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): February 7, 2022

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

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**

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 CFR240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 8.01 Other Events

On February 7, 2022, the Company issued a press release providing preliminary 2021 fourth quarter and full year total revenue estimates, a forecast of 2022 total revenue expectations, and a corporate update. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on February 7, 2022.
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: February 7, 2022

Exhibit 99.1

Catalyst Pharmaceuticals Reports Preliminary Fourth Quarter and Full Year 2021 Total Revenues; Provides 2022 Total Revenue Guidance and Corporate Update

2021 Total Revenues Estimated at $141 Million, Representing 18% YoY Growth

Forecast 2022 Total Revenues of Between $195 Million and $205 Million, Representing YoY Growth of 38% to 45%

Recently Regained Orphan Drug Exclusivity in the U.S. for Amifampridine to Treat LEMS

Entering 2022 with a Strong Cash Position of Approximately $191 Million and No Funded Debt

Poised to Acquire Products, Pipeline and/or Companies in 2022

CORAL GABLES, Fla., Feb. 07, 2022 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare diseases, today provided preliminary 2021 fourth quarter and full year total revenue estimates, a forecast of 2022 total revenue expectations, and a corporate update.

“2021 was a landmark year for Catalyst as we achieved record revenues while attaining a significant milestone in upholding our Orphan Drug Exclusivity for FIRDAPSE® for the treatment of Lambert-Eaton myasthenic syndrome (LEMS). Our strong performance is representative of our exceptional commercial, strategic, and operational capabilities, as well as our continued commitment to the patients we serve,” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. “As a result of our accomplishments, we expect to realize a meaningful increase in 2022 revenues and look forward to building upon this momentum to fully maximize the value of FIRDAPSE. As we enter 2022, we believe that our strong financial position will further empower us to execute on our strategic objectives to build a differentiated portfolio of products to drive long-term sustainable growth. We are excited about the year ahead as we remain focused on executing on our near and longer-term initiatives.”

RECENT EVENT - Conclusion of FDA Lawsuit

- On February 3, 2022, Catalyst announced that the District Court Judge in its case against the FDA had issued an order granting Catalyst Summary Judgment in its action against the FDA.
- As a consequence of that order, the FDA has invalidated Ruzurgi®'s approval.
- The District Court's order put into effect the September 2021 decision of the U.S. Court of Appeals for the 11th Circuit declaring that FDA's approval of Ruzurgi® violated Catalyst's Orphan Drug exclusivity for FIRDAPSE® for LEMS.

CORPORATE HIGHLIGHTS

The information in this press release is based on preliminary unaudited information and management estimates for the full year 2021 and is subject to the completion of Catalyst's financial closing procedures. Catalyst expects to report its 2021 fourth quarter and full year results of operations on or about March 16, 2022.

Preliminary Unaudited 2021 Fourth Quarter and Full Year Financial Results

Total 2021 Revenue

- Fourth quarter 2021 total revenues are estimated to be approximately $38 million, compared to total revenues of approximately $31 million in the fourth quarter of 2020, representing an increase of approximately 24% year-over-year.
- Full year 2021 total revenues are estimated to be approximately $141 million, compared to total revenues of $119 million for 2020, representing an increase of approximately 18% year-over-year.

Total 2021 Cash and Investments

- Year end 2021 cash and investments are expected to be approximately $191 million, with no funded debt.
- Between March 2021, when we commenced our share repurchase program, and December 31, 2021, we repurchased 2.2 million shares of Catalyst common stock in the open market at an average price of $5.47 per share, for a total purchase price of $12.1 million.

2022 Financial Guidance

- The Company forecasts 2022 full year total revenues to be in the range of between $195 million and $205 million, representing a 38%-45% increase in total revenues as compared to 2021.
- Anticipate cash operating expenses for full year 2022 of between $65 million and $70 million.

Key guidance assumptions included in these projections reflect a continued recovery in macroeconomic and healthcare activity throughout 2022 as it relates to the current COVID-19 environment.

Catalyst Pharmaceuticals 2022 Strategic Priorities

- Sustain “patient first” commitment through established access programs to all patients seeking access to FIRDAPSE for LEMS treatment.
- Continue to grow U.S. revenues for FIRDAPSE through awareness and education to both patients and healthcare professionals, with an expanded focus on paraneoplastic LEMS patients and providers.
- Pursue label expansion for FIRDAPSE through a pediatric supplemental new drug application (sNDA) to the FDA in the U.S. to further ensure that all LEMS patients have a treatment option.
- Continue to leverage data from the FIRDAPSE NDA and additional data via third-party relationships to further expand FIRDAPSE regulatory approvals internationally, with initial focus in Japan and Canada.
- Ongoing focused strategic efforts to expand our product pipeline by building a differentiated portfolio of products to treat rare diseases which are currently without any approved therapy to drive long-term sustainable growth.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, first- or best-in-class medicines for rare diseases. Catalyst’s New Drug Application for FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of adults with LEMS was approved in 2018 by the U.S. Food & Drug Administration (FDA), and FIRDAPSE is commercially available in the United States as a treatment for adults with LEMS. Further, Canada’s national healthcare regulatory agency, Health Canada, has approved the use of FIRDAPSE (amifampridine) for the treatment of adult patients in Canada with LEMS.

Forward-Looking Statements

This press release contains 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 (i) the continuing effect of the COVID-19 pandemic on Catalyst’s net product revenues and net income, (ii) Catalyst’s ability to locate and acquire new product candidates through acquisition or in-licensing, (iii) Catalyst’s ability to successfully develop any new product candidates acquired or in-licensed, (iv) Catalyst’s ability to successfully develop and commercialize a long-acting formulation of FIRDAPSE, and (v) those factors described in Catalyst’s Annual Report on Form 10-K for the fiscal year 2020 and Catalyst’s other filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect Catalyst. Copies of Catalyst’s filings with the SEC are available from the SEC, may be found on Catalyst’s website, or may be obtained upon request from Catalyst. Catalyst does not undertake any obligation to update the information contained herein, which speaks only as of this date.

Source: Catalyst Pharmaceuticals, Inc.