
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): March 15, 2019

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)

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.)

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 1.01. Entry into a Material Definitive Agreement.

On March 15, 2019, GW Research Ltd., the principal research subsidiary of GW Pharmaceuticals plc (the “Company”), entered into a definitive agreement to sell its Rare Pediatric Disease Priority Review Voucher (“PRV”) for \$105,000,000 to Biohaven Pharmaceutical Holding Ltd. (the “PRV Transfer Agreement”). The Company was awarded the voucher under a U.S. Food and Drug Administration (“FDA”) program intended to encourage the development of treatments for rare pediatric diseases. GW Research Ltd. received the PRV when EPIDIOLEX[®] (cannabidiol) was approved by the FDA for the treatment of seizures associated with Lennox-Gastaut Syndrome or Dravet syndrome, two rare, severe childhood-onset epilepsies.

The PRV Transfer Agreement contains customary representations, warranties, covenants, and indemnification provisions subject to certain limitations. The transaction remains subject to customary closing conditions, including anti-trust review.

The foregoing summary of the material terms of the PRV Transfer Agreement does not purport to be complete and is qualified in its entirety by the full text of the PRV Transfer Agreement, a copy of which will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2019.

Item 2.01 Completion of Acquisition or Disposition of Assets.

The disclosure regarding the PRV Transfer Agreement contained Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 2.01.

Item 8.01. Other Events.

On March 18, 2019, the Company issued a press release announcing the sale of the PRV. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information contained in Item 8.01 of this Form 8-K, including Exhibit 99.1 furnished herewith, shall not be deemed “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or 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, 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 of Exhibit
<u>99.1</u>	<u>Press Release, dated March 18, 2019, “GW Pharmaceuticals plc Announces the Sale of Priority Review Voucher for \$105M”</u>

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.

Date: March 18, 2019

GW PHARMACEUTICALS PLC

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



GW Pharmaceuticals plc Announces the Sale of Priority Review Voucher for \$105M

Carlsbad, CA, March 18, 2019: GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), the world leader in the development and commercialization of cannabinoid prescription medicines, today announced that GW Research Ltd. has entered into a definitive agreement to sell its Rare Pediatric Disease Priority Review Voucher (PRV) for \$105,000,000. GW was awarded the voucher under a U.S. Food and Drug Administration (FDA) program intended to encourage the development of treatments for rare pediatric diseases. GW Research Ltd. received the PRV when EPIDIOLEX[®] (cannabidiol) was approved by the FDA for the treatment of seizures associated with Lennox-Gastaut Syndrome or Dravet syndrome, two rare, severe childhood-onset epilepsies. The transaction remains subject to customary closing conditions, including anti-trust review.

“Having successfully developed and launched EPIDIOLEX as the first plant-derived cannabinoid medicine approved by the FDA, GW is advancing a pipeline of additional cannabinoid products to address patient needs across a range of therapeutic areas,” stated Justin Gover, GW’s Chief Executive Officer. “The sale of the PRV provides an important source of non-dilutive capital to help advance our pipeline and to continue to invest in the EPIDIOLEX commercial launch in both the U.S. and Europe.”

About the Rare Pediatric Disease Priority Review Voucher Program

The program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. A PRV may be issued to the sponsor of a rare pediatric disease product application and would entitle the holder to priority review of a single New Drug Application or Biologics License Application, which reduces the target review time and could lead to an expedited approval. The sponsor receives the PRV upon approval of the rare pediatric disease product application and it can be sold without limitation, subject to applicable FDA requirements for filing and use.

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-KT filed on February 28, 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.

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