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 3, 2020

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

England and Wales	**001-35892**	**Not Applicable**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 November 3, 2020, GW Pharmaceuticals plc (the "Company") issued a press release announcing the Company's financial and operating results for the quarter ended September 30, 2020. 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 7.01 Regulation FD Disclosure.

The Company issued a press release this morning announcing that the Company along with U.S. subsidiary Greenwich Biosciences, has initiated the first U.S. Phase 3 clinical trial studying nabiximols for multiple sclerosis (MS)-associated spasticity. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

The information in this Item 7.01, and Exhibit 99.2 hereto, shall not be deemed "filed" for purposes of Section 18 of 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

Number	Description
99.1	Earnings press release dated November 3, 2020.
99.2	Press release titled "GW Pharmaceuticals Initiates Pivotal Phase 3 Study of Nabiximols for Multiple Sclerosis-Associated Spasticity" dated November 3, 2020.
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: November 3, 2020

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

GW Pharmaceuticals plc Reports Third Quarter 2020 Financial Results and Operational Progress

- Total revenue increased 51 percent to $137.1 million –
- Epidiolex for seizures associated with TSC launched in the U.S. -
- Nabiximols Phase 3 program in MS spasticity now recruiting -
- Conference call today at 8:30 a.m. EST -

London, UK and Carlsbad, CA, Nov 3, 2020 – GW Pharmaceuticals plc (Nasdaq: GWPH), a world leader in the science, development, and commercialization of cannabinoid prescription medicines, today announced financial results and operating progress for the third quarter ended September 30, 2020.

"We are pleased to report strong revenue growth in the 3rd quarter despite the challenges presented by COVID-19. Epidiolex meets a serious unmet need within the field of epilepsy and we expect the product to demonstrate continued strong growth in the months and years ahead. The recent expanded indication for the treatment of seizures associated with TSC has been very well received by patients, clinicians and payers," stated Justin Gover, GW's Chief Executive Officer. "We have also now commenced the pivotal Phase 3 program for nabiximols in the treatment of multiple sclerosis spasticity, which provides multiple opportunities for an NDA submission, including as early as next year. Beyond nabiximols, we are advancing several clinical-stage pipeline candidates, including the recent start of a Phase 2 trial in schizophrenia."

FINANCIAL RESULTS

- Total revenue for the quarter ended September 30, 2020 was $137.1 million compared to $91.0 million for the quarter ended September 30, 2019
- Total revenue for the first nine months of 2020 of $378.6 million compared to $202.3 million in the prior year period
- Net loss for the quarter ended September 30, 2020 was $12.2 million compared to net loss of $13.8 million for the quarter ended September 30, 2019.

- Cash and cash equivalents at September 30, 2020 were $480.3 million

OPERATIONAL HIGHLIGHTS

- Epidiolex (cannabidiol) progress:
  - Total Q3 net product sales of Epidiolex of $132.6 million
  - U.S. commercial update
    - U.S. Epidiolex Q3 net product sales of $121.6 million
    - TSC indication launched with high prescriber awareness and near universal payer coverage
    - Expanded payer coverage
      - 85 million lives with no/broad prior authorization (+47% year-to-date)
  - Ex-U.S. commercial update
    - Ex-U.S. Epidyolex Q3 net product sales of $11.0 million
    - UK pricing and reimbursement in place. Progress in Germany, France, Italy and Spain
    - TSC EMA submission under review
    - Epidyolex approved in Australia
  - Strengthening commercial exclusivity
    - Orphan exclusivity in both the U.S. and EU
    - 13 patents listed in Orange Book, 12 of which expire in 2035
      - Patents include formulation and method of use
    - Epidiolex composition patent application in process
    - Two further Orange Book listable patents to be allowed or granted by Q1 2021
  - Nabiximols development program:
    - First Phase 3 MS Spasticity trial underway
      - Phase 3 placebo-controlled spasm frequency study (N=450)
    - MS Spasticity trials due to commence
      - Phase 3 placebo-controlled muscle tone studies:
        - N=52; Expected start Q4 2020 (subject to COVID)
        - N=190; Expected start: Q1 2021
        - N=36 (nabiximols responders); Expected start: Q1 2021
      - Additional Phase 3 placebo-controlled spasm frequency study (N=200) in nabiximols responders expected start Q2 2021
    - Spinal Cord Injury (SCI) spasticity clinical program
      - N=~100 (observational clinical discovery study); Expected start: Q1 2021

        - N=~160 (muscle tone in nabiximols responders); Placebo-controlled parallel group design. Expected start: 2021
        - N=~400 (spasm frequency); Placebo-controlled parallel group design. Expected start: 2021
- Additional pipeline programs:
    - Schizophrenia (GWP42003)
        - Phase 2b trial now actively recruiting
    - Autism:
        - CBD formulation Phase 2 study expected to commence in Q1 2021
        - CBDV investigator-led 100 patient placebo-controlled trial in autism – recruitment now resumed
    - New botanical cannabinoid pipeline product (GW541)
        - Phase 1 trial underway
        - Potential targets within field of neuropsychiatry
    - Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
        - Phase 1b safety study in patients continues to recruit
        - Orphan Drug and Fast Track Designations granted from FDA and EMA

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast today at 8:30 am 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: 38272.

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.

Enquiries:

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

	September 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 480,330	$ 536,933
Accounts receivable, net	80,424	48,883
Inventory	115,036	85,528
Prepaid expenses and other current assets	44,485	28,292
Total current assets	720,275	699,636
Property, plant, and equipment, net	131,204	127,765
Operating lease assets	22,297	24,916
Intangible assets	5,564	—
Goodwill	6,959	6,959
Deferred tax assets	18,123	18,123
Other assets	5,839	4,850
Total assets	$ 910,261	$ 882,249
Liabilities and stockholders' equity		
Accounts payable	$ 17,841	$ 9,990
Accrued liabilities	114,898	99,374
Current tax liabilities	—	437
Other current liabilities	7,549	7,760
Total current liabilities	140,288	117,561
Long-term liabilities:		
Finance lease liabilities	5,219	5,573
Operating lease liabilities	19,607	21,650
Other liabilities	10,699	11,431
Total long-term liabilities	35,525	38,654
Total liabilities	175,813	156,215
Commitments and contingencies		
Stockholders' equity:		
Common stock - Ordinary shares par value £0.001; 374,169,836 shares outstanding as of September 30, 2020; 371,068,436 shares outstanding as of December 31, 2019	575	570
Additional paid-in capital	1,672,237	1,632,046
Accumulated deficit	(866,940)	(837,959)
Accumulated other comprehensive loss	(71,424)	(68,623)
Total stockholders' equity	734,448	726,034
Total liabilities and stockholders' equity	$ 910,261	$ 882,249

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,	
	2020	2019	2020	2019
Revenues				
Product net sales	$136,846	$ 90,849	$378,608	$201,312
Other revenue	207	122	375	944
Total revenues	137,053	90,971	378,983	202,256
Operating expenses				
Cost of product sales	7,635	8,150	27,112	19,901
Research and development	56,934	36,301	148,542	99,143
Selling, general and administrative	85,205	64,178	232,282	181,529
Total operating expenses	149,774	108,629	407,936	300,573
Loss from operations	(12,721)	(17,658)	(28,953)	(98,317)
Interest income	208	2,249	1,727	6,646
Interest expense	(269)	(272)	(850)	(805)
Other income	—	—	—	104,117
Foreign exchange (loss) gain	(1,796)	1,889	(430)	2,801
(Loss) income before income taxes	(14,578)	(13,792)	(28,506)	14,442
Income tax (benefit)expense	(2,390)	(35)	475	(1,485)
Net (loss) income	$ (12,188)	$ (13,757)	$ (28,981)	$ 15,927
Net (loss) income per share:				
Basic	$ (0.03)	$ (0.04)	$ (0.08)	$ 0.04
Diluted	$ (0.03)	$ (0.04)	$ (0.08)	$ 0.04
Weighted average shares outstanding:				
Basic	376,281	372,246	375,218	371,286
Diluted	376,281	372,246	375,218	376,985

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

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities		
Net loss	$ (28,981)	$ 15,927
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange (gain) loss	(132)	(418)
Share-based compensation	40,446	35,633
Depreciation and amortization	9,144	7,096
Gain from sale of priority review voucher	—	(104,117)
Other	27	39
Changes in operating assets and liabilities:		
Accounts receivable, net	(31,654)	(37,691)
Inventory	(31,184)	(37,561)
Prepaid expenses and other current assets	(8,466)	(14,869)
Other assets	2,369	2,968
Accounts payable	8,116	(1,161)
Current tax liabilities	(8,570)	(601)
Accrued liabilities	18,030	29,176
Other liabilities	(2,459)	(1,943)
Net cash used in operating activities	(33,314)	(107,522)
Cash flows from investing activities		
Proceeds from sale of priority review voucher	—	104,117
Additions to property, plant and equipment	(14,259)	(29,915)
Additions to capitalized software	(2,365)	(1,183)
Additions to intangible assets	(6,404)	—
Net cash (used) provided by in investing activities	(23,028)	73,019
Cash flows from financing activities		
Proceeds from exercise of stock options	1,577	2,878
Payments in connection with common stock withheld for employee tax obligation	(1,827)	—
Payments on finance leases	(221)	(317)
Payments on landlord financing obligation	(430)	(404)
Net cash (used in) provided by financing activities	(901)	2,157
Effect of exchange rate changes on cash	640	(4,469)
Net decrease in cash and cash equivalents	(56,603)	(36,815)
Cash and cash equivalents at beginning of period	536,933	591,497
Cash and cash equivalents at end of period	$ 480,330	$ 554,682
Supplemental disclosure of cash flow information:		
Income taxes paid	9,106	7,052
Interest paid	530	805
Supplemental disclosure of noncash information:		
Property and equipment purchases in accounts payable and accrued liabilities	1,204	1,534
Right-of-use asset obtained in exchange for operating liabilities	507	—

Exhibit 99.2

GW Pharmaceuticals Initiates Pivotal Phase 3 Study of Nabiximols for Multiple Sclerosis-Associated Spasticity

CARLSBAD, Calif., Nov 3, 2020 - GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), a world leader in the science, development, and commercialization of cannabinoid prescription medicines, along with U.S. subsidiary Greenwich Biosciences, today announced that the Company has initiated the first U.S. Phase 3 clinical trial studying nabiximols for multiple sclerosis (MS)-associated spasticity. Nabiximols, known as Sativex® outside of the U.S. and approved for use to treat MS spasticity in over 25 countries, is a complex botanical medicine formulated from extracts of the cannabis plant administered as an oral spray. Positive results from three previous European Phase 3 clinical studies show nabiximols was well-tolerated and provided continued reductions in patient-reported spasticity for individuals with MS.

This Phase 3 trial is one of five pivotal studies planned for nabiximols in MS spasticity, with the remaining studies on track to commence either later this year or in 2021. GW expects that a positive result in any one of these five studies will enable an NDA submission, potentially as early as mid- next year.

“We are excited that the U.S. Phase 3 clinical program evaluating nabiximols in Multiple Sclerosis spasticity is now recruiting patients, after a delay due to COVID-19. Given the rigorous studies already conducted on the medicine outside of the U.S., and positive discussions with the FDA, we believe that we have a clear path to an NDA submission, potentially as soon as next year, and a significant second product opportunity for GW in the U.S.,” stated Justin Gover, GW’s Chief Executive Officer. “Now is the ideal time to develop nabiximols in the U.S. as research shows a significant percentage of spasticity patients are today self-medicating using unapproved cannabis products to relieve their spasticity.”

“There is a significant need for new treatments to address spasticity in MS patients, a challenging condition with little therapeutic innovation in decades in the United States,” said Dr. Stephen Krieger, Associate Professor of Neurology at the Mount Sinai Hospital. “Nabiximols has the potential to be a rigorously tested and FDA-regulated cannabis-derived medicine for people living with MS. I look forward to participating as an investigator in this study which will evaluate the effect of nabiximols on the frequency of muscle spasms.”

The study is a Phase 3, double-blind, parallel, placebo-controlled study that will evaluate the safety and efficacy of nabiximols for spasm frequency over a 12-week period and is expected to enroll 446 participants. The first patient is now screened and in baseline evaluation.

Beyond this initial study, the Company intends to commence the following additional Phase 3 trials of nabiximols for MS-associated spasticity:

- Phase 3 muscle tone studies – placebo-controlled cross-over design
    - N=52; Expected start: Q4 2020 (subject to COVID)
    - N=190; Expected start: Q1 2021
    - N=36 (nabiximols responders); Expected start: Q1 2021
- Phase 3 spasm frequency studies – placebo-controlled parallel group
    - N=~200 (nabiximols responders); Expected start: Q2 2021

About Nabiximols

Nabiximols is in pivotal Phase 3 development in the United States for the treatment of MS spasticity. The U.S. commercial rights are owned by GW. In addition to MS spasticity, GW expects to develop nabiximols in Spinal Cord Injury spasticity.

Nabiximols is a complex botanical medicine formulated from extracts of the cannabis plant that contains the principal cannabinoids THC and CBD and also contains minor constituents, including other cannabinoid and non-cannabinoid plant components, such as terpenes, sterols, and triglycerides. The product is administered as an oral spray.

Nabiximols is known as Sativex® outside of the U.S. and is indicated in numerous countries as a treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.[1] These approvals were based on multiple pivotal trials conducted in Europe.[2] Sativex is currently not approved for any indication in the U.S.

1 Sativex Oralmucosal Spray, SmPC, https://www.medicines.org.uk/emc/product/602.

2 Markova et al, International Journal of Neuroscience 2019; Novotna et al, European Journal of Neurology 2011; Collin et al, European Journal of Neurology 2007About Nabiximols

About GW Pharmaceuticals plc and Greenwich Biosciences, Inc.

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Forward-looking statement

This news release contains forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding the timing of clinical trials, the timing of regulatory filings and approvals, the timing and outcomes of regulatory or intellectual property decisions, and the clinical benefits and commercial potential of nabiximols (marketed as Sativex® outside the US). Actual events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the risks and uncertainties which 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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