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): September 26, 2023

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 September 26, 2023, Patrick J. McEnany, Chairman and CEO of Catalyst Pharmaceuticals, Inc. (the "Company"), along with other members of the Company's senior management, will participate in the 2023 Cantor Global Healthcare Conference. A webcast of the presentation, which will take place at 11:05 AM Eastern Daylight Time on September 26, 2023, will be available on the Company's website at https://ir.catalystpharma.com/events-and-presentations, and will be available for replay for 14 days thereafter. A copy of the slide deck for the presentation will be available at the same link and 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, 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 September 26, 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 caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Catalyst Pharmaceuticals, Inc.

By: /s/ Alicia Grande
Alicia Grande
Vice President, Treasurer and CFO

Dated: September 26, 2023

Exhibit 99.1

Catalyst pharmaceuticals

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

Forbes 2023 AMERICA'S BEST SMALL COMPANIES

BIOFLORIDA 2022 Company of the Year

NASDAQ: CPRX

September 2023

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

An Emerging Leader in Rare Diseases

Execution Excellence
Proven track record in development and commercialization

Patient Focus
Dedicated to making a meaningful difference in the lives of patients suffering from rare diseases

Positioned For Growth
Focused on optimizing the product portfolio and investing in portfolio expansion opportunities

Catalyst Pharmaceuticals
Significant Growth Potential

Commercial Execution Excellence

Proven commercial capabilities

Full year 2023 total revenue guidance of $380M - $390M

Developing a Differentiated Rare Disease Portfolio

Dedicated to investing in both internal and external opportunities that will pave the way for long-term growth

Strong Financial Results

Record total Revenues of $99.6M for Q2 2023

Record Net Income of $37.8M for Q2 2023

Growing Revenue With A Diversified Portfolio

Focus on Rare Neurological and Epileptic Disorders

Proprietary marketed products

Substantial product portfolio synergy opportunity

Proven U.S. commercial capabilities

Targeted run rate for FY 2023 of between $380M - $390M

Strong FIRDAPSE® Q2 23 net revenues of $64.9M

Compelling FYCOMPA® Q2 23 net revenues of $34.6M

Primary focus is targeting neurologists/neuromuscular specialists

FIRDAPSE® – Successfully Commercialized

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

FIRDAPSE® (amifampridine) Tablets 10mg

Proprietary Product - Orally Delivered Potassium Channel Blocker

Clinically proven to improve muscle strength and mobility

Most patients respond and remain on treatment

Approved in the U.S. in Nov 2018; Launched - Q1 2019

Orphan Drug Exclusivity through 2025

Expanded pediatric indication - Sept 2022

Strong intellectual property estate enhances durability

IP protection to 2037; Six patents listed in the Orange Book

Lambert-Eaton Myasthenic Syndrome (LEMS)

A Rare Neuromuscular Disease & Profound Effect on Mobility & QoL

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

Symptoms include aching muscles, difficulty walking, climbing stairs, or rising from a chair

Onset in LEMS patients - 50 to 60 years of age

50% of people with LEMS have underlying cancer

Observed in ~3% of small cell lung cancer patients

Affects both women and men

FIRDAPSE - U.S. LEMS Market Opportunity

Significant Unmet Need

Research indicates that LEMS affects between 3,600 and 5,600 people (U.S.)[1]

>**1100** LEMS-diagnosed patients ever **treated** with FIRDAPSE [2]

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

\+

> **2,900 LEMS undiagnosed** patients

Making A Meaningful Difference In Patients' Lives

FIRDAPSE® (amifampridine) Tablets 10 mg

[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

Catalyst pharmaceuticals

Multiple Growth Drivers For FIRDAPSE

Proven Commercial Execution

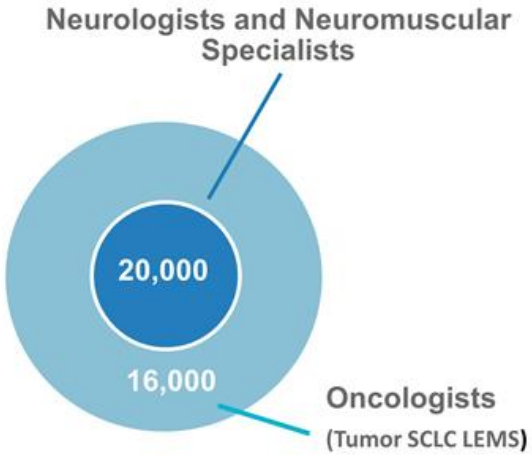
Amplifying HCP, patient education, and communication programs

Expanding disease awareness, including physicians treating LEMS patients with small-cell lung cancer (SCLC)

Targeting approach to reach LEMS patients that are comorbid with SCLC

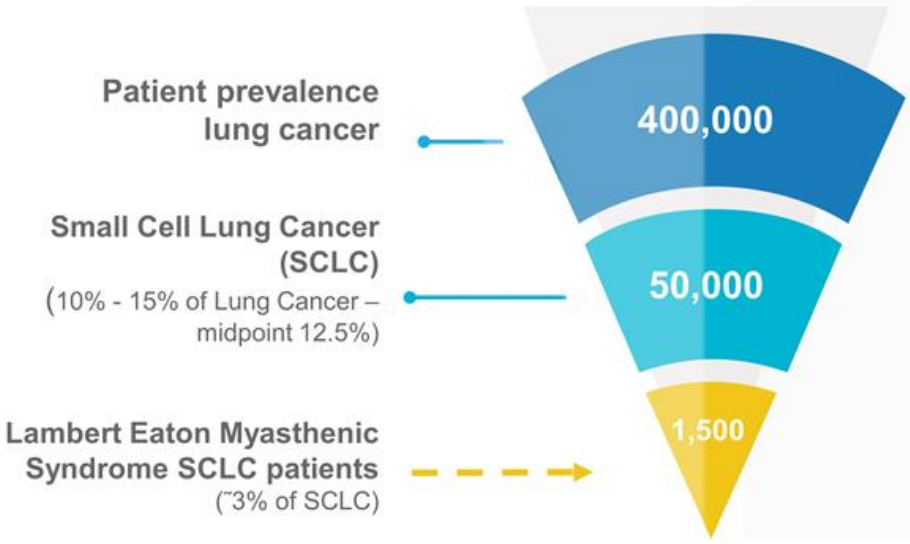
Pursuing plans for label dosing expansion

Growing intellectual patent estate to enhance the commercial durability



Small Cell Lung Cancer Tumor LEMS

Represents a Significant Growth Opportunity



- 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*)

Portfolio Expansion: FYCOMPA® (perampanel) CIII

Established, First-In-Class Commercial Epilepsy Asset

Acquired U.S. rights in Jan 2023

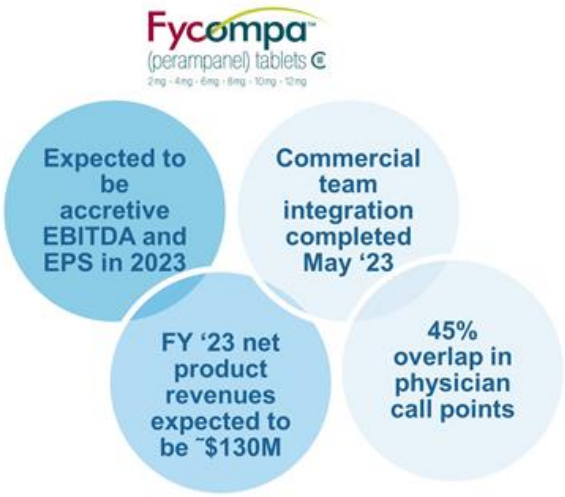
Synergistic product expanding neurology presence

Provides substantial revenue addition

Compelling product net revenue for Q2 '23

FYCOMPA commercial and medical affairs teams onboard and fully engaged in May '23

Establishes gateway to expand reach into rare epilepsy or other adjacencies



FYCOMPA® – Epilepsy Franchise

First and Only Non-competitive AMPA Receptor Antagonist

Specifically Engineered to Block Glutamate Activity at Postsynaptic AMPA Receptors, which are associated with the Generation of Epileptic Activity

U.S. approved in 2012*

For the treatment of partial-onset seizures with or without secondarily generalized seizures in patients ages ≥ 4 years

Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients ages ≥12 years

Patent exclusivity until at least May 2025, with possible patent protection into 2026

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 Alzheimer's disease, migraine, and stroke[1]

~3.5M patients in the U.S. with active epilepsy (~500K 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® (perampanel) CIII

Broad-spectrum efficacy

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

Retention rate >70% for adult patients

Seizure-freedom rate ~ 72% when used adjunctively

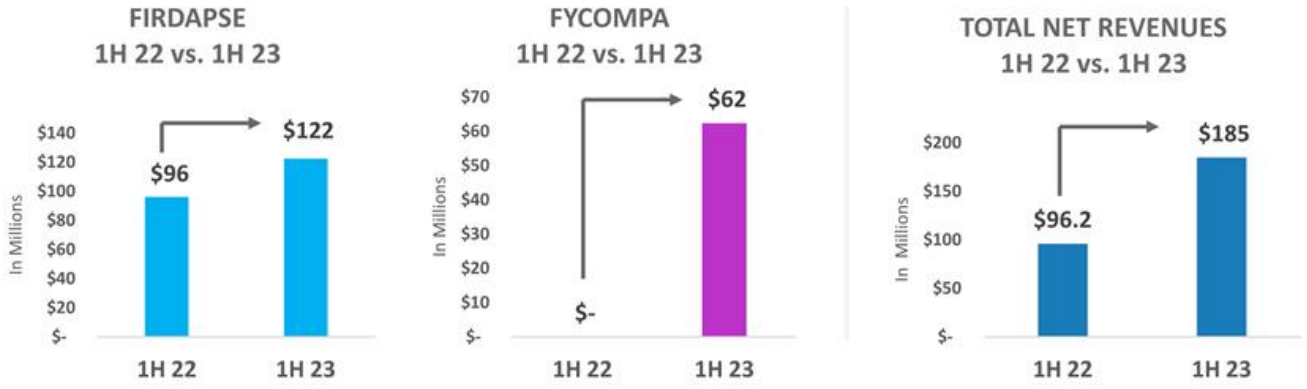
Most common CNS side effects are dizziness, somnolence, and fatigue

[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; [3]Examining the Economic Impact and Implications of Epilepsy, AJMC (US); 2020

Expanded Product Portfolio Growth

Sustained Commercial Execution

H1 22 vs H1 23 Revenue Performance



Forecast 2023 total revenues of between $380M - $390M

Catalyst pharmaceuticals

Portfolio Expansion - Vamorolone

Best-in-Class Dissociative Anti-Inflammatory Steroid Asset

Acquired North America* License from Santhera Pharmaceuticals, July 2023

Delivered on strategic portfolio expansion plans with an innovative, synergistic neuromuscular asset

A well-established mechanism with a differentiated profile for Duchenne Muscular Dystrophy ("DMD")

Leverages FIRDAPSE franchise expertise and optimize existing capabilities with minimal expansion

Potential to deliver meaningful near & long-term value, adding to continued growth momentum

FDA Granted Designations:
- Orphan Drug
- Fast Track
- Rare Pediatric Disease

PDUFA Date: Oct 26, 2023

If Approved:
- Expect a commercial launch in Q1 2024
- Provides a near-term inflection point for continued growth
- Adds a therapeutic advancement in the SoC treatment of DMD
- Addresses an important unmet need for DMD patients

*North American territories consist of the U.S., Canada, and Mexico

Vamorolone – Potential Best-In-Class Disassociated Anti-Inflammatory Steroid

Steroids will remain a backbone of DMD therapy and used concomitantly with other treatments

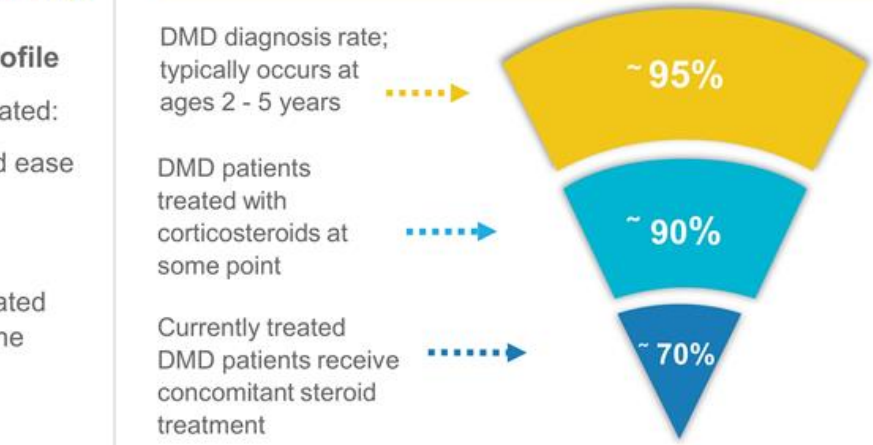
Vamorolone - Compelling Safety Profile

In clinical studies, vamorolone demonstrated:

- Proven efficacy, tolerability, safety, and ease of use
- Equivalent efficacy to prednisone
- Significant reduction of steroid-associated side effect burden with benefits for bone health, growth, and behavior

Address Unmet Need for More Tolerable Steroids

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



Vamorolone Accounting Treatment

Q3 2023 & Q4 2023

Q3 2023

$81.6M total transaction costs[1]

- $75M all-cash license cost
- ~$6.6M transaction-related costs

~ $15M strategic equity investment into Santhera Pharmaceuticals ("Santhera")[2]

Q4 2023

$36M milestone payment to Santhera & 3rd parties' expense assuming U.S. approval on the PDUFA date[3]

~ $5M Launch preparation SG&A expenses

[1] To be expensed in Q3 2023 as a non-recurring (one-time) in-process R&D expense

[2] Purchased 1,414,688 shares of Santhera's common stock at a purchase price of CHF 9.477 per share. Market price will be assessed quarterly, and investment will be marked to market each quarter commencing Q3 2023

[3] This payment will be capitalized as an intangible asset and amortized over 42 quarters

Expanding the Global Reach - FIRDAPSE

Global Expansion Initiatives Underway

Japan

Currently, no approved therapy for LEMS

Japan LEMS prevalence: ~1,200 people

DyDo Pharma* to develop & market the product

Anticipate NDA submission in Japan by YE 2023

Expect 10-year market exclusivity upon approval

Canada

Approved by Health Canada in August 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, will submit their NDA for FIRDAPSE (amifampridine) to the Pharmaceuticals and Medical Devices Agency, ("PMDA"). Upon submitting the NDA for FIRDAPSE in Japan, our territorial rights to develop and market FIRDAPSE under the license with SERB expand to include key markets in Asia, as well as Central and South America.

Catalyst Pharmaceuticals Pipeline

Product In Development	Preclinical	Phase 1	Phase 2	Phase 3	Approval
FIRDAPSE® Pediatric Label [1,2,3] Lambert Eaton myasthenic syndrome					
FIRDAPSE® 100 mg Dose Expansion [1,2,3] Lambert Eaton myasthenic syndrome					
Vamorolone [1,2,4] Duchenne muscular dystrophy					

[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

Strategic Growth Initiatives

Building on the Momentum

Expand Commercial Footprint	Explore commercial add-on assets both in the US & Globally Synergistic expertise to foster innovations Harness operational capabilities and industry expertise
Expand Portfolio in Rare & Orphan Diseases	Seek transformational partnerships to accelerate growth into new therapeutic areas and larger markets Focused on rare neurological and epileptic diseases opportunities
Invest in Portfolio Diversification	Strong balance sheet reinforces delivering attractive opportunities Well-positioned to achieve long-term growth

Strong Foundation to Deliver Long-Term Growth

Achievements

- ✓ Completed the U.S. acquisition of FYCOMPA in Jan 2023
- ✓ Expanded focus on small-cell lung cancer patients comorbid with LEMS in Q1 23
- ✓ Completed the seamless U.S. FYCOMPA commercial and MSL team integration in May 2023
- ✓ Launched Environmental, Social, and Governance "ESG" inaugural report in May 2023
- ✓ Completed the acquisition of vamorolone in July 2023
- ✓ Submitted sNDA seeking to increase FIRDAPSE maximum daily dose to 100mg in Q3 23

Upcoming Milestones

- Anticipate vamorolone approval on the PDUFA date of October 26, 2023
- Expect commercial launch of vamorolone in Q1 2024, if approved
- Expect FIRDAPSE (amifampridine) NDA filing in Japan by YE 2023
- Continue to execute strategic initiatives to diversify the neuroscience product portfolio further

Q2 2023 Financial Highlights

FY 2023 Total Revenue Guidance of Between $380M - $390M

For the Three Months Ended June 30,	2023	2022	% Change
Total Net Product Revenues	$99.5	$53.0	87.5%
FIRDAPSE Net Product Revenues	$64.9	$53.0	22.3%
FYCOMPA Net Product Revenues	$34.6	N/A	N/A
GAAP Net Income	$37.8	$21.6	74.7%
Non-GAAP Net Income*	$60.4	$30.3	99.2%
Earnings per share Diluted – GAAP	$0.33	$0.20	67.9%
Earnings per share Diluted - Non-GAAP*	$0.53	$0.28	91.5%

*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 of Strategic Initiatives

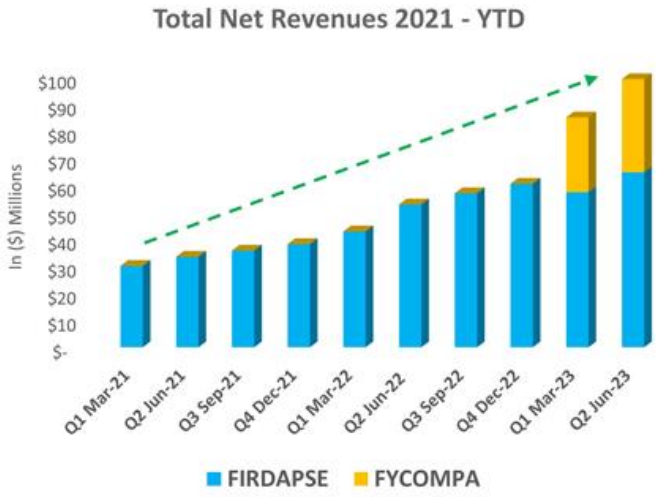
(In Millions)

Q2 23 Results

Cash Position at June 30, 2023*	$178.8
Record Net Product Revenue	$99.5

FY 2023 Projections

Total Net Revenue Estimates	$380 - $390
FIRDAPSE Net Product Revenue	$250 - $260
FYCOMPA Net Product Revenue	$130



*Cash as of June 30, 2023. Post June 30, 2023, $75M for North American license for vamorolone; ¯$15M in equity investment in Santhera; and $10 million payment to Jacobus for previous Ruzurgi acquisition.

Catalyst pharmaceuticals

Catalyst pharmaceuticals

NASDAQ: CPRX

Founded	2002
IPO	2006
Market Cap	~ $1.5B as of Aug 4, 2023
Basic Shares Outstanding	~ 106.5M as of August 7, 2023

AMERICA'S BEST SMALL COMPANIES Forbes 2023

BIOFLORIDA 2022 Company of the Year

Catalyst pharmaceuticals

NASDAQ: CPRX