

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 11, 2023

ELIEM THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40708
(Commission File Number)

83-2273741
(IRS Employer
Identification No.)

**23515 NE Novelty Hill Road
Suite B221 #125
Redmond, WA**
(Address of Principal Executive Offices)

98053
(Zip Code)

Registrant's Telephone Number, Including Area Code: 1-877-ELIEMTX (354-3689)

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(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	ELYM	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

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 2.02 Results of Operations and Financial Condition.

On May 11, 2023, Eliem Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2023. A copy of the press release is attached hereto as Exhibit 99.1.

Item 7.01. Regulation FD Disclosure.

A copy of a slide presentation that the Company will use at investor conferences and presentations is attached to this Current Report as Exhibit 99.2 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information in Items 2.02 and 7.01 (including Exhibits 99.1 and 99.2) are being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, whether filed before or after the date hereof and regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release of Eliem Therapeutics, Inc., dated May 11, 2023
99.2	Investor Presentation, dated May 11, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Eliem Therapeutics, Inc.

Date: May 11, 2023

By: _____ /s/ Andrew Levin
Andrew Levin, M.D., Ph.D.
Executive Chairman of the Board of Directors



Eliem Therapeutics Reports First Quarter Financial Results and Business Highlights

Presented initial preclinical data from ETX-123, Eliem's lead Kv7 program candidate, demonstrating a promising profile and confirming the proposed mechanism of action on neuronal excitability

Additional preclinical data updates for ETX-123 expected in 2023

SEATTLE and CAMBRIDGE, UK, --(GLOBE NEWSWIRE) – May 11, 2023 – Eliem Therapeutics, Inc. (Nasdaq: ELYM), a biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems, today provided a business update and reported financial results for the quarter ended March 31, 2023.

“We were excited to share our initial preclinical data from ETX-123, our lead candidate in the Kv7 program, during the first quarter,” said Andrew Levin, M.D., Ph.D., executive chairman of Eliem Therapeutics. “The initial data demonstrate high potency and differentiated selectivity. The data also confirm the proposed mechanism of action on neuronal excitability, which we believe, has the potential to improve the lives of patients suffering from a variety of CNS disorders. With a strong balance sheet funding operations into 2027, we expect to have the financial strength to fund multiple catalysts and advance this exciting program into the clinic.”

Recent Highlights

- **Presented initial ETX-123 preclinical data at the 7th RSC-BMCS / SCI Symposium on Ion Channels as Therapeutic Targets in March 2023.** The data presented confirmed ETX-123's mechanism of action on neuronal excitability via modulation of Kv7 and demonstrated its high potency and differentiated selectivity for Kv7.2/3 in electrophysiology assays. Further screens also confirmed an encouraging broad selectivity profile, including no GABA_A, hERG or other off-target activities at anticonvulsant doses. Additionally, *in vivo* oral administration of ETX-123 dose-dependently inhibited seizures in the rat maximal electroshock seizures (MES) model, with an encouraging separation versus doses that impaired performance in the rotarod, a CNS side-effect profiling model.
- **Additional preclinical data on ETX-123 will be presented at two upcoming scientific and medical conferences.** The Company will present additional data at the Epilepsy Therapies & Diagnostics Development XVII Conference being held May 31-June 2, 2023 in Aventura, FL and at the 2nd International Kv7 Channels Symposium 2023 being held September 13-15, 2023 in Naples, Italy.

Program Updates and Anticipated Key Milestones

- The Company has initiated synthesis scale-up for its lead Kv7 candidate, ETX-123, to enable the initiation of investigational new drug (IND)-enabling safety studies, with Phase 1 clinical studies currently planned to initiate in the first half of 2024.
- The Company's novel Kv7 compounds, including additional pre-candidates, have demonstrated high potency and differentiated selectivity in electrophysiology assays, and *in vivo* anticonvulsant activity in the MES rat model.
- A comprehensive update can be found in the Company's corporate presentation linked here.

First Quarter 2023 Financial Results

- Cash Position: Cash, cash equivalents and marketable securities was \$109.4 million as of March 31, 2023, as compared to \$123.6 million as of December 31, 2022. The Company's current cash, cash equivalents and marketable securities are expected to fund operations into 2027.
 - Research and Development (R&D) expenses: R&D expenses were \$5.7 million for the three months ended March 31, 2023, compared to \$8.3 million for the same period in 2022.
 - General and Administrative (G&A) expenses: G&A expenses were \$17.7 million for the three months ended March 31, 2023, compared to \$4.9 million for the same period in 2022.
-

- Net loss: Net loss was \$22.3 million for the three months ended March 31, 2023, compared to \$13.2 million for the same period in 2022.
- Net loss for the quarter included \$15.8 million of one-time costs for termination benefits associated with the recently announced corporate restructuring, of which \$9.0 million related to stock-based compensation. Of these costs, \$1.8 million was included in R&D expenses and \$14.0 million in G&A expenses.

About Eliem Therapeutics, Inc.

Eliem Therapeutics, Inc. is a biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems. These disorders often occur when neurons are overly excited or inhibited, leading to an imbalance, and our focus is on restoring homeostasis. We are developing a pipeline of clinically differentiated product candidates focused on validated mechanisms of action with broad therapeutic potential to deliver improved therapeutics for patients with these disorders. Eliem channels its experience, energy, and passion for improving patients' quality of life to fuel our efforts to develop life-changing novel therapies. At its core, the Eliem team is motivated by the promise of helping patients live happier, more fulfilling lives. <https://eliemtx.com/>

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements relating to: the continued development and clinical and therapeutic potential of ETX-123; the progression of the Kv7.2/3 and next-generation anxiolytic preclinical programs, including the initiation of IND -enabling studies and planned initiation of Phase 1 studies in the first half of 2024; the expectation that Eliem's current cash, cash equivalents and marketable securities will fund operations through 2027; future data presentations; and Eliem's commitment to developing therapies targeting debilitating disorders. Words such as "excited," "advance," "look forward," "believe," "potential," "will," "on track," "expects," "opportunity," "continues," "plans," "runway," "initiate," "anticipated," "support," or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. The forward-looking statements in this press release are based upon Eliem's current plans, assumptions, beliefs, expectations, estimates and projections, and involve substantial risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements due to these risks and uncertainties as well as other factors, which include, without limitation: the clinical, therapeutic and commercial value of ETX-123 and Eliem's other preclinical programs; the availability of data at the expected times; Eliem's ability to obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of others; the uncertain timing and level of expenses associated with Eliem's preclinical and clinical development activities; the sufficiency of Eliem's capital and other resources; risks and uncertainties related to regulatory application, review and approval processes and Eliem's compliance with applicable legal and regulatory requirements; market competition; changes in economic and business conditions; impacts on Eliem's business due to external events, including health pandemics or other contagious outbreaks, such as the current COVID-19 pandemic; and other factors discussed under the caption "Risk Factors" in Eliem's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023. This filing, when available, is available on the SEC's website at www.sec.gov. Additional information will also be set forth in Eliem's other reports and filings it will make with the SEC from time to time. The forward-looking statements made in this press release speak only as of the date of this press release. Eliem expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Eliem's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Investors

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Eliem Therapeutics, Inc.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(unaudited)

	March 31, 2023	December 31, 2022
Assets		
Cash, cash equivalents, and marketable securities	\$ 109,372	\$ 123,566
Other assets	12,713	11,426
Total assets	\$ 122,085	\$ 134,992
Liabilities and stockholders' equity		
Liabilities	5,225	6,277
Total stockholders' equity	116,860	128,715
Total liabilities and stockholders' equity	\$ 122,085	\$ 134,992

Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 5,720	\$ 8,260
General and administrative	17,718	4,872
Total operating expenses	23,438	13,132
Loss from operations	(23,438)	(13,132)
Other income (expense), net	1,148	(72)
Net loss	\$ (22,290)	\$ (13,204)
Net loss per share, basic and diluted	\$ (0.84)	\$ (0.50)



Clinical Stage Neurology Company Focused on Neuronal Excitability Disorders

Corporate Presentation | May 2023



Forward-Looking Statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, results of operations, business strategy and plans, and objectives of management for future operations, as well as statements regarding industry trends, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potentially,” “predict,” “should,” “will” or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things, risks related to: the success, cost and timing of our product development activities and clinical trials; our expectations about the timing of achieving regulatory approval and the cost of our development programs; our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates; the impact of the COVID-19 pandemic on our operations; the commercialization of our product candidates, if approved; our plans to research, develop and commercialize our product candidates; our plans to develop additional product candidates; our ability to obtain, maintain, expand, protect and enforce our intellectual property rights; our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of third parties; our ability to attract collaborators with development, regulatory and commercialization expertise; future agreements with third parties in connection with the commercialization of our product candidates; the size and growth potential of the markets for our product candidates and our ability to serve those markets; the rate and degree of market acceptance of our product candidates; regulatory developments in the United States and foreign countries; regulatory application, review and approval processes and our compliance with applicable legal and regulatory requirements; our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; the success of competing products that are or may become available; and our ability to attract and retain key scientific or management personnel. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. More information about the risks and uncertainties faced by Eliem is contained under the caption “Risk Factors” set forth in Eliem’s Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023, which is available on the SEC’s website at www.sec.gov, and in other subsequent reports and filings Eliem will make with the SEC from time to time. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation.

Certain information contained in this presentation relates to, or is based on, studies, publications, surveys and other data obtained from third-party sources and the Company’s own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and make no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this presentation, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

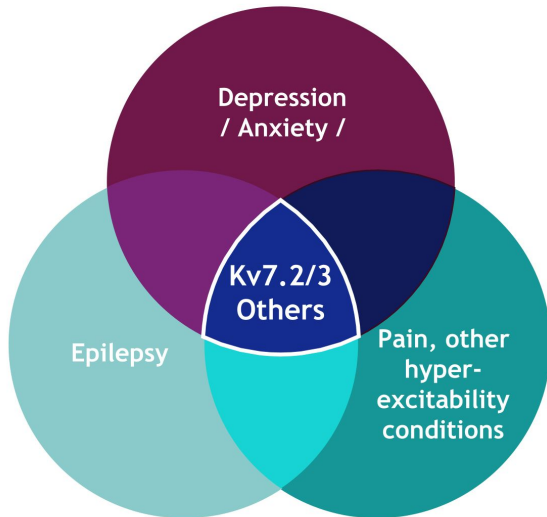


Rethinking treatment for nervous system disorders

- ✓ **Highly experienced** team with deep expertise in neuroscience and ion channel drug discovery and development
- ✓ **Highly differentiated Kv7 program** with broad potential to pursue across multiple neuronal excitability indications
- ✓ **~\$109M* cash runway into 2027** enabling advancement of lead Kv7 asset through Phase 2a clinical proof of concept

* cash, cash equivalents and investments as of March 31, 2023

Addressing multiple interrelated diseases by focusing on core mechanisms of neuronal excitability






Approaching **interrelated disease states** with distinct MOAs

Innovating within **clinically validated** mechanisms of action

Pursuing products with **multiple potential indications**

Eliem Portfolio: Focused on clinically validated Kv7.2/3 mechanism with potential to pursue across multiple neuronal excitability disorders

Product Candidate (Mechanism)	Potential Indications	Lead selection / optimization	IND-enabling studies	Phase 1	Phase 2	Phase 3
ETX-123 (Kv7.2/3 channel opener)	<ul style="list-style-type: none"> Epilepsy Depressive disorders Chronic Pain 			Phase 1 in healthy subjects planned for 1H 2024 initiation		
Backup Kv7.2/3 openers	<ul style="list-style-type: none"> Other CNS hyperexcitability disorders 					
ETX-155* (GABAA PAM neurosteroid)	<ul style="list-style-type: none"> Depression / Anxiety Epilepsy 	 (On hold as of Feb 2023)				

* ETX-155 (GABAA positive allosteric modulator) is a Phase 2-ready asset in Eliem's portfolio but development has been paused as of Feb 2023

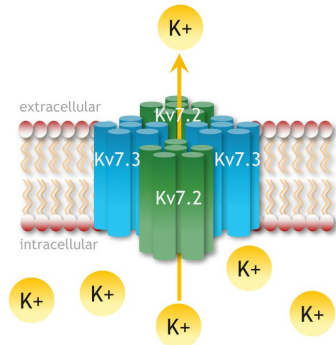
Kv7 Opener

Lead candidate ETX-123 selected
Phase 1 planned 1H 2024



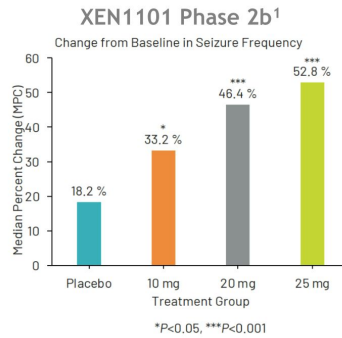
Kv7.2/3 potassium channel: a clinically validated regulator of neuronal hyperexcitability with significant commercial potential

Core mechanism to regulate hyperexcitability



Kv7.2/Kv7.3 heteromers mediate the neuronal M-current, widely regulating neuronal excitability by enabling the outflow of potassium ions, to dial down action potential firing

Highly compelling efficacy for Kv7.2/3 MOA in refractory epilepsy



Broad potential for expansion into numerous CNS hyperexcitability indications

Commercial potential reflected in valuations for clinical stage Kv7 programs

Company	Asset	Stage	Mkt Cap ²
Xenon (XENE)	XEN1101	Ph 3	~\$2.6b
Biohaven (BHAVN)	BHV-7000	Ph 1	~\$921m

BHAVN acquired BHV-7000 program for \$1.24b (\$100M upfront) at preclinical stage in Feb 2022

¹ French et al, AES Annual Meeting 2022

² Est. market cap as of May 4, 2023

Kv7.2/3 Program: Developing a differentiated Kv7.2/3 opener for multiple neuronal excitability indications

Kv7 Opportunity

Strong clinical validation in pain and epilepsy
(retigabine, flupirtine, XEN1101)

Human genetic validation

Metabolic safety liabilities with existing molecules and opportunity to improve tolerability

Clear translational path to clinical efficacy

Eliem Kv7 Program Objectives

Identify novel Kv7 openers with:

- Potent activity at Kv7.2/3
- Better selectivity over other Kv7 subtypes (Kv7.4 / 7.1)
- Improved metabolic stability
- Reduced off-target activity (GABA, other ion channels)
- Improved safety and tolerability

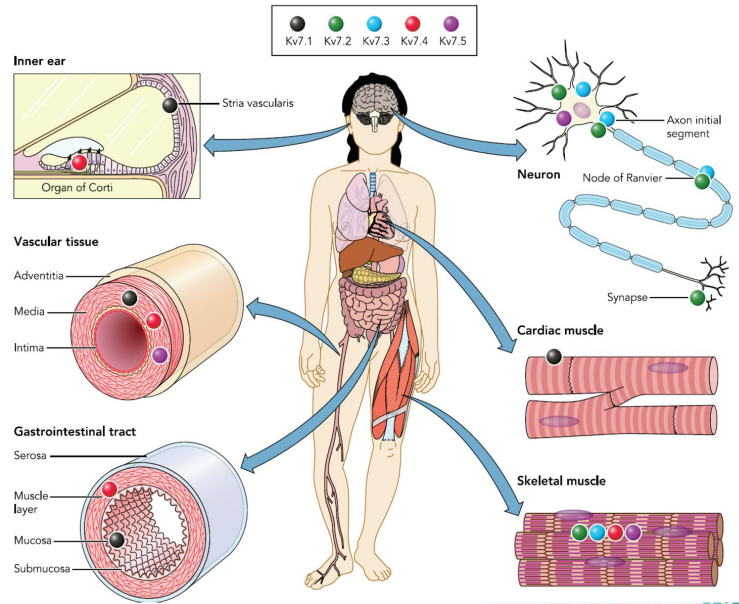
Program Status

- ✓ Foundational IP filed in novel chemical space distinct from known Kv7 openers
- ✓ Lead candidate **ETX-123** selected, progressing into Phase 1 in 1H 2024

Kv7 channels provide a convergent mechanism to control hyperexcitability in CNS, PNS, and other tissues

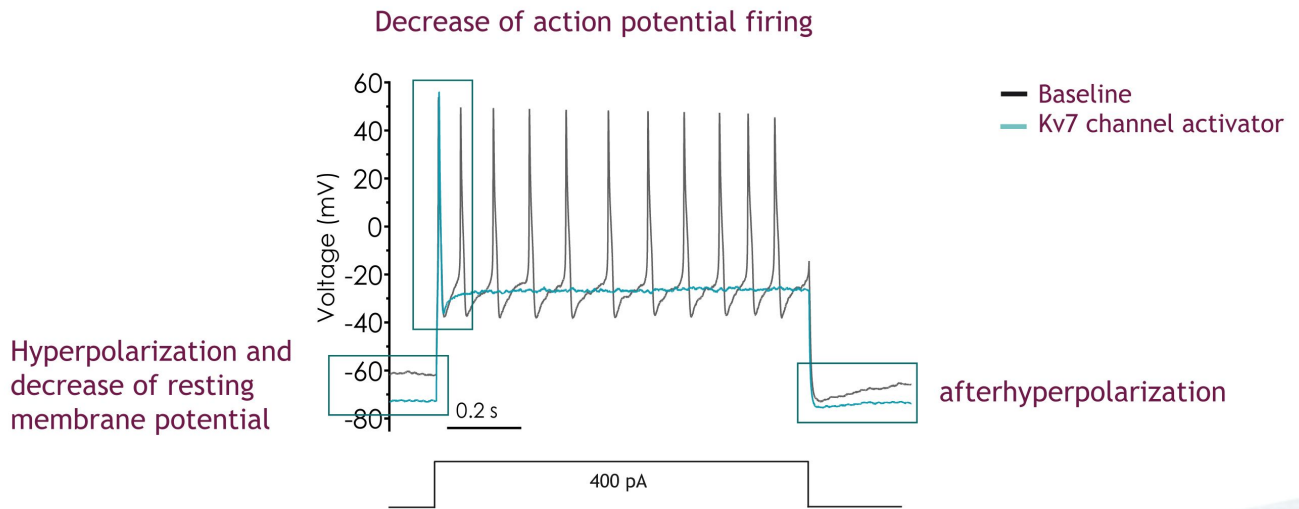
- The Kv7 family consists of 5 different subtypes with different electrophysiological properties and tissue expression:
 - **Kv7.1:** cardiac tissue
 - **Kv7.2 and Kv7.3:** CNS and PNS (all brain resident cells)
 - **Kv7.4:** smooth muscles, cardiac mitochondria, and inner ear
 - **Kv7.5:** CNS, smooth and skeletal muscles

Loss of function mutation of KCNQ2 and 3 (genes encoding for Kv7.2 and 7.3) have been associated with the onset of epilepsy syndromes and encephalopathies

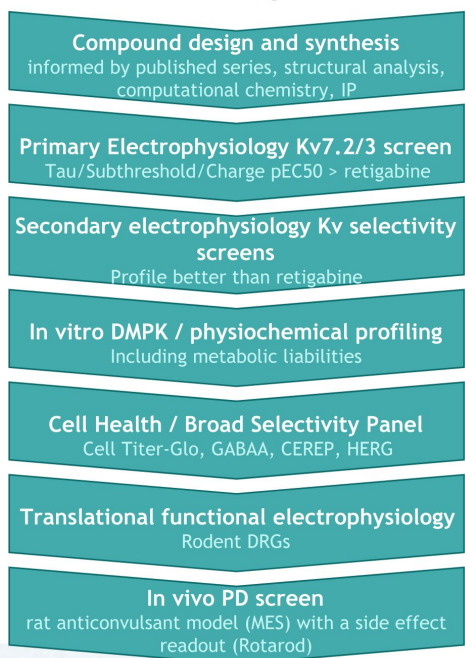


Source: Soldovieri et al., 2011

Mechanism: Kv7.2/3 openers decrease neuronal excitability by hyperpolarizing the membrane potential and reducing of action potential firing in excitable cells

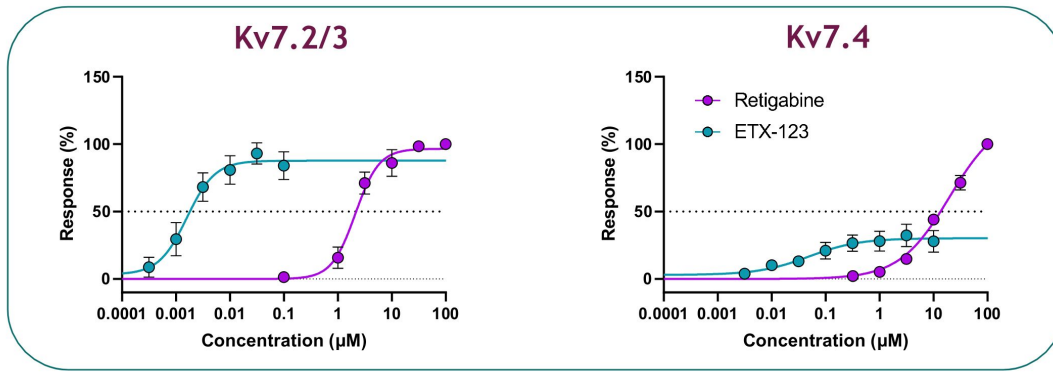


Discovery and optimization: leveraged existing target knowledge and deep ion channel expertise to identify novel class of Kv7 openers



ETX-123 selected as lead clinical candidate based on compelling potency, selectivity, and in vivo profile

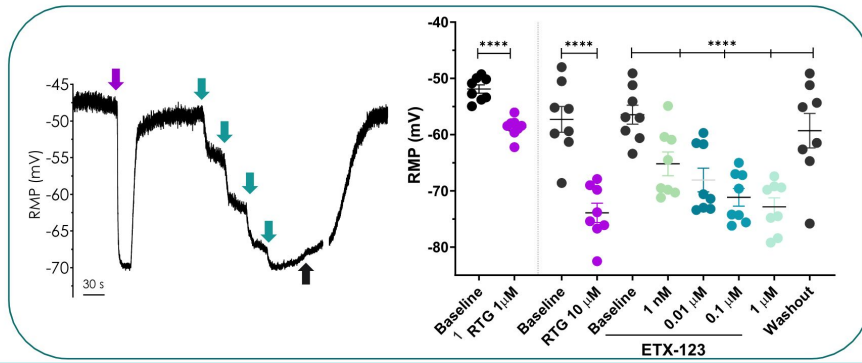
Electrophysiology: ETX-123 demonstrates best-in-class Kv7.2/3 potency and selectivity



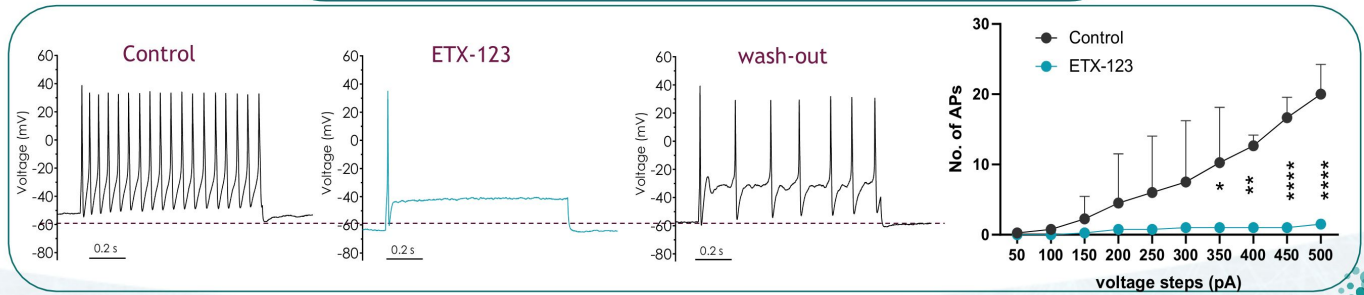
	ETX-123 (μM)	Retigabine (μM)
Kv7.2/3	0.0007-0.002	2
Kv7.4	>10	12-14
Kv7.3/5	0.02	4-7
Kv7.1	>30	>30*

In vitro, ETX-123 is significantly more potent and selective than retigabine, and other published Kv7 openers

Translational pharmacology: ETX-123 decreases rat DRGs excitability by hyperpolarization and significant inhibition of repeat firing of action potentials



¹ Free clinical anticonvulsant exposure



****p < 0.0001, **p < 0.01 and *p < 0.05 - comparisons all groups vs. the control group

In vivo efficacy: ETX-123 showed dose-dependent anticonvulsant activity in the rat MES model, with encouraging separation vs doses showing CNS side effects in the rotarod model

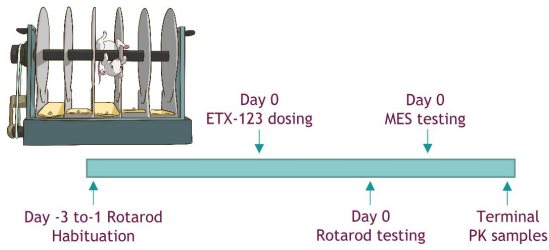
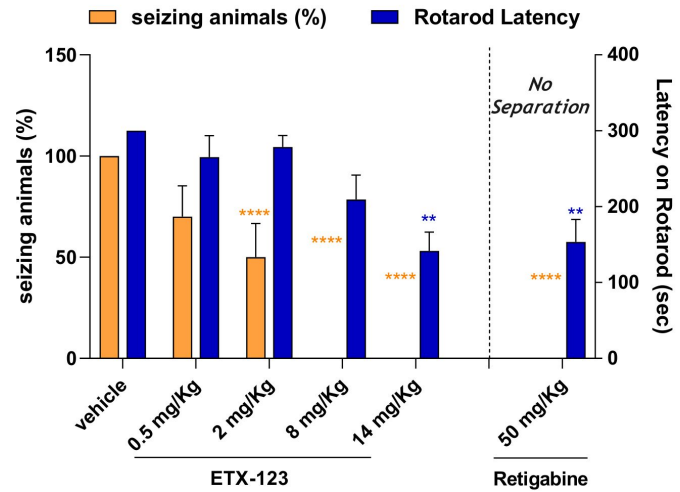


Image Source: <https://conductscience.com/maze/maze-basics-rotarod-test-for-mice/>

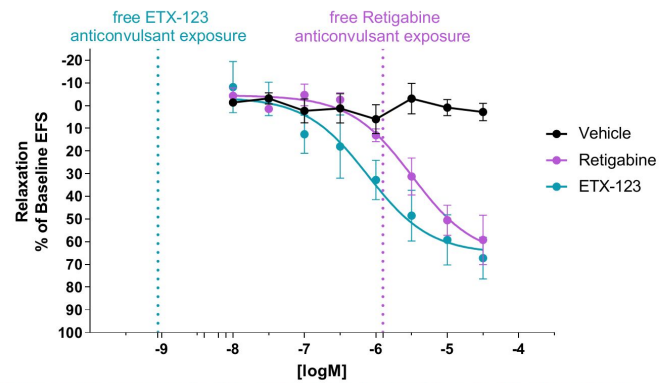
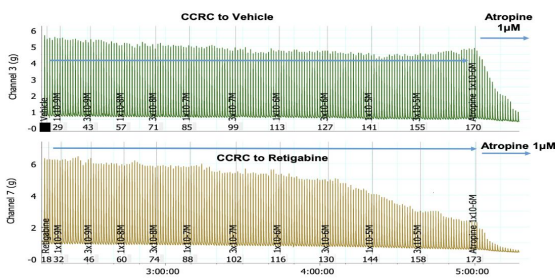


ETX-123 has demonstrated potent in vivo efficacy in a highly translatable model of epilepsy, along with a favorable tolerability profile

****p < 0.0001 and **p < 0.01 - comparisons all groups vs. respective vehicle for each variable

Human bladder contractility assay: Free anticonvulsant concentration of ETX-123 are >700-fold lower than concentration relaxing human bladder, vs only ~4-fold for retigabine

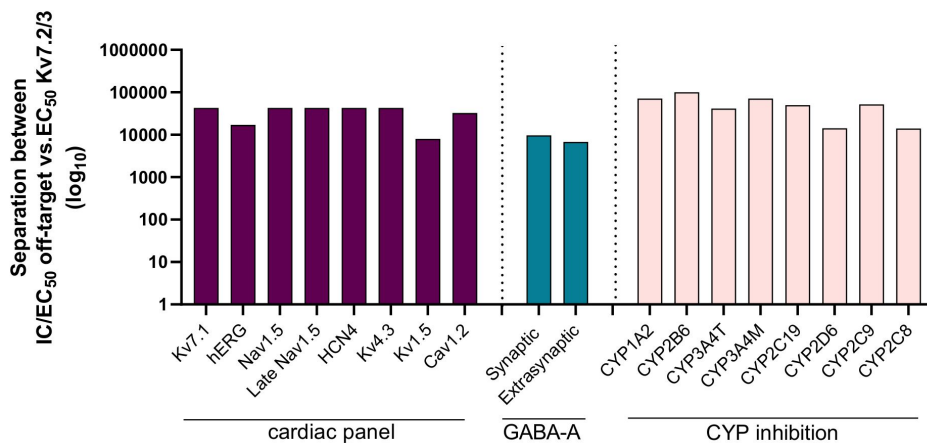
Contraction of human bladder strips evoked by electrical field stimulation (EFS) of endogenous nerves



- Urinary retention adverse events, or related voiding dysfunctions were reported with retigabine/ezogabine in 2% of patients
- Activity at Kv7.4 in the bladder smooth muscle is a key factor

ETX-123 performance vs retigabine/ezogabine in human bladder translational assay is encouraging ahead of clinical studies

Broad Selectivity: multiple screens confirm no off-target activity



ETX-123 shows at least a >1000-fold separation vs. Kv7.2/3 EC₅₀ in multiple screen, including a 48-Target Cerep screening panel

ETX-123 profile to date is significantly superior to retigabine

	ETX-123 (pre-formulation*)	Retigabine
In vitro profile		
Potency at Kv7.2/3	0.7- 2 nanoM	2-14 microM
Selectivity over Kv7.1		
Selectivity over Kv7.4	>14,000-fold selectivity	Poor selectivity
Metabolite profile	<i>In vitro</i>	Toxic azoquinones
In vivo profile		
Rat MES		
Separation in Rat MES vs rotarod		No separation
Chemistry		
Structural features	Novel scaffold, not disclosed	Substituted aniline
IP	COM IP Filed August 2022	n/a (off-market)

* ETX-123 data before formulation optimized to improve solubility and oral bioavailability

Progressing ETX-123 through IND-enabling activities in 2023, with Phase 1 anticipated to begin in 1H 2024

Key activities	Status
Novel “non-retigabine” chemotype (COM IP filed August 22)	✓
Potency and selectivity	✓
No off-target activity (GABA, hERG, CEREP receptor panel)	✓
No genotoxicity risk with Ames test	✓
Confirmation of therapeutic window in preclinical pharmacology and safety studies	Ongoing
Initiate Phase 1 in healthy subjects, including TMS <i>to confirm target engagement at target clinical dose</i>	1H 2024

Opportunity to pursue multiple neuronal excitability indications in Phase 2 and beyond



Rethinking treatment for nervous system disorders

- ✓ **Highly experienced** team with deep expertise in neuroscience and ion channel drug discovery and development
- ✓ **Highly differentiated Kv7 program** with broad potential to pursue across multiple neuronal excitability indications
- ✓ **~\$109M* cash runway into 2027** enabling advancement of lead Kv7 asset through Phase 2a clinical proof of concept

* cash, cash equivalents and investments as of March 31, 2023



For more information:

www.eliemtx.com



InvestorRelations@eliemtx.com

