

**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 12, 2020

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)

N/A
(I.R.S. Employer
Identification No.)

Sovereign House, Vision Park Chivers Way, Histon Cambridge, CB24 9BZ United Kingdom
(Address of Principal Executive Offices, including Zip Code)

Telephone: +44 1223 266 800
(Registrant's Telephone Number, Including Area Code)

N/A
(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 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.

GW Pharmaceuticals plc (the “Company”) disclosed today certain preliminary financial information for the year ended December 31, 2019 ahead of the 38th Annual J.P. Morgan Healthcare Conference. Specifically, the Company disclosed that based on preliminary unaudited financial information, the Company expects total net product sales to be approximately \$108 million for the fourth quarter and approximately \$309 million for the year ended December 31, 2019. Total net product sales of Epidiolex are expected to be approximately \$104 million for the fourth quarter and approximately \$296 million for the full year. Cash and cash equivalents at December 31, 2019 were approximately \$536 million. Fourth quarter and full-year 2019 financial results are expected to be reported on February 25th, 2020. On January 12, 2020, the Company issued a press release announcing these preliminary results and other developments. The press release is attached as Exhibit 99.1 hereto and incorporated by reference herein.

The information in this Item 2.02 and Exhibit 99.1 hereto is unaudited and preliminary, and does not present all information necessary for an understanding of the Company’s financial condition as of December 31, 2019 and its results of operations for the three months and year ended December 31, 2019. The audit of the Company’s financial statements for the year ended December 31, 2019 is ongoing and could result in changes to the information in this Item 2.02.

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>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated January 12, 2020.
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the inline XBRL document

SIGNATURE

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 thereunto duly authorized.

Date: January 13, 2020

GW PHARMACEUTICALS PLC

By: /s/ Douglas B. Snyder

Name: Douglas B. Snyder

Title: Chief Legal Officer



GW Pharmaceuticals Pre-Announces Preliminary Unaudited Fourth Quarter and Full-Year 2019 Net Product Sales

- Total preliminary net product sales of approximately \$108 million for the fourth quarter and approximately \$309 million for the full year -
- Total Epidiolex® preliminary net product sales of approximately \$104 million for the fourth quarter and approximately \$296 million for the first full year of sales—

London, UK, Carlsbad, CA, 12 January, 2020 – 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 2019 and key priorities for 2020. 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 in San Francisco on Tuesday, Jan. 14th at 11:00 a.m. PT (2:00 p.m. ET).

"Our fourth quarter and full year results for 2019 reflect an exceptional launch year for Epidiolex. We are proud of the positive impact this medicine has already had on thousands of patients and believe that this past year provides a compelling foundation for continued success in 2020," said Justin Gover, GW's Chief Executive Officer. "Our goal in 2020 is not only to continue to drive Epidiolex growth but also to leverage our world leadership in cannabinoid science to advance our pipeline. In particular, we see significant market opportunity for nabiximols in several indications in the US and will be progressing multiple late stage clinical programs in 2020."

Preliminary Unaudited Fourth Quarter and Full-Year 2019 Net Product Sales

Based on preliminary unaudited financial information, the company expects total net product sales to be approximately \$108 million for the fourth quarter and approximately \$309 million for the year ended December 31, 2019. Total net product sales of Epidiolex are expected to be approximately \$104 million for the fourth quarter and approximately \$296 million for the full year. Cash and cash equivalents at December 31, 2019 were approximately \$536 million. Fourth quarter and full-year 2019 financial results are expected to be reported on February 25th, 2020.

Key Priorities for 2020

EPIDIOLEX commercialization:

- Continue to drive revenue growth:
 - Build on positive experiences from existing physicians to increase prescribing to appropriate patients
 - Accelerate adoption across a broader prescriber base
 - Work with U.S. commercial and government payors to ensure that appropriate patients have access to Epidiolex with as few restrictions as possible
 - Enter long-term care segment

- Submit and obtain approval of the Tuberous Sclerosis Complex indication in both the U.S. and Europe, thereby significantly expanding the target population
- Successful pricing and reimbursement, and launch execution, in the major five European countries (Germany, France, UK, Spain and Italy)
- Supplement existing 9 Orange Book listed patents (expiry 2035) with additional use patents, and obtain grant of the Epidiolex “composition” patent
- Advance the medical literature regarding Epidiolex through publications in top-tier medical journals and at major scientific and medical meetings, notably the American Academy of Neurology and American Epilepsy Society meetings

Nabiximols (known as “Sativex” outside US) in the US:

- Commence pivotal clinical program in initial target indication of spasticity associated with Multiple Sclerosis
- Commence clinical program to expand future label to include spasticity associated with Spinal Cord Injury
- Commence clinical program in PTSD

Additional pipeline:

- Commence Phase 2b study of a cannabidiol formulation for the treatment of schizophrenia
- Continue to explore CBDV in autism through a combination of open-label and investigator-led placebo controlled clinical trials with data from one or more of these programs in 2020
- Execute NHIE clinical program utilizing an intravenous formulation of cannabidiol

Note: Total Epidiolex sales include global sales of Epidiolex / Epidyolex

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. GW’s lead product, EPIDIOLEX® (cannabidiol) oral solution CV, is commercialized in the US by its U.S. subsidiary Greenwich Biosciences for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. This product has received approval in the European Union under the tradename EPIDYOLEX®. The Company expects to expand the indication of EPIDIOLEX to include seizures associated with Tuberous Sclerosis Complex (TSC), for which it has reported positive Phase 3 data, and is carrying out a Phase 3 trial in Rett syndrome. 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, as well as for the treatment of PTSD. The Company has additional cannabinoid product candidates in Phase 2 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 CV and Sativex® (nabiximols), and the safety profile and commercial potential of both medicines. 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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