

**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 16, 2021

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)

Not Applicable
(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 February 16, 2021, GW Pharmaceuticals plc (the “Company”) issued a press release announcing the Company’s financial and operating results for the fourth quarter and year ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information in this Report, including the press release, is furnished only, is not “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, and is not incorporated by reference into any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in that filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Number</u>	<u>Description</u>
99.1	Press release dated February 16, 2021, reporting Fourth Quarter and Full Year 2020 Financial and Operating Results.
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: February 16, 2021

By: /s/ Douglas B. Snyder

Name: Douglas B. Snyder

Title: Chief Legal Officer



GW Pharmaceuticals plc Reports Fourth Quarter and Year-End 2020 Financial Results and Operational Progress

- Total revenue of \$148.2 million for the fourth quarter and \$527.2 million for the full year –

- Total Epidiolex® net product sales of \$144.1 million for the fourth quarter and \$510.5 million for the full year –

— Previously announced agreement to be acquired by Jazz Pharmaceuticals; transaction expected to close in Q2 2021—

London, UK and Carlsbad, CA, Feb 16, 2021 – 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 fourth quarter and full-year ended December 31, 2020.

“We are very proud of our strong financial performance and operational progress in 2020, as Epidiolex sales increased by more than 70% during the year despite the challenges of COVID-19. We are well positioned to build on our success and continue to deliver strong growth in 2021 in both the U.S. and Europe, where we continue to make progress preparing for several commercial launches that are expected later this year,” said Justin Gover, chief executive officer of GW. “We have commenced our Phase 3 clinical program for nabiximols in the treatment of multiple sclerosis spasticity, which provides multiple opportunities for an NDA submission. Beyond nabiximols, we are advancing a diverse and robust neuroscience pipeline with several preclinical and clinical-stage pipeline candidates as part of our commitment to patients and to developing innovative medicines that address significant unmet needs. We have strong momentum and a tremendous opportunity to continue to build on our global cannabinoid leadership position as we prepare to join Jazz Pharmaceuticals and transform the lives of even more patients and families.”

FINANCIAL RESULTS

- Total revenue for the quarter ended December 31, 2020 was \$148.2 million compared to \$109.1 million for the quarter ended December 31, 2019.

- Total revenue for the full-year 2020 was \$527.2 million, a 69 percent increase compared to \$311.3 million for the prior year period.
- Net loss for the quarter ended December 31, 2020 was \$29.1 million compared to net loss of \$24.9 million for the quarter ended December 31, 2019.
- Cash and cash equivalents at December 31, 2020 were \$486.8 million.

OPERATIONAL HIGHLIGHTS

- Epidiolex (cannabidiol) progress:
 - Total net product sales of Epidiolex of \$144.1 million for the fourth quarter and \$510.5 million for the year ended December 31, 2020.
 - U.S. commercial update
 - U.S. Epidiolex net product sales of \$128.8 million for the fourth quarter and \$467.6 million for the year ended December 31, 2020
 - TSC indication launched with high prescriber awareness and near universal payer coverage
 - Expanded payer coverage
 - More than 110 million lives with no/broad prior authorization (70% increase in 2020)
 - Ex-U.S. commercial update
 - Ex-U.S. Epidiolex Q4 2020 net product sales of \$15.3 million and full-year 2020 sales of \$42.9 million
 - Continued progress expanding global reach of Epidiolex:
 - Pricing and reimbursement approved in Germany, Finland and Israel
 - Swissmedic approval received for the adjunctive therapy of seizures associated with LGS and DS
 - Launches in France, Spain and Italy expected in H1 2021
 - EMA TSC approval expected H1 2021
 - Strengthening commercial exclusivity
 - Orphan exclusivity in both the U.S. and EU
 - 14 patents listed in Orange Book, 13 of which expire in 2035
 - Patents include formulation and method of use
 - An additional patent has been granted and will be listed in the Orange Book in Q1 2021 and a further patent is expected to be granted and listed in the Orange Book in Q2 2021

- Epidiolex composition patent application filed
- Nabiximols development program:
 - MS Spasticity trials underway
 - Phase 3 placebo-controlled spasm frequency study (N=450)
 - Phase 3 placebo-controlled muscle tone study (N=52)
 - MS Spasticity trials due to commence
 - Phase 3 placebo-controlled muscle tone studies:
 - N=190; Expected start: Q2 2021
 - N=36 (nabiximols responders); Expected start: Q2 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
 - First SCI trial underway
 - N=~100 observational clinical discovery study
 - SCI spasticity trials due to commence
 - 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 underway
 - 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
 - Novel cannabinoid molecule synthesis and preclinical development
 - At least one program expected to enter Phase 1 in 2021

- Several other molecules have demonstrated preclinical efficacy and are advancing towards the clinic
- On Feb. 3, 2021, Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and GW announced the companies had entered into a definitive agreement for Jazz to acquire GW for \$220.00 per American Depositary Share (ADS), in the form of \$200.00 in cash and \$20.00 in Jazz ordinary shares (subject to limitations on the maximum and minimum number of Jazz ordinary shares issuable per ADS), for a total consideration of \$7.2 billion. The transaction is subject to the approval of GW shareholders, sanction by the High Court of Justice of England and Wales and other customary closing conditions, including regulatory approvals. Subject to the satisfaction or waiver of the closing conditions, the transaction is expected to close in the second quarter of 2021.

Conference Call/Earnings Materials

Given the recently announced agreement for GW to be acquired by Jazz Pharmaceuticals, GW will no longer hold conference calls. Earnings materials are available publicly on the Investor Relations page of GW's website at <http://www.gwpharm.com>. Questions may be directed to Investor Relations via e-mail at the contact information below.

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.

Forward-Looking Statements

This communication contains forward-looking statements regarding Jazz Pharmaceuticals and GW Pharmaceuticals, including, but not limited to, statements related to 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 nabiximols, and the safety profile and commercial potential of both medicines, the proposed acquisition of GW Pharmaceuticals and the anticipated timing, results and benefits thereof, including the potential for Jazz Pharmaceuticals to accelerate its growth and neuroscience leadership, and for the acquisition to provide long-term growth opportunities to create shareholder value; Jazz Pharmaceuticals' expected financing for the

transaction; and other statements that are not historical facts. You can generally identify forward-looking statements by the use of forward-looking terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “explore,” “evaluate,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” or “will,” or the negative thereof or other variations thereon or comparable terminology. These forward-looking statements are based on each of the companies’ current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties, many of which are beyond Jazz Pharmaceuticals’ or GW Pharmaceuticals’ control. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: Jazz Pharmaceuticals’ and GW Pharmaceuticals’ ability to complete the acquisition on the proposed terms or on the anticipated timeline, or at all, including risks and uncertainties related to securing the necessary regulatory and shareholder approvals, the sanction of the High Court of Justice of England and Wales and satisfaction of other closing conditions to consummate the acquisition; the occurrence of any event, change or other circumstance that could give rise to the termination of the definitive transaction agreement relating to the proposed transaction; risks related to diverting the attention of GW Pharmaceuticals and Jazz Pharmaceuticals management from ongoing business operations; failure to realize the expected benefits of the acquisition; significant transaction costs and/or unknown or inestimable liabilities; the risk of shareholder litigation in connection with the proposed transaction, including resulting expense or delay; the risk that GW Pharmaceuticals’ business will not be integrated successfully or that such integration may be more difficult, time-consuming or costly than expected; Jazz Pharmaceuticals’ ability to obtain the expected financing to consummate the acquisition; risks related to future opportunities and plans for the combined company, including the uncertainty of expected future regulatory filings, financial performance and results of the combined company following completion of the acquisition; GW Pharmaceuticals’ dependence on the successful commercialization of Epidiolex/Epidyolex and the uncertain market potential of Epidiolex; pharmaceutical product development and the uncertainty of clinical success; the regulatory approval process, including the risks that GW Pharmaceuticals may be unable to submit anticipated regulatory filings on the timeframe anticipated, or at all, or that GW Pharmaceuticals may be unable to obtain regulatory approvals of any of its product candidates, including nabiximols and Epidiolex for additional indications, in a timely manner or at all; disruption from the proposed acquisition, making it more difficult to conduct business as usual or maintain relationships with customers, employees or suppliers; effects relating to the announcement of the acquisition or any further announcements or the consummation of the acquisition on the market price of Jazz Pharmaceuticals’ ordinary shares or GW Pharmaceuticals’ American depositary shares or ordinary shares; the possibility that, if Jazz Pharmaceuticals does not achieve the perceived benefits of the acquisition as rapidly or to the extent anticipated by financial analysts or investors, the market price of Jazz Pharmaceuticals’ ordinary shares could decline; potential litigation associated with the possible acquisition; regulatory initiatives and changes in tax laws; market volatility; and other risks and uncertainties affecting Jazz Pharmaceuticals and GW Pharmaceuticals, including those described from time to time under the caption “Risk Factors” and elsewhere in Jazz Pharmaceuticals’ and GW Pharmaceuticals’ Securities and Exchange Commission (SEC) filings and reports, including Jazz Pharmaceuticals’ Annual Report on Form 10-K for the year ended December 31, 2019 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, GW Pharmaceuticals’ Annual Report on Form 10-K for the year ended December 31, 2019 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, and future filings and reports by either company. In addition, while Jazz

Pharmaceuticals and GW Pharmaceuticals expect the COVID-19 pandemic to continue to adversely affect their respective business operations and financial results, the extent of the impact on the combined company's ability to generate sales of and revenues from its approved products, execute on new product launches, its clinical development and regulatory efforts, its corporate development objectives and the value of and market for its ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. Moreover, other risks and uncertainties of which Jazz Pharmaceuticals or GW Pharmaceuticals are not currently aware may also affect each of the companies' forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. Investors are cautioned that forward-looking statements are not guarantees of future performance. The forward-looking statements made in this communication are made only as of the date hereof or as of the dates indicated in the forward-looking statements and reflect the views stated therein with respect to future events as at such dates, even if they are subsequently made available by Jazz Pharmaceuticals or GW Pharmaceuticals on their respective websites or otherwise. Neither Jazz Pharmaceuticals nor GW Pharmaceuticals undertakes any obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

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

	December 31,	
	2020	2019
Assets		
Cash and cash equivalents	\$ 486,752	\$ 536,933
Accounts receivable, net	71,168	48,883
Inventory	129,138	85,528
Prepaid expenses and other current assets	42,472	28,292
Total current assets	<u>729,530</u>	<u>699,636</u>
Property, plant, and equipment, net	143,767	127,765
Operating lease assets	25,118	24,916
Intangible assets	5,565	—
Goodwill	6,959	6,959
Deferred tax assets	20,777	18,123
Other assets	7,795	4,850
Total assets	<u>\$ 939,511</u>	<u>\$ 882,249</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 21,870	\$ 9,990
Accrued liabilities	127,849	99,374
Current tax liabilities	877	437
Other current liabilities	9,210	7,760
Total current liabilities	<u>159,806</u>	<u>117,561</u>
Long-term liabilities:		
Finance lease liabilities	5,454	5,573
Operating lease liabilities	22,127	21,650
Other liabilities	11,034	11,431
Total long-term liabilities	<u>38,615</u>	<u>38,654</u>
Total liabilities	<u>198,421</u>	<u>156,215</u>
Commitments and contingencies		
Stockholders' equity:		
Ordinary shares par value £0.001; 375,196,172 and 371,068,436 shares outstanding as of December 31, 2020 and 2019, respectively	577	570
Additional paid-in capital	1,690,151	1,632,046
Accumulated deficit	(896,087)	(837,959)
Accumulated other comprehensive loss	(53,551)	(68,623)
Total stockholders' equity	<u>741,090</u>	<u>726,034</u>
Total liabilities and stockholders' equity	<u>\$ 939,511</u>	<u>\$ 882,249</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenues				
Product net sales	\$ 148,222	\$ 109,019	\$ 526,830	\$ 310,331
Other revenue	—	57	375	1,001
Total revenues	<u>148,222</u>	<u>109,076</u>	<u>527,205</u>	<u>311,332</u>
Operating expenses				
Cost of product sales	10,419	7,298	37,531	27,199
Research and development	56,854	43,535	205,396	142,678
Selling, general and administrative	103,761	78,351	336,043	259,880
Total operating expenses	<u>171,034</u>	<u>129,184</u>	<u>578,970</u>	<u>429,757</u>
Loss from operations	(22,812)	(20,108)	(51,765)	(118,425)
Interest income	87	1,818	1,814	8,464
Interest expense	(271)	(282)	(1,121)	(1,087)
Other income	—	—	—	104,117
Foreign exchange loss	(3,544)	(5,073)	(3,974)	(2,272)
Loss before income taxes	(26,540)	(23,645)	(55,046)	(9,203)
Income tax expense (benefit)	2,607	1,301	3,082	(184)
Net loss	<u>\$ (29,147)</u>	<u>\$ (24,946)</u>	<u>\$ (58,128)</u>	<u>\$ (9,019)</u>
Net loss per common share, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.07)</u>	<u>\$ (0.15)</u>	<u>\$ (0.02)</u>
Weighted average common shares outstanding, basic and diluted	<u>376,680</u>	<u>372,447</u>	<u>375,586</u>	<u>371,580</u>

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

	Year Ended	
	December 31,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (58,128)	\$ (9,019)
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange loss	910	2,709
Stock-based compensation	58,359	48,030
Depreciation and amortization	12,757	9,240
Deferred income taxes	(2,654)	(9,698)
Gain from sale of priority review voucher	—	(104,117)
Other	528	39
Changes in operating assets and liabilities:		
Accounts receivable, net	(22,104)	(44,623)
Inventory	(39,873)	(51,125)
Prepaid expenses and other current assets	(9,624)	(9,831)
Other assets	3,290	3,888
Accounts payable	9,862	805
Current tax liabilities	(3,404)	(963)
Accrued liabilities	24,890	43,110
Other liabilities	(2,194)	(1,914)
Net cash used in operating activities	<u>(27,385)</u>	<u>(123,469)</u>
Cash flows from investing activities		
Proceeds from sale of priority review voucher	—	104,117
Additions to property, plant and equipment	(18,585)	(40,386)
Additions to capitalized software	(3,018)	(2,102)
Additions to intangible assets—licenses	(6,404)	—
Proceeds from disposal of property, plant and equipment	—	—
Net cash (used in) provided by investing activities	<u>(28,007)</u>	<u>61,629</u>
Cash flows from financing activities		
Proceeds from issuance of ordinary shares, Net of issuance costs	—	—
Proceeds from exercise of stock options	1,579	2,878
Payments in connection with common stock withheld for employee tax obligation	(1,826)	—
Payments on finance leases	(299)	(389)
Payments on landlord financing obligation	(583)	(543)
Net cash (used in) provided by financing activities	<u>(1,129)</u>	<u>1,946</u>
Effect of exchange rate changes on cash	6,340	5,330
Net decrease in cash and cash equivalents	(50,181)	(54,564)
Cash and cash equivalents at beginning of period	536,933	591,497
Cash and cash equivalents at end of period	<u>\$486,752</u>	<u>\$ 536,933</u>