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 26, 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)

CB24 9BZ
(Zip Code)

+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 under any of the following provisions (see General Instruction A.2. below):

☐ 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))

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 26, 2019, GW Pharmaceuticals plc (the "Company") issued a press release announcing its financial results for the three months ended December 31, 2018. The full text of the press release and the related attachment are furnished as Exhibit 99.1 hereto and incorporated by reference herein.

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 Number	Exhibit Description
99.1	Press Release, dated February 26, 2019, "GW Pharmaceuticals plc Reports Financial Results and Operational Progress for the Quarter Ended December 31, 2018."

SIGNATURES

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

GW Pharmaceuticals plc

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

Date: February 26, 2019

Exhibit 99.1

GW Pharmaceuticals plc Reports Financial Results and Operational Progress for the Quarter Ended December 31, 2018

- Epidiolex® (cannabidiol) oral solution (CV), first FDA-approved plant-derived cannabinoid medicine, launched in the U.S. in November to high awareness and demand -
- GW moves to a new fiscal year-end beginning January 1, 2019 -
- Conference call today at 4:30 p.m. EST -

London, UK, Carlsbad, CA, February 26, 2019: GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), the world leader in the development and commercialization of cannabinoid prescription medicines, announces financial results for the quarter ended December 31, 2018.

"We are pleased by the high level of physician and patient demand for Epidiolex, and by the number of payors that have already made favorable coverage determinations for the product. With US launch taking place part way through the quarter, the two month selling period at the end of 2018 was primarily aimed at setting the commercial wheels in motion for the 2019 launch year. As we move into the New Year, prescription growth trajectory has been highly encouraging and we believe that we are on track to deliver a successful market introduction of this important new treatment," stated Justin Gover, GW's Chief Executive Officer. "In addition to the US launch, we look forward to a positive regulatory decision in Europe in the next few months, results of a Phase 3 trial in Tuberous Sclerosis Complex, and a number of advances in the pipeline."

OPERATIONAL HIGHLIGHTS

- Epidiolex® (cannabidiol)
  - U.S. launch progressing to plan
    - First plant-derived cannabinoid pharmaceutical ever approved by FDA and first ever approved medicine in the US for Dravet syndrome
    - Net sales for Nov 1- Dec 31 launch period of $4.7m
    - Approximately 4,500 new patient enrolment forms in first two month selling period
    - Over 500 physicians have generated dispensed prescriptions in first two month selling period
    - Filled prescription growth trend in January 2019 shows approximately 150 percent growth over December 2018
    - Demand coming from major centers of excellence and local epilepsy clinics
    - Pharmacy distribution network expanded from initial 5 specialty pharmacies to over 130 distribution points
    - Approximately 900 expanded access program and open label extension patients expected to migrate to commercial product by end of Q2
  - Rapid and encouraging payor coverage decisions
    - Over 80 percent of all commercial lives (145 million) now have a coverage determination with 60 percent of these lives covered with either no Prior Authorization (PA) or PA to label
    - 99 percent of State Fee for Service Medicaid lives now have a coverage determination
    - Approximately 90 percent of Managed Medicaid lives have a coverage determination

- Target physician coverage
  - The sales organization has to date interacted with about 70 percent of the 5,000 target physicians including all Level 3 and 4 epilepsy centers
- European progress
  - European submission under review by the EMA with a CHMP recommendation expected in Q2 2019
  - Commercial footprint in place in initial 5 major European markets and active preparations well underway for pricing and reimbursement to support 2019 European launches
- Manufacturing
  - Commercial manufacturing and supply chain running smoothly
  - Production capacity sufficient to meet expected demand in both U.S. and Europe
  - Continued investment in manufacturing expansion program to meet anticipated long-term demand
- Clinical trials
  - Second Dravet syndrome Phase 3 trial successful and incorporated into EMA regulatory process
  - Phase 3 trial in Tuberous Sclerosis Complex fully recruited with data expected in Q2 2019
    - sNDA expected in Q4 2019
  - IND open for pivotal Phase 3 trial in Rett Syndrome. Expected start Q2 19.
- Life-cycle management
  - Several new formulations of CBD in development including modified oral solution, capsule and intravenous formulation. PK data expected in 2019.
- Exclusivity
  - 7 years of orphan exclusivity confirmed by FDA, 6-month pediatric extension expected. 10 years of orphan exclusivity in Europe with 2 year pediatric extension
  - Key favorable patent grants by USPTO related to the use of CBD in epilepsy, including claims for the treatment of relevant seizure types associated with LGS and Dravet syndrome, as well as the use of CBD with clobazam
    - Patents align directly with new Epidiolex FDA label and listed in "Orange Book"
    - Patent expiry dates to 2035
  - Additional patent applications under review and being filed as new data is generated

- Pipeline progress
  - Sativex® (nabiximols)
    - FDA meeting in December resulted in regulatory pathway in the U.S.
      - Initial U.S. target indication: Multiple Sclerosis spasticity
      - Single Phase 3 pivotal study expect to commence in Q4 2019
    - U.S. development and commercialization rights wholly owned by GW
    - Over 10 placebo-controlled trials already completed in other indications, representing significant U.S. lifecycle management opportunities
  - CBDV
    - Initial data from 5 patient expanded access program in patients with seizures and autism presented at American Epilepsy Society Annual Meeting suggest that CBDV is well tolerated and has potential as an AED/behavioral/cognitive medicine in the autism/epilepsy population
    - Company sponsored IND open for 30-patient open label study in autism
    - Investigator-led 100 patient placebo-controlled trial in autism spectrum disorder to commence in H1 2019
    - Open label study in Rett syndrome and seizures due to commence H1 2019

FINANCIAL HIGHLIGHTS

- Fiscal year now changed to begin January 1, 2019
- Cash and cash equivalents at December 31, 2018 were $591.5 million compared to $354.9 million as of September 30, 2018
- Revenue for the quarter ended December 31, 2018 was $6.7 million compared to $4.0 million for the quarter ended December 31, 2017
- Net loss for the quarter ended December 31, 2018 was $71.9 million compared to $61.8 million for the quarter ended December 31, 2017

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the quarter ending December 31, 2018 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: 44354.

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, along with its U.S. subsidiary Greenwich Biosciences, has received U.S. FDA approval for EPIDIOLEX (cannabidiol) oral solution for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older and which is now available by prescription in the U.S. The Company has submitted a regulatory application in Europe for the adjunctive treatment of seizures associated with LGS and Dravet syndrome. The company continues to evaluate EPIDIOLEX in additional rare epilepsy conditions and currently has an ongoing clinical trial in tuberous sclerosis complex (TSC). 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 planning a U.S. Phase 3 trial. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for epilepsy, 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-K filed on 29 November 2018. 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
CONSOLIDATED BALANCE SHEETS
(Unaudited; in thousands)

	December 31, 2018	September 30, 2018
Assets		
Cash and cash equivalents	$ 591,497	$ 354,913
Accounts receivable, net	4,192	2,122
Inventory	33,030	19,061
Prepaid expenses and other current assets	17,903	14,615
Total current assets	646,622	390,711
Property and equipment, net	90,832	82,381
Goodwill	6,959	6,959
Deferred tax assets	8,720	7,334
Other assets	2,935	3,150
Total assets	$ 756,068	$ 490,535
Liabilities and stockholders' equity		
Accounts payable	$ 9,796	$ 9,741
Accrued liabilities	52,477	46,739
Current tax liabilities	2,384	1,385
Other current liabilities	1,559	804
Total current liabilities	66,216	58,669
Long-term liabilities		
Capital lease liabilities	1,454	1,535
Build-to-suit financing obligation	4,236	4,378
Other liabilities	10,082	10,794
Total long-term liabilities	15,772	16,707
Total liabilities	81,988	75,376
Stockholders' equity:		
Ordinary shares par value £0.001; 366,616,688 shares outstanding as of December 31, 2018; 340,246,840 shares outstanding as of September 30, 2018	564	530
Additional paid-in capital	1,581,144	1,246,857
Accumulated deficit	(828,940)	(757,034)
Accumulated other comprehensive (loss) income	(78,688)	(75,194)
Total stockholders' equity	674,080	415,159
Total liabilities and stockholders' equity	$ 756,068	$ 490,535

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

	Three Months Ended December 31,	
	2018	**2017**
Revenues		
Product net sales	$ 6,617	$ 2,220
Other revenue	37	1,772
Total revenues	6,654	3,992
Operating expenses		
Cost of product sales	1,829	1,171
Research and development	29,086	36,195
Selling, general and administrative	49,083	25,174
Total operating expenses	79,998	62,540
Loss from operations	(73,344)	(58,548)
Interest income	2,449	604
Interest expense	(295)	(314)
Foreign exchange (loss) gain	(982)	160
Loss before income taxes	(72,172)	(58,098)
Income tax (benefit) expense	(266)	3,718
Net loss	$ (71,906)	$ (61,816)
Net loss per common share, basic and diluted	$ (0.20)	$ (0.20)
Weighted average common shares outstanding, basic and diluted	366,458	313,730

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

	Three Months Ended December 31,	
	2018	**2017**
Cash flows from operating activities		
Net loss	$ (71,906)	$ (61,816)
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange loss (gain)	742	(180)
Stock-based compensation	9,683	5,592
Depreciation and amortization	2,534	2,163
Deferred income taxes	(1,265)	(1,152)
Other	—	8
Changes in operating assets and liabilities:		
Accounts receivable, net	(2,125)	(223)
Inventory	(14,460)	378
Prepaid expenses and other current assets	(3,635)	(516)
Other assets	(47)	(166)
Accounts payable	(1,211)	(1,802)
Current tax liabilities	878	4,898
Accrued liabilities	5,942	3,004
Other current liabilities	93	(2,071)
Long-term liabilities	317	325
Net cash used in operating activities	(74,460)	(51,558)
Cash flows from investing activities		
Additions to property, plant and equipment	(18,687)	(7,748)
Additions to capitalized software	(63)	(993)
Proceeds from disposal of property, plant and equipment	—	—
Net cash used in investing activities	(18,750)	(8,741)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares, net of issuance costs	324,638	297,932
Proceeds from exercise of stock options	—	1
Payments on build-to-suit financing obligation	—	(26)
Payments on capital leases	(40)	(39)
Payments on landlord financing obligation	(130)	(125)
Net cash provided by (used in) financing activities	324,468	297,743
Effect of exchange rate changes on cash	5,326	(551)
Net increase (decrease) in cash and cash equivalents	236,584	237,073
Cash and cash equivalents at beginning of period	354,913	322,154
Cash and cash equivalents at end of period	$ 591,497	$ 559,227