

**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 25, 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.

On February 25, 2020, GW Pharmaceuticals plc (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 2019. A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 of Form 8-K and the information incorporated by reference herein, including Exhibit 99.1 attached hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The exhibits to this Current Report on Form 8-K are as follows:

INDEX TO EXHIBITS

- 99.1** [Press release of GW Pharmaceuticals plc dated February 25, 2020](#)
- 104** Cover Page Interactive File (the cover page 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: February 25, 2020

GW PHARMACEUTICALS PLC

By: /s/ Douglas B. Snyder

Name: Douglas B. Snyder

Title: Chief Legal Officer



GW Pharmaceuticals plc Reports Fourth Quarter and Year-End 2019 Financial Results and Operational Progress

- Total revenue of \$109.1 million for the fourth quarter and \$311.3 million for the full year -
- Total Epidiolex® net product sales of \$104.5 million for the fourth quarter and \$296.4 million for the first full year of sales-
- Conference call today at 4:30 p.m. EST -

London, UK and Carlsbad, CA, February 25, 2020 – GW Pharmaceuticals plc (Nasdaq: GWPH), a world leader in the science, development, and commercialization of cannabinoid prescription medicines, today announces financial results for the fourth quarter and full-year ended December 31, 2019.

“2019 was an exceptional and transformative year for GW, led by the successful launch of Epidiolex in the US and approval in Europe. The positive impact this medicine has had on thousands of patients and their families provides a compelling foundation for continued growth in 2020,” said Justin Gover, GW’s Chief Executive Officer. “We also expect 2020 to be an important year for our growing and developing product pipeline beyond Epidiolex as we build on our world leadership in cannabinoid science. We are focused on advancing nabiximols in the US in several indications and clinical programs with other potential products whilst continuing to bring Epidiolex to more patients in the US and Europe.”

OPERATIONAL HIGHLIGHTS

- Significant progress with Epidiolex (cannabidiol)
 - Total net product sales of Epidiolex of \$104.5 million for the fourth quarter and \$296.4 million for the full year
 - U.S. commercial update
 - 2020 focus on broadening prescriber base, expanding payer coverage, entering long term care segment, and expected launch of TSC indication
 - European launch underway
 - German commercial launch in Q4 2019
 - Secured positive NICE recommendation in the UK with commercial launch in Q1 2020
 - Commercial launches in France, Spain and Italy expected later this year, following pricing and reimbursement
 - Clinical progress with further indications – broadening addressable market

- Tuberos Sclerosis Complex (TSC) sNDA filed with FDA earlier this month and MAA submission to EMA expected in Q1 2020
- Phase 3 trial in Rett Syndrome recruiting
- Several new formulations of CBD advancing into additional Phase 1 studies in 2020, including modified oral solution, and capsule
- Improved intellectual property rights and exclusivity
 - In addition to orphan exclusivity, 9 granted patents listed in “Orange Book” and align directly with Epidiolex FDA label with expiry dates to 2035
 - Epidiolex composition patent application recently published
 - 2 new allowed patents broadly covering use in LGS and Dravet syndrome
 - Additional patent applications under review, including patents related to the use of Epidiolex in TSC and other indications
- Pipeline progress
 - Nabiximols (Sativex® outside of the US)
 - Multiple Sclerosis spasticity -3 positive Phase 3 trials completed in Europe
 - US pivotal clinical program expected to commence in Q2 2020 to augment existing data package
 - Spinal cord injury spasticity - clinical program expected to commence in H2 2020
 - PTSD – clinical program expected to commence in H2 2020
 - Schizophrenia (GWP42003)
 - Positive Phase 2a trial published and Phase 2b trial expected to commence H1 2020
 - CBDV in autism
 - 30-patient open label study in autism underway. Initial data expected in 2020.
 - Investigator-led 100 patient placebo-controlled trial in autism underway
 - Open label study in Rett syndrome and seizures underway
 - Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
 - Phase 1b safety study in patients underway
 - Orphan Drug and Fast Track Designations granted from FDA and EMA

FINANCIAL HIGHLIGHTS

- Total revenue for the quarter ended December 31, 2019 was \$109.1 million compared to \$6.7 million for the quarter ended December 31, 2018
- Net loss for the quarter ended December 31, 2019 was \$24.9 million compared to a net loss of \$71.9 million for the quarter ended December 31, 2018
- Cash and cash equivalents at December 31, 2019 were \$536.9 million compared to \$591.5 million as of December 31, 2018

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast today at 4:30 pm EST. To participate in the conference call, please dial 877-407-8133 (toll free from the U.S. and Canada) or 201-689-8040 (international). Investors may also access a live audio webcast of the call via the investor relations section of the Company’s website at <http://www.gwpharm.com>. A replay of the call will also be available through the GW website shortly after the call and will remain available for 90 days.

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 CV, is commercialized in the U.S. by its U.S. subsidiary Greenwich Biosciences for the treatment of seizures associated with Lennox-Gastaut syndrome 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 has submitted a supplemental New Drug Application to the U.S. Food and Drug Administration (FDA) to expand the indication for Epidiolex to include seizures associated with Tuberous Sclerosis Complex, 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.

Enquiries:

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GW PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)
(unaudited)

	December 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	\$ 536,933	\$ 591,497
Accounts receivable, net	48,883	4,192
Inventory	85,528	33,030
Prepaid expenses and other current assets	28,292	17,903
Total current assets	<u>699,636</u>	<u>646,622</u>
Property, plant, and equipment, net	127,765	90,832
Operating lease assets	24,916	—
Goodwill	6,959	6,959
Deferred tax assets	18,123	8,720
Other assets	4,850	2,935
Total assets	<u>\$ 882,249</u>	<u>\$ 756,068</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 9,990	\$ 9,796
Accrued liabilities	99,374	52,477
Current tax liabilities	437	2,384
Other current liabilities	7,760	1,559
Total current liabilities	<u>117,561</u>	<u>66,216</u>
Long-term liabilities:		
Finance lease liabilities	5,573	5,690
Operating lease liabilities	21,650	—
Other liabilities	11,431	10,082
Total long-term liabilities	<u>38,654</u>	<u>15,772</u>
Total liabilities	<u>156,215</u>	<u>81,988</u>
Commitments and contingencies		
Stockholders' equity:		
Ordinary shares par value £0.001; 371,068,436 and 366,616,688 shares outstanding as of December 31, 2019 and 2018, respectively	570	564
Additional paid-in capital	1,632,046	1,581,144
Accumulated deficit	(837,959)	(828,940)
Accumulated other comprehensive loss	(68,623)	(78,688)
Total stockholders' equity	<u>726,034</u>	<u>674,080</u>
Total liabilities and stockholders' equity	<u>\$ 882,249</u>	<u>\$ 756,068</u>

GW PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(unaudited)

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	2019	2018	2019	2018
Revenues				
Product net sales	\$ 109,019	\$ 6,617	\$ 310,331	\$ 14,866
Other revenue	57	37	1,001	533
Total revenues	109,076	6,654	311,332	15,399
Operating expenses				
Cost of product sales	7,298	1,829	27,199	6,644
Research and development	43,535	29,086	142,678	146,627
Selling, general and administrative	78,351	49,083	259,880	165,727
Total operating expenses	129,184	79,998	429,757	318,998
Loss from operations	(20,108)	(73,344)	(118,425)	(303,599)
Interest income	1,818	2,449	8,464	5,490
Interest expense	(282)	(295)	(1,087)	(1,230)
Other income	—	—	104,117	—
Foreign exchange loss	(5,073)	(982)	(2,272)	(6,105)
Loss before income taxes	(23,645)	(72,172)	(9,203)	(305,444)
Income tax expense (benefit)	1,301	(266)	(184)	(187)
Net loss	\$ (24,946)	\$ (71,906)	\$ (9,019)	\$ (305,257)
Net loss per share:				
Basic	\$ (0.07)	\$ (0.20)	\$ (0.02)	\$ (0.88)
Diluted	\$ (0.07)	\$ (0.20)	\$ (0.02)	\$ (0.88)
Weighted average shares outstanding:				
Basic	372,447	366,458	371,580	347,123
Diluted	372,447	366,458	371,580	347,123

GW PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Year Ended December 31,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (9,019)	\$(305,257)
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange loss	2,709	5,839
Stock-based compensation	48,030	35,718
Depreciation and amortization	9,240	9,661
Deferred income taxes	(9,698)	(430)
Gain from sale of priority review voucher	(104,117)	—
Other	39	233
Changes in operating assets and liabilities:		
Accounts receivable, net	(44,623)	(2,706)
Inventory	(51,125)	(28,484)
Prepaid expenses and other current assets	(9,831)	11,370
Other assets	3,888	(445)
Accounts payable	805	2,829
Current tax liabilities	(963)	(3,966)
Accrued liabilities	43,110	19,445
Other liabilities	(1,914)	1,423
Net cash used in operating activities	<u>(123,469)</u>	<u>(254,770)</u>
Cash flows from investing activities		
Proceeds from sale of priority review voucher	104,117	—
Additions to property, plant and equipment	(40,386)	(42,301)
Additions to capitalized software	(2,102)	(1,112)
Proceeds from disposal of property, plant and equipment	—	517
Net cash provided by (used in) investing activities	<u>61,629</u>	<u>(42,896)</u>
Cash flows from financing activities		
Proceeds from issuance of ordinary shares, net of issuance costs	—	324,637
Proceeds from exercise of stock options	2,878	620
Payments on finance leases	(389)	(251)
Payments on landlord financing obligation	(543)	(527)
Net cash provided by (used in) financing activities	<u>1,946</u>	<u>324,479</u>
Effect of exchange rate changes on cash	5,330	5,457
Net increase (decrease) in cash and cash equivalents	(54,564)	32,270
Cash and cash equivalents at beginning of period	591,497	559,227
Cash and cash equivalents at end of period	<u>\$ 536,933</u>	<u>\$ 591,497</u>