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): October 1, 2018

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 266800
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 8.01 Other Events

On October 1, 2018, GW Pharmaceuticals plc (the "Company") filed with the Securities and Exchange Commission (the "SEC") a preliminary prospectus supplement pursuant to Rule 424(b)(5) under the Securities Act of 1933, as amended (the "Preliminary Prospectus Supplement"), relating to a proposed public offering of the Company's American Depositary Shares (the "Public Offering"). The Preliminary Prospectus Supplement for the Public Offering contains updated Company risk factor disclosure as well as an updated description of certain aspects of the Company's business. Accordingly, the Company is filing information for the purpose of supplementing and updating the risk factor disclosure contained in the Company's prior public filings, including those discussed under the heading "Item 3D. Risk Factors" in the Company's Annual Report on Form 20-F for the year ended September 30, 2017, filed with the SEC on December 4, 2017 (the "20-F"). The Company is also updating certain aspects of the description of its business from that described under the heading, "Item 4B. Business" in the 20-F. The updated disclosures are filed herewith as Exhibit 99.1 and are incorporated herein by reference.

On October 1, 2018, the Company issued a press release related to the Public Offering. The press release is attached as Exhibit 99.2 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are filed as part of this Current Report:

99.1	Updated Company Disclosure
99.2	Press release dated October 1, 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: October 1, 2018

Exhibit 99.1

As used in this Current Report on Form 8-K ("Current Report"), "GW Pharma," the "Group," the "Company," "we," "us" and "our" refer to GW Pharmaceuticals plc and its consolidated subsidiaries, except where the context otherwise requires. Epidiolex®, Sativex®, the GW logo and other trademarks or service marks of GW Pharma appearing in this Current Report are the property of GW Pharma. Trade names, trademarks and service marks of other companies appearing in this Current Report are the property of their respective owners.

FORWARD-LOOKING STATEMENTS

This Current Report contains forward-looking statements that are based on our current expectations, assumptions, estimates and projections about us and our industry. All statements other than statements of historical fact in this Current Report are forward-looking statements.

These forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause our actual results of operations, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results, as well as those of the markets we serve or intend to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. These forward-looking statements are based on assumptions regarding our present and future business strategies and the environment in which we expect to operate in the future. Important factors that could cause those differences include, but are not limited to:

- the inherent uncertainty of product development;
- successful commercialization and marketing of Epidiolex and market acceptance of Epidiolex;
- our and our contract manufacturers' ability to successfully manufacture commercial quantities of our products in compliance with regulatory requirements;
- our ability to establish and maintain commercialization organizations in the United States, Europe and elsewhere;
- our ability to submit and maintain Investigational New Drug applications, or INDs, and New Drug Applications, or NDAs, with the U.S. Food and Drug Administration, or FDA, and comparable filings outside of the United States;
- our ability to successfully design, commence and complete clinical trials;
- our ability to receive and maintain regulatory exclusivities, including Orphan Drug Designations, for our drugs and our drug candidates;
- patents, including, but not limited to, our ability to have patents issued covering our drugs, drug candidates and processes, as well as oppositions and legal challenges;
- government regulation and approvals;
- future revenue being lower than expected;
- the level of pricing and reimbursement for our products and product candidates, if approved;
- increasing competitive pressures in our industry;
- general economic conditions or conditions affecting demand for the products offered by us in the markets in which we operate, both domestically and internationally, being less favorable than expected;
- currency fluctuations and hedging risks;
- worldwide economic and business conditions and conditions in the industry in which we operate;
- our relationships with our customers and suppliers;
- increased competition from other companies in the industry in which we operate;
- changing technology;

- our ability to manage and maintain our applications and data systems from security breaches and data loss;
- claims for personal injury or death arising from the use of products and product candidates produced by us;
- the occurrence of accidents or other interruptions to our production processes;
- changes in our business strategy or development plans, and our expected level of capital expenses;
- our ability to attract and retain qualified personnel, including with respect to our preparation for commercialization of Epidiolex;
- regulatory, environmental, legislative and judicial developments;
- our intention not to pay dividends; and
- factors that are not known to us at this time.

Additional factors that could cause actual results, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results to differ materially include, but are not limited to, those discussed under "Risk Factors." Additional risks that we may currently deem immaterial or that are not presently known to us could also cause the forward-looking events discussed in this Current Report not to occur. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect" and similar words are intended to identify estimates and forward-looking statements. Estimates and forward-looking statements speak only at the date they were made, and we undertake no obligation to update or to review any estimate and/or forward-looking statement because of new information, future events or other factors. Estimates and forward-looking statements involve risks and uncertainties and are not guarantees of future performance. Our future results may differ materially from those expressed in these estimates and forward-looking statements. In light of the risks and uncertainties described above, the estimates and forward-looking statements discussed in this Current Report might not occur and our future results and our performance may differ materially from those expressed in these forward-looking statements due to, inclusive of, but not limited to, the factors mentioned above. Because of these uncertainties, you should not make any investment decision based on these estimates and forward-looking statements.

COMPANY OVERVIEW

We are a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from our proprietary cannabinoid product platform in a broad range of disease areas. We have established a world leading position in the development of plant-derived cannabinoid therapeutics through our proven drug discovery and development processes, our intellectual property portfolio and regulatory and manufacturing expertise. Our lead cannabinoid product is Epidiolex®, a pharmaceutical oral formulation of cannabidiol, or CBD, for which we retain global commercial rights. Epidiolex was approved by the U.S. Food and Drug Administration, or FDA, on June 25, 2018, for the treatment of seizures associated with lennox-gastaut syndrome, or LGS, or dravet syndrome, or Dravet syndrome, in patients two years of age and older. LGS and Dravet syndrome are severe childhood-onset, drug-resistant epilepsy syndromes. On September 28, 2018, the DEA rescheduled Epidiolex into Schedule V. We expect to make Epidiolex available to U.S. patients in the fall of 2018. In Europe, we submitted an application to the EMA's Committee for Medical Products for Human Use (CHMP) in December 2017, and we expect a decision on the application in the first quarter of 2019. We have received Orphan Drug Designation from the FDA for Epidiolex for LGS, Dravet syndrome and tuberous sclerosis complex, or TSC. We also received Orphan Designation from the EMA's Committee for Orphan Medical Products (COMP) for Epidiolex for Dravet syndrome, LGS, and TSC. We continue to develop Epidiolex for additional indications, including the treatment of seizures associated with TSC and plan to commence a pivotal trial in the treatment of Rett syndrome.

Previously, we developed 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 U.S. In the U.S., we have full commercial rights to this product and plan to meet with the FDA in the second half of 2018 to discuss data from the completed Phase 3 trials in Europe and to determine the optimal regulatory pathway in the U.S.

We have a deep pipeline of additional cannabinoid product candidates focusing primarily on orphan childhood-onset neurologic conditions and oncology. Our pipeline includes research in autism spectrum disorders, or ASD, using both CBD and cannabidivarin, or CBDV. We reported positive Phase 2 data for our CBD:THC product in the treatment of glioblastoma multiforme. We have also reported positive Phase 2 data in schizophrenia. In addition, we have received Orphan Drug Designation and Fast Track Designation from the FDA for intravenous CBD for the treatment of Neonatal Hypoxic Ischemic Encephalopathy, or NHIE, for which a Phase 1 trial has been completed.

Our Product and Product Candidates

GW Product Pipeline Summary

Epilepsy and Pediatric Neurology

Product/Product Candidates	Indication	Partner(s)	Status	Expected Next Steps
Epidiolex (CBD)	Childhood-onset epilepsy	We retain global rights	Approved by the FDA in the U.S.	Epidiolex commercial launch expected in the fall of 2018
	Initial targets: Treatment of seizures in LGS and Dravet syndrome in patients two years of age and older.		Under review by EMA in Europe	EMA decision expected in Q1 2019

Product/Product Candidates	Indication	Partner(s)	Status	Expected Next Steps
	Additional target: TSC		Phase 3 trial in TSC fully recruited	Data from Phase 3 TSC trial expected in H1 2019. Subject to positive results, sNDA in H2 2019
	Rett syndrome			IND for pivotal trial in Rett syndrome to be submitted in Q4 2018
GWP42006 (CBDV)	ASD	We retain global rights	Investigator-led placebo-controlled trial in autism; expanded access IND to treat seizures associated with autism underway	Trial expected to commence in Q4 2018.
	Rett syndrome		Investigator-led Phase 2 open label trial in Rett syndrome FDA orphan designation in Rett syndrome	Trial expected to commence in Q4 2018
	Epilepsy		Phase 2A trial completed	Under evaluation
Intravenous GWP42003	Neonatal hypoxic-ischemic encephalopathy	We retain global rights	Phase 1 trial in healthy volunteers complete	Phase 2 trial in planning

Other Pipeline Product Candidates

Product/Product Candidates	Indication	Partner(s)	Status	Expected Next Steps
Sativex (nabiximols)	MS spasticity (ex-U.S.)	Almirall, Bayer, Ipsen and Neopharm	Approved in numerous countries	
	MS spasticity (U.S.)	We retain rights	Meeting with FDA to determine next steps	Meeting expected to take place in Q4 2018
	Neuropathic pain/other neurological symptoms		Multiple placebo-controlled trials completed	Pivotal program in planning

Product/Product Candidates	Indication	Partner(s)	Status	Expected Next Steps
Combination of CBD and THC	Glioblastoma	We retain global rights	Phase 2 trial complete and reported in February 2017. Data presented at ASCO. FDA orphan designation.	Open IND for pivotal clinical program
GWP42003	Schizophrenia	We retain global rights	Positive Phase 2 proof-of-concept.	Phase 2b trial

FDA Approval for Epidiolex (cannabidiol) Oral Solution LGS and Dravet Syndrome and U.S. Launch

Following an April 19, 2018 FDA Advisory Committee unanimous vote (13 to 0) in favor of supporting the approval, Epidiolex was approved by the FDA on June 25, 2018 for the treatment of seizures associated with LGS or Dravet syndrome in patients two years of age and older. Following the approval, the FDA confirmed orphan drug exclusivity for Epidiolex and granted us a rare pediatric disease voucher.

We have reported results from two LGS Phase 3 pivotal trials, both achieving the primary endpoint of a median reduction in monthly drop seizures compared with placebo. The first study compared a single Epidiolex 20 mg/kg dose arm to placebo in 171 patients (p=0.0135) and the second compared both a 20 mg/kg and 10 mg/kg Epidiolex dose arm to placebo in 225 patients (p=0.0047 and p=0.0016 respectively). In January 2018, the results of the single-dose LGS trial was published in The Lancet and in May 2018, the results of the second multi-dose trial was published in The New England Journal of Medicine.

We have also reported results from the first Dravet syndrome Phase 3 pivotal efficacy and safety trial in 120 patients, achieving the primary endpoint of a median reduction in monthly convulsive seizures compared with placebo (p=0.012). In May 2017, the results of this trial was published in The New England Journal of Medicine.

Epidiolex demonstrated an acceptable safety profile in these Phase 3 pivotal trials. The most common adverse reactions that occurred in Epidiolex-treated patients were somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder and poor quality sleep; and infections. The Company's development program represents the only well-controlled clinical evaluation of a cannabinoid medication for patients with LGS and Dravet syndrome.

We are conducting a second Phase 3 trial of Epidiolex in Dravet syndrome. This placebo-controlled trial differs from the first Phase 3 trial in that it includes two Epidiolex dose arms, at 20 mg/kg per day and at 10 mg/kg per day. Enrollment is complete in this trial at 199 patients with data expected in the fourth quarter of 2018.

With Epidiolex approved by the FDA and rescheduled by the DEA, the U.S. commercial team now has completed the build-out of an experienced commercial organization consisting of sales, medical affairs and marketing, and market access/payor teams. The U.S. sales team includes two National Directors, eight Regional Managers and 66 Neurology Account Managers and will target approximately 5,000 physicians who may treat patients with LGS or Dravet syndrome. In addition, our medical affairs organization has been in place for over two years and includes 15 Medical Science Liaisons.

In advance of the U.S. product launch, we have set a list price per 100 mL bottle of $1,235. Based on anticipated dosing and patient weight assumptions, we believe that this translates to a weighted average gross price in the first year of $32,500, which is in line with other branded anti-epileptic drugs used to treat these conditions. A comprehensive patient support program is in development to help provide resources that may lower patients' out-of-pocket costs or provide product at no cost to eligible patients. Preparations

with the payor community have been active and detailed reviews with major payors have been completed. We have held one-on-one and advisory board interactions with a wide variety of insurers and other third-party payors, including some of the larger commercial and state/federal payors.

As of the date of this Current Report, we have approximately 647 patients in the United States on Epidiolex through our Expanded Access Program. We expect to carefully manage the transition of those patients over to commercial access gradually to ensure they have continued and uninterrupted access to Epidiolex.

Epidiolex Manufacturing

We manufacture Epidiolex through utilization of in-house and external third-party facilities for various steps in the production process. We have expanded various parts of the production process both in-house and with external third parties in readiness for commercial launch. As part of the NDA review, the FDA pre-approval inspections of our manufacturing facilities were successfully completed and did not result in any Form 483 observations. We are continuing to expand our Epidiolex manufacturing capacity in anticipation of post-U.S. launch and European Union demand.

Epidiolex EU Regulatory

In Europe, we have submitted a marketing authorization application in December 2017 for both the Dravet syndrome and LGS indications. This application has been validated by the EMA and the outcome is expected in first quarter of 2019. We have submitted 121-day responses to the Committee for Medicinal Products for Human Use, or CHMP, questions. We have also received Orphan Designation from COMP for Epidiolex for Dravet syndrome, LGS, and TSC.

Epidiolex EU Commercial

We continue to make good organizational progress for the commercialization of Epidiolex in Europe. We continue to expect an outcome to the EMA regulatory review in Q1 2019 and are planning for launches in the five major European markets in 2019. We have submitted 121-day responses to the CHMP questions. Our commercial leadership team consisting of experienced and epilepsy disease experts is now fully recruited and in place. This team is focused on progressing the necessary pricing and reimbursement, medical and pre-commercial activities required to deliver a successful European launch. In particular, significant progress is now being made on building out the local country organizations in the five major European markets.

Epidiolex Follow-On Target Indication: TSC

A number of patients with TSC have been treated with Epidiolex in the expanded access program. Treatment experience in 18 TSC patients with refractory epilepsy from the Massachusetts General Hospital for Children enrolled in the expanded access program has been published in Epilepsia (Hess et al — 2016). The findings from this study suggest that cannabidiol may be an effective and well-tolerated treatment option for patients with refractory seizures in TSC.

We are progressing a Phase 3 trial of Epidiolex in patients with TSC. This dose-ranging trial, which is now fully recruited (n=210), is a 16-week comparison of Epidiolex versus placebo to assess the safety and efficacy of Epidiolex as an adjunctive anti-epileptic treatment. The primary measure of this trial is the percentage change from baseline in seizure frequency during the treatment period. Primary endpoint seizure types include focal motor seizures with or without impairment of consciousness or awareness and generalized convulsive seizures. Data from this trial is expected in the first half of 2019. Subject to positive results, we expect to submit a supplemental NDA ("sNDA") for Epidiolex in TSC in the second half of 2019.

Epidiolex Intellectual Property

In addition to seven years of orphan exclusivity plus the expected six-month (which runs concurrently with 5-year new molecular entity exclusivity) pediatric extension, we seek to protect Epidiolex through the expansion of our patent portfolio. Our patent portfolio relating to the use of CBD in the treatment of

epilepsy includes 21 distinct patent families which are either granted or filed. Most of the patent families in this portfolio claim the use of CBD in the treatment of particular childhood epilepsy syndromes, seizure sub-types and interactions with other concomitantly dosed anti-seizure drugs. To date, we have obtained nine patents and received notices of allowance in three applications from the U.S. Patent and Trademark Office, or USPTO, including claims for the use of CBD for the treatment of convulsive seizures associated with both LGS and Dravet syndrome, as well as the use of CBD with clobazam, and the teaching that dose adjustment may be needed when concomitantly prescribed. Some of these patents are directly aligned with the Epidiolex label and we expect them to be listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book). These patents have expiry to 2035. We continue to identify novel findings and submit patent applications resulting from the Epidiolex development program and we expect additional grants from these applications.

Transition to U.S. Domestic Filer Reporting

We determined that, as of March 31, 2018, we no longer qualified as a "foreign private issuer" under the rules and regulations of the U.S. Securities and Exchange Commission, or SEC. While we were a foreign private issuer, we were exempt from compliance with certain laws and regulations of the SEC, and certain Nasdaq regulations, including the proxy rules, the short-swing profits recapture rules and certain governance requirements, such as independent director oversight of the nomination of directors and executive compensation. In addition, we were not required to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies registered under the U.S. Securities Exchange Act of 1934, as amended (the "Exchange Act"). As a result of this determination, beginning on October 1, 2018, we will no longer be entitled to "foreign private issuer" exemptions and we plan to report as a domestic U.S. filer, including filing quarterly reports on Form 10-Q, current reports on Form 8-K and proxy statements under Section 14 of the Exchange Act. In addition, commencing on October 1, 2018, we will prepare our financial statements in U.S. dollars in accordance with generally accepted accounting principles in the United States rather than International Financial Reporting Standards. In addition, after October 1, 2018, our "insiders" will also be subject to the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act and will be no longer exempt from the requirements of Regulation FD promulgated by the SEC under the Exchange Act. Moreover, as a domestic filer, we will no longer be permitted to follow our home country rules in lieu of the corporate governance obligations imposed by The Nasdaq Stock Market LLC, and will be required to comply with the governance practices required of U.S. domestic issuers.

In connection with our loss of foreign private issuer status, we made amendments to our Articles of Association, which were approved at the Company's Annual General Meeting held on March 14, 2018 to comply with Nasdaq listing requirements for domestic companies on quorum requirements. These amendments now provide that a quorum will be present for a general meeting where (i) there are two persons present and entitled to vote upon the business to be transacted, each being either a shareholder or a proxy for a shareholder or a duly authorized representative of a corporation which is a shareholder, and (ii) such two persons together hold (or are the representative or proxy of members in relation to the meeting holding) at least one-third in number of the issued shares entitled to vote on the business to be transacted. See also "Risk Factors — We are currently not subject to certain Nasdaq corporate governance rules applicable to U.S. listed companies and until October 1, 2018, we are subject to reporting obligations that are different and less frequent than those of a U.S. listed company. As a result, investors in our securities may not have the same protections afforded to shareholders of companies that are not foreign private issuers."

RISK FACTORS

Risks Related to Our Business

Our prospects are highly dependent on the successful commercialization of Epidiolex, which received approval in June 2018 from the FDA as a treatment for seizures associated with LGS or Dravet syndrome in patients two years of age and older. To the extent Epidiolex is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our ADSs may decline.

Epidiolex is our only drug that has been approved for sale in the U.S. and it has only been approved for the treatment of seizures associated with LGS and Dravet syndrome in patients two years of age and older. We are focusing a significant portion of our activities and resources on Epidiolex, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize Epidiolex in the U.S.

Successful commercialization of Epidiolex is subject to many risks. Prior to Epidiolex, we have only launched or commercialized one product, Sativex, outside of the U.S., and there is no guarantee that we will be able to successfully launch or commercialize Epidiolex for its approved indications. While we have established our commercial team and have hired our U.S. sales force, we will need to maintain and further develop the team in order to successfully coordinate the launch and commercialization of Epidiolex. Even if we are successful in maintaining and continuing to develop our commercial team, there are many factors that could cause the launch and commercialization of Epidiolex to be unsuccessful, including a number of factors that are outside our control. Because no drug has previously been approved by the FDA for the treatment of seizures associated with Dravet syndrome prior to 2018, it is especially difficult to estimate Epidiolex's market potential. The commercial success of Epidiolex depends on the extent to which patients and physicians accept and adopt Epidiolex as a treatment for LGS and Dravet syndrome, and we do not know whether our or others' estimates in this regard will be accurate. We have limited information about how physicians, patients and payors will respond to the pricing of Epidiolex. Physicians may not prescribe Epidiolex and patients may be unwilling to use Epidiolex if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for Epidiolex in the market after launch, in clinical development in additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of Epidiolex. Thus, significant uncertainty remains regarding the commercial potential of Epidiolex.

While we have been using the period between receipt of approval from the FDA in June 2018 and the rescheduling of Epidiolex into Schedule V by the DEA in September 2018 to prepare for the commercial launch of Epidiolex, the timing of launch is also subject to many risks. In particular, any delays in the shipment of our product into the United States, the manufacturing of additional product, or the execution of our sales, distribution and marketing plans by our U.S. sales and commercial organization, failure to obtain or any delays in obtaining the necessary import and export licenses, or the failure to coordinate well any of the foregoing, may adversely impact the timing of launch and the success of commercialization.

If the launch or commercialization of Epidiolex is delayed, unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our company could be harmed.

If we do not obtain regulatory approval of Epidiolex for other indications in the U.S., or for any indications in foreign jurisdictions, we will not be able to market Epidiolex for other indications or in other jurisdictions, which will limit our commercial revenues.

While Epidiolex has been approved by the FDA for the treatment of seizures associated with LGS and Dravet syndrome in patients two years of age and older, it has not been approved by the FDA for any other indications, and it has not been approved in any other jurisdiction for these indications or for any other indication. In order to market Epidiolex for other indications or in other jurisdictions, we must obtain regulatory approval for each of those indications and in each of the applicable jurisdictions, and we may never be able to obtain such approval. Approval of Epidiolex by the FDA for the treatment of seizures associated with LGS and Dravet syndrome in patients two years of age and older does not ensure that the

foreign jurisdictions will also approve Epidiolex for these indications, nor does it ensure that Epidiolex will be approved by the FDA for any other indication. The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, whose regulations differ from country to country. We will be required to comply with different regulations and policies of the jurisdictions where we seek approval for our product candidates, and, outside of the U.S. and Europe we have not yet identified all of the requirements that we will need to satisfy before submitting Epidiolex for approval for other indications or in other jurisdictions. In addition, some jurisdictions, including the U.S., may impose further restrictions through designation of our products as controlled substances. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support our NDA submission in LGS and Dravet syndrome. In addition, strategic considerations need to be taken into account when determining whether and when to submit Epidiolex for approval in other jurisdictions. If we do not receive marketing approval for Epidiolex for any other indication or from any regulatory agency other than the FDA, we will never be able to commercialize Epidiolex for any other indication in the U.S. or for any indication in any other jurisdiction. Even if we do receive additional regulatory approvals, we may not be successful in commercializing those approved products.

If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or nonclinical studies, or other activities, actions or decisions related to Epidiolex do not meet our or others' expectations, the market price of our common stock could decline significantly.

In June 2018, we received FDA approval for Epidiolex for the treatment of seizures associated with LGS or Dravet syndrome in patients two years of age and older. That approval subjects us to ongoing obligations and continued regulatory review, which may result in significant additional expense. If we do not meet those ongoing obligations, we could be subject to significant penalties, including market withdrawal and/or civil or criminal penalties. Additionally, our other product candidates, if approved, could be subject to labeling and other restrictions and we may be subject to penalties (including market withdrawal) if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

In June 2018, we received FDA regulatory approval for Epidiolex for the treatment of seizures associated with LGS or Dravet syndrome in patients two years of age and older. In Europe, we submitted an application to the European Medicines Agency, or EMA, in December 2017 and we expect a decision on the application in the first quarter of 2019. We have received Orphan Drug Designation from the FDA for Epidiolex for seizures associated with LGS, Dravet syndrome and TSC. We also received Orphan Designation from the EMA's COMP for Epidiolex for Dravet syndrome, LGS, and TSC, although there is no guarantee that upon approval, the designation will be reconfirmed. The FDA approval and other regulatory approvals for any of our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the approved product candidate. With respect to the FDA's approval of Epidiolex, we are subject to certain post-marketing requirements. Failure to comply with these post-marketing requirements could result in withdrawal of our marketing approval for Epidiolex and/or other civil or criminal penalties. In addition, with respect to Epidiolex, and any product candidate that the FDA or a comparable foreign regulatory authority approves, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practices, or GMPs, with Good Clinical Practices, or GCPs, for any clinical trials that we conduct post-approval, and with Good Laboratory Practices, or GLPs, for any non-clinical studies.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, mandatory safety labeling changes, or product recalls;

- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us, or suspension or revocation of product approvals;
- imposition of risk evaluation and mitigation strategies, or REMS;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any of our product candidates or future indications for currently approved products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we could lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Epidiolex has only been studied in a limited number of patients and in limited populations. As we continue our commercial launch, Epidiolex will become available to a much larger number of patients, and we do not know whether the results of Epidiolex use in such larger number of patients will be consistent with the results from our clinical trials.

Epidiolex has been administered only to a limited number of patients and in limited populations in clinical trials, including our two LGS Phase 3 pivotal studies and first Dravet syndrome Phase 3 pivotal efficacy and safety trial. While the FDA granted approval of Epidiolex based on the data included in the NDA, and we believe such data to be robust, we do not know whether the results will be consistent with those resulting from administration of the drug to a large number of patients. New data relating to Epidiolex, including from adverse event reports and post-marketing studies in the U.S., and from other ongoing clinical trials, may result in changes to the product label and/or imposition of a REMs and may adversely affect sales, or result in withdrawal of Epidiolex from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing Epidiolex marketing applications for indications other than our approved uses in other jurisdictions, or impose additional post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

We are dependent on the success of our product candidates, some of which may not receive regulatory approval or be successfully commercialized.

Our success will depend on our ability to successfully commercialize our product pipeline, including commercialization of Epidiolex, Sativex and our other cannabinoid product candidates. While we have received U.S. regulatory approval for the use of Epidiolex for the treatment of seizures associated with LGS or Dravet syndrome in patients two years of age and older, we are evaluating Epidiolex for the treatment of other conditions such as TSC. We also continue to develop Epidiolex for additional rare childhood-onset epilepsy disorders including TSC and Rett syndrome. Epidiolex may never receive regulatory approval for the treatment of any other indications in the U.S. or elsewhere. Even if completed Phase 3 clinical trials and/or ongoing or future Phase 3 clinical trials show positive results, there can be no assurance that the FDA, EMA or any other regulatory authority will approve Epidiolex for any additional indications or that any other product candidate will receive approval.

Our ability to successfully commercialize Epidiolex, Sativex and our other product candidates will depend on, among other things, our ability to:

- successfully complete pre-clinical and other non-clinical studies and clinical trials, including assessment of abuse potential;
- demonstrate to the FDA and similar foreign regulatory authorities that the efficacy of Epidiolex, Sativex, or any other product candidates in clinical trials, can be attributed to the investigative

product and not exclusively to its interaction with concomitant medications. It is possible that FDA may convene an advisory committee of external experts to consider any of our other drug candidates, and the course and outcome of meetings with these advisory committees can be hard to predict;

- receive regulatory approvals from the FDA and similar foreign regulatory authorities;
- produce, through a validated process, in manufacturing facilities inspected and approved by regulatory authorities, including the FDA, sufficiently large quantities of the product candidate, and the related Botanical Drug Substances, or BDSs, to permit successful commercialization;
- build and maintain strong sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates, or otherwise establish collaborations with third parties for the commercialization of our product candidates;
- obtain reimbursement from payors such as government health care programs and insurance companies and other third-party payors, as well as achieve commercially attractive levels of pricing;
- secure acceptance of our product candidates from physicians, health care payers, patients and the medical community;
- create positive publicity surrounding our product candidates;
- manage our spending as costs and expenses increase due to clinical trials and commercialization; and
- obtain and enforce sufficient intellectual property for our product candidates.

Our failure or delay with respect to any of the factors above could have a material adverse effect on our business, results of operations and financial condition.

We have limited marketing experience, and have only recently established our sales force, distribution and reimbursement capabilities, and we may not be able to successfully commercialize Epidiolex, or any of our product candidates if they are approved in the future.

Our ability to generate revenues ultimately depends on our ability to sell our approved products and secure adequate third-party reimbursement. We currently have limited experience in marketing and selling our products. Our product Sativex is currently our only product being commercialized and is currently approved and sold through marketing partners in a number of countries outside of the U.S. for treatment of MS spasticity. Epidiolex for treatment of LGS and Dravet syndrome in patients two years of age and older is our only product approved for sale in the U.S., and we have only recently completed the build-out of an experienced commercial organization consisting of sales, medical affairs, marketing, and market access teams.

The commercial success of Epidiolex and Sativex depends on a number of factors beyond our control, including the willingness of physicians to prescribe Epidiolex and Sativex to patients, payors' willingness and ability to pay for the drug, the level of pricing achieved, patients' response to Epidiolex and Sativex, and the ability of our marketing partners to generate sales. There can be no guarantee that we will be able to establish or maintain the personnel, systems, arrangements and capabilities necessary to successfully commercialize Epidiolex, Sativex or any product candidate approved by the FDA in the future. If we fail to establish or maintain successful marketing, sales and reimbursement capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues may suffer.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize Epidiolex may be harmed.

Epidiolex will be a newly-marketed drug and, therefore, none of the members of our sales force will have ever promoted Epidiolex. As a result, we are and will continue to be required to expend significant time and resources to train our sales force to be credible, persuasive, and compliant with applicable laws in marketing Epidiolex for the treatment of LGS and Dravet syndrome to physicians. In addition, we must

train our sales force to ensure that a consistent and appropriate message about Epidiolex is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of Epidiolex and its proper administration, our efforts to successfully commercialize Epidiolex could be jeopardited, which would negatively impact our ability to generate product revenues.

We have recently grown our business and will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in managing our growth and executing our growth strategy.

Our management and personnel, systems and facilities currently in place may not be adequate to support our business plan and future growth. With the FDA approval for Epidiolex and the decision to promote and market in the U.S. the product candidates for which we receive marketing approval from the FDA, we have increased our number of full-time equivalent employees from 194 on September 30, 2013 to 776 as of the date of this Current Report, primarily because we were conducting all of our Phase 2 and 3 clinical trials of Epidiolex and our other product candidates ourselves and establishing a commercial organization and our commercial infrastructure. As a result of these activities, the complexity of our business operations has substantially increased. We will need to further expand our scientific, manufacturing, sales and marketing, managerial, compliance, operational, financial and other resources to support our planned research, development, manufacturing and commercialization activities.

Our need to effectively manage our operations, growth and various projects requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- manage our commercialization activities effectively and in a cost-effective manner;
- manage our clinical trials effectively;
- manage our internal manufacturing operations effectively and in a cost effective manner;
- manage our development efforts effectively while carrying out our contractual obligations to contractors and other third parties; and
- continue to improve our facilities.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants and contractors to perform a number of tasks for us, including tasks related to compliance programs, clinical trial management, regulatory affairs, formulation development and other drug development functions. Our growth strategy may entail expanding our use of consultants and contractors to implement these and other tasks going forward. If we are not able to effectively expand our organization by hiring new employees and expanding our use of consultants and contractors, we may be unable to successfully implement the tasks necessary to effectively execute on our planned research, development, manufacturing and commercialization activities and, accordingly, may not achieve our research, development and commercialization goals.

Our product candidates, if approved, may be unable to achieve the expected market acceptance and, consequently, limit our ability to generate revenue from new products.

Even when product development is successful and regulatory approval has been obtained, our ability to generate sufficient revenue depends on the acceptance of our products by physicians and patients. We cannot assure you that Epidiolex or Sativex and our other product candidates will achieve the expected level of market acceptance and revenue if and when they obtain the requisite regulatory approvals. The market acceptance of any product depends on a number of factors, including the indication statement and warnings required by regulatory authorities in the product label. Market acceptance can also be influenced by continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product, reimbursement from third-party payors such as government health care programs and private third-party payors, the price of the product, the nature of any post-approval risk management activities

mandated by regulatory authorities, competition, and marketing and distribution support. Further, our U.S. distribution depends on the adequate performance of a reimbursement support hub and contracted specialty pharmacies in a closed-distribution network. An ineffective or inefficient U.S. distribution model at launch may lead to inability to fulfill demand, and consequently a loss of revenue. The success and acceptance of a product in one country may be negatively affected by our activities in another. If we fail to adapt our approach to clinical trials in the U.S. market to meet the needs of EMA or other European regulatory authorities, or to generate the health economics and outcomes research data needed to support pricing and reimbursement negotiations in Europe, we may have difficulties obtaining marketing authorization for our products from EMA and may have difficulties obtaining pricing and reimbursement approval for our products at a national level. Any factors preventing or limiting the market acceptance of our products could have a material adverse effect on our business, results of operations and financial condition.

In respect of our product candidates targeting rare indications, orphan drug exclusivity may afford limited protection, and if another party obtains orphan drug exclusivity for the drugs and indications we are targeting, we may be precluded from commercializing our product candidates in those indications during that period of exclusivity.

The first NDA applicant with an Orphan Drug Designation for a particular active moiety to treat a specific disease or condition that receives FDA approval is usually entitled to a seven-year exclusive marketing period in the U.S. for that drug, for that indication. We rely in part on this orphan drug exclusivity and other regulatory exclusivities to protect Epidiolex and, potentially, our other products and product candidates from competitors, and we expect to continue relying in part on these regulatory exclusivities in the future. The duration of that exclusivity period could be impacted by a number of factors, including the FDA's later determination that the request for designation was materially defective, that the manufacturer is unable to supply sufficient quantities of the drug, or that the extension of the exclusivity period established by the Improving Regulatory Transparency for New Medical Therapies Act does not apply. There is no assurance that we will successfully obtain Orphan Drug Designation for other product candidates or other rare diseases or that a product candidate for which we receive Orphan Drug Designation will be approved, or that we will be awarded orphan drug exclusivity upon approval as, for example, the FDA may reconsider whether the eligibility criteria for such exclusivity have been met and/or maintained. Moreover, a drug product with an active moiety that is a different cannabinoid from that in our drug candidate or, under limited circumstances, the same drug product, may be approved by the FDA for the same indication during the period of marketing exclusivity. The limited circumstances include a showing that the second drug is clinically superior to the drug with marketing exclusivity through a demonstration of superior safety or efficacy or that it makes a major contribution to patient care. In addition, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a product candidate we are pursuing for the same indication before us, approval of our product candidate would be blocked during the period of marketing exclusivity unless we could demonstrate that our product candidate is clinically superior to the approved product. In addition, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a product candidate we are pursuing for a different orphan indication, this may negatively impact the market opportunity for our product candidate. There have been legal challenges to aspects of the FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, including whether two drugs are the same drug product, and future challenges could lead to changes that affect the protections potentially afforded our products in ways that are difficult to predict. In a recent successful legal challenge, a court invalidated the FDA's denial of orphan exclusivity to a drug on the grounds that the drug was not proven to be clinically superior to a previously approved product containing the same ingredient for the same orphan use. In response to the decision, the FDA released a policy statement stating that the court's decision is limited just to the facts of that particular case and that the FDA will continue to require the sponsor of a designated drug that is the "same" as a previously approved drug to demonstrate that its drug is clinically superior to that drug upon approval in order to be eligible for orphan drug exclusivity, or in some cases, to even be eligible for marketing approval. In the future, there is the potential for additional legal challenges to the FDA's orphan drug regulations and policies, and it is uncertain how such challenges might affect our business.

In the European Union, if a marketing authorization is granted for a medicinal product that is designated an orphan drug, that product is entitled to ten years of marketing exclusivity. During the period of marketing exclusivity, subject to limited exceptions, no similar medicinal product may be granted a marketing authorization for the orphan indication. There is no assurance that we will successfully obtain Orphan Drug Designation for future rare indications or orphan exclusivity upon approval of any of our product candidates that have already obtained designation. Even if we obtain orphan exclusivity for any product candidate, the exclusivity period can be reduced to six years if at the end of the fifth year it is established that the orphan designation criteria are no longer met or if it is demonstrated that the orphan drug is sufficiently profitable that market exclusivity is no longer justified. Further, a similar medicinal product may be granted a marketing authorization for the same indication notwithstanding our marketing exclusivity if we are unable to supply sufficient quantities of our product, or if the second product is safer, more effective or otherwise clinically superior to our orphan drug. In addition, if a competitor obtains marketing authorization and orphan exclusivity for a product that is similar to a product candidate we are pursuing for the same indication, approval of our product candidate would be blocked during the period of orphan marketing exclusivity unless we could demonstrate that our product candidate is safer, more effective or otherwise clinically superior to the approved product.

If the price for Epidiolex, Sativex or any future approved products decreases or if governmental and other third-party payors do not provide coverage and adequate reimbursement levels, our revenue and prospects for profitability will suffer.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals generally must be obtained on a country-by-country basis. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for Epidiolex, Sativex or other products we may market, the resulting reimbursement payment rates may require co-payments that patients find unacceptably high. Patients may not use Epidiolex or Sativex if coverage is not provided or reimbursement is inadequate to cover a significant portion of its cost.

In addition, the market for Epidiolex and Sativex will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available, even if not approved for the indication for which Epidiolex or Sativex is approved.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The current environment is putting pressure on companies to price products below what they may feel is appropriate. Selling Epidiolex and Sativex at less than an optimized price could impact our revenues and overall success as a company. We do not know if the price we have selected for Epidiolex or Sativex is the optimized price. In addition, in the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for Epidiolex may differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of Epidiolex or Sativex to each payor separately, with no assurance that coverage will be obtained. If we are unable to obtain coverage of, and adequate payment levels for, Epidiolex, Sativex or any other products we may market to third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize Epidiolex, Sativex, or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition, and future success.

In addition, where we have chosen to collaborate with a third party on product candidate development and commercialization, our partner may elect to reduce the price of our products in order to increase the

likelihood of obtaining reimbursement approvals. In many countries, products cannot be commercially launched until reimbursement is approved and the negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions taken in other countries, which can lead to mandatory price reductions and/or additional reimbursement restrictions across a number of other countries, which may thereby adversely affect our sales and profitability. In the event that countries impose prices that are not sufficient to allow us or our partners to generate a profit, our partners may refuse to launch the product in such countries or withdraw the product from the market, which would adversely affect sales and profitability. For example, whereas the All Wales Medicines Strategy Group has recommended Sativex for use in MS spasticity in Wales, the National Institute for Clinical Excellence published MS treatment guidelines which did not recommend Sativex for use in England. While this example refers to the commercialization of Sativex, the same or similar events, such as price decreases, government mandated rebates or unfavorable reimbursement decisions could affect the pricing and reimbursement of Epidiolex and our other product candidates and could have a material adverse effect on our business, reputation, results of operations and financial condition.

We expect to face intense competition, often from companies with greater resources and experience than we have.

The pharmaceutical industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of these competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than we have. Some of these competitors and potential competitors have more experience than we have in the development of pharmaceutical products, including validation procedures and regulatory matters. In addition, Epidiolex and Sativex compete with, and our product candidates, if successfully developed, will compete with, product offerings from large and well-established companies that have greater marketing and sales experience and capabilities than we or our collaboration partners have. In particular, Insys Therapeutics, Inc. is developing CBD in Infantile Spasms, or IS, and potentially other indications. Zogenix, Inc. has reported positive data in two Phase 3 trials of low dose fenfluramine in Dravet syndrome and has commenced a Phase 3 trial with this product in LGS. Biocodex recently received regulatory approval from the FDA for the drug Stiripentol (Diacomit) for the treatment of Dravet syndrome. Other companies with greater resources than us may announce similar plans in the future. In addition, there are non-FDA approved CBD preparations being made available from companies in the medical marijuana industry, which might attempt to compete with Epidiolex. If we are unable to compete successfully, our commercial opportunities will be reduced and our business, results of operations and financial conditions may be materially harmed.

Product shipment delays could have a material adverse effect on our business, results of operations and financial condition.

The shipment, import and export of Epidiolex, Sativex and our other product candidates require import and export licenses. In the U.S., the FDA, U.S. Customs and Border Protection, and the DEA, and in the United Kingdom, the Home Office, and in other countries, similar regulatory authorities regulate the import and export of pharmaceutical products that contain controlled substances, including Epidiolex, Sativex and our other product candidates. Specifically, the import and export process requires the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country. We may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of Epidiolex, Sativex and our product candidates may be held up in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipment resulting in a partial or total loss of revenue from one or more shipment of Epidiolex, Sativex or our other product candidates. A partial or total loss of revenue from one or more shipments of Epidiolex, Sativex or our other product candidates could have a material adverse effect on our business, results of operations and financial condition.

Problems in our manufacturing process, failure to comply with manufacturing regulations or unexpected increases in our manufacturing costs could harm our business, results of operations and financial condition.

We are responsible for the manufacture and supply of Sativex to our collaboration partners and for the manufacture and supply of Epidiolex, Sativex and other product candidates for commercial use and for use in clinical trials. The manufacturing of Epidiolex, Sativex and our product candidates necessitates compliance with GMP and other regulatory requirements in jurisdictions internationally. Our ability to successfully manufacture Epidiolex, Sativex and other product candidates involves cultivation of botanical raw material from specific cannabinoid plants, extraction and purification processes, manufacture of finished products and labeling and packaging, which includes product information, tamper evidence and anti-counterfeit features, under tightly controlled processes and procedures. For Epidiolex, Sativex and our product candidates, production also requires the cultivation of cannabinoid plants under highly controlled and standardized conditions. In addition, we must ensure chemical consistency among our batches, including clinical batches and, if approved, marketing batches. Demonstrating such consistency may require typical manufacturing controls as well as clinical data. We must also ensure that our batches conform to complex release specifications. For each step in the manufacturing process for Sativex, we are currently reliant on single manufacturing facilities and no back-up facilities are yet in place. We have a second site at which we can grow the specific cannabinoid plants which produce the CBD used in Epidiolex, a second site at which we can extract CBD from botanical raw material and a second site at which we can crystallize the purified CBD from the liquid plant extract, but we are currently reliant on a single manufacturing facility, and no back-up facilities are yet in place, for the other steps in the Epidiolex production process. Because Sativex is a complex mixture manufactured from plant materials, and because the release specifications may not be identical in all countries, certain batches may fail release testing and not be able to be commercialized. A number of our product candidates (excluding Epidiolex) also consist of a complex mixture manufactured from plant materials, and are therefore subject to a similar risk. If we are unable to manufacture Epidiolex, Sativex or other product candidates in accordance with regulatory specifications, including GMP or if there are disruptions in our manufacturing process due to damage, loss or otherwise, or failure to pass regulatory inspections of our manufacturing facilities, we may not be able to meet current demand or supply sufficient product for use in clinical trials, and this may also harm our ability to commercialize Epidiolex, Sativex and our product candidates on a timely or cost-competitive basis, if at all. We have an on-going program for expanding and upgrading parts of our growing and manufacturing facilities and we are working with a number of contract manufacturing partners. This has allowed us to implement a manufacturing program that we believe includes a sufficient number of growing and manufacturing sites that should provide sufficient quantities to meet initial demand, and meet FDA's stringent requirements for demonstrating equivalence of the scaled up manufacturing process. This program requires significant time and resources and may not be successful, for example the FDA may refuse to accept our facilities or those of our contract manufactures as being suitable for the production of Epidiolex. We are planning a significant expansion of our growing facilities over the next few years in order to meet potential peak demand for Epidiolex, including working with several new contractor manufacturers and adopting new methods in order to handle and process bulk quantities of botanical raw material. We are planning to increase the scale in which we manufacture Epidiolex over the next few years in order to meet potential peak demand for Epidiolex, including working with several new contractors and, potentially, adopting new processes. These activities may be unsuccessful, may lead to delays, interruptions to supply, or may prove to be more costly than anticipated.

We may fail to expand our growing and manufacturing capability in time to meet market demand for our products and product candidates, and the FDA may refuse to accept our facilities or those of our contract manufactures as being suitable for the production of our products and product candidates. Any problems in our growing or manufacturing process could have a material adverse effect on our business, results of operations and financial condition.

In addition, before we can begin commercial manufacture of any product candidates for sale in the U.S., we must obtain FDA regulatory approval for the product, which requires a successful FDA inspection of our manufacturing facilities and those of our contract manufacturers, processes and quality systems in addition to other product-related approvals. We have successfully navigated this pre-approval inspection process as it relates to Epidiolex in the U.S. However, pharmaceutical manufacturing facilities are continuously subject to post-approval inspection by the FDA and foreign regulatory authorities. Due to the

complexity of the processes used to manufacture our product candidates, we may be unable to initially or continue to pass federal, state or international regulatory inspections in a cost effective manner. If we are unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of any approved products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our business, results of operations and financial condition.

Further, the processes we use for cultivation of botanical raw material and the production of product candidates for use in clinical trials may be different to the processes we use to produce commercial product and/or may not be capable of producing sufficient quantities of product for commercial purposes. We may therefore need to undertake additional manufacturing process development and scale-up activities before we can commercialize a product. This may include the conduct of bioequivalence studies to demonstrate that product produced by the process used to manufacture on a commercial scale is the same as the material used in clinical trials. If we cannot demonstrate that our commercial scale product is the same as material used in our clinical trials, we may not be permitted to sell that product, which could have an impact on our business, results of operations and financial condition.

Product recalls or inventory losses caused by unforeseen events, cold chain interruption and testing difficulties may adversely affect our operating results and financial condition.

Epidiolex, Sativex and our product candidates are manufactured and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture of our products, subjects us to production risks. While product batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following product release. Some of our products must be stored and transported at temperatures within a certain range, which is known as "strict cold chain" storage and transportation. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches.

Epidiolex, Sativex and our product candidates contain controlled substances, the use of which may generate public controversy.

Since Epidiolex, Sativex and our other product candidates contain controlled substances, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, Epidiolex, Sativex and our product candidates. These pressures could also limit or restrict the introduction and marketing of Epidiolex, Sativex and our product candidates. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid products may adversely affect the commercial success or market penetration achievable by Epidiolex, Sativex and our product candidates. The nature of our business attracts a high level of public and media interest, and in the event of any resultant adverse publicity, our reputation may be harmed.

Business interruptions could delay us in the process of developing our product candidates and could disrupt our product sales.

Loss of our manufacturing facilities, our growing plants, stored inventory or laboratory facilities through fire, theft or other causes, or loss of our botanical raw material due to pathogenic infection or other causes, could have an adverse effect on our ability to meet demand for Sativex or Epidiolex or to continue product development activities and to conduct our business. Failure to supply our partners with commercial product may lead to adverse consequences, including the right of partners to take over responsibility for product supply. We currently have insurance coverage to compensate us for such business interruptions; however, such coverage may prove insufficient to fully compensate us for the damage to our business resulting from any significant property or casualty loss to our inventory or facilities.

We have significant and increasing liquidity needs and may require additional funding.

Our operations have consumed substantial amounts of cash since inception. For the nine months ended June 30, 2018, we reported a net operating cash outflow of $146.9 million (£111.4 million) and a net

cash outflow from investing activities of $21.9 million (£16.6 million). This is consistent with our cash outflow guidance for the second half of the fiscal year of $120 million to $140 million (£90 million to £105 million).

Research and development, management and administrative expenses and cash used for operations will continue to be significant and may increase substantially in the future in connection with new research and development initiatives, continued product commercialization efforts and the launch of Epidiolex and continue to grow as a U.S. public company. We may need to raise additional capital to fund our operations, continue to conduct clinical trials to support potential regulatory approval of marketing applications, and to fund commercialization of our products.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the timing of FDA approval, if any, and approvals in international markets of our product candidates, if at all;
- the timing and amount of revenue from sales of our products, or revenue from grants or other sources;
- the rate of progress and cost of our clinical trials and other product development programs;
- costs of establishing or outsourcing sales, marketing and distribution capabilities;
- costs and timing of completion of expanded in-house manufacturing facilities as well as any outsourced growing and commercial manufacturing supply arrangements for our product candidates;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- costs of operating as a U.S. public company;
- the effect of competing technological and market developments;
- personnel, facilities and equipment requirements; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

While we expect to fund our future capital requirements from a number of sources including cash flow from operations, the proceeds from further public offerings, and the proceeds from the exercise of share options, we cannot assure you that any of these funding sources will be available to us on favorable terms, or at all. Further, even if we can raise funds from all of the above sources, the amounts raised may not be sufficient to meet our future capital requirements.

We will present our financial results in U.S. dollars under generally accepted accounting principles in the U.S., or U.S. GAAP, beginning with filings made after October 1, 2018. These results may be materially different than our historical results presented under International Financial Reporting Standards, or IFRS which could have an adverse effect on the market price of our ADSs.

We currently prepare our financial statements and report our financial results in pounds sterling under IFRS. Beginning on October 1, 2018, we will report as a U.S. domestic filer and present our historical and future financial statements in our SEC filings and financial reports in U.S. dollars under U.S. GAAP. There have been and there may in the future be certain significant differences between IFRS and U.S. GAAP including the accounting for inventory, revenue recognition, share-based compensation expense, income taxes and classification of research and development tax credits. We do not plan to provide a reconciliation of IFRS to U.S. GAAP. Our functional currency will also change from pounds sterling to U.S. dollars, which could have a material impact on our historical and future financial results. We do not expect this change to affect our reported cash position. When reported in U.S. dollars under U.S. GAAP, our financial results may be significantly different than previously disclosed historical financial results, which could negatively impact the market price of our ADSs.

Operating results may vary significantly in future periods.

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our financial results are unpredictable and may fluctuate, for among other reasons, due to:

- commercial sales of Epidiolex and Sativex;
- our achievement of product development objectives and milestones;
- clinical trial enrollment and expenses;
- research and development expenses; and
- the timing and nature of contract manufacturing and contract research payments.

A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect financial results in a quarter. Because of these factors, our financial results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline.

If product liability lawsuits are successfully brought against us, we will incur substantial liabilities and may be required to limit the commercialization of Epidiolex, Sativex and our product candidates.

Although we have never had any product liability claims or lawsuits brought against us, we face potential product liability exposure related to the testing of our product candidates in human clinical trials, and we currently face exposure to claims in jurisdictions where we currently or potentially market and distribute our products. We may face exposure to claims by an even greater number of persons when we begin marketing and distributing our products commercially in the U.S. and elsewhere. Now, and in the future, an individual may bring a liability claim against us alleging that Epidiolex, Sativex or one of our product candidates caused an injury. While we continue to take what we believe are appropriate precautions, we may be unable to avoid significant liability if any product liability lawsuit is brought against us. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Although we have purchased insurance to cover product liability lawsuits, if we cannot successfully defend ourselves against product liability claims, or if such insurance coverage is inadequate, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for Epidiolex, Sativex and our product candidates if such product candidates are approved;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- increased cost of liability insurance;
- loss of revenue; and
- the inability to successfully commercialize our products.

Counterfeit versions of our products could harm our business.

Counterfeiting activities and the presence of counterfeit products in a number of markets and over the Internet continue to be a challenge for maintaining a safe drug supply for the pharmaceutical industry. Counterfeit products are frequently unsafe or ineffective, and can be life-threatening. To distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs along with increased levels of counterfeiting could be mistakenly attributed to the authentic product, affect patient confidence in the authentic product and harm the business of companies such as ours. If our products were to be the subject of counterfeits, we could incur reputational and financial harm.

We depend upon our key personnel and our ability to attract and retain employees.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results. Due to the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense. Due to this intense competition, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with applicable manufacturing standards, comply with other federal and state laws and regulations, report information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information, including information obtained in the course of clinical trials, or illegal appropriation of drug product, which could result in government investigations and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent these prohibited activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we are unable to use net operating loss carry-forwards and certain built-in losses to reduce future tax payments, or benefit from favorable tax legislation, our business, results of operations and financial condition may be adversely affected.

As a U.K. resident trading company, we are predominantly subject to U.K. corporate taxation. At September 30, 2017, we had cumulative carry-forward tax losses of £204.1 million, available to offset against future profits (subject to the restrictions on the use of such losses described below). The majority of these tax loss attributes have not been recognized on our balance sheet at September 30, 2017. It should, however, be noted that the use of carried forward losses is restricted such that they are not available for offset against more than 50% of taxable profits in any accounting period (subject to a £5 million annual allowance). Additionally, as we carry out extensive research and development activities in the U.K., we benefit from the U.K. research and development tax credit regime. Up until the end of the financial year ended September 30, 2017, we have benefitted from the U.K. research and development tax credit regime for small and medium sized companies, whereby our principal research subsidiary, GW Research Ltd, was able to surrender a portion of available losses that arise from research and development activity for a refundable credit of up to approximately 33.4% of the eligible research and development expenditure. However, due to the increase in the size of our employee workforce in the U.K. and our annual turnover we are now subject to the U.K. research and development tax credit regime for large companies. Starting with the financial year ending September 30, 2018, GW Research Ltd is able to claim a refundable research and development expenditure credit, but that credit is payable at a lower effective rate of approximately 9.7%. We may also benefit in the future from the UK's "patent box" regime, which would allow certain profits attributable to revenue from patented products to be taxed at a lower rate of 10%. When taken in combination with our available carry-forward tax losses and the enhanced relief available on our research and development expenditure, we expect that this may result in a long-term low rate of corporation tax. If, however, we are unable to generate sufficient future taxable profits, or for any reason to utilize our carry-forward losses (as currently restricted), or there are unexpected adverse changes to the U.K. research and development tax credit regime or "patent box" regime, or we are unable to qualify for such advantageous tax legislation, our business, results of operations and financial condition may be adversely affected.

We are subject to the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, FCPA and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Additionally, under the Bribery Act there could be an offence if we failed to prevent a third party from committing bribery in the performance of services for us or on our behalf. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the U.S., and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

However, there is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by the United Kingdom, the U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Our proprietary information, or that of our customers, suppliers and business partners, may be lost or we may suffer security breaches.

In the ordinary course of our business, we collect and store sensitive data, including valuable and commercially sensitive intellectual property, clinical trial data, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers, clinical trial subjects and employees, patients, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, disrupt our operations, damage our reputation, and cause a loss of confidence in our products and our ability to conduct clinical trials, which could adversely affect our business and reputation and lead to delays in gaining regulatory approvals for Epidiolex. Although we maintain business interruption insurance coverage, our insurance might not cover all losses from any future breaches of our systems.

Failure of our information technology systems, including cybersecurity attacks or other data security incidents, could significantly disrupt the operation of our business.

Our business increasingly depends on the use of information technologies, which means that certain key areas such as research and development, production and sales are to a large extent dependent on our information systems or those of third party providers. Our ability to execute our business plan and to

comply with regulators' requirements with respect to data control and data integrity, depends, in part, on the continued and uninterrupted performance of our information technology systems, or IT systems and the IT systems supplied by third-party service providers. As information systems and the use of software and related applications by us, our business partners, suppliers, and customers become more cloud-based, there has been an increase in global cybersecurity vulnerabilities and threats, including more sophisticated and targeted cyber-related attacks that pose a risk to the security of our information systems and networks and the confidentiality, availability and integrity of data and information. In addition, our IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and backup measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we and our third-party service providers have taken to prevent unanticipated problems that could affect our IT systems, a successful cybersecurity attack or other data security incident could result in the misappropriation and/or loss of confidential or personal information, create system interruptions, or deploy malicious software that attacks our systems. It is also possible that a cybersecurity attack might not be noticed for some period of time. In addition, sustained or repeated system failures or problems arising during the upgrade of any of our IT systems that interrupt our ability to generate and maintain data, and in particular to operate our proprietary technology platform, could adversely affect our ability to operate our business. The occurrence of a cybersecurity attack or incident could result in business interruptions from the disruption of our information technology systems, or negative publicity resulting in reputational damage with our shareholders and other stakeholders and/or increased costs to prevent, respond to or mitigate cybersecurity events. In addition, the unauthorized dissemination of sensitive personal information or proprietary or confidential information could expose us or other third-parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including legally protected patient health information, credit card information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers, or viruses, breaches or interruptions due to employee error, malfeasance or other disruptions, or lapses in compliance with privacy and security mandates. Any such virus, breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. We have measures in place that are designed to prevent, and if necessary to detect and respond to such security incidents and breaches of privacy and security mandates. However, in the future, any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA and General Data Protection Regulation, or GDPR, government enforcement actions and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process samples, provide test results, share and monitor safety data, bill payors or patients, provide customer support services, conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business and may damage our reputation, any of which could adversely affect our business, financial condition and results of operations.

In May 2016, the European Union formally adopted the GDPR, which applies to all EU member states from May 25, 2018 and replaced the EU Data Protection Directive. The regulation introduces stringent new data protection requirements in the European Union and substantial fines for breaches of the

data protection rules. It has increased our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. The GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how the GDPR should be applied in the context of clinical trials or other transactions from which we may gain access to personal data. These changes in the law will increase our costs of compliance and result in greater legal risks.

Legislative or regulatory reform of the health care system in the U.S. and foreign jurisdictions may affect our ability to profitably sell our products, if approved.

Our ability to commercialize our future products successfully, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers and other third-party payers. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payers for health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. For example, the 2010 Affordable Care Act, or the ACA, substantially changed the way healthcare is financed by both governmental and private insurers. Both Congress and the U.S. President have already taken some actions that are intended to limit significantly the ACA, and we expect efforts to further modify or repeal the ACA to continue. The success and potential effects of these efforts to repeal or modify the ACA are not clear.

We expect additional federal and state legislative proposals for health care reform, which could limit the prices that can be charged for the products we develop and may limit our commercial opportunity.

The continuing efforts of government and other third-party payors to contain or reduce the costs of health care through various means may limit our commercial opportunity. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare, Medicaid and other governmental health programs and from and private payors. Our products may not be considered cost effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by ACA, changes to the ACA, and by other health care reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the U.S. will continue to put downward pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our ability to generate revenue in the U.S. market and maintain profitability.

In some foreign countries, including major markets in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a pharmacoeconomic study that compares the cost-effectiveness of our product candidates to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

We may acquire other companies which could divert our management's attention, result in additional dilution to our shareholders and otherwise disrupt our operations and harm our operating results.

We may in the future seek to acquire businesses, products or technologies that we believe could complement or expand our product offerings, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not

they are consummated. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, effectively manage the combined business following the acquisition or realize anticipated cost savings or synergies. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- incurrence of acquisition-related costs;
- diversion of management's attention from other business concerns;
- unanticipated costs or liabilities associated with the acquisition;
- harm to our existing business relationships with collaboration partners as a result of the acquisition;
- harm to our brand and reputation;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results arising from the impairment assessment process. Acquisitions may also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, results of operations and financial condition may be adversely affected.

The United Kingdom's vote in favor of withdrawing from the European Union could lead to increased market volatility which could adversely impact the market price of our ADSs and make it more difficult for us to do business in Europe or have other adverse effects on our business.

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as "Brexit"). On March 29, 2017, the U.K. government delivered to the European Council notice of its intention to leave the European Union and, in the absence of an executed withdrawal agreement with the European Union, the effective date of the United Kingdom's withdrawal from the European Union will, unless extended by the European Council in agreement with the United Kingdom, be March 29, 2019. There are many ways in which our business could be affected by this event, only some of which we can identify at this time. The negotiation of the withdrawal agreement has been, to date, a lengthy and contentious process, and we do not, as at the date of this Current Report, have certainty as to the terms of the United Kingdom's future relationship with the European Union. Indeed, the negotiations may, ultimately, be unsuccessful and the United Kingdom may not reach agreement with the European Union on the future terms of the United Kingdom's relationship with the European Union. If no agreement is reached, there will be a period of considerable uncertainty particularly in relation to United Kingdom financial and banking markets as well as on the regulatory process in Europe. As a result of this uncertainty, financial markets could experience volatility which could adversely affect the market price of our ADSs. We may also face new regulatory costs and challenges that could have a material adverse effect on our operations. In this regard, the EMA has already issued a notice reminding marketing authorization holders of centrally authorized medicinal products for human and veterinary use of certain legal requirements that need to be considered as part of Brexit, such as the requirement for the marketing authorization holder of a product centrally approved by European Commission to be established in the European Union, and the requirement for some activities relating to centrally approved products, such as batch release and pharmacovigilance, be performed in the European Union. As a result of the foregoing, and in the absence of any clear indication that the withdrawal agreement will contain a contrary requirement, we are already in the process of establishing a network of subsidiary undertakings in the major European markets and planning to establish pharmacovigilance and batch release operations in the European Union. Depending on the terms of Brexit, the United Kingdom could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in

increased trade barriers which could make our doing business worldwide more difficult. In addition, currency exchange rates in the pound sterling and the euro with respect to each other and the U.S. dollar have already been adversely affected by Brexit. Should this foreign exchange volatility continue it could cause volatility in our quarterly financial results.

Risks Related to Development and Regulatory Approval of Epidiolex, Sativex and Our Product Candidates

Clinical trials for our product candidates are expensive, time-consuming, uncertain and susceptible to change, delay or termination. The results of clinical trials are open to differing interpretations

Clinical trials are expensive, time consuming and difficult to design and implement. Regulatory agencies may analyze or interpret the results differently than us. Even if the results of our clinical trials are favorable, the clinical trials for a number of our product candidates are expected to continue for several years and may take significantly longer to complete. In addition, we, the FDA or other regulatory authorities, including state and local authorities, or an Institutional Review Board, or IRB, with respect to a trial at its institution, may suspend, delay or terminate our clinical trials at any time, require us to conduct additional clinical trials, require a particular clinical trial to continue for a longer duration than originally planned, require a change to our development plans such that we conduct clinical trials for a product candidate in a different order, e.g., in a step-wise fashion rather than running two trials of the same product candidate in parallel, or the DEA could suspend or terminate the registrations and quota allotments we require in order to procure and handle controlled substances, for various reasons, including:

- lack of effectiveness of any product candidate during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues, such as drug interactions, including those which cause confounding changes to the levels of other concomitant medications.
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints;
- inadequacy of or changes in our manufacturing process or product formulation;
- delays in obtaining regulatory authorization to commence a trial, including “clinical holds” or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, before or after a trial is commenced;
- DEA-related recordkeeping, reporting or security violations at a clinical site, leading the DEA or state authorities to suspend or revoke the site’s controlled substance license and causing a delay or termination of planned or ongoing trials;
- changes in applicable regulatory policies and regulation, including changes to requirements imposed on the extent, nature or timing of studies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- delay or failure to supply product for use in clinical trials which conforms to regulatory specification;
- unfavorable results from ongoing pre-clinical studies and clinical trials;
- failure of our contract research organizations, or CROs, or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;

- failure by us, our employees, our CROs or their employees to comply with all applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for controlled substances;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- regulatory concerns with cannabinoid products generally and the potential for abuse;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols; or
- difficulty in maintaining contact with patients during or after treatment, which may result in incomplete data.

Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

Any failure by us to comply with existing regulations could harm our reputation and operating results.

We are subject to extensive regulation by U.S. federal and state and foreign governments in each of the markets where we currently sell or plan to sell Epidiolex and Sativex, as applicable, or in markets where we have product candidates progressing through the approval process.

We must also adhere to all regulatory requirements including FDA's GLP, GCP, and cGMP requirements, pharmacovigilance requirements, advertising and promotion restrictions, reporting and recordkeeping requirements, and their European equivalents. If we or our suppliers fail to comply with applicable regulations, including FDA pre-or post-approval cGMP requirements, then the FDA or other foreign regulatory authorities could sanction us. Even if a drug is FDA-approved, regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-marketing trials. Epidiolex, and any of our product candidates that may be approved in the U.S. in the future, will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, import, export, advertising, promotion, sampling, recordkeeping and submission of safety and other post-market information, including both federal and state requirements in the U.S. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to GMP. As such, we and our contract manufacturers (in the event contract manufacturers are appointed in the future) are subject to continual review and periodic inspections to assess compliance with GMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, quality control and quality assurance. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of the product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;

- impose restrictions on our operations, including by requiring us to enter in to a Corporate Integrity Agreement or closing our contract manufacturers' facilities, if any; or
- seize or detain products or require a product recall.

In addition, our products are regulated by the DEA, under the Controlled Substances Act. DEA scheduling is a separate process that can delay when a drug may become available to patients beyond an NDA approval date, and the timing and outcome of such DEA process is uncertain. See also "Risks Related to Controlled Substances".

In addition, any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from Epidiolex, Sativex and our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our business and our operating results may be adversely affected.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. We expend significant resources on compliance efforts and such expenses are unpredictable and might adversely affect our results. Changing laws, regulations and standards might also create uncertainty, higher expenses and increase insurance costs. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment might result in increased management and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

We are subject to federal, state and foreign healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell Epidiolex or Sativex, as applicable, and any other potential products. If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines, individual imprisonment, exclusion from federal health care programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with Epidiolex, and any other products we may market, which could negatively impact our profitability.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product, including Epidiolex. There have been judicial challenges to certain aspects of the ACA and numerous legislative attempts to repeal and/or replace the ACA in whole or in part, and we expect there will be additional challenges and amendments to the ACA in the future. At this time, the full effect that the ACA will have on our business in the future remains unclear. An expansion in the government's role in the U.S. healthcare industry may cause general downward pressure on the prices of

prescription drug products, lower reimbursements or any other product for which we obtain regulatory approval, reduce product utilization and adversely affect our business and results of operations. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize Epidiolex or any other products for which we may receive regulatory approval.

Information obtained from expanded access studies may not reliably predict the efficacy of our product candidates in company-sponsored clinical trials and may lead to adverse events that could limit approval.

The expanded access studies we are currently supporting are uncontrolled, carried out by individual investigators and not typically conducted in strict compliance with GCPs, all of which can lead to a treatment effect which may differ from that in placebo-controlled trials. These studies provide only anecdotal evidence of efficacy for regulatory review. These studies contain no control or comparator group for reference and these patient data are not designed to be aggregated or reported as study results. Moreover, data from such small numbers of patients may be highly variable. Information obtained from these studies, including the statistical principles that we and the independent investigators have chosen to apply to the data, may not reliably predict data collected via systematic evaluation of the efficacy in company-sponsored clinical trials or evaluated via other statistical principles that may be applied in those trials. Reliance on such information to design our clinical trials may lead to Phase 2 and 3 trials that are not adequately designed to demonstrate efficacy and could delay or prevent our ability to seek approval of our product candidates.

Expanded access programs provide supportive safety information for regulatory review. Physicians conducting these studies may use our product candidates in a manner inconsistent with the protocol, including in children with conditions beyond those being studied in trials which we sponsor. Any adverse events or reactions experienced by subjects in the expanded access program may be attributed to our product candidates and may limit our ability to obtain regulatory approval with labeling that we consider desirable, or at all.

There is a high rate of failure for drug candidates proceeding through clinical trials.

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. For example, as the endpoint preferred by EMA was not achieved in our first Phase 3 trial of Epidiolex for Dravet syndrome, our Marketing Authorization Application, or MAA for Dravet syndrome may not be accepted even though our NDA has been approved by the FDA. In the event that we obtain negative results from clinical trials for product candidates or other problems related to potential chemistry, manufacturing and control issues or other hurdles occur and our product candidates are not approved, we may not be able to generate sufficient revenue or obtain financing to continue our operations, our ability to execute on our current business plan may be materially impaired, our reputation in the industry and in the investment community might be significantly damaged and the price of our ADSs could decrease significantly. In addition, our inability to properly design, commence and complete clinical trials may negatively impact the timing and results of our clinical trials and ability to seek approvals for our drug candidates.

If we are found in violation of federal or state "fraud and abuse" laws, we may be required to pay a penalty and/or be suspended from participation in federal or state health care programs, which may adversely affect our business, financial condition and results of operations.

In the U.S., we are subject to various federal and state health care "fraud and abuse" laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse in federal and state health care programs, which could affect us particularly upon successful commercialization of our products in the U.S. The Medicare and Medicaid Patient Protection Act of 1987, or federal Anti-Kickback Statute, makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf),

to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a federal health care program, such as Medicare or Medicaid. Under federal law, some arrangements, known as safe harbors, are deemed not to violate the federal Anti-Kickback Statute. Although we seek to structure our business arrangements in compliance with all applicable requirements, it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute and Federal False Claims Act. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exclusion or suspension from federal and state health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal anti-kickback statute, some of which apply to the referral of patients for health care services reimbursed by any source, not just governmental payors. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. While we believe we have structured our business arrangements to comply with these laws, it is possible that the government could allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we could be required to pay a penalty and could be suspended or excluded from participation in federal or state health care programs, and our business, results of operations and financial condition may be adversely affected.

Our ability to research, develop and commercialize Epidiolex, Sativex and our product candidates is dependent on our ability to maintain licenses relating to the cultivation, possession and supply of controlled substances.

Our research and manufacturing facilities are located exclusively in the United Kingdom. In the United Kingdom, licenses to cultivate, possess and supply cannabis for medical research are granted by the Home Office on an annual basis. Although the Home Office has renewed our licenses each year since 1998, it may not do so in the future, in which case we may not be in a position to carry on our research and development program in the United Kingdom. In addition, we are required to maintain our existing commercial licenses to cultivate, produce and supply cannabis. However, if the Home Office were not prepared to renew such licenses, we would be unable to manufacture and distribute our products on a commercial basis in the United Kingdom or beyond. In order to carry out research in countries other than the United Kingdom, similar licenses to those outlined above are required to be issued by the relevant authority in each country. In addition, we will be required to obtain licenses to export from the United Kingdom and to import into the recipient country. To date, we have obtained necessary import and export licenses to over 30 countries. Although we have an established track record of successfully obtaining such licenses as required, this may change in the future.

In the U.S., the DEA regulates the cultivation, possession and supply of cannabis for medical research and commercial development, including the requirement of annual registrations to manufacture or distribute pharmaceutical products derived from cannabis extracts. See also “Risks Related to Controlled Substances”.

Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our product candidates, limit the scope of any approved label or market acceptance, or cause the recall or loss of marketing approval of products that are already marketed.

If Epidiolex, Sativex or any of our product candidates prior to or after any approval for commercial sale, cause serious or unexpected side effects, or are associated with other safety risks such as misuse, abuse or diversion, a number of potentially significant negative consequences could result, including:

- regulatory authorities may interrupt, delay or halt clinical trials;

- regulatory authorities may deny regulatory approval of our product candidates;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, and/or impose restrictions on distribution in the form of a REMS in connection with approval or post-approval;
- regulatory authorities may withdraw their approval, require more onerous labeling statements, impose a more restrictive REMS, or require us to recall any product that is approved;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- our relationships with our collaboration partners may suffer;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer. The reputational risk is heightened with respect to those of our product candidates that are being developed for pediatric indications.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our product candidates are unlikely to receive regulatory approval or unlikely to be successfully commercialized. Following receipt of approval for commercial sale of a product we may voluntarily withdraw or recall that product from the market if at any time we believe that its use, or a person's exposure to it, may cause adverse health consequences or death. To date we have not withdrawn, recalled or taken any other action, voluntary or mandatory, to remove an approved product from the market. To date, we have only voluntarily suspended clinical trials when recruitment of the target patients has proven to be too difficult or, temporarily, to properly investigate suspected adverse events. In addition, regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, if we elect or are forced to suspend or terminate a clinical trial of any of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events may result in labeling statements such as warnings or contraindications. In addition, such events or labeling could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

The development of a REMS for Epidiolex or our product candidates could cause delays in the approval process and would add additional layers of regulatory requirements that could impact our ability to commercialize our product candidates in the U.S. and reduce their market potential.

Although the FDA approved our NDA for Epidiolex without requiring a REMS as a condition of approval of the NDA, the FDA may, post-approval, require a REMS for Epidiolex if it becomes aware of new safety information that makes a REMS necessary to ensure that the benefits of the drug outweigh the potential risks. REMS elements can include medication guides, communication plans for health care professionals, and ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. We may be required to adopt a REMS for our product candidates to ensure that the benefits outweigh the risks of abuse, misuse, diversion and other potential safety concerns. There can be no assurance that the FDA will approve a manageable REMS for our product candidates, which could create material and significant limits on our ability to successfully commercialize our product candidates in the U.S. Delays in the REMS approval process could result in delays in the NDA approval process. In addition, as part of the REMS, the FDA could require significant restrictions, such as restrictions on the prescription, distribution and patient use of the product, which could significantly

impact our ability to effectively commercialize our product candidates, and dramatically reduce their market potential thereby adversely impacting our business, financial condition and results of operations. Even if initial REMS are not highly restrictive, if, after launch, our product candidates were to be subject to significant abuse/non-medical use or diversion from licit channels, this could lead to negative regulatory consequences, including a more restrictive REMS.

Risks Related to Our Reliance Upon Third Parties

Our existing collaboration arrangements and any that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize Epidiolex, Sativex and our product candidates.

We are a party to, and may seek additional, collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of Epidiolex, Sativex and our product candidates. We may, with respect to our product candidates, enter into new arrangements on a selective basis depending on the merits of retaining commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for each product candidate, both in the U.S. and internationally. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators and the terms of any collaboration or other arrangements that we may establish may not be favorable to us.

Any existing or future collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding development, intellectual property, regulatory or commercialization matters, can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority. Any such termination or expiration could harm our business reputation and may adversely affect us financially.

We depend on a limited number of suppliers for materials and components required to manufacture Epidiolex, Sativex and our product candidates. The loss of these suppliers, or their failure to supply us on a timely basis, could cause delays in our current and future capacity and adversely affect our business.

We depend on a limited number of suppliers for the materials and components required to manufacture Epidiolex, Sativex and our product candidates. As a result, we may not be able to obtain sufficient quantities of critical materials and components in the future. A delay or interruption by our suppliers may also harm our business, results of operations and financial condition. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify for and, in some cases, obtain regulatory approval for a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Our dependence on single-source suppliers exposes us to numerous risks, including the following: our suppliers may cease or reduce production or deliveries, raise prices or renegotiate terms; our suppliers may become insolvent or cease trading; we may be unable to locate a suitable replacement supplier on acceptable terms or on a timely basis, or at all; and delays caused by supply issues may harm our reputation, frustrate our customers and cause them to turn to our competitors for future needs.

A significant portion of our cash and cash equivalents are held at a small number of banks.

A significant portion of our cash and cash equivalents is presently held at a small number of banks. Although our board has adopted a treasury policy requiring us to limit the amount of cash held by each banking group taking into account their credit ratings, we are subject to credit risk if any of these banks are unable to repay the balance in the applicable account or deliver our securities or if any bank should become bankrupt or otherwise insolvent. Any of the above events could have a material and adverse effect on our business, results of operations and financial condition.

Risks Related to Our Intellectual Property

We may not be able to adequately protect Epidiolex, Sativex, our product candidates or our proprietary technology in the marketplace.

Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We rely upon a combination of patents, plant variety rights, trade secret protection (i.e., know-how), and confidentiality agreements to protect the intellectual property of Epidiolex, Sativex and our product candidates. The strengths of patents in the pharmaceutical field involve complex legal and scientific questions, and can be uncertain. Where appropriate, we seek patent protection for certain aspects of our products and technology. However, patent protection for naturally occurring compounds is exceedingly difficult to obtain, defend and enforce. Filing, prosecuting and defending patents throughout the world would be prohibitively expensive, so our policy is to look to patent technologies with commercial potential in jurisdictions with significant commercial opportunities. However, patent protection may not be available for some of the products or technology we are developing. If we must spend significant time and money protecting, defending or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business, results of operations and financial condition may be harmed. We may not develop additional proprietary products that are patentable.

The patent positions of pharmaceutical products are complex and uncertain. The scope and extent of patent protection for Epidiolex, Sativex and our product candidates are particularly uncertain. To date, our principal product candidates, including Epidiolex and Sativex, have been based on specific formulations of certain previously known cannabinoids found in nature in the cannabis sativa plant. While we have sought patent protection, where appropriate, directed to, among other things, composition-of-matter for our specific formulations, their methods of use, and methods of manufacture, we do not have and will not be able to obtain composition of matter protection on these previously known cannabinoids per se. We anticipate that the products we develop in the future will continue to include or be based on the same or other naturally occurring compounds, as well as synthetic compounds we may discover. Although we have sought and expect to continue to seek patent protection for our product candidates, their methods of use, and methods of manufacture, any or all of them may not be subject to effective patent protection. For example, we are unable to obtain composition of matter patent protection for CBD, the active ingredient in Epidiolex, as it is a naturally occurring compound. To date, we have obtained from the USPTO nine patents and received notices of allowance in three applications that claim methods of using the active ingredient. We expect to be able to list several of these patents in the Orange Book as covering the indications and usage included in the approved label. We continue to prosecute a number of pending patent applications. If any of our products is approved and marketed for an indication for which we do not have an issued patent, our ability to use our patents to prevent a competitor from commercializing a non-branded version of our commercial products for that non-patented indication could be significantly impaired or even eliminated.

Publication of information related to Epidiolex, Sativex and our product candidates by us or others may prevent us from obtaining or enforcing patents relating to these products and product candidates. Furthermore, others may independently develop similar products, may duplicate our products, or may design around our patent rights. In addition, any of our issued patents may be opposed and/or declared invalid or unenforceable. Two of our recently issued European patents, including our European patent claiming the use of CBD in the treatment of partial seizures, have received a notice of opposition, which may result in claims in these patents being narrowed or cancelled such that the scope of the opposed patent may not be as broad, or the opposed patent may be revoked in its entirety. In one of the opposition proceedings, the opponent failed to show the patent invalid. The other opposition proceeding relating to CBD in the treatment of partial seizures resulted in an initial decision that is under appeal. One of our U.S. patents is involved in an *Inter Partes* Review proceeding before the USPTO that could result in the revocation of the claims of that patent. If we fail to adequately protect our intellectual property, we may face competition from companies who attempt to create a generic product to compete with Sativex or Epidiolex. We may also face competition from companies who develop a substantially similar product to Epidiolex, Sativex or one of our other product candidates that is not covered by any of our patents.

Many companies have encountered significant problems in protecting, defending and enforcing intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly

certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

If third parties claim that intellectual property used by us infringes upon their intellectual property, our operating profits could be adversely affected.

There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the pharmaceutical industry. We may, from time to time, be notified of claims that we are infringing upon patents, trademarks, copyrights or other intellectual property rights owned by third parties, and we cannot provide assurances that other companies will not, in the future, pursue such infringement claims against us, our commercial partners or any third-party proprietary technologies we have licensed. If we were found to infringe upon a patent or other intellectual property right, or if we failed to obtain or renew a license under a patent or other intellectual property right from a third party, or if a third party that we were licensing technologies from was found to infringe upon a patent or other intellectual property rights of another third party, we may be required to pay damages, including damages of up to three times the damages found or assessed, if the infringement is found to be willful, suspend the manufacture of certain products or reengineer or rebrand our products, if feasible, or we may be unable to enter certain new product markets. Any such claims could also be expensive and time consuming to defend and divert management's attention and resources. Our competitive position could suffer as a result. In addition, if we have declined or failed to enter into a valid non-disclosure or assignment agreement for any reason, we may not own the invention or our intellectual property, and our products may not be adequately protected. Thus, we cannot guarantee that Epidiolex, Sativex or our other product candidates, or our commercialization thereof, does not and will not infringe any third party's intellectual property.

Risks Related to Controlled Substances

Controlled substance legislation differs between countries and legislation in certain countries may restrict or limit our ability to sell Epidiolex, Sativex and our product candidates.

Most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances, including cannabis extracts. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to our obtaining regulatory approval for Epidiolex, Sativex and our other products in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit Epidiolex, Sativex or our other products to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time. In the case of countries with similar obstacles, we would be unable to market Epidiolex, Sativex and our product candidates in countries in the near future or perhaps at all if the laws and regulations in those countries do not change.

Epidiolex is and the product candidates we are developing will be subject to U.S. controlled substance laws and regulations and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition.

Epidiolex, Sativex and our product candidates we are developing contain controlled substances as defined in the federal Controlled Substances Act of 1970, or CSA. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, no currently "accepted medical use" in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. which contain a controlled substance are listed as Schedule II, III, IV or V,

with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

While cannabis is a Schedule I controlled substance, products approved for medical use in the U.S. that contain cannabis or cannabis extracts should be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If and when any of our product candidates receive FDA approval, the DEA will make a scheduling determination. Having now been rescheduled into Schedule V, the manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use of Epidiolex will still be subject to specific and potentially significant levels of regulation by the DEA. If any foreign regulatory authority determines that Epidiolex may have potential for abuse, or if FDA or DEA makes a similar determination for Sativex, it may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of that product.

DEA registration and inspection of facilities. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining the necessary registrations may result in delay of the importation, manufacturing or distribution of Sativex and/or Epidiolex or other products. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

State-controlled substances laws. Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule Epidiolex or our product candidates as well. State scheduling may delay commercial sale of Epidiolex or any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Clinical trials. Because our products are controlled substances in the U.S., to conduct clinical trials in the U.S., each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense our products and to obtain product from our importer. If the DEA delays or denies the grant of a research registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain an importer registration and an import permit for each import. We do not currently conduct any manufacturing or repackaging/relabeling of Sativex or its active ingredients (i.e., the cannabis extract) in the U.S.

Importation. If one of our product candidates is approved and classified as a Schedule II or III substance, an importer can import for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect product availability and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third party comments to be submitted. It is always possible that adverse comments may delay the grant of an importer registration.

If one of our product candidates is approved and classified as a Schedule II controlled substance, federal law may impose additional restrictions on importation for commercial purposes.

Manufacture in the U.S. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the U.S., our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of Epidiolex and Sativex, cannabis and the BDSs comprising the active ingredient in the final dosage form are currently Schedule I controlled substances and would be subject to such quotas as these substances could remain listed on Schedule I. The annual quota allocated to us or our contract manufacturers for the active ingredients in our products may not be sufficient to complete clinical trials or meet commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and operations.

Distribution in the U.S. If any of our product candidates is scheduled as Schedule II or III, we would also need to identify wholesale distributors with the appropriate DEA and state registrations and authority to distribute the product to pharmacies and other health care providers. We would need to identify distributors to distribute the product to pharmacies; these distributors would need to obtain Schedule II or III distribution registrations. The failure to obtain, or delay in obtaining, or the loss any of those registrations could result in increased costs to us. If any of our product candidates is a Schedule II drug, pharmacies would have to maintain enhanced security with alarms and monitoring systems and they must adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying either or both of these products. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

The legalization and use of medical and recreational marijuana in the U.S. and elsewhere may impact our business.

There is a substantial amount of change occurring in the U.S. regarding the use of medical and recreational marijuana products. While marijuana products not approved by FDA are Schedule I substances as defined under federal law, and their possession and use is not permitted according to federal law, at least 30 jurisdictions and the District of Columbia have enacted state laws to enable possession and use of marijuana for medical purposes, and at least ten jurisdictions for recreational purposes. A proposal in the U.S. Farm Bill, currently pending before the Senate could deschedule extracts and other material derived from certain hemp plants with extremely low THC content, although as proposed, the marketing of such products for medical purposes would still be subject to regulatory pre-marketing approval requirements and other FDA rules. Although our business is quite distinct from that of online and dispensary marijuana companies, future legislation authorizing the sale, distribution, use, and insurance reimbursement of non-FDA approved marijuana products could affect our business.

Exhibit 99.2

GW Pharmaceuticals Announces Proposed Public Offering of ADSs

London, UK, Carlsbad, CA, 1 October 2018: GW Pharmaceuticals plc (Nasdaq: GWPH, "GW," "the Company" or "the Group"), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform and whose U.S. subsidiary is Greenwich Biosciences, announced today that it intends to sell, subject to market and other conditions, $300 million of American Depositary Shares ("ADSs") representing ordinary shares of GW on the Nasdaq Global Market in an underwritten U.S. public offering. GW expects to grant the underwriters a 30-day option to purchase up to an additional $45 million of ADSs at the offering price. There can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering. The price for the offering has not yet been determined.

Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC, J.P. Morgan and Cowen and Company, LLC are acting as joint book-running managers for the offering.

The ADSs described above are being offered by GW pursuant to a shelf registration statement filed by GW with the Securities and Exchange Commission ("SEC") that became automatically effective on April 17, 2017. A preliminary prospectus supplement related to the offering will be filed with the SEC and will be available on the SEC's website at *http://www.sec.gov*. Copies of the preliminary prospectus supplement and the accompanying prospectus relating to this offering, when available, may be obtained from Goldman Sachs & Co. LLC, Attention: Prospectus Department, 200 West Street, New York, NY 10282, telephone: 1-866-471-2526, facsimile: 212-902-9316 or by emailing prospectusgroup-ny@ny.email.gs.com; Morgan Stanley & Co. LLC, Attention: Prospectus Department, 180 Varick Street, 2nd Floor, New York, New York 10014; J.P. Morgan Securities LLC, c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY 11717, or by telephone at (866) 803-9204, or Cowen and Company, LLC, c/o Broadridge Financial Solutions, 1155 Long Island Avenue, Edgewood, NY 11717, Attention: Prospectus Department, or by telephone at (631) 592-5973 or by emailing PostSaleManualRequests@broadridge.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

This press release is not directed to, or intended for distribution or use by, any person or entity that is a citizen or resident or located in any locality, state, country or other jurisdiction where such distribution, publication, availability or use would be contrary to law or regulation or which would require any registration or licensing within such jurisdiction.

The distribution of this press release may be restricted by law in certain jurisdictions. Persons into whose possession this announcement comes should inform themselves about and observe any such restrictions.

For readers in the European Economic Area

In any EEA Member State that has implemented the Prospectus Directive, this communication is only addressed to and directed at qualified investors in that Member State within the meaning of the Prospectus Directive. The term "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including Directive 2010/73/EU, to the extent implemented in each relevant Member State), together with any relevant implementing measure in the relevant Member State. This communication does not constitute a prospectus within the meaning of the Prospectus Directive and there will be no offer of securities to the public for the purposes of the Prospectus Directive.

For readers in the United Kingdom

This communication, in so far as it constitutes an invitation or inducement to enter into investment activity (within the meaning of s21 Financial Services and Markets Act 2000 as amended) in connection with the securities which are the subject of the offering described in this press release or otherwise, is being directed only at (i) persons who are outside the United Kingdom or (ii) persons who have professional experience in matters relating to investments who fall within Article 19(5) ("Investment professionals") of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order") or (iii) certain high value persons and entities who fall within Article 49(2)(a) to (d) ("High net worth companies, unincorporated associations etc") of the Order; or (iv) any other person to whom it may lawfully be communicated (all such persons in (i) to (iv) together being referred to as "relevant persons"). The ADSs are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such ADSs will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

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. The Company has submitted a regulatory application in Europe for the adjunctive therapy of seizures associated with LGS and Dravet syndrome. The company continues to evaluate EPIDIOLEX in additional rare epilepsy conditions and currently has ongoing clinical trials 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 Phase 2 trials for epilepsy, glioblastoma, autism spectrum disorder and schizophrenia.

Forward-looking statements

This news release contains forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding the amount of ADSs GW intends to sell. A further list and description of risks and uncertainties associated with an investment in GW can be found in GW's filings with the SEC, including the most recent annual report on Form 20-F filed on December 4, 2017. 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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