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): January 8, 2024

CATALYST PHARMACEUTICALS, INC.
(Exact Name Of Registrant As Specified In Its Charter)

Delaware	**001-33057**	**76-0837053**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

355 Alhambra Circle **Suite 801** **Coral Gables, Florida**	**33134**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (305) 420-3200

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	**Name of Exchange on Which Registered**	**Ticker Symbol**
Common Stock, par value $0.001 per share	NASDAQ Capital Market	CPRX

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

On January 8, 2024, the Company posted a corporate presentation to its website that representatives of the Company may use from time to time in presentations or discussions with investors, analysts, or other parties.

The information in this Item 7.01, including Exhibit 99.1, is furnished pursuant to Exhibit 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the limitations of that section, 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 expressly set forth by specific reference in such a filing. The Company's submission of this Form 8-K shall not be deemed as an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Forward-Looking Statements

This Form 8-K, the presentation, and the slide deck contain forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties, which may cause Catalyst's actual results in future periods to differ materially from forecasted results. A number of factors, including those factors described in the Company's Annual Report on Form 10-K for the fiscal year 2022 and its other filings with the U.S. Securities and Exchange Commission ("SEC"), could adversely affect the Company. Copies of the Company's filings with the SEC are available from the SEC, may be found on the Company's website, or may be obtained upon request from the Company. The Company does not undertake any obligation to update the information contained herein or therein, which speak only as of this date.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Presentation, dated January 8, 2024
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 caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Catalyst Pharmaceuticals, Inc.

By: /s/ Richard J. Daly
Richard J. Daly
President and CEO

Dated: January 8, 2024

Catalyst pharmaceuticals

Dedicated to Making a Meaningful Difference in the Lives of Patients Suffering from Rare and Difficult to Treat Diseases

Forbes 2024 AMERICA'S MOST SUCCESSFUL SMALL COMPANIES

NASDAQ: CPRX

BIOFLORIDA 2022 Company of the Year

January 2024

Safe Harbor

This presentation contains forward-looking statements that are subject to a number of risks and uncertainties, many of which are outside our control. All statements regarding our strategy, future operations, financial position, estimated revenues or losses, projected costs, prospects, plans, and objectives, other than statements of historical fact included in our filings with the U.S. Securities and Exchange Commission ("SEC"), are forward-looking statements. The language reflected in these statements only speaks as of the date that appears on the front cover of the presentation; the words "may," "will," "could," "would," "expect," "intend," "plan," "anticipate," "believe," "estimate," "project," "potential," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. You should not place undue reliance on forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement that we make, we caution you that these statements are based on a combination of facts and factors currently known by us and projections of future events or conditions, about which we cannot be certain. Forward-looking statements in this presentation should be evaluated together with the many uncertainties that affect our business, particularly those mentioned in the "Risk Factors" section of our Annual Report on Form 10-K filed with the SEC, reporting our financial position and results of operations as of and for the year ended December 31, 2022, as well as our subsequent reports filed with the SEC. In addition, market and industry statistics contained in this presentation are based on information available to us that we believe is accurate. This information is generally based on publications that are not produced for purposes of securities offerings or economic analysis. All forward-looking statements speak only as of the date that appears on the front cover of the presentation or the date of this presentation. Except as required by law, we assume no obligation to update these forward-looking statements publicly or to update the factors that could cause actual results to differ materially, even if new information becomes available in the future.

Catalyst Pharmaceuticals

A Differentiated Growth Rare Disease Company

Commercial Excellence

Proven track record commercializing innovative, rare, and best-in-class neurological medicines

Strategic Portfolio Expansion

Demonstrated success acquiring and integrating high-value, complimentary neurological assets to drive strong and sustained growth

Highly Qualified Leadership Team

Decades of combined industry experience, with extensive expertise spanning neurology, rare disease, and new product launches

Strong Financial Position

Positive cash flow and strong revenue growth enable continued execution against strategic priorities including neurological portfolio expansion to further drive growth

Growing Revenues with a Diversified Portfolio

Focus on Rare Neurological and Epileptic Disorders

Proprietary Portfolio

Neuromuscular

FIRDAPSE® - rare neuromuscular disease

AGAMREE® - rare muscular dystrophy disease

Epilepsy

FYCOMPA® - epileptic seizures

Product Franchises

Neuromuscular	Epilepsy
FIRDAPSE® (amifampridine) Tablets 10 mg aGamree® (vamorolone) oral suspension 40 mg/mL	Fycompa® (perampanel) tablets

Proven U.S. Commercial Capabilities

Neuromuscular Franchise

FIRDAPSE: Proprietary Flagship Product

Only U.S. Approved Treatment for Lambert Eaton Myasthenic Syndrome (LEMS)

FIRDAPSE® (amifampridine) Tablets 10mg
Orally Delivered Potassium Channel Blocker

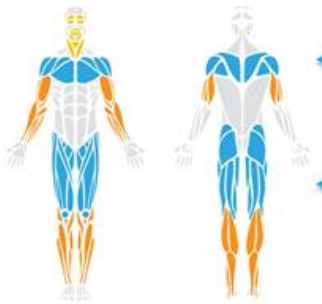
Clinically Proven to Maintain Muscle Strength and Mobility
Most Patients Respond and Remain on Treatment

- Flagship product; approved in the U.S. in November 2018
- Product launched - Q1 2019
- Approved in people ≥6 years of age
- Orphan Drug Exclusivity through 2025
- Strong intellectual property estate enhances durability
- IP protection to 2037
- Total of 8 patents: 6 Listed in the Orange Book and 2 pending

Lambert Eaton Myasthenic Syndrome (LEMS)

A Rare Neuromuscular Autoimmune Disease

Affects Nerve-Muscle Communication



Most affected

Sometimes affected

Least affected

May cause:

- Weakening of upper arms and shoulders muscles
- Severe, debilitating, and progressive weakness in the upper legs and hips
- Life-threatening weakness in respiratory muscles

Causes Debilitating, Progressive Muscle Weakness and Fatigue

50% of people with LEMS have underlying cancer

Observed in ~3% of small cell lung cancer patients

Affects both women and men

*O'Neill, J H, Murry, N M, Newson-Davis, J: (1988): The Lambert-Eaton myasthenic syndrome. A review of 50 cases: doi: 10.1093/brain/111.3.577

Catalyst pharmaceuticals

FIRDAPSE: U.S. LEMS Market Opportunity

Significant Unmet Need

Affects ~3,600 - 5,600 people (U.S.)[1]

>**1,100** LEMS-diagnosed patients ever **treated** with FIRDAPSE [2]

~**800** LEMS patients **diagnosed but not yet treated** with FIRDAPSE

> **2,900 LEMS undiagnosed** patients

Multiple Growth Drivers

Expanded educational programs to SCLC LEMS HCP's

100mg label expansion – assigned PDUFA date of June 4, 2024

Seek to expand global footprint

Making A Meaningful Difference In Patients' Lives

[1] *Lambert Eaton Myasthenic Syndrome is Underrecognized in Small Cell Lung Cancer: An Analysis of Real-World Data*; presented IASLC 2023 World Conference on Lung Cancer; authors: David Morrell, Benjamin Drapkin, Guy Shechter, Regina Grebla;[2] Includes 225 patients now deceased

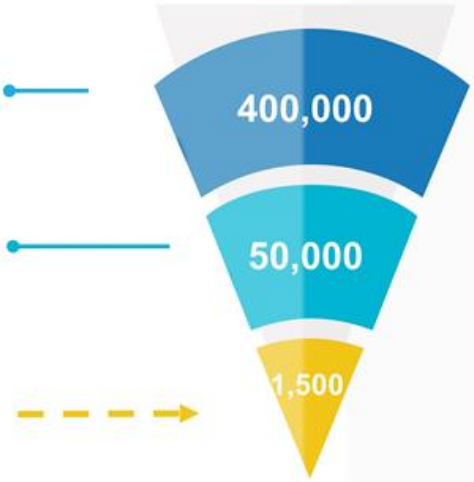
FIRDAPSE: Small Cell Lung Cancer Tumor LEMS

Represents a Significant Growth Opportunity

Patient prevalence Lung Cancer

Small Cell Lung Cancer (SCLC)
(10% - 15% of Lung Cancer – midpoint 12.5%)

Lambert Eaton Myasthenic Syndrome SCLC patients
(~3% of SCLC)



- Many SCLC LEMS patients are undiagnosed with LEMS and are being treated by oncologists
- Oncologists typically refer SCLC patients diagnosed with LEMS to neurologists or neuromuscular specialists
- **~ 1,000 new potential** SCLC LEMS patients each year (*includes diagnosed and undiagnosed*)

FIRDAPSE: Expanding the Global Reach

Global Expansion Initiatives Underway

Japan

Currently, no approved therapy for LEMS

LEMS prevalence: ~1,200 people

DyDo Pharma* to develop & market the product

NDA submitted to PMDA in December 2023*

Expect 10-year market exclusivity upon approval

Canada

Approved by Health Canada on July 31, 2020

Canada LEMS Prevalence: ~300 people

KYE Pharmaceuticals has the exclusive license to market FIRDAPSE

Innovative drug data exclusivity to 2028

No drug application referencing data accepted before 2026

*DyDo, our partner in Japan, has submitted their NDA for FIRDAPSE (amifampridine) to the Pharmaceuticals and Medical Devices Agency ("PMDA"). Upon acceptance of the submission of the NDA for FIRDAPSE in Japan, our territorial rights to develop and market FIRDAPSE under the license agreement with SERB will expand to include key markets in Asia, as well as in Central and South America.

AGAMREE: Novel Corticosteroid

Treatment for Duchenne Muscular Dystrophy (DMD)

aGamree® (vamorolone) oral suspension 40mg/mL

Designations:
Orphan Drug
Rare Pediatric Disease

Potential to Deliver Meaningful Near & Long-term Value, Adding to Continued Growth Momentum

- Approved in the U.S. for treatment in DMD patients ≥ 2yrs - October 2023
- May increase ambulation duration and mobility, improving QoL
- Product launch expected in Q1 2024
- Optimize neuromuscular franchise capabilities with minimal expansion
- Comprehensive Patient Assistance Program available upon launch
- Orphan drug designation offers 7 years of market exclusivity
- Pending patents out to 2040

Acquired North America License from Santhera Pharmaceuticals, July 2023. North American territories consist of the U.S., Canada, and Mexico
†Santhera Pharmaceuticals to commercialize in European Union. Germany launch expected 1Q 2024.

AGAMREE: Addresses Need for Tolerable Steroid

Steroids are the Backbone of DMD Therapy

AGAMREE - Compelling Safety Profile

In Clinical Studies, Demonstrated[1]

Proven efficacy, tolerability, safety, and ease of use

Equivalent efficacy to prednisone

Potential of significant reduction of steroid associated side effect burden when compared with another corticosteroid, with benefits for:

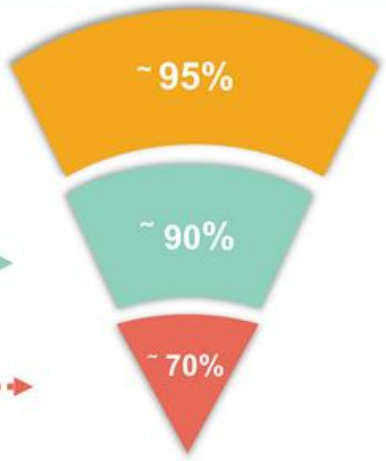
- Bone Health
- Growth
- Behavior

U.S. DMD patient prevalence: ~ 11,000 to 13,000

DMD diagnosis rate; typically occurs at ages 2 - 5 years

DMD patients treated with corticosteroids at some point

Currently treated DMD patients receive concomitant steroid treatment



[1]Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014.doi:10.1001/jamaneurol.2022.2480; Mah JK et al (2022). JAMA NetwOpen.2022; e2144178.doi:10.1001/jamanetworkopen.2021.44178.; Guglieri M et al (2022) JAMA. doi:10.1001/jama.2022.4315;Heier CR et al (2019); Life Science Alliance DOI: 10.26508; Liu X et al (2020). Proc Natl Acad Sci USA 117:24285-24293

Catalyst pharmaceuticals

Epilepsy Franchise

FYCOMPA® (perampanel) CIII

Established, First-in-Class Commercial Epilepsy Asset

Synergistic Neurology Expansion

Acquired U.S. rights in January 2023

Franchise teams fully engaged - May 2023

Franchise physician call points overlap - 45%

Compelling product net revenue contribution

Seek to expand into rare epilepsy or other neuroscience adjacencies

FYCOMPA® is approved to treat:

SEIZURES WITH CONVULSIONS		SEIZURES WITHOUT CONVULSIONS
Partial-onset seizures that **secondarily generalize***	**Primary generalized** tonic-clonic seizures†	**Partial-onset** seizures that do not secondarily generalize*

*Taken with another antiseizure medication or alone for patients 4 years of age and older.
†Taken with another antiseizure medication for patients 12 years of age and older.

FYCOMPA: Broad Spectrum Efficacy

Only Non-Competitive AMPA Receptor Antagonist

Well-tolerated, minimal drug-to-drug interactions, and no contraindications

Simple once-a-day dosing

Long half-life, relieving the anxiety of breakthrough seizures if a dose is missed

>70% retention rate for adult patients

Seizure-freedom rate is ~ 72% when used adjunctively

Patent exclusivity until at least May 2025

FYCOMPA has been designated in the U.S. as a federally-controlled substance (CIII). For Full Prescribing Information, including Boxed WARNING for FYCOMPA®, please visit www.fycompa.com.

Catalyst pharmaceuticals

FYCOMPA: Significant Market Opportunity

Epilepsy - High Unmet Medical Need

Epilepsy is 4th most common neurological disorder after migraine, stroke and Alzheimer's disease[1]

- ~3.4M patients in the U.S. with active epilepsy and ~470K children[2]
- ~150,000 new patients per year in U.S.[3]
- ~30 - 40% of all people with epilepsy still fail to respond to treatment despite the availability of a wide variety of anti-seizure medications

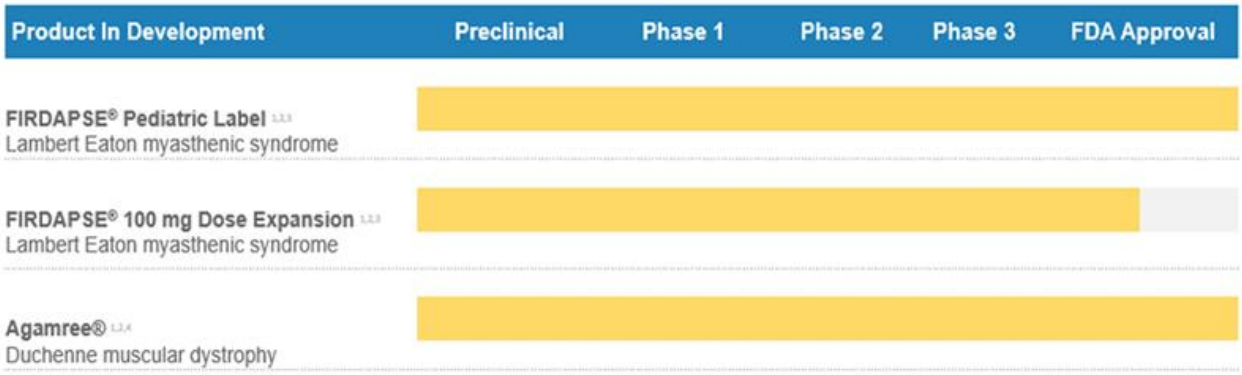
Evolving into a precision medicine composed of a variety of well-defined rare epilepsies of genetic origin

Fycompa™

[1]England MJ, Liverman CT, Schultz AM, Strawbridge LM, eds. Epilepsy Across the Spectrum: Promoting Health and Understanding. Washington, DC: National Academies Press (US); 2012. [2]CDC Epilepsy Data and Statistics; Epilepsy Prevalence in the US (data as of 2015); [3]Examining the Economic Impact and Implications of Epilepsy, AJMC (US); 2020

Catalyst Pipeline

Catalyst Pharmaceuticals Pipeline



[1]EAP=Expanded Access Program; ISI investigator Sponsored IND

[2]Orphan Drug Designation

[3]Breakthrough Therapy Designation

[4]Lead Indication

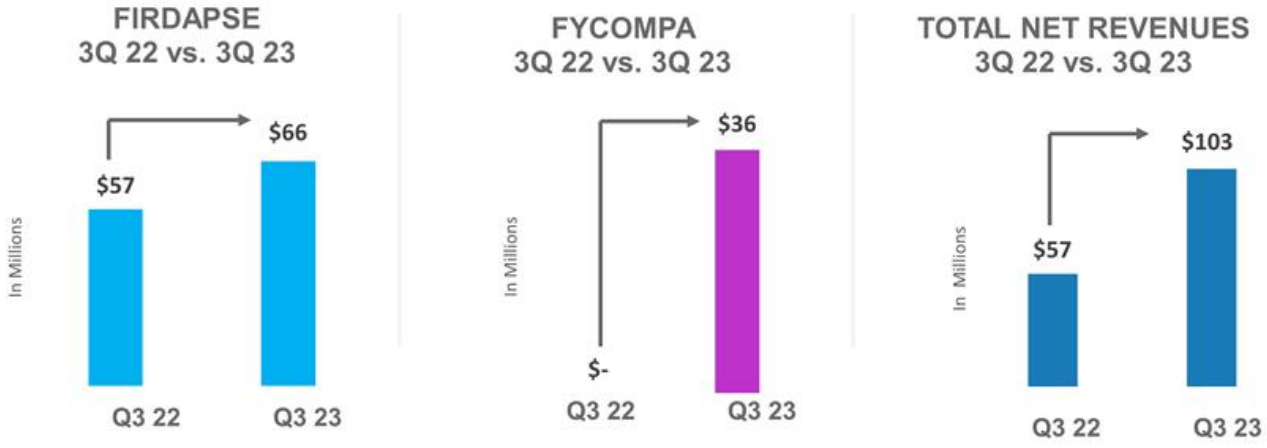
*FIRDAPSE is currently approved in the U.S. for the treatment of LEMS in patients 6 years of age and older

Corporate Highlights

Sustained Product Portfolio Growth

Demonstrated Commercial Execution

3Q 22 vs 3Q 23 Net Revenue Performance



Catalyst pharmaceuticals

Q3 2023 Financial Highlights

FY 2023 Total Revenue of Between $390M - $395M

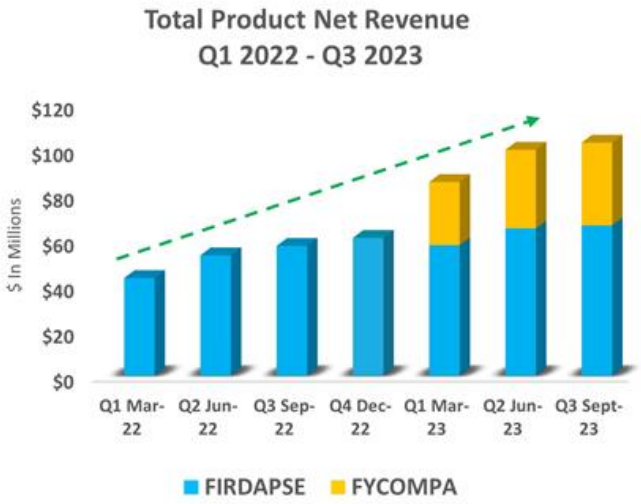
For the Three Months Ended September 30th	2023	2022	% Change
Total Net Product Revenues	$102,617	$57,173	79.5%
FIRDAPSE Net Product Revenues	$66,224	$57,173	15.8%
FYCOMPA Net Product Revenues	$36,393	N/A	N/A
GAAP Net Income (Loss)	$(30,764)	$22,748	(235.2)%
Non-GAAP Net Income *	$55,870	$28,615	95.2%
GAAP Net Income (Loss) Per Share – Diluted	$(0.29)	$0.20	(242.1)%
Non-GAAP Net Income Per Share – Diluted*	$ 0.49	$0.26	88.5%

* Non-GAAP net income excludes from the calculation of net income (i) the expense associated with non-cash stock-based compensation, (ii) non-cash depreciation expense, (iii) non-cash amortization of intangible assets expense, (iv) the provision (benefit) for income taxes and (v) acquired in-process research & development costs. Non-GAAP financial measures are provided as additional information and not as an alternative to Catalyst's financial statements presented in accordance with U.S. generally accepted accounting principles (GAAP). These non-GAAP financial measures are intended to enhance an overall understanding of Catalyst's current financial performance.

Strong Financial Position
Underscores Successful Execution

(In Millions)

Q3 23 Results	
Cash Position as of Sept 30, 2023	$121.0
Total Revenues for the three months ended Sept 30, 2023	$102.7
Total Revenue Growth compared to Q3 2022	79.4%
Net Product Revenue Growth Increase	
FIRDAPSE 2023 YTD, as of Sept 30, 2023	23.1%
FYCOMPA compared to Q2 2023	5.2%



Continued Drivers to Deliver Long-Term Value

	2023 Accomplishments	Anticipated 2024 Milestones
Catalyst pharmaceuticals	Launched inaugural ESG report Appointed new CEO and CFO effective 2024	Continue to pursue synergistic rare CNS opportunities
FIRDAPSE® (amifampridine) Tablets 10 mg	Expanded focus to SCLC patients comorbid with LEMS	Pursuing global expansion of FIRDAPSE as a treatment for LEMS
	sNDA for 100mg maximum daily dose accepted	**June 4, 2024:** assigned U.S. PDUFA date
	NDA submission in Japan complete	Approximately 10-month PMDA review period in Japan: Submitted by partner DyDo Pharma
	Received two new patent allowances	**Q1 2024**: Expect patents to be listed in Orange Book
aGamree® (vamorolone)	Received FDA approval	**Q1 2024:** Expect U.S. commercial launch
Fycompa® (perampanel) tablets	Completed U.S. commercial and MSL team integration	

Strategic Growth Initiatives

Building on the Momentum

Expand Commercial Footprint	Explore commercial add-on assets both in the U.S. and globally Synergistic expertise to foster innovations Harness operational capabilities and industry expertise
Expand Portfolio in Rare & Orphan Diseases	Seek partnerships to accelerate growth into new therapeutic areas and global markets focused on rare neurological and epileptic disease opportunities Geographical expansion of our portfolio products
Invest in Portfolio Diversification	Strong balance sheet reinforces delivering attractive opportunities Well-positioned to achieve long-term growth

Catalyst pharmaceuticals

NASDAQ: CPRX

2002 Founded	2006 IPO	Market Cap ~$1.8B*

BIOFLORIDA 2022 Company of the Year

AMERICA'S MOST SUCCESSFUL SMALL COMPANIES Forbes 2024

*Market Cap as of Dec 28, 2023

Catalyst pharmaceuticals

NASDAQ: CPRX