

**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 11, 2021

GW PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

England and Wales
(State or other jurisdiction
of incorporation)

001-35892
(Commission
File Number)

Not Applicable
(IRS Employer
Identification No.)

Sovereign House, Vision Park Chivers Way, Histon Cambridge, CB24 9BZ United Kingdom
(Address of principal executive offices, including zip code)

+44 1223 266 800
(Registrant's telephone number, including area code)

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	Name of each exchange on which registered
American Depositary Shares, each representing 12 Ordinary Shares, par value £0.001 per share	GWPH	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 January 11, 2021, GW Pharmaceuticals plc (the “Company”) issued a press release announcing the Company’s preliminary, unaudited net product sales for the fourth quarter and full year 2020 and key priorities for 2021. A copy of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information in this Item 2.02, and Exhibit 99.1 hereto, 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Number</u>	<u>Description</u>
99.1	Press release dated January 11, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

GW PHARMACEUTICALS PLC

Date: January 12, 2021

By: /s/ Douglas B. Snyder

Name: Douglas B. Snyder

Title: Chief Legal Officer



GW Pharmaceuticals Provides Preliminary Fourth Quarter and Full-Year 2020 Net Product Sales Results and 2021 Program Milestones

- Total preliminary net product sales of approximately \$148 million for the fourth quarter and approximately \$526 million for the full year -
- Total Epidiolex® preliminary net product sales of approximately \$144 million for the fourth quarter and approximately \$510 million for the full year –
- Pivotal US clinical program for nabiximols in MS spasticity underway. Initial data expected in 2021—

LONDON and CARLSBAD, Calif., Jan. 11, 2021—GW Pharmaceuticals plc (Nasdaq: GWPH), the world leader in the science, development, and commercialization of cannabinoid prescription medicines, today reported preliminary, unaudited net product sales for the fourth quarter and full year 2020 and key priorities for 2021. Justin Gover, GW’s Chief Executive Officer, expects to discuss these updates as part of a webcast presentation at the 38th Annual J.P. Morgan Healthcare Conference on Tuesday, Jan. 12th at 10:00 a.m. ET.

“Epidiolex sales increased by over 70% in 2020 despite the challenges of COVID-19, reflecting the positive impact this medicine has on patients as well as the performance of our commercial team. We remain encouraged by our patients’ experience on this product, as demonstrated by high persistence and refill rates. This, combined with our expansion of payer coverage and the recently approved Tuberous Sclerosis Complex indication, leads us to expect continued strong growth in 2021 in both the US and Europe,” said Justin Gover, GW’s Chief Executive Officer. “Our goals in 2021 include driving further Epidiolex growth and advancing multiple US pivotal trials for nabiximols in the treatment of MS spasticity, with the first data readout expected this year. In addition to our previously announced pipeline activities, we are leveraging our world leadership in cannabinoid science to design and synthesize novel cannabinoid molecules and expect our first novel product candidate to enter the clinic in 2021.”

Preliminary Unaudited Fourth Quarter and Full-Year 2020 Net Product Sales

Based on preliminary unaudited financial information, the Company expects total net product sales to be approximately \$148 million for the fourth quarter and approximately \$526 million for the year ended December 31, 2020. Total net product sales of Epidiolex are expected to be approximately \$144 million for the fourth quarter, comprising \$129 million in the US and \$15 million ex-US. Total net product sales of Epidiolex for the year ended December 31, 2020 are expected to be approximately \$510 million compared to \$296 million in 2019. Cash and cash equivalents at December 31, 2020 were approximately \$486 million.

Key Priorities for 2021

EPIDIOLEX commercialization:

- Continue to drive revenue growth in US and Europe:

- Execute on TSC label expansion and continued penetration in Dravet and LGS
- Build further on expanded payer coverage achievements
- Accelerate adoption across a broader prescriber base
- Increase penetration in long-term care segment
- Continue launches in Germany and UK and achieve successful pricing and reimbursement, and launch execution in France, Spain and Italy, as well as other European countries
- Obtain approval of the Tuberous Sclerosis Complex indication in Europe
- Supplement existing 14 Orange Book listed patents (expiry 2035) with additional use patents, and obtain grant of the Epidiolex “composition” patent
- Commence pivotal trial in fourth target orphan epilepsy indication

Nabiximols in the US:

- Continue recruitment of two ongoing pivotal MS spasticity trials and commence three additional pivotal trials in MS spasticity
- Achieve data from at least one pivotal MS spasticity trial in 2021
- NDA submission expected following first positive pivotal MS spasticity trial
- Commence clinical program to expand future label to include spasticity associated with Spinal Cord Injury

Additional pipeline:

- Continue recruitment of ongoing Phase 2b study of a cannabidiol formulation for the treatment of schizophrenia
- Conduct placebo-controlled trials with both CBDV and CBD in autism
- Advance NHIE clinical program utilizing an intravenous formulation of cannabidiol
- Complete Phase 1 trial for novel botanical drug candidate GW541
- Advance first novel NCE cannabinoid candidate into Phase 1

About GW Pharmaceuticals plc and Greenwich Biosciences, Inc.

Founded in 1998, GW is a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. The Company’s lead product, EPIDIOLEX® (cannabidiol) oral solution, is commercialized in the U.S. by its U.S. subsidiary Greenwich Biosciences for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome, or tuberous sclerosis complex (TSC) in patients one year of age and older. This product has received approval in the European Union under the tradename EPIDYOLEX® for the adjunctive treatment of seizures associated with LGS or Dravet syndrome in conjunction with clobazam in patients two years and older and is under EMA review for the treatment of TSC. The Company has a deep pipeline of additional cannabinoid product candidates, in particular nabiximols, for which the Company is advancing multiple late-stage clinical programs in order to seek FDA approval in the treatment of spasticity associated with multiple sclerosis and spinal cord injury. The Company has additional cannabinoid product candidates in clinical trials for autism and schizophrenia. For further information, please visit www.gwpharm.com.

Forward-looking statements

This news release contains forward-looking statements that reflect GW’s current expectations regarding future events, including statements regarding financial performance, the timing of clinical trials, the timing and outcomes of regulatory or intellectual property decisions, the relevance of GW products commercially available and in development, the clinical benefits of EPIDIOLEX®/EPIDYOLEX® (cannabidiol) oral solution and Sativex® (nabiximols), and the safety profile and commercial potential of both medicines, and those associated with the COVID-19 pandemic. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the success of GW’s research strategies, the applicability of the discoveries made therein, the successful and timely completion and uncertainties related to the regulatory process, and the acceptance of

EPIDIOLEX®/EPIDYOLEX®, Sativex® and other products by consumer and medical professionals. A further list and description of risks and uncertainties associated with an investment in GW can be found in GW's filings with the U.S. Securities and Exchange Commission. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. GW undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

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