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): November 5, 2019

GW PHARMACEUTICALS PLC
(Exact name of registrant as specified in its charter)

England and Wales	**001-35892**	**N/A**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 Section13(a) of the Exchange Act ☐

Item 2.02 Results of Operations and Financial Condition.

On November 5, 2019, GW Pharmaceuticals plc (the "Company") issued a press release announcing its financial results for the third quarter of 2019. The full text of the press release and the related attachment are 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

Exhibit No.	Description
99.1	Press release dated November 5, 2019.
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: November 5, 2019

GW PHARMACEUTICALS PLC

By: /s/ Douglas B. Snyder
Name: Douglas B. Snyder
Title: Chief Legal Officer

Exhibit 99.1

GW Pharmaceuticals plc Reports Financial Results and Operational Progress for the Third Quarter Ended September 30, 2019

- Epidiolex U.S. year to date net sales of $188.0 million, including Q3 net sales of $86.1 million -
- Conference call today at 4:30 p.m. ET -

Carlsbad, CA, November 5, 2019: GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), the world leader in the discovery, development and commercialization of cannabinoid prescription medicines, announces financial results for the third quarter ended September 30, 2019.

"In this first year of launch, we are pleased to report continued Epidiolex revenue growth in the US. Receptivity to the introduction of this breakthrough treatment continues to be highly encouraging as a result of positive physician and patient experiences as well as strong payer coverage", stated Justin Gover, GW's Chief Executive Officer. "We see significant opportunity for the short, medium and long term and believe that all the fundamentals are in place to make Epidiolex a very successful brand. We can expect to see additional momentum from Europe as well as the launch of the Tuberous Sclerosis indication during 2020. On top of this, GW is ideally placed to consolidate its leadership in cannabinoid science through advancing several mid and late stage pipeline programs in the months ahead."

OPERATIONAL HIGHLIGHTS

- Epidiolex® (cannabidiol)
  - U.S. commercial update
    - Q3 Net sales of $86.1M; $188.0M net sales in the first three quarters of 2019
    - Over 15,000 patients have received Epidiolex prescriptions since launch
    - Over 3,000 physicians have generated dispensed prescriptions since launch
    - Strong payor coverage with approximately 93 percent of all Commercial, Medicaid and Medicare lives in the US having a coverage determination, of which 65 percent are PA to indication or less restrictive
  - European launch update
    - European Commission approval in September 2019
    - Commercialization underway in France and Germany
    - UK NICE guidance expected in Q4 2019; Spain and Italy launches to follow in 2020
    - Early Access Program now includes over 1,100 patients across 5 major EU countries, and over 400 physicians from 250 top epilepsy centers
  - New Indications
    - Tuberous Sclerosis Complex
      - TSC Phase 3 data to be presented at American Epilespy Society annual meeting in December 2019
      - TSC sNDA expected to be filed with FDA in early 2020, approval decision expected mid-2020
      - TSC EMA submission expected in Q1 2020
    - Rett Syndrome
      - Phase 3 trial in Rett Syndrome recruiting
  - Life-cycle management
    - Several new formulations of CBD in development including modified oral solution, capsule and intravenous formulation

- PK data generated in 2019 supports advancing multiple new formulations into additional Phase 1 studies in 2020

- Exclusivity
  - 7 years of orphan exclusivity confirmed by FDA, plus 6-month pediatric extension expected. 10 years of orphan exclusivity in Europe plus 2 year pediatric extension expected
  - 9 granted patents listed in "Orange Book" and align directly with Epidiolex FDA label
    - Patent expiry dates to 2035
  - Additional patent applications under review, including patents related to the use of Epidiolex in TSC and other indications
  - Patent application recently published indicating that Epidiolex is more efficacious than synthetic CBD in pre-clinical epilepsy models based on the key difference that Epidiolex comprises up to 2 percent of other cannabinoids.

- Pipeline progress
  - Sativex® (nabiximols)
    - Initial U.S. target indication: Multiple Sclerosis spasticity
      - 3 positive Phase 3 trials completed in Europe
      - Clinical IND open, FDA feedback received on clinical plan
      - Clinical program expected to commence in Q1 2020 to augment existing pivotal data package
    - Clinical program in additional indications in planning for 2020-2021
  - CBDV
    - IND open for 30-patient open label study in autism expected to commence Q4 19. Initial data in 2020.
    - Investigator-led 100 patient placebo-controlled trial in autism underway
    - Open label study in Rett syndrome and seizures ongoing
  - Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
    - Phase 1b safety study in patients expected to commence in Q4
    - Orphan Drug and Fast Track Designations granted from FDA and EMA
  - Schizophrenia (GWP42003)
    - Positive Phase 2a trial published
    - Phase 2b trial expected to commence H1 2020

FINANCIAL HIGHLIGHTS

- Revenue for the quarter ended September 30, 2019 was $91.0 million compared to $2.4 million for the quarter ended September 30, 2018
- Cash and cash equivalents at September 30, 2019 were $554.7 million compared to $591.5 million as of December 31, 2018
- Net loss for the quarter ended September 30, 2019 was $13.8 million compared to a net loss of $79.9 million for the quarter ended September 30, 2018

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the quarter ending September 30, 2019 financial results 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. Replay Numbers: (toll free):1-877-481-4010 or 919-882-2331 (international). For both dial-in numbers please use conference Replay ID: 54868.

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) 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 Europe under the tradename EPIDYOLEX. The Company continues to evaluate EPIDIOLEX in additional rare conditions including Tuberous Sclerosis Complex (TSC) and Rett syndrome. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex® (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the United States and for which the Company is now advancing a late stage program in order to seek FDA approval. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for epilepsy, autism, glioblastoma, 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 (cannabidiol) oral solution and Sativex (nabiximols) and the safety profile and commercial potential of EPIDIOLEX and Sativex. 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 Sativex, EPIDIOLEX 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, including the most recent Form 10-KT filed on 26 February 2019. 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)

	September 30, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 554,682	$ 591,497
Accounts receivable, net	41,818	4,192
Inventory	69,288	33,030
Prepaid expenses and other current assets	32,196	17,903
Total current assets	697,984	646,622
Property, plant, and equipment, net	110,161	90,832
Operating lease assets	20,438	—
Goodwill	6,959	6,959
Deferred tax assets	8,425	8,720
Other assets	3,884	2,935
Total assets	$ 847,851	$ 756,068
Liabilities and stockholders' equity		
Accounts payable	$ 6,934	$ 9,796
Accrued liabilities	81,704	52,477
Current tax liabilities	—	2,384
Other current liabilities	6,627	1,559
Total current liabilities	95,265	66,216
Long-term liabilities:		
Finance lease liabilities	5,297	5,690
Operating lease liabilities	17,007	—
Other liabilities	10,627	10,082
Total long-term liabilities	32,931	15,772
Total liabilities	128,196	81,988
Commitments and contingencies		
Stockholders' equity:		
Common stock - Ordinary shares par value £0.001; 370,937,744 shares outstanding as of September 30, 2019; 366,616,688 shares outstanding as of December 31, 2018	570	564
Additional paid-in capital	1,619,649	1,581,144
Accumulated deficit	(813,013)	(828,940)
Accumulated other comprehensive loss	(87,551)	(78,688)
Total stockholders' equity	719,655	674,080
Total liabilities and stockholders' equity	$ 847,851	$ 756,068

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues				
Product net sales	$ 90,849	$ 2,343	$201,312	$ 8,249
Other revenue	122	77	944	496
Total revenues	90,971	2,420	202,256	8,745
Operating expenses				
Cost of product sales	8,150	1,399	19,901	4,815
Research and development	36,301	28,943	99,143	117,541
Selling, general and administrative	64,178	52,685	181,529	116,644
Total operating expenses	108,629	83,027	300,573	239,000
Loss from operations	(17,658)	(80,607)	(98,317)	(230,255)
Interest income	2,249	1,283	6,646	3,041
Interest expense	(272)	(297)	(805)	(935)
Other income	—	—	104,117	—
Foreign exchange gain (loss)	1,889	(823)	2,801	(5,123)
(Loss) income before income taxes	(13,792)	(80,444)	14,442	(233,272)
Income tax (benefit) expense	(35)	(565)	(1,485)	79
Net (loss) income	$ (13,757)	$ (79,879)	$ 15,927	$(233,351)
Net (loss) income per share:				
Basic	$ (0.04)	$ (0.23)	$ 0.04	$ (0.68)
Diluted	$ (0.04)	$ (0.23)	$ 0.04	$ (0.68)
Weighted average shares outstanding:				
Basic	372,246	341,302	371,286	340,675
Diluted	372,246	341,302	376,985	340,675

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities		
Net income (loss)	$ 15,927	$ (233,351)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Foreign exchange (gain) loss	(418)	5,097
Share-based compensation	35,633	26,035
Depreciation and amortization	7,096	7,127
Deferred income taxes	—	835
Gain from sale of priority review voucher	(104,117)	—
Other	39	233
Changes in operating assets and liabilities:		
Accounts receivable, net	(37,691)	(581)
Inventory	(37,561)	(14,024)
Prepaid expenses and other current assets	(14,869)	15,005
Other assets	2,968	(398)
Accounts payable	(1,161)	4,040
Current tax liabilities	(601)	(4,844)
Accrued liabilities	29,176	13,503
Other liabilities	(1,943)	1,013
Net cash used in operating activities	(107,522)	(180,310)
Cash flows from investing activities		
Proceeds from sale of priority review voucher	104,117	—
Additions to property, plant and equipment	(29,915)	(23,614)
Additions to capitalized software	(1,183)	(1,049)
Proceeds from disposal of property, plant and equipment	—	517
Net cash provided by (used in) investing activities	73,019	(24,146)
Cash flows from financing activities		
Proceeds from exercise of stock options	2,878	619
Payments on finance leases	(317)	(211)
Payments on landlord financing obligation	(404)	(397)
Net cash provided by financing activities	2,157	11
Effect of exchange rate changes on cash	(4,469)	131
Net decrease in cash and cash equivalents	(36,815)	(204,314)
Cash and cash equivalents at beginning of period	591,497	559,227
Cash and cash equivalents at end of period	$ 554,682	$ 354,913