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 13, 2025

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 13, 2025, 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 corporate presentation is attached to this Form 8-K as Exhibit 99.1.

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, and the corporate presentation 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 2023 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 13, 2025
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/ Michael W. Kalb
Michael W. Kalb
Executive Vice President and Chief Financial Officer

Dated: January 13, 2025

Exhibit 99.1

Catalyst pharmaceuticals

Improving the Lives of Patients with Rare Diseases

NASDAQ: CPRX

J.P. Morgan Healthcare Conference January 2025

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, 2023, 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.

Patients are at the center of every decision we make

Catalyst Pharmaceuticals is a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases

Growth-Oriented, Rare Disease-Focused

Catalyst pharmaceuticals

What we are doing

Commercial-Focused Business Model

Maximizing the value of our innovative and differentiated commercial portfolio to serve patients with rare diseases

How we will continue to grow

Ongoing Lifecycle Management

Driving organic growth and expanding patient access to best-in-class rare disease therapies

Strategic Portfolio Expansion

Buy-and-build strategy acquiring and integrating high-value, orphan designated, synergistic assets

Why we will continue to succeed

Operational Excellence

Continued emphasis on efficiency, innovation, and execution

Proven Capabilities

Successful track record of launching products and delivering value

Financial Flexibility

Record revenue and sustainable profitability enable future investments

Building a Leading Orphan Drug Portfolio

Organic-Driven Growth

Market penetration and label expansion represent significant opportunities

Geographic expansion prioritizing strategic markets through licensing opportunities

Acquisition-Focused Growth

Focus on immediate or near-term accretive orphan opportunities

Strong financial and business position enables flexible decision-making

Prioritizing Patient Access to Rare Disease Treatments

Catalyst PATHWAYS®

Facilitating seamless care through comprehensive personalized treatment support and patient assistance

Patient-Centric Support

- Patient Access Liaisons (PALs) support throughout the patient journey which may lead to improved outcomes
- Patient ambassador programs to foster connections within the rare disease patient community

Access to Therapy

- Accelerating treatment initiation with free bridge medication, insurance navigation, and copay programs

Healthcare Provider Education

- Provide disease education and outreach enabling providers to make more informed diagnostic decisions

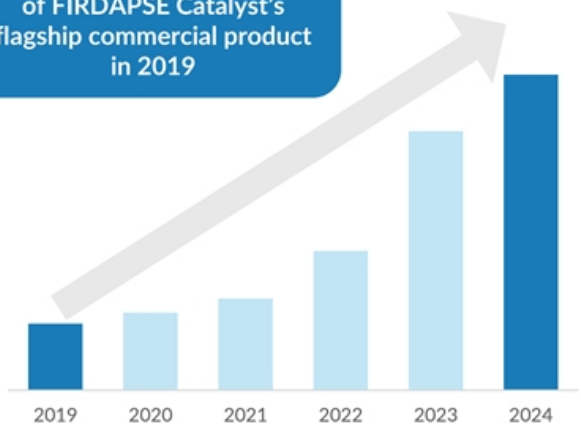
Additional Patient Support Initiatives

- Free LEMS testing (VGCC[1]) provided for potential patients who may be eligible for FIRDAPSE
- Partnerships with independent advocacy groups to deepen understanding of patient unmet needs and experiences

1) Voltage-Gated Calcium Channel antibody test is a definitive diagnostic tool for Lambert-Eaton myasthenic syndrome, and Catalyst Pharmaceuticals, Inc. offers the test for free to uninsured patients or those whose insurance does not cover it.

Diversified U.S. Commercial Portfolio of Innovative Assets with Multiple Expansion Opportunities

37% CAGR since launch of FIRDAPSE Catalyst's flagship commercial product in 2019



FIRDAPSE® (amifampridine) Tablets 10 mg

The only evidence-based approved product in the U.S. for Lambert Eaton myasthenic syndrome (LEMS)

aGamree™ (vamorolone) oral suspension 40mg/mL

A novel corticosteroid treatment for Duchenne Muscular Dystrophy (DMD)

Fycompa® (perampanel)

The only non-competitive AMPA receptor antagonist for epilepsy

CAGR calculation includes 2019 total revenues and upper end of 2024 total revenue guidance provided on November 6, 2024.

LEMS is a Debilitating Nerve-Muscle Communication Disorder Causing Progressive Weakness and Fatigue

~3,600

U.S. patient prevalence potential of up to 5,400 patients[1]

~50%

LEMS patients believed to have cancer-associated LEMS

~500

Currently identified patients in LEMS diagnostic journey not yet treated with FIRDAPSE

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.

FIRDAPSE: The Only Evidence Based Approved Product in the U.S. for LEMS

Orphan drug exclusivity until November 2025; IP estate out to 2037; 6 Orange Book listed patents

1) Long-term follow-up, quality of life, and survival of patients with Lambert-Eaton myasthenic syndrome; authors: Alexander F Lipka, Marion I Boldingh, Erik W van Zwet, Marco WJ Schreurs, Jan BM Kuks, Chantal M Tallaksen, Maarten J Titulaer, Jan JGM Verschuuren

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FIRDAPSE® (amifampridine) Tablets 10 mg

14 quarters of 15%+ growth with similar continued growth anticipated

Key Growth Drivers

- 100 mg maximum daily dose label expansion
- Misdiagnosed patients in need of LEMS treatment
- Growth opportunity in cancer-associated LEMS[1]

FIRDAPSE Well Positioned for Sustained Growth

>$1 Billion

Total Addressable Market for LEMS Population[1]

- The only evidence-based approved product in the U.S. for LEMS
- Education campaigns increasing usage of LEMS diagnostic testing (VGCC)
- Prescription approval rates exceed 90% across payers
- High patient response and retention
- Enhanced prescriber engagement to support adoption

1) Based on internal Company estimates and anticipated 2025 market dynamics, represents future market potential and does not represent the Company's 2025 product forecast

DMD is a Rare and Life Threatening Neuromuscular Disorder

~11k-13k[1]

U.S. DMD patient prevalence

~95%

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

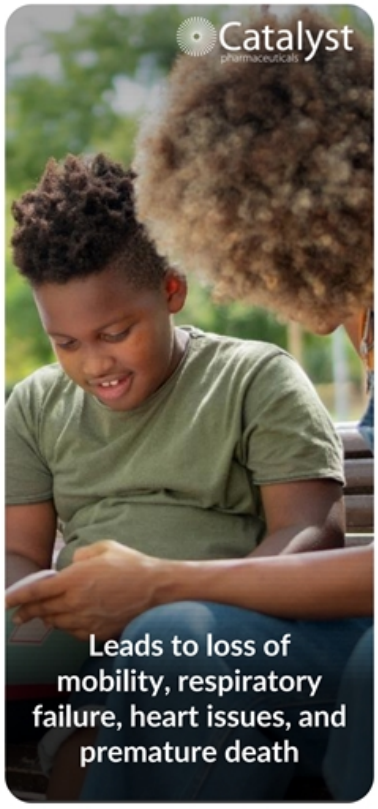
~90%[2]

DMD patients are treated with corticosteroids at some point

~70%

DMD patients currently receiving concomitant steroid treatment; an opportunity to re-engage lapsed patients

Steroids will continue to be the standard of care for the treatment of DMD



1) Neuroepidemiology. 2023;57(2):90-99. doi: 10.1159/000528962. Epub 2023 Jan 9. 2) Neurology. 2016 Feb 2;86(5):465-72. doi: 10.1212/WNL.0000000000002337

AGAMREE: A Novel Corticosteroid Treatment for DMD

Orphan drug designation offers market exclusivity until October 2030; Patent protection to 2040; 6 Orange Book listed patents

Catalyst pharmaceuticals

aGamree (vamorolone) oral suspension 40mg/mL

84% of DMD Centers of Excellence writing prescriptions

Conversions from existing treatments account for ~90% of patients

Key Growth Drivers

- Current standard of care is associated with behavioral and safety issues
- Differentiated product profile supports earlier treatment adoption and longer treatment duration
- Investing in SUMMIT study in an effort to demonstrate potential enhanced clinical benefits of AGAMREE, including behavior, bone growth, and stature[1]

1) Clinicaltrials.gov

AGAMREE Differentiated Profile Uniquely Positioned to Address Unmet Need in DMD Treatment Landscape

>$1 Billion

Total Addressable Market for DMD Population[1]

- Clinically proven to improve muscle strength and function[2]
- Equivalent efficacy to prednisone
- Potential for significant reduction of steroid-associated side effect burden when compared with other corticosteroids

1) Based on internal Company estimates and anticipated 2025 market dynamics, represents future market potential and does not represent the Company's 2025 product forecast. 2) AGAMREE (vamorolone) [package insert]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc.; 2023.

SUMMIT Study Seeks to Demonstrate Potential Clinical Superiority of AGAMREE

Open label, five-year follow up of ~250 DMD patients across ~25 Centers of Excellence[1]

Real-world data to assess potential long-term benefits of AGAMREE to current standard of care

- Behavioral improvements (e.g., reduced aggression)
- Stature / growth parameters
- Bone health
- Ophthalmological status
- Cardiovascular health

SUMMIT [*SU*pplemental assess*M*ents of d*M*d patients *I*nvestigating ou*T*comes]

Evaluate AGAMREE as a monotherapy and in conjunction with other treatment options

1) Clinicaltrials.gov

FYCOMPA: The Only Non-Competitive AMPA Receptor Antagonist for Epilepsy

Epilepsy is 4th most common neurological disorder[1]

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Fycompa™ (perampanel) TABLETS 2 • 4 • 6 • 8 • 10 • 12 mg ORAL SUSPENSION 0.5 mg/mL

Key Value Drivers

- Patient preference to remain on existing epilepsy treatment expected to support commercial durability following anticipated generic entry May 2025
- Strong product profile: Well tolerated with minimal drug-drug interactions and no contraindications[2]
- Seizure freedom rate of ~72% when used adjunctively[3]

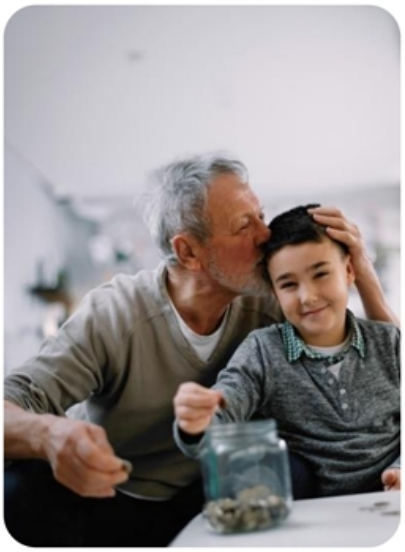
AMPA = α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid.

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.

Clear and Focused Acquisition Growth Strategy

Exploring all synergistic opportunities inclusive of

- Orphan, rare-disease products across therapeutic areas
- Differentiated therapies that address significant medical needs
- Immediate / near-immediate accretive acquisitions



Proven Partnership Model that Maximizes Value of Orphan Products

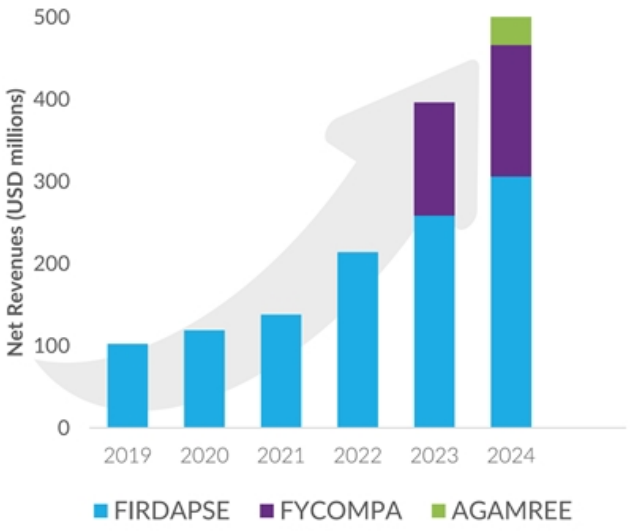
Established track record of identifying and integrating orphan products

Exceptional commercial capabilities and expanding therapeutic footprint

Best-in-class patient support programs

Deep expertise in serving rare disease communities

2024 Total Net Revenues Slightly Exceed Upper End of Latest Guidance



2024 Full Year Total Revenue Guidance

$475M - $485M

2024 Net Product Revenue Guidance

FIRDAPSE	$300M - $310M
FYCOMPA	$130M - $135M
AGAMREE	$40M - $45M

Cash position of $500+M, no debt as of 12/31/2024

The total revenue also included net product revenue as represented above.

Accelerating Momentum: Strategic, Disciplined Execution

2024 Achievements

Third quarter net product revenue growth of 23.2% YoY

AGAMREE

- Commenced U.S. commercial launch for DMD
- Initiated SUMMIT study
- Expanded in Canada through licensing (Kye Pharmaceuticals)

FIRDAPSE

- Received U.S. approval for 100 mg maximum daily dose enhancing dosing flexibility
- MHLW Japan approval of NDA (DyDo Pharma)

2025 Priorities

Continue to protect FIRDAPSE intellectual property portfolio

- Settled with Teva on January 8, 2025

Continuous pursuit of new assets

Sustain organic growth of FIRDAPSE

Continue to drive the success of the U.S. AGAMREE launch

Increase patient access and health equity

- FIRDAPSE launch in Japan (DyDo Pharma)
- AGAMREE application submission filing to Health Canada (Kye Pharmaceuticals)

NASDAQ: CPRX