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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

**Date of Report (Date of Earliest Event Reported): August 6, 2020**

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**GW PHARMACEUTICALS PLC**

(Exact name of registrant as specified in its charter)

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**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)

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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
<b>American Depositary Shares, each representing 12 Ordinary Shares, par value £0.001 per share</b>	<b>GWPH</b>	<b>The Nasdaq Global Market</b>

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

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**Item 2.02 Results of Operations and Financial Condition.**

On August 6, 2020, GW Pharmaceuticals plc (the “Company”) issued a press release announcing its financial results for the second quarter of 2020. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release dated August 6, 2020.</a>

**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: August 6, 2020

**GW PHARMACEUTICALS PLC**

By: /s/ Douglas B. Snyder

Name: Douglas B. Snyder

Title: Chief Legal Officer



## **GW Pharmaceuticals plc Reports Second Quarter 2020 Financial Results and Operational Progress**

- Total revenue increased 68 percent to \$121.3 million -
- Epidiolex approved in the U.S. for seizures associated with TSC, launch expected this month -
- Conference call today at 4:30 p.m. EDT –

**London, UK and Carlsbad, CA, Aug 6, 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 second quarter ended June 30, 2020.

“We were pleased with the strength of U.S. Epidiolex sales in the second quarter in spite of the COVID-19 pandemic. Further, the recent approval and imminent launch of Epidiolex for the treatment of seizures associated with TSC provides a meaningful new opportunity to accelerate momentum through the second half of 2020 and beyond,” stated Justin Gover, GW’s CEO. “We also continue to be excited about the potential of our product pipeline, in particular nabiximols, for which we recently outlined our accelerated US development strategy in the treatment of spasticity in patients with MS and other conditions. We look forward to commencing the nabiximols Phase 3 program as well as multiple other pipeline clinical trials in the second half of the year.”

### **FINANCIAL RESULTS**

- Total revenue for the quarter ended June 30, 2020 was \$121.3 million compared to \$72.0 million for the quarter ended June 30, 2019
- Net loss for the quarter ended June 30, 2020 was \$8.8 million compared to net income of \$79.7 million for the quarter ended June 30, 2019. The prior year quarter included net proceeds of \$104.1 million from the sale of a Rare Pediatric Priority Review Voucher.
- Cash and cash equivalents at June 30, 2020 were \$477.6 million

### **OPERATIONAL HIGHLIGHTS**

- Epidiolex (cannabidiol) progress:
  - Total Q2 net product sales of Epidiolex of \$117.7 million

- U.S. commercial update
  - U.S. Epidiolex Q2 net product sales of \$111.1 million
  - TSC indication approved by FDA, August commercial launch planned
  - TSC payer reimbursement anticipated quickly following launch
- European commercial update
  - Ex-U.S. Epidiolex Q2 net product sales of \$6.6 million
  - Pricing & reimbursement progress in Germany, France and Italy
  - TSC EMA submission under review
- Clinical progress with additional indications
  - Phase 3 trial in Rett Syndrome expected to re-commence in H2 2020
- Strengthening commercial exclusivity
  - Orphan exclusivity in both the U.S. and EU
  - 3 new patents granted and listed in Orange Book, bringing total of 13 patents listed in Orange Book, 12 of which expire in 2035
    - One recent patent listed is a non-use patent directed to the oral formulation
  - Epidiolex composition patent application in process
  - TSC patent applications under review
- Nabiximols
  - MS Spasticity Clinical program
    - Three positive Phase 3 MS spasticity trials already completed outside of the U.S.
    - Five new MS Spasticity Phase 3 trials expected to commence in H2 2020 (2) and H1 2021 (3), any one of which could enable a NDA submission
      - Phase 3 muscle tone studies – placebo-controlled cross-over design
        - N=52; Expected start: Q4 2020
        - N=190; Expected start: Q1 2021
        - N=36 (nabiximols responders); Expected start: Q1 2021
      - Phase 3 spasm frequency studies – placebo-controlled parallel group
        - N=450; Expected start: Q4 2020
        - N=~200 (nabiximols responders); Expected start: Q2 2021
  - Spinal Cord Injury (SCI) spasticity clinical program
    - Three SCI trials expected to be initiated in 2020 and 2021
    - N=~100 (observational clinical discovery study); Expected start: Q4 2020
    - N=~100 (muscle tone in nabiximols responders); Placebo-controlled parallel group design. Expected start: Q2 2021

- N≈400 (spasm frequency); Placebo-controlled parallel group design. Expected start: H2 2021
- Post-Traumatic Stress Disorder (PTSD) clinical program
  - Phase 2/3 study in PTSD (N≈ 325); Expected start: H1 2021
- Additional pipeline programs
  - Schizophrenia (GWP42003)
    - Phase 2b trial expected to commence H2 2020
  - CBDV in autism trials expected to recommence in H2 2020
    - 30-patient open label study in autism
    - Investigator-led 100 patient placebo-controlled trial in autism
  - 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 4:30 pm EDT. To participate in the conference call, please dial 833-937-1050 (toll free from the U.S. and Canada) or 845-403-8302 (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: 35770.

### **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. GW is currently 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](http://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:

### **GW Pharmaceuticals plc**

Stephen Schultz, VP Investor Relations

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### **U.S. Media Enquiries:**

#### **Sam Brown Inc. Healthcare Communications**

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### **Ex-U.S. media enquiries**

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

	<u>June 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>Assets</b>		
Cash and cash equivalents	\$ 477,557	\$ 536,933
Accounts receivable, net	80,357	48,883
Inventory	99,620	85,528
Prepaid expenses and other current assets	30,183	28,292
Total current assets	<u>687,717</u>	<u>699,636</u>
Property, plant, and equipment, net	125,106	127,765
Operating lease assets	22,333	24,916
Intangible assets	5,627	—
Goodwill	6,959	6,959
Deferred tax assets	18,123	18,123
Other assets	4,715	4,850
Total assets	<u>\$ 870,580</u>	<u>\$ 882,249</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable	\$ 16,238	\$ 9,990
Accrued liabilities	93,313	99,374
Current tax liabilities	2,004	437
Other current liabilities	6,947	7,760
Total current liabilities	<u>118,502</u>	<u>117,561</u>
Long-term liabilities:		
Finance lease liabilities	5,066	5,573
Operating lease liabilities	19,659	21,650
Other liabilities	10,416	11,431
Total long-term liabilities	<u>35,141</u>	<u>38,654</u>
Total liabilities	<u>153,643</u>	<u>156,215</u>
Commitments and contingencies		
<b>Stockholders' equity:</b>		
Common stock - Ordinary shares par value £0.001; 373,709,720 shares outstanding as of June 30, 2020; 371,068,436 shares outstanding as of December 31, 2019	575	570
Additional paid-in capital	1,655,500	1,632,046
Accumulated deficit	(854,752)	(837,959)
Accumulated other comprehensive loss	(84,386)	(68,623)
Total stockholders' equity	<u>716,937</u>	<u>726,034</u>
Total liabilities and stockholders' equity	<u>\$ 870,580</u>	<u>\$ 882,249</u>



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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
<b>Revenues</b>				
Product net sales	\$ 121,230	\$ 71,489	\$ 241,762	\$ 110,463
Other revenue	67	549	168	822
Total revenues	<u>121,297</u>	<u>72,038</u>	<u>241,930</u>	<u>111,285</u>
<b>Operating expenses</b>				
Cost of product sales	8,708	6,620	19,477	11,751
Research and development	45,734	32,467	91,608	62,842
Selling, general and administrative	75,894	62,273	147,077	117,351
Total operating expenses	<u>130,336</u>	<u>101,360</u>	<u>258,162</u>	<u>191,944</u>
Loss from operations	(9,039)	(29,322)	(16,232)	(80,659)
Interest income	250	2,310	1,519	4,397
Interest expense	(297)	(268)	(581)	(533)
Other income	—	104,117	—	104,117
Foreign exchange gain	1,386	2,026	1,366	912
(Loss) income before income taxes	<u>(7,700)</u>	<u>78,863</u>	<u>(13,928)</u>	<u>28,234</u>
Income tax expense (benefit)	1,128	(885)	2,865	(1,450)
Net (loss) income	<u>\$ (8,828)</u>	<u>\$ 79,748</u>	<u>\$ (16,793)</u>	<u>\$ 29,684</u>
Net loss per share:				
Basic	<u>\$ (0.02)</u>	<u>\$ 0.21</u>	<u>\$ (0.04)</u>	<u>\$ 0.08</u>
Diluted	<u>\$ (0.02)</u>	<u>\$ 0.21</u>	<u>\$ (0.04)</u>	<u>\$ 0.08</u>
Weighted average shares outstanding:				
Basic	375,525	371,712	374,680	370,776
Diluted	375,525	377,435	374,680	376,674

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

	<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>
<b>Cash flows from operating activities</b>		
Net loss	\$ (16,793)	\$ 29,684
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange (gain) loss	(488)	882
Share-based compensation	24,677	23,330
Depreciation and amortization	5,514	4,808
Gain from sale of priority review voucher	—	(104,117)
Other	27	21
Changes in operating assets and liabilities:		
Accounts receivable, net	(31,794)	(27,924)
Inventory	(19,669)	(27,070)
Prepaid expenses and other current assets	(4,312)	(6,819)
Other assets	1,884	1,542
Accounts payable	6,625	3,488
Current tax liabilities	2,732	619
Accrued liabilities	(599)	13,887
Other liabilities	(2,145)	(2,192)
Net cash used in operating activities	<u>(34,341)</u>	<u>(89,861)</u>
<b>Cash flows from investing activities</b>		
Proceeds from sale of priority review voucher	—	104,117
Additions to property, plant and equipment	(11,362)	(22,515)
Additions to capitalized software	(1,455)	(1,017)
Additions to intangible assets	(6,404)	—
Net cash (used) provided by in investing activities	<u>(19,221)</u>	<u>80,585</u>
<b>Cash flows from financing activities</b>		
Proceeds from exercise of stock options	5	2,878
Payments in connection with common stock withheld for employee tax obligation	(1,223)	—
Payments on finance leases	(146)	(250)
Payments on landlord financing obligation	(283)	(273)
Net cash (used in) provided by financing activities	<u>(1,647)</u>	<u>2,355</u>
Effect of exchange rate changes on cash	(4,167)	(893)
Net decrease in cash and cash equivalents	(59,376)	(7,814)
Cash and cash equivalents at beginning of period	536,933	591,497
Cash and cash equivalents at end of period	<u>\$ 477,557</u>	<u>\$ 583,683</u>
<b>Supplemental disclosure of cash flow information:</b>		
Income taxes paid	251	3,907
Interest paid	581	533
<b>Supplemental disclosure of noncash information:</b>		
Property and equipment purchases in accounts payable and accrued liabilities	1,727	856
Right-of-use asset obtained in exchange for operating liabilities	275	—