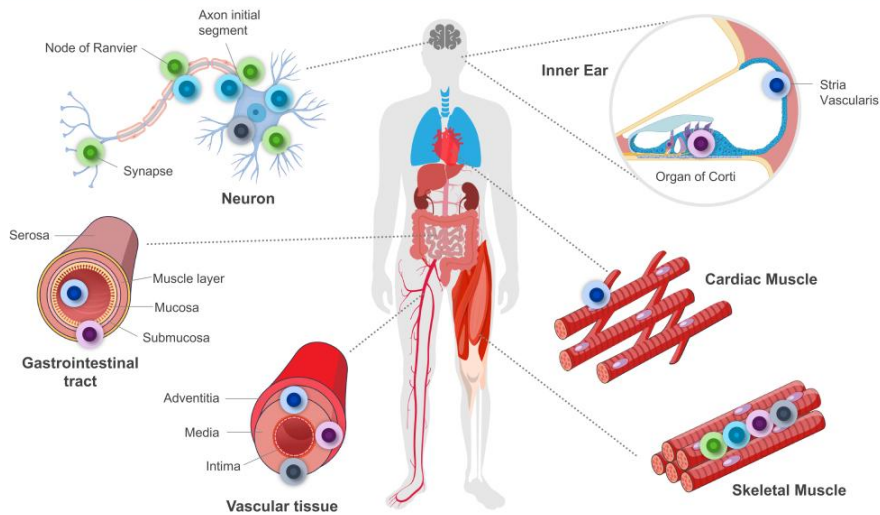


**TAIYE** | Associate Scientist

Key Programs

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# Kv7 Ion Channels: Key Regulators of Neuronal Function



Source: PHYSIOLOGY 26: 365–376, 2011; doi:10.1152/physiol.00009.2011 (Maria Virginia Soldovieri,1, Francesco Miceli,2,3 and Maurizio Tagliatela1,2)

## 5 FAMILY SUBTYPES

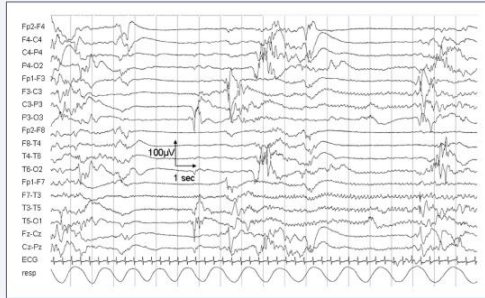
### Primary localizations:

-  Kv7.1: cardiac
-  Kv7.2: CNS  
**BHV-7000/7010 activator**
-  Kv7.3: CNS  
**BHV-7000/7010 activator**
-  Kv7.4: smooth muscle and inner ear
-  Kv7.5: vascular tissue, neurons, skeletal muscle

# Kv7 Potassium Channels Regulate Neuronal Excitability and Loss of Function Causes Epilepsy

## Impaired Kv7 Channel Activity Causes Certain Types of Epilepsy

Loss-of-function mutations in Kv7.2 channel



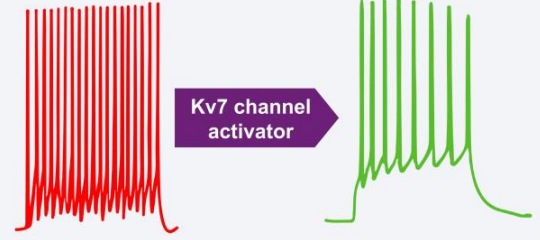
## Abnormal EEG with Epileptic Activity

Dalen Meurs-van der Schoor, Front Pediatr (2014).

## Kv7 Activation Normalizes Action Potential Firing

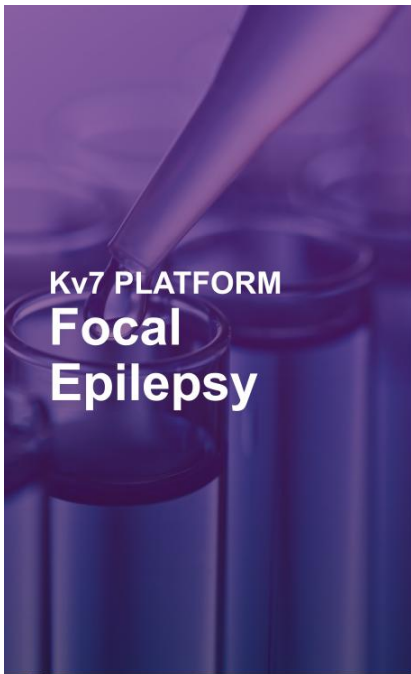
Increased frequency of action potential firing

Normal frequency of action potential firing



## Hyperexcitability — Epilepsy and Mood Disorders

Adapted from Wulff, Nat Rev Drug Discov (2009).



Kv7 PLATFORM  
**Focal  
Epilepsy**

**Potential Best-in-Class, Fast-Follower Approach**

Clinically validated mechanism of action

**Pursuing Differentiation**

Preclinical data suggests wide therapeutic index in the clinic by dialing out GABA risk (*somnolence, sedation, dizziness*)

**Translatability**

Preclinical data in epilepsy models is predictive of clinical efficacy

**Broad Potential in Adjacent Indications**

Warrants further evaluation in BPD, depression, pain, others

**Patent Protection**

Both BHV-7000 and BHV-7010 covered until 2039

**Status Update**

BHV-7000 Phase 1 SAD/MAD study completed (Canada)  
BHV-7010 IND anticipated in 2023

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# 1st and 2nd Gen Kv7 Activators Show Clinical Anti-seizure POC, But Off-target Activities, Opportunity for 3rd Gen Kv7 Differentiation

## EZO GABINE

- **Unstable** when exposed to light
- **Label warnings** for skin discoloration
- **Black box warning** for retinal abnormalities/vision loss

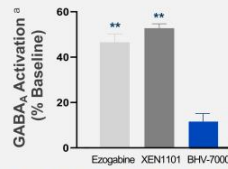


FDA Drug Safety Communication: Potiga (ezogabine) [04-26-2013]

**BHV-7000 is chemically stable to photo-oxidation**

## XEN1101

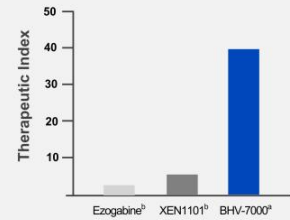
- **XEN1101** and ezogabine **significantly greater** GABA<sub>A</sub> receptor allosteric activators than BHV-7000 in vitro<sup>a</sup>
- GABA<sub>A</sub> receptor activation: somnolence, dizziness, fatigue, diplopia



**BHV-7000 is selective for Kv7 over GABA<sub>A</sub> receptors<sup>a</sup>**

## BHV-7000

- **Potent activator** of Kv7 channels
- **Effective and well-tolerated** in preclinical seizure assays



**BHV-7000 has a wide therapeutic index preclinically<sup>a</sup>**

<sup>a</sup> Biohaven data on file (2022). <sup>b</sup> Calculated as ratio of TD<sub>50</sub> (rotarod) to ED<sub>50</sub> (MES seizure assay) data presented by Xenon at Epilepsy Foundation Pipeline Conference, San Francisco (Feb 2018). Preclinical results are consolidated from separate reports and graphed together. Data presented is not the result of any head-to-head clinical trials and does not mean or suggest that BHV-7000 is clinically more safe and effective.

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## BHV-7000 Exhibits Highly Differentiated Preclinical Profile

	Ezogabine	XEN1101	BHV-7000
<b>Kv7.2/7.3 Activator</b>	✓ Activator, clinical and preclinical anti-seizure activity	✓ Activator, clinical and preclinical anti-seizure activity	✓ <b>Activator, clinical and preclinical anti-seizure activity</b>
<b>GABA<sub>A</sub> Activity "dialed-out"</b>	✗ GABA <sub>A</sub> activity present	✗ GABA <sub>A</sub> activity present	✓ <b>Negligible GABA<sub>A</sub> activity</b>
<b>Wide Therapeutic Index</b>	✗ <3x reported <sup>a,b</sup>	✗ <5x reported <sup>a</sup>	✓ <b>&gt;40x<sup>b</sup></b>

a. Calculated as ratio of TD<sub>50</sub> (rotarod) to ED<sub>50</sub> (MES seizure assay) data presented by Xenon at Epilepsy Foundation Pipeline Conference, San Francisco (Feb 2018). b. Biohaven data on file (2022). Preclinical results are consolidated from separate reports and not a result from head-to-head comparisons. Data presented is not the result of any head-to-head clinical trials and does not mean or suggest that BHV-7000 is clinically more safe and effective.

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## BHV-7000 Phase I SAD/MAD Study Update: Dosing Completed

### Preliminary Safety

- Single doses up to 100 mg and multiple doses up to 40 mg daily x15 days generally well-tolerated
- Most AEs mild and resolved spontaneously
- No serious or severe AEs
- No dose limiting toxicities

### Preliminary Pharmacokinetics

- Target concentrations for efficacy exceeded based on preclinical MES model
- High fat meal had no effect on exposures

Pooled Adverse Events*	N = 61
Headache	7 (11.5)
Back pain	3 (4.9)
Constipation	2 (3.3)
Abdominal discomfort	2 (3.3)
Urinary frequency	2 (3.3)

*Pooled adverse events from SAD and MAD cohorts occurring in more than 1 subject (preliminary blinded data including BHV-7000 and placebo groups)*

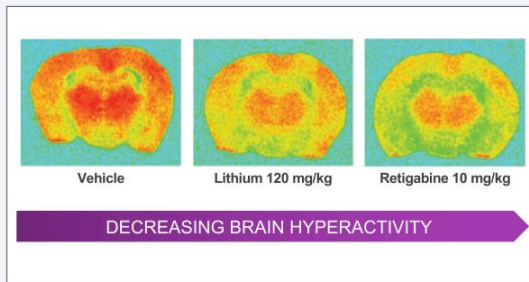
\* MedDRA® Preferred Term



# Preclinical and Clinical Data Suggest a Role for Kv7 in Bipolar Disorder and Depression

## Mania

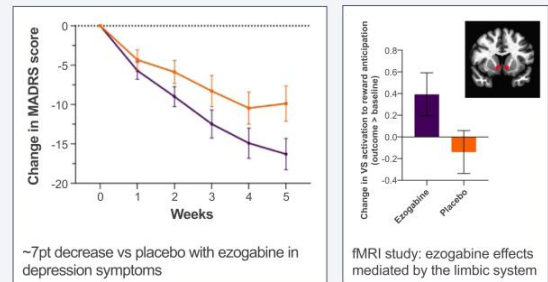
In mania models, Kv7 activation reduces hypermetabolism and hyperactive behavior<sup>1</sup>



Retigabine normalizes a mania model hypermetabolic signature to a higher degree than lithium

## Depression

Robust MDD efficacy likely to translate to bipolar disorder<sup>2</sup>



3/3 positive studies of fluoxetine in bipolar depression indicate effects in MDD translate to bipolar disorder<sup>3</sup>

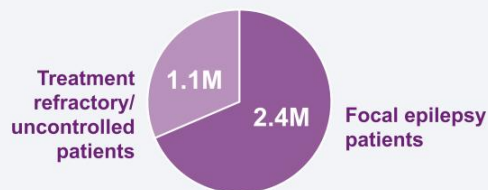
1. Kristensen et al. J Neurochem (2012), 2. Costi et al. Am J Psychiatry (2021); 178(5):437-446. 3. Golberg et al. J Clin Psychiatry (2021) 82(1):20ed13649

## Blockbuster Peak Sales Potential for Kv7 Platform

### Epilepsy

**3.5M EPILEPSY PATIENTS**

adult and pediatric, US<sup>1-3</sup>



**200-300  
KCNQ2-DEE**  
incidence in live births

- ✓ **Easy to Prescribe**  
Convenient dosing,  
no titration, no food effect
- ✓ **Safe/Tolerable**  
Side effects negatively  
impacted other recent  
epilepsy launches

### Mood Disorders

**7-11M**  
BIPOLAR DISORDER (US)<sup>4</sup>

**34.5M**  
MAJOR DEPRESSIVE DISORDER (US)<sup>5</sup>

- ✓ **Biohaven Proven  
Commercial  
Expertise in  
Neuroscience**

1. <https://www.cdc.gov/epilepsy/data/index.html> (1.2% of the population has epilepsy, 60% is focal onset). 2. Kammerman S. West J Med. 2001 Aug;175(2):99-103. 3. Hauser WA. Epilepsia. 1991 Jul-Aug;32(4):429-45. 4. <https://www.nimh.nih.gov/health/statistics/bipolar-disorder> (2.8% of US adults have had BPD within last year and 4.4% of population over their lifetime). 5. Hasin DS. JAMA Psychiatry. 2018 Apr 1;75(4):336-346.

# TRPM3: A Novel Peripheral Target for Neuropathic Pain

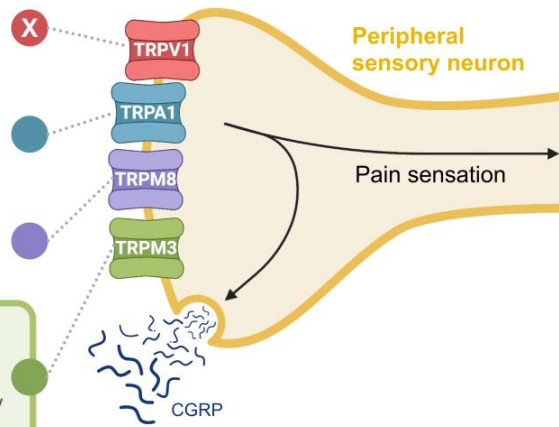
Differentiated from existing programs targeting TRPV1 and TRPA1

Appeared effective, but **class terminated for hyperthermia** despite significant investment

**Difficult target to drug** with PK/solubility issues; remains in active drug development (Lilly)

**Conflicting data for pro- and anti-nociceptive role**; remains in active drug development

**Promising as a novel target:** expressed at similar levels as TRPV1 and TRPA1 in peripheral neurons but unlikely to have thermal liabilities



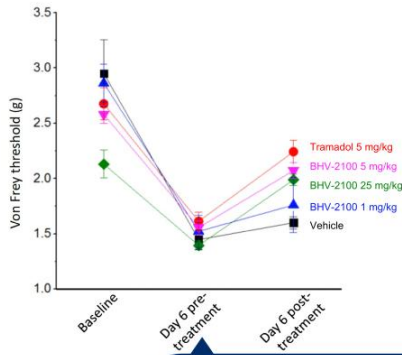
- Current SoC comes with liabilities — addiction (opioids), sedation
- Pre-clinical data shows reversal of pain in various models, without sedative effects
- IND planned for 2H 2023

See Koivisto et al, Nature Reviews Drug Discovery 2022 for background on TRP channel drug development.

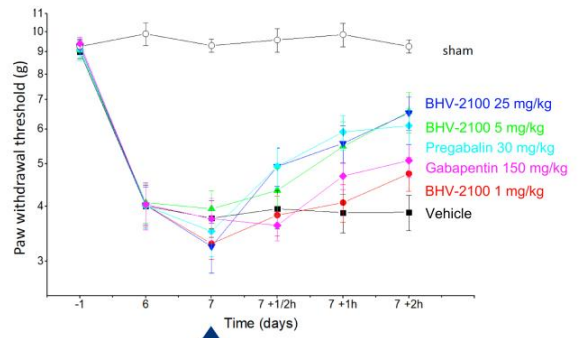
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# BHV-2100 Reduces Pain in Preclinical Models of Chemotherapy and Diabetic Neuropathy

**Encouraging evidence of pain reduction without the sedation observed with high dose tramadol/gabapentin**



Drug administered 6 days after oxaliplatin in mice



Drug administered 7 days after diabetic induction with STZ in rats



## TRORILUZOLE SCA and OCD

### SPINOCEREBELLAR ATAXIA (SCA)

- Reduction in fall risk + treatment effect in SCA3 genotype
- Safe and well-tolerated profile
- **Regulatory engagement planned for H1 2023**

### OBSESSIVE COMPULSIVE DISORDER (OCD)

- Compelling mechanistic rationale for cortico-striatal glutamate abnormalities in OCD patients
- Strong PoC in Phase 2
- Well-characterized in 1,000+ patients
- Two Phase 3 studies ongoing; **enrollment completion anticipated YE 2023**



## TALDEFGROBEP ALFA SMA

### **Pivotal Phase 3 Study Initiated July 2022**

- Large pre-clinical and clinical safety package licensed from BMS
- Limited additional work needed to support BLA submission
- 34 sites total, 13 open

### **POC for Mechanism of Action**

Supported by clinical data and multiple disease models

### **Muscle and Bone Improvements**

Observed in non-clinical studies

### **Strong Supporting Efficacy Signal**

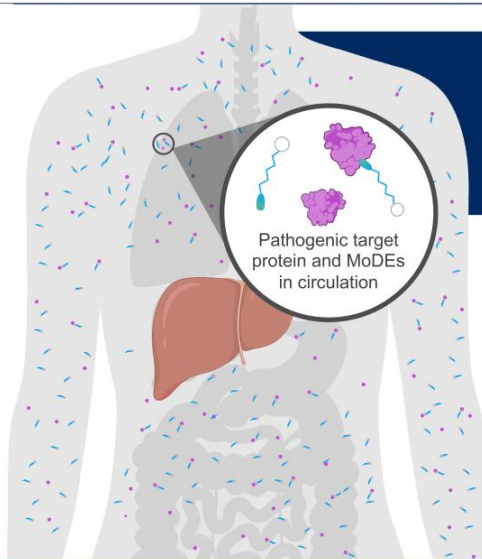
Muscle mass growth in healthy subjects

### **Large Safety Database**

Established in prior pediatric studies

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## Bispecific Platform: IgG Degradation via MoDE™



**MoDE** small molecules bind extracellular target proteins and cause them to be removed from the body *through the liver*

- Harnesses the body's own machinery for degrading proteins
- Extracellular protein targets are **eliminated** via the asialoglycoprotein receptor (ASGPR)

Binds liver  
(ASGPR)



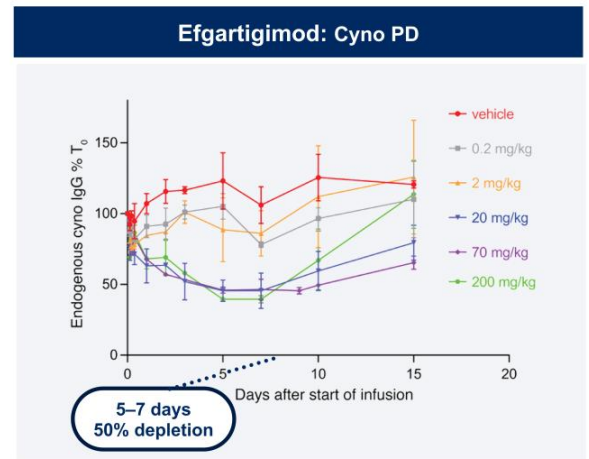
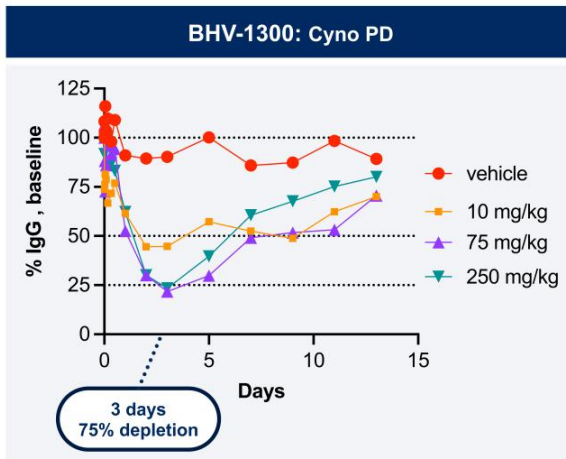
Binds protein  
target

- Protein targets are degraded via endolysosomal proteolysis

\* formerly BH 2640

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## Pan-IgG Degradator (BHV-1300) Shows Superiority Over SoC (Efgartigimod)



IND ready in H2 2023

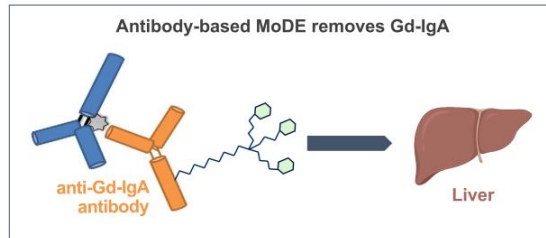
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## Bispecific Platform: IgA Degradar for IgA Nephropathy

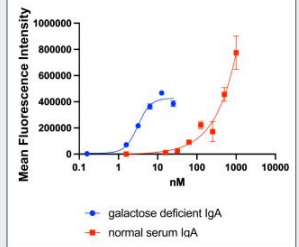
**Therapeutic Hypothesis:** Galactosyl deficient-IgA (Gd-IgA) containing-immune complexes drive glomerular injury in IgA nephropathy.<sup>1</sup> Specific removal of this pathogenic Gd-IgA with preservation of “normal” IgA (and other Ig’s) permits disease remission without incurring an infection risk.

- Highly selective, rat mAb conjugate binds Gd-IgA with high affinity
- Antibody humanization ongoing, subsequent conjugation with established degrader technology will allow rapid and efficient hepatic extraction, leaving “normal” IgA



1. Canetta et al, 2014, others. 2. Untested therapeutic hypothesis.

**Chimeric antibody-ASGPR ligand conjugate specifically mediates endocytosis of galactose deficient IgA**



**Gd-IgA removal drives efficacy without infection risk<sup>2</sup>**

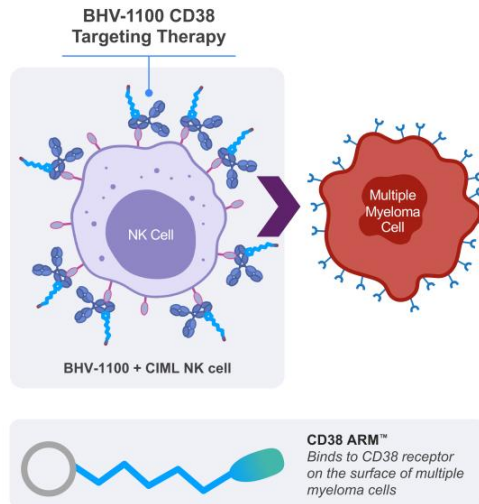
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# Bispecific Platform: CD38 Targeted Cell Therapy for Multiple Myeloma

ARM

## CD38 Antibody Recruiting Molecule (ARM™)

- Modular bispecific molecules with two moieties, each designed for non-covalent binding to a specific target
- Redirect endogenous antibodies to target cancerous or virally infected cells for immune destruction

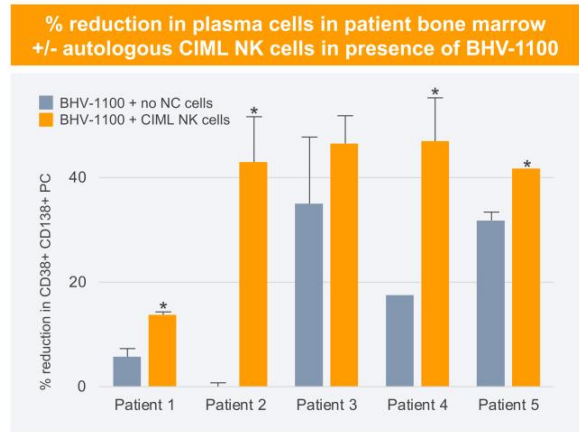
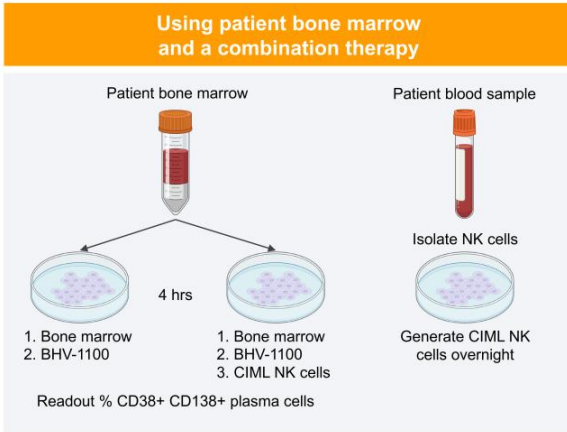


## Key Potential Advantage Over Biologics

- ✓ Lower manufacturing cost
- ✓ More versatile — smaller and tunable
- ✓ Faster and less expensive to develop
- ✓ Better safety and efficacy
  - Non-immunogenic; better dosing
  - Enhanced PK properties
  - Reduce NK cell fratricide compared to daratumumab

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# Ex Vivo Patient Plasma Study: 4 Out of 5 Patients Showed Reduction in Plasma Cells (Multiple Myeloma)



**ONGOING CLINICAL STUDY**

**MRD + post-transplant multiple myeloma patients ongoing at Dana Farber Institute**

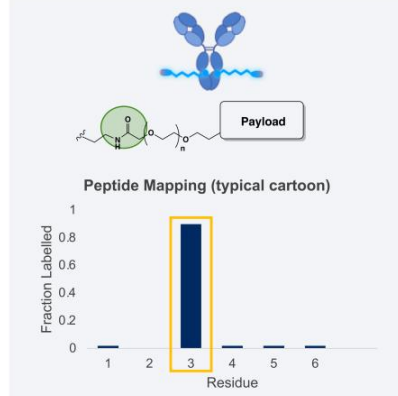
- First patient survival to one year
- Two additional patients randomized

Journal of Clinical Oncology 2020 38:15\_suppl, 8523-8523.

# Bispecific Platform: Advancing Next-Generation, Site-Specific Antibody Drug Conjugates (ADCs)

Potential for best-in-class

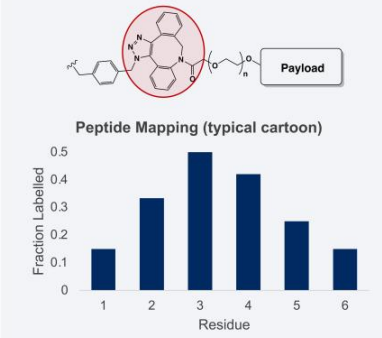
## Biohaven third-generation technology



\*DAR = Drug antibody ratio

## Second-generation ADC-linker technologies

Click chemistry to engineered antibody



A single residue per heavy chain is available for conjugation

- Controlled DAR\* ratio is critical to therapeutic index
- MATE tech precisely defines DAR\*

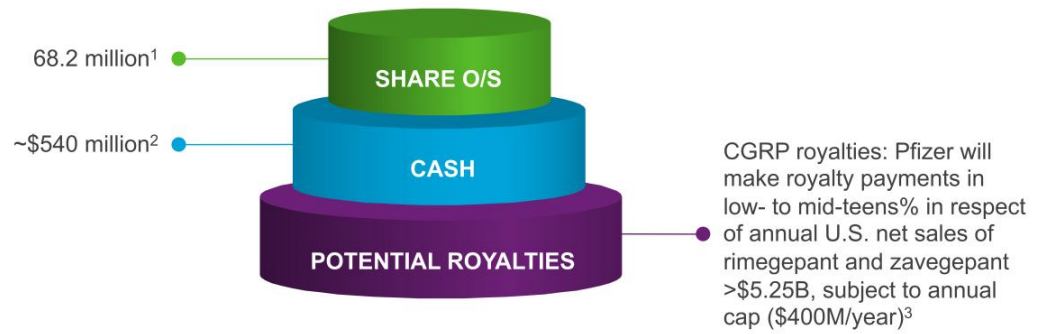
Improved linker stability should yield wider therapeutic index

- Improved safety:** less systemic, untargeted payload
- Improved efficacy:** targeted payload delivered to tumor

**Uses native antibody:** potentially improved CMC vs. current tech

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## Capitalization Considerations



1. Excludes 9.1 million options (\$7.00 strike price). 2. As of October 2022. 3. Cap reached if aggregate annual U.S. net sales of rimegepant and zavegepant amount to \$8.15B. Royalty payments would be in respect of years ended on or before 12/31/40.

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## Near-Term Milestones (Anticipated)

 Milestone achieved

DRUG NAME	INDICATIONS	2H 2022	1H 2023	2H 2023
<b>BHV-7000</b> Kv7 channel activator	Focal epilepsy		Phase 1 Topline Initiate EEG Study	Initiate Phase 2/3
	Bipolar disorder			Initiate Phase 2/3
<b>BHV-7010</b> Kv7 channel activator	Epilepsy and mood disorder			File IND
<b>BHV-2100</b> TRPM3	Chronic pain disorders			File IND
<b>Troiriluzole</b> NCE prodrug of riluzole	Spinocerebellar ataxia		Regulatory Interaction	
	Obsessive-compulsive disorder			Complete Enrollment
<b>Taldefgrobep alfa</b> Anti-myostatin adnectin	Spinal muscular atrophy	Initiated Phase 3		
<b>BHV-1300</b> IgG degrader	Undisclosed			File IND

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The background of the slide is a dark blue collage. On the left, there's a molecular structure. In the center, a pipette is shown. On the right, there's a line graph with several data points and a bar chart. The text is overlaid on these images.

BHVN  
LISTED  
NYSE

HIGH VALUE  
PLATFORMS

Pursuing  
novel paths  
of science

INNOVATIVE  
PORTFOLIO

A broad  
therapeutic  
portfolio

PROVEN BUSINESS  
FORMULA

Formula for  
continued  
growth

BIOHAVEN TODAY

