GW pharmaceuticals

The global leader in prescription cannabinoid medicines

Multiple Sclerosis

Cancer pain

Diabetes

Epilepsy

Schizophrenia

Annual Report 2013

Highlights 2013

Initial public offering on the NASDAQ Global Market completed in May 2013 raising total net proceeds before expenses of $30.7m (£19.8m)

Two US-targeted Sativex® Phase III pivotal programmes advanced in 2013

- Cancer Pain: two pivotal Sativex Phase III trials in recruitment
  - First Phase III top-line results expected in the second half of 2014
  - Data intended to lead to a New Drug Application ("NDA") filing with the US Food and Drug Administration ("FDA")
- Multiple Sclerosis ("MS"): Phase III Investigational New Drug ("IND") application opened with the FDA for Sativex in the treatment of MS spasticity
  - Special Protocol Assessment ("SPA") to be requested prior to anticipated start of Phase III trial in 2014
- All Sativex Phase III clinical trials targeted at FDA approval are fully funded by US partner, Otsuka
- Sativex US patent position further strengthened through two additional US Notices of Allowance

Sativex now approved in 22 countries (ex-US) as a treatment for MS spasticity

- In-market sales by partners increased by 25%
- Commercial launch in Italy in July 2013
- Germany pricing agreement reached in September 2013
- Recommendation for approval in France in October 2013
- Ongoing commercial launches in planning over next 12 months
- New Sativex data presented at ECTRIMS in October 2013

Expansion of epilepsy research program through commencement of a new orphan paediatric epilepsy program for Epidiolex® (purified extract of Cannabidiol, or CBD)

- FDA orphan drug designation granted by FDA for Epidiolex in Dravet syndrome
- Seven physician-led INDs granted by FDA to treat 125 paediatric epilepsy patients in the US with Epidiolex
- Epidiolex paediatric epilepsy clinical trials in planning for 2014
  Additional epilepsy pipeline candidate, GWP42006 (Cannabidivarin or CBDV), commenced Phase I trial in September 2013

Significant clinical activity for GW's other cannabinoid pipeline product candidates, including:

- Positive preliminary data reported from a Phase IIa exploratory clinical trial of the novel cannabinoid medicine GWP42004 in type 2 diabetes with a Phase II dose ranging trial expected to commence in early 2014
- Phase II trial of GWP42003 for the treatment of ulcerative colitis ongoing with data expected in the first half of 2014
- Phase II trial of GWP42003 for the treatment of schizophrenia expected to commence in the first half of 2014
- Phase Ib/IIa trial of THC:CBD for the treatment of glioma commenced in November 2013

Chairman and CEO's Statement

"We are pleased to report a highly successful year marked by the completion of an initial public offering of shares on the Nasdaq stock market."

We are pleased to report a highly successful year marked by the completion of an initial public offering of shares on the Nasdaq stock market, the advance of Phase III programs for Sativex in the United States, and the emergence of a new exciting orphan development program in childhood epilepsy. As we enter 2014, we believe that the Company is poised to meet a number of significant clinical, regulatory and commercial milestones for our investors.

In our 15 years of operations, we are proud that GW has established a world leading position in the development of plant-derived cannabinoid therapeutics and believe that Sativex and our other product candidates have the potential to address significant unmet medical needs across a diverse range of therapeutic areas. The new orphan epilepsy program which has emerged to the foreground during 2013 represents an important example of GW's corporate values in seeking to help patients with serious unmet needs, our close relationship with the medical community, the benefits of our lead position in cannabinoid science, and the multitude of opportunities for value creation within our platform.

We believe that our business is characterized by a compelling set of strengths, as follows:

- We have successfully commercialized our lead product, Sativex, and believe this provides important validation of our proprietary cannabinoid product platform.
- We are pursuing a significant late stage opportunity for Sativex in cancer pain, with Phase III trials underway to support a future filing in the US and other parts of the world.
- Our pipeline also includes clinical stage candidates targeting therapeutic areas such as type-2 diabetes, ulcerative colitis, schizophrenia, and cancer.
- We have collaborations with major pharmaceutical companies for Sativex.
- We benefit from a strong competitive position in a highly specialized and regulated field.

This past year has seen progress which reflects the broad scope of these strengths. We have achieved solid recruitment into our Phase III trials program for Sativex in cancer pain, which comprises three global trials and is expected to involve over 1,000 patients. We have opened an IND from the FDA to allow us to proceed into Phase III for the MS Spasticity indication for the US market. We have seen steady volume growth of Sativex in-market sales and further regulatory approvals of this important medicine. In addition, a key objective of the $30 million Nasdaq offering was to accelerate investment in our product pipeline and we are now making clinical progress across the key pipeline candidates. From a strategic perspective, the Nasdaq offering has also allowed the company to reduce our historic reliance upon out-licensing and partner-funding of our research. In some cases, the balance of risk versus reward and the cost of future development will dictate that out-licensing of certain product candidates will remain appropriate but we now expect to develop and retain commercial rights to selected valuable pipeline assets, including the orphan pediatric epilepsy program.

We are mindful of the considerable interest in Epidiolex, our liquid formulation of purified cannabidiol (CBD), among U.S. pediatric epilepsy specialists and patient organizations. In parallel with our plans to advance a sponsored clinical development program in 2014, we have made arrangements to provide Epidiolex in the near term to patients under expanded access INDs from the FDA. In 2013, seven INDs were granted by the FDA to independent U.S. clinicians to allow treatment of approximately 125 pediatric epilepsy patients with Epidiolex and we are aware of further interest from additional U.S. physicians to host similar INDs.

Chairman and CEO's Statement continued

"In 2014, we believe that GW is poised to meet a number of significant milestones for our investors."

Above: The GW management and support team at the NASDAQ bell ring ceremony to celebrate the Company's IPO on the NASDAQ Global Market on 1 May 2013.

Our ability to respond to these INDs results from the extensive pre-clinical and clinical safety information that GW has generated on CBD over several years.

In 2014, we believe that GW is poised to meet a number of significant milestones for our investors. The Sativex Phase III cancer pain program will continue to advance towards completion and we also expect to initiate the Phase III trial designed to obtain approval of the MS spasticity indication in the U.S. We expect further regulatory approvals and commercial launches for Sativex outside the U.S. We also expect material pipeline progress with clinical activity in the orphan epilepsy program and plan to expand our portfolio of orphan cannabinoid opportunities. In addition, we look forward to Phase II data for our ulcerative colitis product candidate, and clinical trials advancing for product candidates in glioma, type-2 diabetes, and schizophrenia.

During the 2013 financial year, the Board of Directors appointed Christopher Tovey to the newly created position of Chief Operating Officer and Cabot Brown as a non-executive director. Mr Tovey brings a wealth of commercial experience from more than 25 years in the pharmaceutical industry, including most recently as Vice President Global Marketing Operations at UCB Pharmaceuticals. Mr Brown brings more than 30 years of experience in the financial industry specialising in the health care sector and sits on the Nominations, Audit, and Remuneration Committees.

Finally, we should like to thank our dedicated staff and management team for their commitment to our Company and for their hard work and considerable achievements during the course of this year. We look forward to continued progress in 2014.

Dr Geoffrey W Guy
Chairman
25 November 2013

Justin Gover
Chief Executive Officer
25 November 2013

As filed with the Securities and Exchange Commission on November 25, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended September 30, 2013

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File Number 001-35892

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

England and Wales
(Jurisdiction of incorporation or organization)

Porton Down Science Park, Salisbury
Wiltshire, SP4 0JQ
United Kingdom
(Address of principal executive offices)

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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing 12 Ordinary Shares, par value £0.001 per share	The Nasdaq Global Market

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 177,521,287 ordinary shares, par value £0.001 per share.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐

International Financial Reporting Standards as issued by the International Accounting Standards Board ☒

Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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GENERAL INFORMATION

In this annual report on Form 20-F ("Annual 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.

PRESENTATION OF FINANCIAL AND OTHER DATA

The consolidated financial statement data as at September 30, 2013 and 2012 and for the years ended September 30, 2013, 2012 and 2011 have been derived from our consolidated financial statements, as presented elsewhere in this Annual Report, which have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, and as adopted by the European Union and audited in accordance with the standards of the Public Company Accounting Oversight Board (United States). The consolidated financial statement data as at September 30, 2011 and for the year ended September 30, 2010 have been derived from our consolidated financial statements, which are not presented herein, which have also been prepared in accordance with IFRS as issued by the IASB, and as adopted by the European Union and audited in accordance with the standards of the Public Company Accounting Oversight Board (United States).

The consolidated financial data as at September 30, 2010 and 2009 and for the year ended September 30, 2009 has been derived, after certain reclassifications to conform to the current presentation, from our consolidated financial statements, which have been prepared in accordance with IFRS as adopted by the European Union, or IFRS-EU, and which are not included elsewhere in this prospectus. These consolidated financial statements have not been audited in accordance with the standards of the Public Company Accounting Oversight Board (United States). There are no differences applicable to us between IFRS as issued by the IASB and IFRS-EU for any of the periods presented herein.

All references in this prospectus to "$" are to U.S. dollars, all references to "£" are to pounds sterling and all references to "€" are to Euros. Solely for the convenience of the reader, unless otherwise indicated, all pounds sterling amounts as at and for the year ended September 30, 2013 have been translated into U.S. dollars at the rate at September 30, 2013, the last business day of our year ended September 30, 2013, of £0.6181 to $1.00. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as at that or any other date.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains estimates and forward-looking statements, principally in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Some of the matters discussed concerning our operations and financial performance include estimates and forward-looking statements within the meaning of the Securities Act and the Exchange Act.

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;
- manufacturing and commercialization;

- patents, including, but not limited to, legal challenges;
- government regulation and approval, including, but not limited to, the expected regulatory approval dates for Sativex;
- future revenue being lower than expected;
- the level of pricing and reimbursement for our products;
- increasing competitive pressures in the industry;
- general economic conditions or conditions affecting demand for the services offered by us in the markets in which it operates, both domestically and internationally, being less favorable than expected;
- fluctuations in the price of raw materials and utilities;
- currency fluctuations and hedging risks;
- worldwide economic and business conditions and conditions in the industries in which we operate;
- our relationships with our customers and suppliers;
- increased competition from other companies in the industries in which we operate;
- changing technology;
- claims for personal injury or death arising from the use of products 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;
- regulatory, environmental, legislative and judicial developments;
- our intention 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" and "Operating and Financial Review and Prospects," or elsewhere in this Annual Report. 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 Annual 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 Annual 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.

PART I

Item 1 Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2 Offer Statistics and Expected Timetable

Not applicable.

Item 3 Key Information

A. Selected Financial Data

The following table summarizes our consolidated financial data as at the dates and for the periods indicated. The consolidated financial statement data as at September 30, 2013 and 2012 and for the years ended September 30, 2013, 2012 and 2011 have been derived from our consolidated financial statements, as presented elsewhere in this Annual Report, which have been prepared in accordance with IFRS, as issued by the IASB, and as adopted by the European Union and audited in accordance with the standards of the Public Company Accounting Oversight Board (United States), The consolidated financial statement data as at September 30, 2011 and for the year ended September 30, 2010 have been derived from our consolidated financial statements, which are not presented herein, which have also been prepared in accordance with IFRS as issued by the IASB, and as adopted by the European Union and audited in accordance with the standards of the Public Company Accounting Oversight Board (United States).The selected consolidated financial data as at September 30, 2010 and 2009 and for the year ended September 30, 2009 has been derived, after certain reclassifications to conform to the current presentation, from our consolidated financial statements, which have been prepared in accordance with IFRS-EU, and which are not included elsewhere in this Annual Report. These consolidated financial statements have not been audited in accordance with the standards of the Public Company Accounting Oversight Board (United States). There are no differences applicable to us between IFRS as issued by the IASB and IFRS-EU for any of the periods presented herein.

Our consolidated financial statements are prepared and presented in pounds sterling, our presentation currency. Solely for the convenience of the reader our consolidated financial statements as at and for the year ended September 30, 2013 have been translated into U.S. dollars at $1.00 = £0.6181 based on the certified foreign exchange rates published by Federal Reserve Bank of New York on September 30, 2013. Such convenience translation should not be construed as a representation that the pound sterling amounts have been or could be converted into U.S. dollars at this or at any other rate of exchange, or at all.

Our historical results are not necessarily indicative of the results that may be expected in the future. The following selected consolidated financial data should be read in conjunction with our

audited consolidated financial statements included elsewhere in this Annual Report and the related notes and Item 5, "Operating and Financial Review and Prospects" below.

	Year Ended September 30,					
	2013	2013(1)	2012(1)	2011(1)	2010(1)	2009(2)
	$	£	£	£	£	£
	(in thousands, except per share data)					
Income Statement Data:						
Revenue	44,158	27,295	33,120	29,627	30,676	24,121
Cost of sales	(2,064)	(1,276)	(839)	(1,347)	(752)	(433)
Research and development expenditure	(52,897)	(32,697)	(27,578)	(22,714)	(22,145)	(19,649)
Management and administrative expenses	(6,135)	(3,792)	(3,660)	(3,298)	(3,267)	(3,015)
Operating (loss)/profit	(16,938)	(10,470)	1,043	2,268	4,512	1,024
Interest expense	(104)	(64)	(1)	(3)	(8)	(8)
Interest income	288	178	200	263	100	136
(Loss)/profit before tax	(16,754)	(10,356)	1,242	2,528	4,604	1,152
Tax	9,395	5,807	1,248	221	37	353
(Loss)/profit for the year	(7,359)	(4,549)	2,490	2,749	4,641	1,505
(Loss)/earnings per share						
Basic	(0.05)	(0.03)	0.02	0.02	0.04	0.01
Diluted	(0.05)	(0.03)	0.02	0.02	0.03	0.01
Weighted average number of shares						
Basic	151.5	151.5	133.0	131.7	129.7	122.3
Diluted	158.2	158.2	137.5	135.8	133.2	127.9

	As at September 30,					
	2013	2013(1)	2012(1)	2011(1)	2010(2)	2009(2)
	$	£	£	£	£	£
			(in thousands)			
Balance Sheet Data:						
Non-current assets	17,288	10,686	7,642	7,078	6,776	7,068
Current assets						
Inventories	7,541	4,661	3,537	1,424	780	551
Trade and other receivables	8,944	5,528	2,408	2,281	1,217	811
Cash and cash equivalents	61,588	38,069	29,335	28,319	25,219	20,601
Total current assets	78,072	48,258	35,280	32,024	27,216	22,323
Total assets	95,360	58,944	42,922	39,102	33,992	29,391
Current liabilities						
Trade and other payables	(15,272)	(9,440)	(9,114)	(6,562)	(4,554)	(4,496)
Deferred revenue	(5,146)	(3,181)	(2,449)	(3,459)	(5,120)	(4,594)
Non-current liabilities						
Obligations under finance leases	(3,082)	(1,905)	—	—	(6)	(45)
Deferred revenue	(14,424)	(8,916)	(10,127)	(11,422)	(11,599)	(13,499)
Share capital	288	178	133	133	131	129
Share premium	135,903	84,005	65,947	65,866	64,433	63,755
Net assets/Total equity	57,274	35,402	21,232	17,652	12,673	6,722

	Year Ended September 30,					
	2013	2013(1)	2012(1)	2011(1)	2010(1)	2009(2)
	$	£	£	£	£	£
			(in thousands)			
Cash Flow Data:						
Net cash inflow/(outflow) from operating activities	(12,080)	(7,468)	1,801	2,361	4,324	1,220
Net cash (outflow)/inflow from investing activities	(3,359)	(2,076)	(1,060)	(647)	(334)	(934)
Net cash inflow from financing activities	29,529	18,253	73	1,393	620	6,261

(1) The selected historical consolidated financial data as at September 30, 2013 and 2012 and for the years ended September 30, 2013, 2012, 2011 and 2010 have been derived from our consolidated financial statements, which have been prepared in accordance with IFRS as issued by the IASB and as adopted by the European Union, and audited in accordance with the standards of the Public Company Accounting Oversight Board (United States).

(2) The selected historical consolidated financial data as at September 30, 2010 and 2009 and for the year ended September 30, 2009 has been derived, after certain reclassifications to conform to the current presentation, from our consolidated financial statements, which have been prepared in accordance with IFRS-EU and which are not included elsewhere in this Annual Report. Reclassifications made impacted on the presentation of our share-based payment charge in our consolidated income statement. Such reclassification had no impact on operating profit, profit before tax or profit for the year. There are no differences applicable to us between IFRS as issued by the IASB and IFRS-EU for any of the periods presented herein. These consolidated financial statements have not been audited in accordance with the standards of the Public Company Accounting Oversight Board (United States).

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the offer and use of proceeds

Not applicable.

D. Risk Factors

Investing in the ADSs involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this Annual Report, including our consolidated financial statements and the related notes, before investing in the ADSs. The risks and uncertainties described below are those significant risk factors, currently known and specific to us that we believe are relevant to an investment in the ADSs. If any of these risks materialize, our business, results of operations or financial condition could suffer, the price of the ADSs could decline and you could lose part or all of your investment. Additional risks and uncertainties not currently known to us or that we now deem immaterial may also harm us and adversely affect your investment in the ADSs.

Risks Related to Our Business

We are substantially dependent on the success of our only commercial product Sativex.

Our future success will depend heavily on the continued successful commercialization of Sativex, which is now in the early stages of its commercial life. Although Sativex is currently approved in 22 countries outside of the United States for spasticity due to multiple sclerosis, or MS, and is sold in 11 of those countries, it may never be successfully commercialized in all of these jurisdictions. Sativex's commercial success depends on a number of factors beyond our control, including the willingness of

physicians to prescribe Sativex to patients, payers' willingness and ability to pay for the drug, the level of pricing achieved, patients' response to Sativex and the ability of our marketing partners to generate sales. Accordingly, we cannot assure you that we will succeed in generating revenue growth through the commercialization of Sativex for MS spasticity. If we are not successful in the continued commercialization of Sativex, our business, results of operations and financial condition will be materially harmed.

We are dependent on the success of our product candidates, including Sativex for cancer pain, none of which may receive regulatory approval or be successfully commercialized.

Our success will depend on our ability to successfully commercialize our product pipeline, including commercialization of Sativex for cancer pain, currently in Phase 3 trials, and our other cannabinoid product candidates for type-2 diabetes, ulcerative colitis, cancer, epilepsy and schizophrenia. We are evaluating Sativex in Phase 3 trials for the treatment of cancer pain in the United States and it may never receive U.S. regulatory approval. We have met with, and received guidance from, the U.S. Food and Drug Administration, or FDA, regarding the development program for Sativex for MS spasticity in the United States, and have opened an Investigational New Drug Application, or IND, with the FDA for this indication. However, we may never receive U.S. regulatory approval for this indication either. Even if completed Phase 3 clinical trials and/or Phase 3 clinical trials conducted for U.S. approval show positive results, there can be no assurance that the FDA will approve Sativex for any given indication for several potential reasons, including failure to follow Good Clinical Practice, or GCP, negative assessment of risk:benefit, unacceptable risk of abuse or diversion, insufficient product quality control and standardization, non-GMP compliant manufacturing facilities, unreliable dose counter, and failure to agree on appropriate clinical endpoints. For example, discussions with the FDA about its recommended primary endpoints for a pivotal study in MS spasticity are expected to lead to use of the Modified Ashworth Scale (MAS) and the Physician Global Impression of Change (PGIC) rather than the primary endpoints we used in our previous Phase 3 studies. In those studies, we demonstrated statistical improvements on the PGIC and approached statistical significance on the MAS. The new proposed study is powered to detect a statistical difference on both endpoints.

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

- successfully complete pre-clinical and clinical trials;
- 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 Sativex, the related Botanical Drug Substances, or BDSs, and our product candidates to permit successful commercialization;
- establish collaborations with third parties for the commercialization of our product candidates, or otherwise build and maintain strong sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates;
- obtain reimbursement from payers such as government health care systems and insurance companies, as well as achieve commercially attractive levels of pricing;
- secure acceptance of Sativex and our product candidates from physicians, health care payers, patients and the medical community;
- create positive publicity surrounding Sativex and our other product candidates;

- manage our spending as costs and expenses increase due to clinical trials and commercialization; and
- obtain and enforce sufficient intellectual property for Sativex and our other product candidates.

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

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 significant revenue depends on the acceptance of our products by physicians and patients. Although Sativex is already known in certain markets for the treatment of MS spasticity, we cannot assure you that it or our other planned products will achieve the expected 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 approved by regulatory authorities in the product label, continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product, reimbursement from third-party payers such as government health care systems and insurance companies, the price of the product, the nature of any post-approval risk management plans mandated by regulatory authorities, competition, and marketing and distribution support. 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 orphan 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.

The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. There is no assurance that we will successfully obtain orphan drug exclusivity for any of our product candidates. Even if we do obtain orphan drug exclusivity for any product candidate, orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective, or if the manufacturer is unable to assure sufficient quantity of the drug. Moreover, a different drug or, under limited circumstances, the same drug, may be approved by the FDA for the same orphan indication during the period of marketing exclusivity. The limited circumstances include an inability to supply the drug in sufficient quantities or where the second drug has been shown to be 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.

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

The shipment, import and export of Sativex and our product candidates require import and export licenses. In the United States, the FDA, U.S. Customs and Border Protection, and the Drug Enforcement Administration, or 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 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 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 Sativex or our other product candidates. A partial or total loss of revenue from one or more shipment of Sativex or our other product candidates could have a material adverse effect on our business, results of operations and financial condition.

If we fail to obtain and sustain an adequate level of reimbursement for our products by third-party payers, sales and profitability would be adversely affected.

The course of medical treatment for patients is and will continue to be expensive. We expect that most patients and their families will not be capable of paying for our products themselves. There will be no commercially viable market for Sativex or our other product candidates without reimbursement from third-party payers. Additionally, even if there is a commercially viable market, if the level of third-party reimbursement is below our expectations, our revenue and gross margins will be adversely affected.

Third-party payers, such as government programs, including Medicare, or private health care insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for medical products and services, and many third-party payers limit coverage of or reimbursement for newly approved health care products. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. A current trend in the U.S. health care industry as well as in other countries around the world is toward cost containment. Large public and private payers, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. In particular, third-party payers may limit the covered indications. Cost-control initiatives could decrease the price we might establish for any product, which could result in product revenue and profitability being lower than anticipated. For example, in March 2013, the German National Association of Statutory Health Insurance Funds imposed a price reduction for Sativex in Germany effective for sales from July 1, 2012. This price reduction adversely affected our Sativex sales in our 2013 fiscal year results by £1.1 million due to the recognition of a £1.1 million provision for a rebate we expect to pay to our commercial partner, Almirall, following the pricing decision in Germany. Subsequently, in September 2013, the German authorities agreed to increase the price from the previously reduced level with effect from January 1, 2014, albeit not to the level at which the product had been launched in that country. Future cost-control initiatives in Germany or other markets could have a material adverse effect on our business, results of operations and financial condition.

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

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Our partners 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 which 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, in Germany, a revised price has caused us to initiate the renegotiation of supply terms with our partner, Almirall, in order to maintain a level of profitability of our sales of Sativex in Germany. In addition, in Australia, we have not yet obtained public reimbursement for Sativex, which may lead to our partner, Novartis, deciding not to launch in that country or elsewhere in the region for which they have commercial rights until reimbursement is obtained. Future price decreases or unfavorable reimbursement decisions 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 use in clinical trials. The manufacturing of Sativex necessitates compliance with international Good Manufacturing Practice, or GMP, and other international regulatory requirements. Our ability to successfully manufacture Sativex involves cultivation of botanical raw material from specific cannabinoid plants under highly controlled and standardized conditions, extraction and purification processes, manufacture of finished products and labeling and packaging, which includes product information, tamper evidence and anti-counterfeit features. In addition, we must ensure therapeutic 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, we are currently reliant on single manufacturing facilities and no back-up facilities are yet in place. 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. If we are unable to manufacture Sativex or other product candidates in accordance with regulatory specifications, 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 the current demand for Sativex or supply sufficient product for use in clinical trials, and this may also harm our ability to commercialize Sativex and our product candidates on a timely or cost-competitive basis, if at all. In addition, we are in the process of expanding and upgrading parts of our manufacturing facilities in order to meet future demand and FDA requirements, a program which requires significant time and resources. We also expect to expand and upgrade other parts of our manufacturing facilities in the future. These activities may lead to delays, interruptions to supply, or may prove to be more costly than anticipated. Any problems in our manufacturing process could have a material adverse effect on our business, results of operations and financial condition.

In addition, under the Sativex license agreements, we generate revenue from the supply of commercial product to our partners at a fixed percentage of partners' net sales, and hence any increases in our manufacturing costs will adversely affect our margins and our financial condition.

In addition, before we can begin commercial manufacture of Sativex for sale in the United States, we must obtain FDA regulatory approval for the product, which requires a successful FDA inspection of our manufacturing facilities, processes and quality systems in addition to other product-related approvals. Further, pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA and foreign regulatory authorities, before and after product approval. Due to the complexity of the processes used to manufacture Sativex and 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.

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

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. For example, during the manufacturing process we have from time to time experienced defects in components which have caused vial sealing faults, resulting in vial leakage, pump dispenser faults which have resulted in under-filling of vials and misalignment of labels and tamper evident seals. While product batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. Most of our products must be stored and transported at temperatures within a certain range, which is known as "strict cold chain" storage and transportation. If these environmental conditions deviate, our products' remaining shelf-lives could be impaired or their efficacy and safety could become adversely affected, making them no longer suitable for use. 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.

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

Since Sativex and our 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, Sativex and our product candidates. These pressures could also limit or restrict the introduction and marketing of 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 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, stored inventory or laboratory facilities through fire 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, 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. Excluding receipts from milestone fees, our cash flow used for operating activities for the years ended September 30, 2013 and September 30, 2012 was £7.7 million and £8.0 million, respectively. We expect our operating and management and administrative expenses and cash used for operations to continue to be significant and to increase substantially in connection with our planned research, development and continued product

commercialization efforts and as we establish ourselves as a U.S. public company. Over the next two years, excluding receipts from product sales, milestone fees and any potential fees resulting from new business development activity, we estimate that cash flow used for operating expenses will be approximately £30.0 million. We may need to raise additional capital to fund our operations and continue to conduct clinical trials to support potential regulatory approval of marketing applications.

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 Sativex and our other product candidates, if at all;
- the timing and amount of revenue from sales of Sativex, 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 commercial manufacturing supply arrangements for Sativex and 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;
- the continuation of our existing collaboration agreements;
- 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 cash flow from operations, including milestone and other payments from our partners, we cannot assure you that any of these funding sources will be available to us on favorable terms, or at all.

The presence or absence of one or more new large orders in a specific quarter, our ability to process orders or the cancellation of previous orders may cause our results of operations to fluctuate significantly on a quarterly basis.

We supply products to our commercial partners in response to their monthly purchase order schedules. Historically, the size of each purchase order has fluctuated. As a result, the presence or absence in a specific quarter of one or more new large orders or delays in our ability to process large orders or the cancellation of previous orders may cause our results of operations to fluctuate on a quarterly basis. These fluctuations may be significant from one quarter to the next. Any demands that require us to quickly increase production may create difficulties for us. In addition, our limited commercial history and the characteristic of our orders in any quarterly period make it very difficult to accurately predict or forecast our future operating results.

We are exposed to risks related to currency exchange rates.

We conduct a significant portion of our operations outside the United Kingdom. Because our financial statements are presented in pounds sterling, changes in currency exchange rates have had and

could have a significant effect on our operating results. Exchange rate fluctuations between local currencies and the pound sterling create risk in several ways, including the following: weakening of the pound sterling may increase the pound sterling cost of overseas research and development expenses and the cost of sourced product components outside the United Kingdom; strengthening of the pound sterling may decrease the value of our revenues denominated in other currencies; the exchange rates on non-sterling transactions and cash deposits can distort our financial results; and commercial Sativex pricing and profit margins are affected by currency fluctuations.

If product liability lawsuits are successfully brought against us, we will incur substantial liabilities and may be required to limit the commercialization of 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 market and distribute Sativex. We may face exposure to claims by an even greater number of persons if we begin marketing and distributing our products commercially in the United States and elsewhere, including those relating to misuse of Sativex. Now, and in the future, an individual may bring a liability claim against us alleging that 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. 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 Sativex and our other 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.

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 loss of the services of any member of our senior management, including our Chairman, Dr. Geoffrey Guy, our Chief Executive Officer, Justin Gover and our Research and Development Director, Dr. Stephen Wright, or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results. Because of 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.

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, Sativex competes with, and our other therapeutics, 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. If we are unable to compete successfully, we may be unable to grow and sustain our revenue.

If we are unable to use net operating loss carryforwards 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 entity, we are subject to U.K. corporate taxation. At September 30, 2013, we had cumulative carry forward tax losses of £33.6 million. These are available to carry forward and offset against future operating profits. As a company that carries out extensive research and development activities, we benefit from the U.K. research and development tax credit regime, whereby we are able to surrender losses that arise from research and development activity for a cash rebate that equals 24.75% of the eligible research and development expenditure. We also expect to benefit in the future from the new "patent box" initiative, which started to come into effect in the United Kingdom in April 2013. This initiative effectively allows profits attributable to revenue from patented products to be taxed at a lower rate than other revenues that over time will be reduced to 10%. When taken in combination with the enhanced relief available on our research and development expenditure, we expect that this will result in a long-term low rate of corporation tax. If, however, there are unexpected adverse changes to the U.K. research and development tax credit regime or "patent box" initiative, 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. 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 United States, 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 U.K., U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Failure of our information technology systems could significantly disrupt the operation of our business.

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. These 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 back-up 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 have taken to prevent unanticipated problems that could affect our IT systems, 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.

Legislative or regulatory reform of the health care system in the United States 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 payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of 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 United States 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, enacted in the United States in March 2010, substantially changes the way healthcare is financed by both governmental and private insurers.

We expect further federal and state proposals and health care reforms to continue to be proposed by legislators, 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 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 PPACA and by other health care reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put 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 6 to 12 months or longer after the receipt of regulatory marketing 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, or effectively manage the combined business following the acquisition. 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.

Risks Related to Our Reliance Upon Third Parties

We depend substantially on the commercial expertise of our collaboration partners.

We do not have a sales and marketing operation and rely on the expertise and commercial skills of our collaboration partners to sell Sativex. We have entered into agreements for the commercialization of Sativex with Almirall S.A., or Almirall, in Europe (excluding the United Kingdom) and Mexico; Otsuka in the United States; Novartis Pharma AG, or Novartis, in Australia and New Zealand, Asia (excluding Japan, China and Hong Kong), the Middle East (excluding Israel) and Africa; Bayer HealthCare AG in the United Kingdom and Canada; and Neopharm Group in Israel. Our ability to successfully market and sell Sativex in each of these markets depends entirely on the expertise and commercial skills of our collaboration partners. Our partners have the right, under certain circumstances, to terminate their agreements with us, and three of our partners, Almirall, Otsuka and Novartis, have the right to terminate their agreements with us without cause. A failure by our partners to successfully market Sativex, or the termination of agreements with our partners, will have a material adverse effect on our business, results of operations and financial condition.

We rely heavily on Otsuka for funding of our research and development programs and overhead, and Otsuka is a joint owner of the intellectual property resulting from our pre-clinical research collaboration.

We rely heavily on our relationship with Otsuka for the funding of our research and development programs and for overhead expenses. Under the terms of our agreement with Otsuka with respect to Sativex in the United States, Otsuka funds all pre-clinical and clinical trials for the development of Sativex in the treatment of cancer pain. As provided for under the terms of this agreement, we also expect Otsuka to fund pre-clinical and clinical trials required for the development of Sativex in the treatment of MS spasticity in the United States. If Otsuka were to terminate this agreement, we would be required to find alternative funding for our clinical program for the development of Sativex in the treatment of cancer pain and MS spasticity or face substantial delays in, or possible termination of, that program. In addition, under a separate global research collaboration for research of cannabinoids in central nervous system, or CNS, and oncology, we received funds from Otsuka from 2007 to June 2013. The term of this research collaboration agreement with Otsuka ended in June 2013 and we expect an increase in our GW-funded research and development expenditure as a result of this change.

In addition, the research collaboration agreement provided that all intellectual property rights (including both patents and non-manufacturing related know-how) that was conceived by either Otsuka or us during the course of the collaboration is to be jointly owned by Otsuka and us. We have 11 patent families with 219 jointly owned patent applications relating to our collaboration with Otsuka, including those directed to the use of Sativex in the CNS and/or oncology field or that are otherwise relevant to Sativex. Because Otsuka exercises some control over this jointly owned intellectual property, we may need to seek Otsuka's consent to pursue, use, license and/or enforce some of this collaboration intellectual property in the future. In addition, Otsuka has the right to develop and commercialize a synthetic cannabinoid molecule product (a molecule not based on a phytocannabinoid but which has an effect on the endocannabinoid system) subject to payment of a royalty to us. An unexpected deterioration in our relationship with Otsuka would have a material adverse effect on our business, reputation, results of operations and financial condition.

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 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 our current and potential product candidates, including for the commercialization of Sativex. We may 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 United States and internationally. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish, implement and maintain collaborations or other alternative arrangements if we choose to enter into such arrangements. 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.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We depend on a limited number of suppliers for materials and components required to manufacture Sativex and our other 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 Sativex and our other product candidates. For example, we rely on single-source suppliers to supply various components of Sativex, including the glass vial, pump actuator and dose counter. In addition, we rely on a single contractor for commercial supply of botanical raw material. 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; 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 Development and Regulatory Approval of Sativex and Our Product Candidates

Clinical trials for our product candidates are expensive, time consuming, uncertain and susceptible to change, delay or termination.

Clinical trials are expensive, time consuming and difficult to design and implement. 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, an Institutional Review Board, or IRB, or other regulatory authorities, including state and local, may suspend, delay or terminate our clinical trials at any time, 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;
- 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;
- 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; or
- failure to design appropriate clinical trial protocols; or regulatory concerns with cannabinoid products generally and the potential for abuse.

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

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 instance, because a large percentage of subjects in our pivotal trials for Sativex in cancer pain are being enrolled at sites outside the United States, differences in efficacy results between U.S. and ex-U.S. sites could cause the FDA to require additional trials. In the event that we obtain negative results from the Sativex cancer pain Phase 3 trials or from the planned Phase 3 clinical trial of Sativex for MS spasticity or cannot reach agreement with the FDA on the design of the Phase 3 trial for MS spasticity, or receive poor clinical results for our other product candidates, or the FDA places a clinical hold on our Phase 3 trials due to potential Chemistry, Manufacturing and Controls issues or other hurdles or does not approve our New Drug Application, or NDA, for Sativex, 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 will be materially impaired, our reputation in the industry and in the investment community would likely be significantly damaged and the price of our ADSs would likely decrease significantly.

Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our product candidates, or limit the scope of any approved label or market acceptance.

If 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 Risk Evaluation and Mitigation Strategy, or REMS, in connection with approval, if any;
- regulatory authorities may withdraw their approval, require more onerous labeling statements or impose a more restrictive REMS of 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.

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. To date, we have only voluntarily suspended clinical trials when recruitment of the target patients has proven to be too difficult. 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 Sativex or any other 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 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.

Our ability to research, develop and commercialize 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 34 countries. Although we have an established track record of successfully obtaining such licenses as required, this may change in the future.

In the United States, the DEA regulates the cultivation, possession and supply of cannabis for medical research and/or commercial development, including the requirement of annual registrations to manufacture or distribute pharmaceutical products derived from cannabis extracts. We do not currently conduct any manufacturing or repackaging/relabeling of either Sativex or its active ingredients, or any product candidates, in the United States. In the event that we sought to do so in the future, a decision to manufacture, or supply cannabis extracts for medical research or commercial development in the United States would require that we and/or our contract manufacturers maintain such registrations, and be subject to other regulatory requirements such as manufacturing quotas, and if the DEA failed to issue or renew such registrations, we would be unable to manufacture and distribute any product in the United States on a commercial basis.

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 Sativex or in markets where we have product candidates progressing through the approval process. We must adhere to all regulatory requirements including the FDA's Good Laboratory Practice, current Good Manufacturing Practice, or cGMP, and Good Clinical Practice requirements. 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.

If Sativex, or any of our other product candidates, is approved in the United States, it will be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information, including both federal and state requirements in the United States. In addition, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. 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 cGMP. 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. As such, we may not promote our products for indications or uses for which they do not have FDA approval.

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, a regulatory agency 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 closing our contract manufacturers' facilities, if any; or
- seize or detain products or require a product recall.

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 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 will be adversely affected. Additionally, if we are unable to generate revenue from sales of Sativex, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

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.

The anticipated development of a REMS for Sativex and our other product candidates could cause delays in the approval process and would add additional layers of regulatory requirements that could impact our ability to commercialize Sativex and our other product candidates in the United States and reduce their market potential.

As a condition of approval of an NDA, the FDA may require a REMS 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 elements to assure safe use, or 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 Sativex and our other product candidates to ensure that the benefits outweigh the risks of abuse, misuse, diversion and other potential safety concerns. Even if abuse, misuse and diversion are not as high as for other cannabinoid products, there can be no assurance that the FDA will approve a manageable REMS for Sativex and our product candidates, which could create material and significant limits on our ability to successfully commercialize Sativex and our product candidates in the United States. 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 Sativex and 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, Sativex and 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.

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.

After we obtain marketing approval for our products in the United States, if any, we will be 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 United States. 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 government regulations, 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, these laws are broadly written, and 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. False claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payers, including government payers, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the provision of kickbacks has resulted in the submission of false claims to governmental health care programs. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying,

concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. 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 payers. In addition, California and a few other states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals. In addition, several states impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. 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.

Risks Related to Controlled Substances

Controlled substance legislation differs between countries and legislation in certain countries may restrict or limit our ability to sell 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 marketing approval for 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 Sativex or our other products to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time. For example, we are currently unable to file a regulatory application in Mexico due to a national law which the regulators consider prevents the approval of a cannabis-based medicine. Until recently, France had similar legal obstacles in place preventing the filing of a regulatory application for Sativex, but that legal obstacle was satisfactorily resolved in 2013 and the French regulatory authorities have recently recommended approval of Sativex. In the case of countries with similar obstacles, we would be unable to market 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.

Sativex and the other 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.

Sativex and certain 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 United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be 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 United States that contain cannabis or cannabis extracts must be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If and when Sativex receives FDA approval, the DEA will make a scheduling determination and place it in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. If approved by the FDA, we expect the finished dosage form of Sativex to be listed by the DEA as a Schedule II or III controlled substance. Consequently, its manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will be subject to a significant degree of regulation by the DEA. In addition, the scheduling process may take one or more years, thereby delaying the launch of Sativex in the United States. Furthermore, if the FDA, DEA, or any foreign regulatory authority determines that Sativex may have potential for abuse, 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 Sativex.

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. 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 Sativex and our product candidates as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of 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 Sativex contains cannabis extracts, which are Schedule I substances, to conduct clinical trials with Sativex in the United States prior to approval, 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 Sativex and to obtain the 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 a Schedule I importer registration and an import permit for each import. We do not currently conduct any manufacturing or repackaging/relabeling of either Sativex or its active ingredients (i.e., the cannabis extract) in the United States. Sativex is imported in its fully-finished, packaged and labeled dosage form.

Importation. If Sativex 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 the availability of Sativex 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.

If Sativex is approved and classified as a Schedule II controlled substance, federal law may prohibit the import of the substance for commercial purposes. If Sativex is listed as a Schedule II substance, we will not be allowed to import the drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. Moreover, Schedule I controlled substances, including BDSs, have never been registered with the DEA for importation commercial purposes, only for scientific and research needs. Therefore, if neither Sativex nor its BDSs could be imported, Sativex would have to be wholly manufactured in the United States, and we would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity.

Manufacture in the United States. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the United States, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of 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 ingredient in Sativex may not be sufficient to meet commercial demand or complete clinical trials. 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 United States. If Sativex is scheduled as Schedule II or III, we would also need to identify wholesale distributors with the appropriate DEA 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 Sativex 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, coupled with the fact that Sativex must be

refrigerated, may discourage some pharmacies from carrying the product. 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 approval and use of "medical marijuana" in the U.S. may impact our business.

There is a substantial amount of change occurring in various states of the United States regarding the use of "medical marijuana." While marijuana is a Schedule 1 substance as defined under federal law, and its possession and use is not permitted according to federal law, a number of individual states have enacted state laws to enable possession and use of marijuana for medical purposes, and in some states for recreational purposes also. Our business is quite distinct from that of crude herbal marijuana, however, our prospects may be impacted by developments of these laws at the state level in the United States.

Risks Related to Our Intellectual Property

We may be forced to litigate to enforce or defend our intellectual property rights, and/or the intellectual property rights of our licensors.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors, and to protect our trade secrets. In so doing, we may place our intellectual property at risk of being invalidated, unenforceable, or limited or narrowed in scope. Further, an adverse result in any litigation or defense proceedings may place pending applications at risk of non-issuance. In addition, if any licensor fails to enforce or defend their intellectual property rights, this may adversely affect our ability to develop and commercialize our product candidates and prevent competitors from making, using, and selling competing products. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence and/or outcome of any such litigation could harm our business, results of operations and financial condition. Further, because the content of much of our intellectual property concerns cannabis and other activities that are not legal in some state jurisdictions, we may face additional difficulties in defending our intellectual property rights.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ADSs.

We may not be able to protect 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, trade secret protection (i.e., know how), and confidentiality agreements to protect the intellectual property of Sativex and our product candidates. The strengths of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. Where appropriate, we seek patent protection for certain aspects of our products and technology. Filing, prosecuting and defending patents throughout the world would be prohibitively expensive, so our policy is to patent commercially potential technology 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 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 Sativex and our product candidates are particularly uncertain. To date, our principal product candidates, including Sativex, have been based on specific formulations of certain previously known cannabinoids found in nature in the cannabis sativa plant. 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. Publication of information related to 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 declared invalid. 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. We may also face competition from companies who develop a substantially similar product to 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 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.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection, or failure to adequately protect our intellectual property could enable competitors to develop generic products or use our proprietary information to develop other products that compete with our products or cause additional, material adverse effects upon our business, results of operations and financial condition.

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 United States, 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 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 triple damages 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 to enter into a valid non-disclosure or assignment agreement for any reason, we may not own the invention or our intellectual property and may not be adequately protected. Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to Sativex, we have not conducted a full freedom-to-operate search or analysis for Sativex, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing Sativex. Thus, we cannot guarantee that Sativex, or our commercialization thereof, does not and will not infringe any third party's intellectual property.

Risks Related to Ownership of our American Depositary Shares (ADSs) and Ordinary Shares

The price of our ADSs and ordinary shares may be volatile.

Many factors may have a material adverse effect on the market price of the ADSs, including, but not limited to:

- the loss of any of our key scientific or management personnel;
- announcements of the failure to obtain regulatory approvals or receipt of a complete response letter from the FDA;
- announcements of restricted label indications or patient populations, or changes or delays in regulatory review processes;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to Sativex and our product candidates;
- any adverse changes to our relationship with licensors, manufacturers or suppliers;
- the failure of our testing and clinical trials;
- the failure to retain our existing, or obtain new, collaboration partners;
- announcements concerning our competitors or the pharmaceutical industry in general;
- the achievement of expected product sales and profitability;
- the failure to obtain reimbursements for our products or price reductions;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- our cash position;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions;

- the trading volume of ADSs on Nasdaq and of our ordinary shares on the Alternative Investment Market, or AIM;
- sales of our ADSs or ordinary shares by us, our executive officers and directors or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the United States equity markets; and
- changes in accounting principles.

In addition, the stock market in general, and Nasdaq in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may negatively affect the market price of our ADSs, regardless of our actual operating performance.

The liquidity of our ADSs and ordinary shares may have an adverse effect on share price.

As at September 30, 2013, we had 177,521,487 ordinary shares outstanding. 43,741,692 of these shares are held as ADSs and 133,779,795 held as ordinary shares (which are not held in the form of ADSs). In connection with our May 2013 initial public offering, or IPO, of ADSs on the Nasdaq Global Market, we issued 3,678,000 million ADSs. There is a risk that there may not be sufficient liquidity in the market to accommodate significant increases in selling activity or the sale of a large block of our securities. Our ADSs have historically had limited trading volume, which may also result in volatility.

Additionally, our ADSs are traded on Nasdaq and our ordinary shares are traded on the AIM. We cannot predict the effect of this dual listing on the value of our ordinary shares and ADSs. However, the dual listing of our ordinary shares and ADSs may dilute the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the United States. The price of the ADSs could also be adversely affected by trading in our ordinary shares on the AIM. We may decide in the future to delist our ordinary shares from the AIM. We cannot predict the effect such delisting of our ordinary shares would have on the market price of the ADSs.

Securities traded on the AIM may carry a higher risk than shares traded on other exchanges that may impact the value of your investment.

Our ordinary shares are currently traded on the AIM. Investment in equities traded on the AIM is perceived to carry a higher risk than an investment in equities quoted on exchanges with more stringent listing requirements, such as the London Stock Exchange, New York Stock Exchange or Nasdaq. This is because the AIM imposes less stringent corporate governance and ongoing reporting requirements than those other exchanges. In addition, the AIM requires only semi-annual, rather than quarterly, financial reporting. You should be aware that the value of our ordinary shares may be influenced by many factors, some of which may be specific to us and some of which may affect AIM-listed companies generally, including the depth and liquidity of the market, our performance, a large or small volume of trading in our ordinary shares, legislative changes and general economic, political or regulatory conditions, and that the prices may be volatile and subject to extensive fluctuations. Therefore, the market price of our ordinary shares underlying the ADSs may not reflect the underlying value of our company.

Substantial future sales of our ordinary shares or the ADSs in the public market, or the perception that these sales could occur, could cause the price of the ADSs to decline.

Sales of our ordinary shares or ADSs in the public market, or the perception that these sales could occur, could cause the market price of the ADSs to decline. The ordinary shares held by our directors,

including our officers, are available for sale since the lock-up period at the time of the Nasdaq IPO has now expired. If any of our large shareholders or members of our management team seek to sell substantial amounts of our ADSs, particularly if these sales are in a rapid or disorderly manner, or other investors perceive that these sales could occur, the market price of our ADSs could decrease significantly.

You may not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise your right to vote.

As a holder of ADSs, you will not have the right to vote the shares underlying the ADSs directly unless you cancel the ADS in accordance with the terms of the Deposit Agreement and vote the underlying shares at the applicable shareholders meeting. Holders of the ADSs will appoint the depositary or its nominee as their representative to exercise the voting rights attaching to the ordinary shares represented by the ADSs. You may not receive voting materials in time to instruct the depositary to vote, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

You may not receive distributions on our ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.

The depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of your ADSs.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the Securities and Exchange Commission than U.S. companies. This may limit the information available to holders of the ADSs.

We are a "foreign private issuer," as defined in the Securities and Exchange Commission's, or SEC, rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the United States. For example, we are exempt from certain rules under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

As a foreign private issuer, we will file an annual report on Form 20-F within four months of the close of each year ended September 30 and reports on Form 6-K relating to certain material events promptly after we publicly announce these events. However, because of the above exemptions for foreign private issuers, our shareholders will not be afforded the same protections or information generally available to investors holding shares in public companies organized in the United States.

As a foreign private issuer, we are not subject to certain Nasdaq corporate governance rules applicable to U.S. listed companies.

We rely on a provision in Nasdaq's Listed Company Manual that allows us to follow English corporate law and the Companies Act 2006 with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on Nasdaq.

For example, we are exempt from Nasdaq regulations that require a listed U.S. company to:

- have a majority of the board of directors consist of independent directors;
- require non-management directors to meet on a regular basis without management present;
- promptly disclose any waivers of the code for directors or executive officers that should address certain specified items;
- have an independent nominating committee;
- solicit proxies and provide proxy statements for all shareholder meetings; and
- seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares.

As a foreign private issuer, we are permitted to, and we will, follow home country practice in lieu of the above requirements.

In accordance with our Nasdaq listing, our Audit Committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and Rule 10A-3 of the Exchange Act, both of which are also applicable to Nasdaq-listed U.S. companies. Because we are a foreign private issuer, however, our Audit Committee is not subject to additional Nasdaq requirements applicable to listed U.S. companies, including an affirmative determination that all members of the Audit Committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer.

If we fail to establish and maintain proper internal controls, our ability to produce fairly presented financial statements or comply with applicable regulations could be impaired.

Section 404(a) of the Sarbanes-Oxley Act, requires that beginning with our annual report for the year ending September 30, 2014, management assess and report annually on the effectiveness of our internal controls over financial reporting and identify any material weaknesses in our internal controls over financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal controls over financial reporting, we are an "emerging growth company," as defined in the Jumpstart Our Business Start-ups Act of 2012, or the JOBS Act, and have elected to take advantage of the exemption from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. This may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected and may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find the ADSs less attractive because we may rely on these exemptions. We will not be required to comply with SEC rules that implement Section 404(b) of the Sarbanes-Oxley Act until the earlier of such time as we are no longer an emerging growth company or our annual report for our year ending September 30, 2018.

The presence of material weaknesses could result in financial statement errors which, in turn, could lead to errors in our financial reports, delays in our financial reporting, we could require us to restate our operating results or our auditors may be required to issue a qualified audit report. We might not identify one or more material weaknesses in our internal controls in connection with

evaluating our compliance with Section 404(a) of the Sarbanes-Oxley Act. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If either we are unable to conclude that we have effective internal controls over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal controls over financial reporting as required by Section 404(b) of the Sarbanes-Oxley Act, investors may lose confidence in our operating results, the price of our ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, we may not be able to remain listed on the Nasdaq.

We incur significant increased costs as a result of operating as a company whose ADSs are publicly traded in the United States, and our management is required to devote substantial time to new compliance initiatives.

As a company whose ADSs commenced trading in the United States in May 2013, we incur significant legal, accounting, insurance and other expenses which we did not previously incur. In addition, the Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform, Consumer Protection Act and related rules implemented by the SEC and Nasdaq, have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs, relative to companies that are listed solely in the United Kingdom, and make some activities more time-consuming and costly. We estimate that our annual compliance expenses are approximately £1.0 million in each of the next two fiscal years. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially civil litigation.

U.S. investors may have difficulty enforcing civil liabilities against our Company, our directors or members of senior management and the experts named in this Annual Report.

Our directors and the experts named in this Annual Report are non-residents of the United States, and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Mayer Brown International LLP, our English solicitors, advised us that there is doubt as to whether English courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in the United Kingdom. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in the United Kingdom will depend on the particular facts of the case as well as the laws and treaties in effect at the

time. The United States and the United Kingdom do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the Companies Act 2006, and by our Articles. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations. See "Description of Share Capital—Differences in Corporate Law" in this Annual Report for a description of the principal differences between the provisions of the Companies Act 2006 applicable to us and, for example, the Delaware General Corporation Law relating to shareholders' rights and protections.

Item 4 Information On The Company

A. History and Development of the Company

GW Pharmaceuticals plc was founded in 1998 is a public limited company incorporated under the laws of England and Wales. Since June 28, 2001, our ordinary shares have been listed on the Alternative Investment Market, or AIM, a market operated by London Stock Exchange plc, under the symbol GWP. On May 1, 2013, we completed our initial public offering of American Depositary Shares, or ADSs, on the Nasdaq Global Market. Our ADSs are traded under the symbol GWPH.

Our registered and principal executive offices are located at Porton Down Science Park, Salisbury, Wiltshire, SP4 0JQ, United Kingdom, our general telephone number is (+44) 198 055-7000 and our internet address is http://www.gwpharm.com. Our website and the information contained on or accessible through our website are not part of this document. Our agent for service of process in the United States is CT Corporation System, 111 Eighth Avenue, 13th Floor, New York, NY 10011.

In the three year period ended September 30, 2013, we have invested a total of £6.2 million in equipment and facilities. In addition, in our year ended September 30, 2013 we used finance lease arrangements to fund certain items of laboratory equipment costing £2.6 million. We have recently entered into contracts for the construction, fitout and 20 year lease of a new 10,000 square feet manufacturing facility and expect to enter into an operating lease for a further 3,261 square feet of property within the near term. The rental cost, under the terms of the operating lease for these facilities is expected to be £0.4 million per annum. In addition, the landlord has agreed to provide up to £7.8 million of fit-out funding, which will be repaid via additional rental payments of £1.0 million per annum over the first 15 years of the lease. The fit-out improvement funding will be accounted for as a finance lease, reflecting the financing nature of this transaction.

We have not received any takeover offers from third parties, nor have we made any offers to acquire the business of any third parties.

Since incorporation in 2001, there have been no changes to our company name, or to the way in which we conduct our business. Since our incorporation, we have traded solvently and have not been subject to any bankruptcy proceedings.

B. Business Overview

Business 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. In our 14 years of operations, 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 our regulatory and manufacturing expertise. We commercialized the world's first plant-derived cannabinoid prescription drug, Sativex®, which is approved for the treatment of spasticity due to multiple sclerosis, or MS, in 22 countries outside the United States. We are also evaluating Sativex in a Phase 3 program for the treatment of cancer pain, and we anticipate that top-line results from at least one of the two ongoing pivotal Phase 3 trials will be available towards the end of 2014. Top-line results from the second pivotal Phase 3 trial are expected shortly after the first Phase 3 trial. This program is intended to support the submission of a New Drug Application, or NDA, for Sativex in cancer pain with the U.S. Food and Drug Administration, or FDA, and in other markets around the world. We believe that MS spasticity also represents an attractive indication for Sativex in the United States and in August 2013 we opened an Investigational New Drug Application, or IND, with the FDA to pursue a Phase 3 clinical development program for this significant opportunity. We expect to commence a pivotal U.S. Phase 3 trial in 2014. If successful, we intend to submit the results of that study, along with the foreign clinical data collected in our clinical development program for MS spasticity to date, in an NDA for MS spasticity. We have a deep pipeline of additional cannabinoid product candidates, including orphan drug opportunities with a particular focus on pediatric epilepsy. In November 2013, we received Orphan Drug Designation from the FDA for Epidiolex®, our proprietary product candidate that contains plant-derived CBD as its active ingredient, for the treatment of Dravet syndrome, a severe infantile-onset, genetic, drug-resistant epilepsy syndrome. We expect to advance further orphan drug opportunities in the next 12 months. Our product pipeline also includes compounds in Phase 1 and 2 clinical development for glioma, ulcerative colitis type-2 diabetes and schizophrenia.

Our lead product, Sativex, is an oromucosal spray consisting of a formulated extract of the cannabis sativa plant that contains the principal cannabinoids delta-9-tetrahydrocannabinol, or THC, and cannabidiol, or CBD. We are evaluating Sativex in a Phase 3 program to treat persistent pain in people with advanced cancer who experience inadequate pain relief from optimized chronic opioid therapy, the current standard of care. This program represents the lead target indication for Sativex in the United States and is based on positive data from two Phase 2 trials of Sativex involving over 530 patients in this indication. According to Fallon, et al. in the March/April 2006 edition of Clinical Medicine, pain is uncontrolled with opioid treatments in approximately 20% of patients with advanced cancer, or 420,000 people in the United States. There are currently no approved non-opioid treatments for patients who do not respond to, or experience negative side effects with, opioid medications. We believe that Sativex has the potential to address a significant unmet need in this large market by treating patients with a product that employs a differentiated non-opioid mechanism of action, and offers the prospect of pain relief without increasing opioid-related adverse side effects. Our ongoing Phase 3 program is being conducted under an Investigational New Drug Application, or IND, and consists of three clinical trials, the first two of which are expected to enroll 760 patients in total and are intended to form the basis of the NDA. These two Phase 3 trial protocols mirror our Phase 2b trial of Sativex with respect to patient population and treatment duration, and employ a primary efficacy endpoint which yielded statistically significant results in favor of Sativex in both Phase 2 trials. The costs of the Phase 3 program are fully funded by Otsuka Pharmaceutical Co. Ltd., or Otsuka.

Sativex is commercially available for the treatment of MS spasticity in 11 countries outside the United States. We have also received regulatory approval for Sativex for MS spasticity in 11 additional countries, and we anticipate commercial launches in the majority of these countries in the next

12 months. Two additional countries have recommended approval for Sativex in this indication and regulatory filings are under review in 10 other countries. While we believe that MS spasticity represents an attractive indication for the United States, we also believe that cancer pain is the optimal entry point for Sativex in the United States from a commercial and regulatory perspective since we performed our MS spasticity pre-clinical and clinical program outside of the United States, and we anticipate that we will be required to conduct an additional development program prior to the submission of an NDA with the FDA for this indication. In August 2013, we opened an IND to conduct a pivotal efficacy and safety clinical trial to evaluate Sativex for the treatment of MS spasticity. The FDA provided initial feedback on design features necessary for the study to serve as a pivotal study in our development program. Consistent with the FDA's recommendations, we expect to submit a request for Special Protocol Assessment, or SPA, to the FDA in the near future prior to commencing this Phase 3 trial in 2014. According to the World Health Organization, MS affects 1.3 million people worldwide, of which up to 80% suffer from spasticity, a symptom of MS characterized by muscle stiffness and uncontrollable spasms. There is no cure for spasticity, and it is widely recognized that currently available oral treatments afford only partial relief and have unpleasant side effects. Sativex offers the prospect of treating patients who have failed existing oral therapies and who might otherwise require invasive and costly alternative treatment options.

The cannabis plant is the unique source of more than 70 structurally related plant-derived cannabinoids. Although one cannabinoid, THC, is known to cause psychoactive effects associated with the use of illicit herbal cannabis, none of the other cannabinoids are known to share this property. In recent decades, there have been major scientific advances that have led to the discovery of new plant-derived cannabinoids and a cannabinoid receptor system in the human body, known as the endocannabinoid system. We are at the forefront of this new area of science and our research into a large number of these cannabinoids suggests that each has distinct pharmacological effects and potential therapeutic applications.

Our proprietary cannabinoid product platform consists of a continually evolving library of internally generated novel cannabis plant types that produce selected cannabinoids, discovery of novel cannabinoid pharmacology through our worldwide network of leading scientists, our intellectual property portfolio, in-house formulation, processing and manufacturing capabilities, and development and regulatory expertise. We believe that our proprietary cannabinoid product platform uniquely positions us to discover and develop cannabinoids as new therapeutics, and we are evaluating the potential for cannabinoids in the treatment of type-2 diabetes, ulcerative colitis, disorders of the central nervous system, or CNS, including epilepsy and schizophrenia, cancer, and neurodegenerative disease.

We believe that the successful development and regulatory approval of Sativex provides important validation of our proprietary cannabinoid product platform. In addition to Sativex, we are developing other cannabinoid product candidates, including orphan drug opportunities with an initial focus on pediatric epilepsy. According to Russ in the February 2012 edition of Pediatrics, 6.3 per 1,000 children are currently diagnosed with epilepsy. Based on these findings, we estimate that there are 466,000 childhood epilepsy patients in the United States and 765,000 patients in Europe, of which an estimated 20%, or 93,200 patients in the United States and 153,000 in Europe, are deemed medically intractable. Although we do not have a commercial IND open for Epidiolex, in 2013, the FDA granted seven expanded access INDs to independent investigators in the United States to treat a total of approximately 125 children suffering from intractable epilepsy with Epidiolex, our liquid formulation of a highly purified CBD extract.

In November 2013, we received Orphan Drug Designation for Epidiolex for the treatment of Dravet syndrome, a severe infantile-onset, genetic, drug-resistant epilepsy syndrome for which there are currently no FDA approved treatments. According to Dravet et al in the 2012 edition of Epileptic Syndromes in Infancy, Childhood and Adolescence, up to 5% of epilepsies diagnosed in the first year of life are Dravet syndrome, equating to an estimated 5,440 patients in the United States and 6,710

patients in Europe under the age of 20. It is likely that these figures will be an underestimate as this syndrome is underdiagnosed. We expect to hold a pre-IND meeting with the FDA in the near future to discuss the investigational plan for Epidiolex in Dravet syndrome, and we expect to commence clinical development in 2014. In addition to Dravet syndrome, we expect to apply for Orphan Drug Designation for Epidiolex for other pediatric epilepsy syndromes. Our epilepsy product candidates also include GWP42006, which features CBDV as the primary cannabinoid and which has shown anti-epileptic properties in pre-clinical studies. In the second half of 2013, we advanced GWP42006 into a Phase 1 trial. Beyond epilepsy-related orphan diseases, in October 2013 we commenced a Phase 1b trial of our GWP42002:GWP42003 product in the treatment of recurrent glioblastoma, or GBM, a particularly aggressive brain tumor which is considered an orphan disease by the FDA and the European Medicines Agency. According to the New England Journal of Medicine, GBM accounts for approximately 46% of the 22,500 new cases of brain cancer diagnosed in the United States each year. We expect to advance at least one further orphan drug opportunity in the next 12 months.

Our cannabinoid product pipeline also includes GWP42004, which has completed a Phase 2a trial in the treatment of dyslipidemia in subjects with type-2 diabetes. Although, in this small trial, GWP42004 did not show a benefit in lipid control, GWP42004 did show some evidence of anti-diabetic effects. We plan to initiate a Phase 2 dose-ranging trial in early 2014 of GWP42004 to further explore the evidence of anti-diabetic effects seen in the earlier trial. In addition, we are developing GWP42003, a cannabinoid which has shown anti-inflammatory properties in pre-clinical studies. GWP42003 is currently in a Phase 2 trial for ulcerative colitis for which we expect data in the first half of 2014. We expect at least one additional program to advance into Phase 2 clinical trials in the next 12 months. Our early clinical development activities are conducted outside of the United States and we expect to submit INDs in the United States for our product candidates at a later stage in their development. For orphan product candidates, we generally expect to submit INDs in the United States at an earlier stage of clinical development.

Our commercialized product and key ongoing development programs are shown in the tables below:

Product/Product Candidates	Indication	Partner(s)	Status	Expected Next Steps
Sativex	MS spasticity	Otsuka, Almirall, Novartis, Bayer and Neopharm	Approved in 22 countries	U.S. Phase 3 trial to commence in 2014. Additional ex-U.S. submissions, approvals and launches
Sativex	Cancer pain	Otsuka, Almirall, Novartis, Bayer and Neopharm	Phase 3 program ongoing	Phase 3 data towards the end of 2014
GWP42004	Type-2 diabetes	We retain global rights	Phase 2a trial complete	Phase 2 dose ranging trial to commence in the first half of 2014
GWP42003	Ulcerative colitis	We retain global rights	Phase 2 trial ongoing	Phase 2 data in the first half of 2014
GWP42003	Schizophrenia	We retain global rights	Phase 1	Phase 2a to commence in the first half of 2014
GWP42006	Epilepsy	We retain global rights	Phase 1	Phase 1 data in the first half of 2014

Our current and proposed orphan drug development programs are shown in the table below:

Product/Product Candidates	Indication	Partner(s)	Status	Expected Next Steps
Epidiolex	Pediatric epilepsy Initial targets: Dravet syndrome and Lennox-Gastaut syndrome	We retain global rights	Orphan Drug Designation granted by FDA for Dravet syndrome. INDs granted by FDA to outside investigators	Open sponsor IND in Dravet syndrome and commence Phase 2 trial. Obtain additional orphan drug designations.
Combination of GWP42002 and GWP42003	Glioblastoma	We retain global rights	Phase 1b trial ongoing	Phase 1b data from initial phase of trial in 2014
Intravenous GWP42003	Neonatal Hypoxic-Ischemic Encephalopathy	We retain global rights	Pre-clinical	Apply for Orphan Drug Designation

To support the development and commercialization of Sativex, we have entered into license and development agreements with the following major pharmaceutical companies in selected territories: Otsuka in the United States; Almirall S.A., or Almirall, in Europe (excluding the United Kingdom) and Mexico; Novartis Pharma AG, or Novartis, in Australia and New Zealand, Asia (excluding Japan, China and Hong Kong), the Middle East (excluding Israel) and Africa; Bayer HealthCare AG, or Bayer, in the United Kingdom and Canada; and Neopharm Group, or Neopharm, in Israel. These agreements provide our collaborators with the sole right to commercialize Sativex in exclusive territories for all indications. From our incorporation through September 30, 2013, these agreements have yielded cash of £67.5 million in upfront fees and milestone payments. In addition, we are entitled to receive up to an additional £201 million in potential payments upon the achievement of regulatory and commercial milestones. Upon commercialization, we are also entitled to receive revenue from the supply of products and royalties on product sales. In addition, under the terms of our agreement with Otsuka, all pre-clinical and clinical costs associated with the development of Sativex in the United States are fully funded by Otsuka.

Our Strengths

We are a leading biopharmaceutical company focused on discovering, developing and commercializing novel plant-derived cannabinoid therapeutics. We believe that we offer the following key distinguishing characteristics:

- *Commercialized lead product and validated development and regulatory pathway.* We believe that the successful development and regulatory approval of Sativex in MS spasticity provides important validation of our proprietary cannabinoid product platform. Sativex for MS spasticity is now approved in 22 countries outside of the United States, recommended for approval in two countries, and submitted for approval in ten additional countries. On this basis, we believe we can expand the approved indications for Sativex and develop a portfolio of additional cannabinoid therapeutics.
- *Significant late stage opportunity in cancer pain, a large market.* We are currently evaluating Sativex in a Phase 3 program to support the submission of an NDA in the United States and regulatory applications across other parts of the world for the treatment of advanced cancer pain. Our Phase 3 program follows positive Phase 2 data from clinical trials of Sativex involving over 530 patients. Our ongoing Phase 3 program consists of three clinical trials, the first two of which are expected to enroll 760 patients in total and are intended to form the basis of the NDA. These two Phase 3 trial protocols mirror our Phase 2b trial with respect to patient population and treatment duration, and employ a primary efficacy endpoint which yielded statistically significant results in both Phase 2 trials. The Phase 3 trials are fully funded by Otsuka, and we anticipate that top-line results from at least one of the Phase 3 trials will be available towards the end of 2014.
- *Additional late stage opportunity in the United States for MS spasticity.* Sativex is approved for MS spasticity in 22 countries outside the United States. We believe that MS spasticity represents an attractive indication for Sativex in the United States and we will be required to conduct an additional development program prior to the submission of a separate NDA with the FDA for this indication. In August 2013, we opened an IND to the FDA for a proposed Phase 3 trial in the MS spasticity indication and expect this trial to commence in 2014.
- *A new emerging pipeline of cannabinoid orphan drug opportunities for which we retain global commercial rights.* In November 2013, we received orphan drug designation for Epidiolex in the treatment of Dravet syndrome, a severe, infantile-onset, genetic, drug-resistant epilepsy syndrome. Also in 2013, the FDA granted seven INDs to independent investigators in the United States in 2013 to treat a total of approximately 125 children suffering from intractable

epilepsy. We are aware of other independent investigators in the United States who also intend to apply to the FDA for INDs to treat their patients with Epidiolex. We do not currently have a commercial IND open for Epidiolex and we now intend to apply for a commercial IND initially for Dravet syndrome and subsequently to seek commercial INDs for other potential orphan drug indications, including Lennox-Gastaut syndrome. We have also commenced a Phase 1b trial of a product to treat GBM, an aggressive brain tumor and potential orphan drug indication, and also plan on advancing at least one further cannabinoid orphan drug opportunity during 2014.

- *Opportunity for first-in-class treatments across a large number of therapeutic targets.* We are at the forefront of the commercialization of cannabinoid therapeutics using our proprietary product platform to identify, validate and develop innovative first-in-class therapeutics that are designed to meet significant unmet medical needs. Sativex and each of our other product candidates represent a novel approach and aim to provide benefits that are superior to existing treatment options, by providing efficacy where current treatments have failed and/or offering an improved safety profile. We believe our cannabinoid research may yield new product candidates in a broad range of diseases, including in the treatment of type-2 diabetes, ulcerative colitis, CNS disorders, including epilepsy and schizophrenia, cancer and neurodegenerative disease.
- *Collaborations with major global pharmaceutical companies for Sativex.* We have entered into collaboration agreements for Sativex, including with Otsuka, Almirall, Novartis and Bayer. From our incorporation through September 30, 2013, we have received cash of £67.5 million in upfront fees and milestones. In addition, we are eligible to receive up to an additional £201 million in potential milestone payments, plus product supply revenue and royalties upon commercialization. In addition, Otsuka is required to fund all pre-clinical and clinical research activities towards achieving FDA approval for Sativex in all indications.
- *Strong competitive position in a highly specialized and regulated field.* We believe we are uniquely positioned to benefit from the significant potential within the field of cannabinoid therapeutics in which we have developed a successful track record and expertise during our 15 years of operations. In addition, we believe the highly specialized area of research and high degree of international regulations by governmental authorities, create substantial barriers to entry. We have an intellectual property portfolio including 46 patent families with issued and/or pending claims directed to plants, plant extracts, extraction technology, pharmaceutical formulations, drug delivery and the therapeutic uses of cannabinoids. Supplementing our traditional intellectual property, we own plant variety rights and possess a significant body of know-how and trade secrets pertaining to plant breeding and growing.
- *In-house manufacturing capabilities and expertise in controlled substances.* We operate under good manufacturing practice, or GMP, commercial manufacturing licenses in the United Kingdom, which give us the capability to supply our products to global markets. We have successfully exported cannabinoid commercial or research materials to 34 countries and have substantial expertise in, and experience with, relevant international and national regulations in relation to the research, distribution and commercialization of cannabinoid therapeutics.
- *Highly experienced management team and network of leading scientists.* Several members of our leadership team have been in place for over ten years. We have a fully integrated in-house research and development organization, regulatory capabilities and commercial manufacturing expertise. As of September 30, 2013, our work force of 194 staff included 111 in research and development, 43 in manufacturing and operations, 23 in quality control and quality assurance and 17 in commercial and administrative functions. We closely collaborate with a broad network of leading scientists in the cannabinoid field, including 31 academic institutions in eight countries.

Our Proprietary Cannabinoid Product Platform

We believe we have established a world leading position in cannabinoid therapeutics through our proven proprietary cannabinoid product platform. Our platform consists of a continually evolving library of internally generated novel cannabis plant types that produce selected cannabinoids, discovery of novel cannabinoid pharmacology through our network of world leading scientists, an intellectual property portfolio, in-house formulation, processing and manufacturing capabilities, and development and regulatory expertise. We further believe that we are in a unique position to develop and manufacture plant-derived cannabinoid formulations worldwide at sufficient quality, uniformity, scale and sophistication for the purposes of pharmaceutical development and to meet international regulatory requirements.

Cannabinoid Science Overview

Although one cannabinoid, THC, is known to cause psychoactive effects associated with the use of illicit herbal cannabis, none of the other cannabinoids are known to share these properties. In recent decades, there have been major scientific advances that have led to the discovery of new plant-derived cannabinoids and the endocannabinoid system. We are at the forefront of this new area of science and our research into a large number of these cannabinoids suggests that each has distinct pharmacological effects and potential therapeutic applications.

Our research to date has focused on the following plant-based cannabinoids:

THC (Delta-9 Tetrahydrocannabinol)
D8-THC (Delta-8 Tetrahydrocannabinol)
THCA (Tetrahydrocannabinol—Acid)
THCV (Tetrahydrocannabivarin)
THCVA (Tetrahydrocannabivarin—Acid)
CBD (Cannabidiol)
CBDA (Cannabidiol—Acid)
CBDV (Cannabidivarin)
CBDVA (Cannabidivarin—Acid)
CBC (Cannabichromene)
CBG (Cannabigerol)
CBGA (Cannabigerol—Acid)
CBGV (Cannabigerovarin)
CBN (Cannabinol)
CBNV (Cannabinovarin)

Initial academic research in the field of cannabinoid science focused almost exclusively on THC. It has been widely published in scientific literature that THC has pain suppression, anti-spasmodic, anti-tremor, anti-inflammatory, appetite stimulant and anti-nausea properties. Our research and development, however, has focused primarily on exploring cannabinoids other than THC and identifying potential therapeutic applications of these other cannabinoids. We have focused particularly on CBD, which has shown in pre-clinical testing conducted by us and supported by publications in scientific literature to have anti-inflammatory, anti-convulsant, anti-psychotic, anti-oxidant, neuroprotective and immunomodulatory effects. In addition, we believe CBD is not intoxicating as evidenced by its distinct pharmacology from THC as well as evidence from clinical trials. In particular, the intoxicating effects of THC result from its activity as a partial agonist at the CB1 receptor; CBD does not have this same pharmacologic activity. There is a significant body of scientific literature on the properties of CBD, which consistently describes CBD as a cannabinoid without psychotropic effects. Furthermore, according to publications in scientific literature, in particular pre-clinical research published by Zuardi, et al. in the Journal of Psychopharmacology 1982 and clinical research published by Karniol, et al. in the European Journal of Pharmacology 1974, research suggests that the presence of CBD may mitigate some of the side-effects of THC. We have also identified important pharmacological effects of other cannabinoids, such as the anti-convulsant effects of CBDV, anti-diabetic effects of THCV, anti-nausea effects of CBDA and anti-cancer effects of CBG.

There are at least two types of cannabinoid receptors, CB1 and CB2, in the human endocannabinoid system. CB1 receptors are considered to be among the most widely expressed G protein-coupled receptors in the brain and are particularly abundant in areas of the brain concerned with movement and postural control, pain and sensory perception, memory, cognition, emotion, autonomic and endocrine function. CB1 receptors are also found in peripheral tissues including peripheral nerves and non-neuronal tissues such as muscle, liver tissues and fat. CB2 receptors are expressed primarily in tissues in the immune system and are believed to mediate the immunological effects of cannabinoids. In addition, research suggests the endocannabinoid system interacts with other important neurotransmitter and neuromodulatory systems in the human body, including TRP channels, adenosine uptake, and serotonin receptors. We believe that the far-reaching and diverse pharmacology of the numerous cannabinoids provides significant potential for development of cannabinoid therapeutics across many indications and disease areas.

Our Product Development Approach

Our approach to early product development of novel cannabinoids consists of the following stages:

Cannabinoid Chemotype Development. Our research activities commence with the generation of novel and proprietary cannabinoid plant types that produce selected cannabinoids. Our plant geneticists breed unique and protected "chemotypes," or plants characterized by their chemical content, such that we can precisely control the cannabinoid composition of a plant. We employ traditional methods of plant breeding, with no use of genetic modification. We select chemotypes on the basis of their cannabinoid profile, appropriate levels of concentration and botanical characteristics that enable commercial viability. We seek protection for chemotypes in the form of plant variety rights, which protect the plants and the material obtained therefrom in Europe.

Extract Preparation. After we generate the unique and protected chemotypes, we develop and characterize preparations from an extract of the chemotype. In addition to preparing whole plant extracts, we also modify the extract preparations by adding or removing certain components or purifying preparations to produce a purified cannabinoid. Each of these steps may give rise to patentable opportunities.

Pharmacologic Evaluation. We then conduct in vitro and in vivo pharmacologic evaluation studies in validated disease models, testing the potential activity, safety and routes of drug metabolism of each cannabinoid preparation as well as combinations of preparations. These studies seek to identify the pharmacology of cannabinoid preparations and allow us to determine the potential therapeutic area in which they might have promise. We then conduct additional pharmacology, toxicology and pre-clinical development on promising preparations.

We conduct most of our pharmacologic evaluations in collaboration with cannabinoid scientists at academic institutions around the world. We enter into research collaboration agreements and other arrangements that enable us to benefit from the expertise of external scientists while retaining intellectual property rights that emerge from the study of our research materials.

Product Composition and Formulation Development. In parallel with the later stages of pharmacological evaluation, we identify optimum extraction and processing methods for the most promising preparations and then develop clinical formulations from the plant extract and analytical methodologies to further study the formulations. We are able to develop formulations of potential product candidates that focus on one or more cannabinoids as key active constituents as well as formulations that focus on a single cannabinoid. Each of these steps may give rise to patentable opportunities.

Our formulation approach is exemplified by Sativex, the first approved cannabinoid therapeutic based on whole plant extracts from the cannabis plant. The main active ingredients of Sativex, THC

and CBD, are extracted from two protected chemotypes. In addition to THC and CBD, Sativex contains additional cannabinoid and non-cannabinoid plant components. In order to achieve a fully standardized formulation of these complex extracts, we employ a range of advanced analytical technologies to demonstrate batch-to-batch uniformity. We standardize the formulation across the extracts as a whole, not simply by reference to their key active components.

Clinical development. Selected cannabinoid product candidates progress into clinical development. We have an in-house clinical operations team that has the proven capability to execute Phase 1, 2 and 3 trials rapidly and cost-effectively. Since our inception, we have undertaken an extensive program of clinical trials in over 3,000 patients, including over 20 Phase 2 and Phase 3 trials.

Cannabinoid Product Production Process

There are three principal steps in the manufacturing process for Sativex and our cannabinoid product candidates—production of botanical raw material, or BRM, botanical drug substance, or BDS, and botanical drug product, or BDP, in each instance as defined by FDA Guidance for Industry—Botanical Drug Products. We hold inventories of BRM and BDS, both of which have extended shelf lives that enable us to manufacture BDP on demand. We have in-house facilities that can perform all steps in the production process.

BRM Production. Once a cannabinoid plant type is selected to form the basis of a pharmaceutical product candidate, we reproduce the chemotype solely through propagation of plant cuttings, or clones, in order to ensure that all subsequent plant material is genetically uniform. Our plants are grown under highly controlled conditions in indoor glasshouses, in which all key features of the growing climate and growing process are standardized. The cultivation process lasts 11 weeks from plant cutting to harvest. Plant material is grown throughout the year and batches are harvested each week. Following harvest, plant material is dried and milled under standardized conditions. All of the plant-based raw materials for Sativex and our other pipeline product candidates are sourced from either our own in-house growing operations or from our sole growing sub-contractor.

BDS Production. BRM from each chemotype is processed and controlled separately to yield a well characterized and standardized extract as our BDS for a particular product or product candidate. Conversion from BRM to BDS involves several processing steps as well as employment of extraction technologies. A proprietary liquid carbon dioxide extraction method is employed for Sativex production.

BDP Production. BDP is the finished product manufactured from one or more BDS's at our in-house manufacturing facility. We manufacture Sativex and our other product candidates through a controlled series of processes resulting in a reproducible finished product manufactured to GMP standards. We are able to manufacture spray products (such as Sativex) and capsules.

Advantages of Our Approach

We believe that our focus on the development of therapeutics from plant-derived cannabinoids offers the following important advantages:

- Our approach offers advantages over development programs that focus on synthetic single-target potent molecules. There is an increasing recognition within the pharmaceutical industry that the aetiology of complex disease is multifactorial and that improved treatments will involve multiple or poly-pharmacology. We believe that our focus on the development of plant extract formulations containing one or more principal cannabinoids offers a multi-target profile designed to address many of the causative factors of complex diseases.
- Our approach is optimally suited to targeting the endocannabinoid system. This system has been shown to be altered by, and to contribute to, several chronic conditions, especially involving the

CNS. The inherent complexity of this system, and the ability of one part of the system to compensate for abnormalities elsewhere in the system makes the "single-target" approach to therapeutics unlikely to be successful.

- Our platform enables us to evaluate the therapeutic potential of single cannabinoids as well as combinations of cannabinoids. As demonstrated with Sativex, this approach offers the prospect of developing a product that enhances the efficacy and safety features of one cannabinoid with complementary features of another cannabinoid while remaining defined as a single new medicinal entity by regulatory authorities.
- Our research has generated pre-clinical evidence in a number of disease areas where cannabinoids contained within plant extract formulations may offer superior therapeutic promise compared with the corresponding pure cannabinoids.
- The chemical complexity of our plant-based formulations provides additional hurdles for potential generic competitors who will be required to demonstrate essential similarity.

Scientific Collaborators

Our research network extends to 31 academic institutions in eight countries. We work closely with the most eminent cannabinoid pharmacologists in the world, including Professor Roger Pertwee, Aberdeen University and Professor Vincenzo di Marzo, the Institute of Biomolecular Chemistry of the National Research Council (ICB-CNR). In target disease areas, we identify lead scientists and institutions with relevant expertise and enter into collaborations to advance our research efforts. In cancer, we collaborate with the research team at Complutense University, Madrid and with Professor Karol Sikora, Dean of Buckingham University and former Global Clinical Expert in Oncology at AstraZeneca. We conduct metabolic and inflammation research in collaboration with Professor Mike Cawthorne, University of Buckingham, Professor Jimmy Bell, Imperial College, London, and Professor Angelo Izzo, University of Naples. We conduct epilepsy research with Dr. Ben Whalley, University of Reading. All research with our collaborators is conducted under collaboration agreements, and any expert advice provided outside of research activity is governed by consulting agreements. The expertise of these collaborators relates principally to the pharmacology of cannabinoids and the early pre-clinical phases of product development.

All results and the accumulated knowledge gained from this work is written up and reported to us on a quarterly basis and is usually shared among the network of collaborators such that no specific individuals have retained knowledge that is critical to any of our development programs. In addition, having completed the early phases of product development for our main product candidates, future developments will largely be focused on human clinical trials which are entirely managed by our in-house clinical management teams. As a result, we do not consider any single collaboration in isolation to be material to our business.

Our Business Strategy

Our goal is to capitalize on our leading position in the field of cannabinoid therapeutics by pursuing the following strategies:

- *Secure regulatory approval of Sativex for advanced cancer pain in the United States and around the world.* We plan to expand the market for Sativex by concluding our Phase 3 program, involving over 1,000 patients, evaluating Sativex in the treatment of persistent pain in patients with advanced cancer. We expect data from at least one of the Phase 3 trials to be available towards the end of 2014 and data from the second Phase 3 trial shortly thereafter, following which we expect to submit an NDA with the FDA and regulatory applications across other parts of the world.

- *Advance our proprietary pipeline of cannabinoid orphan drug opportunities.* In November 2013, we received orphan drug designation for Epidiolex in the treatment of Dravet syndrome, a severe, infantile-onset, genetic, drug-resistant epilepsy syndrome. Also in 2013, the FDA granted seven INDs to independent investigators in the United States to treat a total of approximately 125 children suffering from intractable epilepsy. We are aware of other outside investigators in the United States who also intend to apply to the FDA for INDs to treat their patients. We do not currently have a commercial IND open for Epidiolex and we now intend to apply for a commercial IND initially for Dravet syndrome and subsequently to seek commercial INDs for other potential orphan drug indications, including Lennox-Gastaut syndrome. We have commenced a Phase 1b trial of another product, GWP42002:GWP42003, to treat GBM, an aggressive brain tumor and potential orphan drug indication, and also plan on advancing at least one further cannabinoid orphan drug opportunity during 2014. We retain global commercial rights to our orphan pipeline.
- *Achieve global commercialization of Sativex for MS spasticity.* Sativex was recently launched for MS spasticity in 11 countries, and we anticipate commercial launches in several additional countries in the next 12 months. Additionally, we intend to seek and obtain approval for Sativex in this indication in countries in Asia, Middle East, Africa and Latin America, and to commence a Phase 3 clinical trial of Sativex for MS spasticity in 2014 required for submission of a separate NDA with the FDA.
- *Advance additional product candidates in our pipeline towards commercialization with a particular focus on the United States market.* We have a deep product pipeline which includes two other cannabinoid product candidates in Phase 2 trials for the treatment of type-2 diabetes and ulcerative colitis, a product candidate in Phase 1 trials for the treatment of epilepsy, and a product candidate expected to enter Phase 2 trials for the treatment of schizophrenia.
- *Leverage our proprietary cannabinoid product platform to discover, develop and commercialize additional novel first-in-class cannabinoid products.* We intend to advance our leading position in cannabinoid therapeutics through the continuing discovery and development of new cannabinoid product candidates for multiple indications. We believe our established platform, including our in-house development expertise, allows us to achieve candidate selection and proof of concept in an efficient manner.
- *Continue to selectively enter into new collaboration agreements for certain programs and retain full ownership and/or co-promotion opportunities for other programs.* We plan to seek future collaboration agreements for certain programs, while retaining commercial interests in other selected product opportunities where the development and commercialization activities are appropriate for our size and financial resources.
- *Further strengthen our competitive position.* We will continue to develop our extensive international network of the most prominent scientists in the cannabinoid field and secure additional intellectual property rights in the form of patents relating to plant extracts, process technologies, formulations and therapeutic uses, as well as plant variety rights, know-how and trade secrets.

Sativex

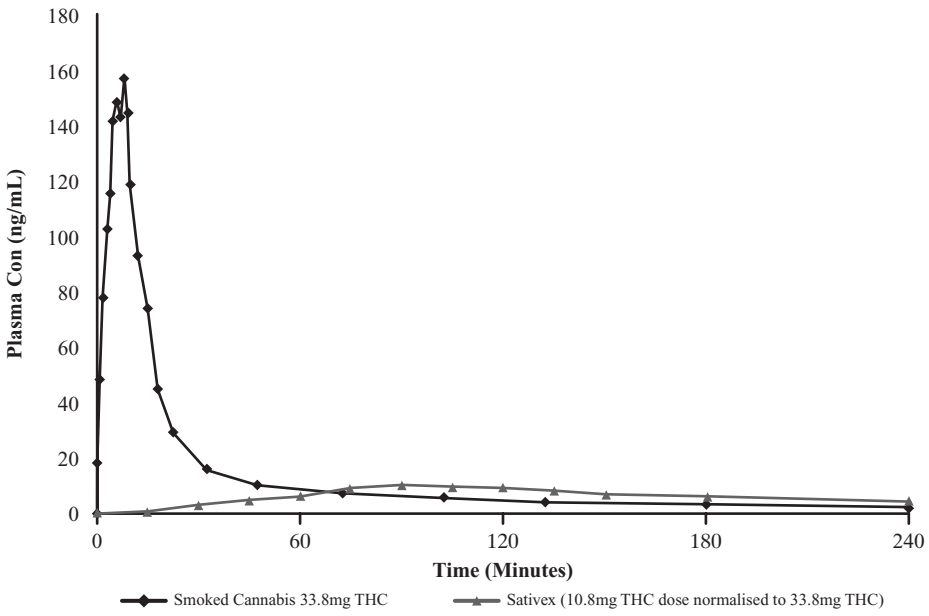
Our lead product, Sativex, is an oromucosal spray of a formulated extract of the cannabis sativa plant that contains the principal cannabinoids THC and CBD as well as specific minor cannabinoids and other non-cannabinoid components. Because cannabinoids are virtually insoluble in water, we use organic solvents, ethanol and propylene glycol, to formulate the extract. The product has been granted the U.S. Adopted Name, or USAN, of nabiximols.

We developed Sativex to be administered as an oral spray, whereby the active ingredients are absorbed in the lining of the mouth, either under the tongue or inside the cheek. This route of administration is intended to achieve a reliable rate of absorption and high level of bioavailability of THC and CBD. The spray cannot be inhaled due to the particle size. The spray provides patients with the flexibility to self-manage their dosage in order to achieve and maintain an optimal therapeutic response. In the United States, the FDA will require the spray to be incorporated within additional packaging which features a dose counter in order to reduce the potential for diversion. We are developing a dose counter with funding from Otsuka in parallel with our Phase 3 cancer pain program.

Sativex Pharmacokinetics

Although Sativex contains THC, both the composition of its formulation and its route of administration means that the resulting THC blood levels achieved are quite distinct from those associated with smoked cannabis. We have compared the pharmacokinetics of Sativex to data reported in a separate study published by Marilyn Huestis, et al., in the September 1992 issue of Journal of Analytical Toxicology involving smoked cannabis. This comparison illustrates differences in the speed of absorption and maximum concentration, or Cmax, of THC in the blood. Rapid concentration of high levels of THC in the blood, as achieved by smoked cannabis, is known to be associated with intoxication.

Comparison of the Plasma Concentration Time Curves for Smoked Cannabis and Sativex Oromucosal Spray



Sativex for Cancer Pain

We are evaluating Sativex in a Phase 3 program to treat persistent pain in people with advanced cancer who experience inadequate pain relief from optimized chronic opioid therapy. This program represents the lead target indication for Sativex in the United States and is also intended to form the basis for future regulatory applications in the rest of the world. This Phase 3 program follows positive data from two Phase 2 trials of Sativex in this indication involving over 530 patients. We believe that Sativex has the potential to address a significant unmet need in this large market by treating patients with a product that employs a differentiated non-opioid mechanism of action, and offering the prospect of pain relief without increasing opioid-related adverse side effects.

Cancer Pain Opportunity. Chronic, unremitting persistent pain in deep tissues that results from cancer adversely affects a significant patient population.

The primary treatment for cancer pain is analgesic narcotics, also known as opioids. Morphine and oxycodone are the most prescribed opioids, and morphine is the standard regimen for treating cancer pain in palliative care and hospice care programs and facilities. Opioids are often added to non-opioid analgesics and other adjuvant medications to control cancer pain. These agents act on the CNS by binding to various opiate receptors. The use of opioids is frequently met with undesirable side effects such as constipation, sedation, respiratory depression and analgesic tolerance as well as the risk of addiction. Studies in animal models of pain suggest that there may be pharmacodynamic synergy between cannabinoids and opioids.

According to Data Monitor Stakeholder Insight: Cancer Pain, Dec 2009, there were 4.75 million cancer patients in the United States in 2009. Approximately 70% of those patients, or 3.3 million individuals, experience pain. According to market research conducted on behalf of Otsuka as part of our collaboration, approximately 72%, or 2.4 million of these patients, have advanced cancer, of which 89%, or approximately 2.1 million patients, are treated with opioid medications. According to Fallon, et al. in the March/April 2006 edition of Clinical Medicine, pain is uncontrolled with opioid treatments in approximately 20% of patients with advanced cancer, or 420,000 people in the United States.

There are currently no approved non-opioid treatments for patients who do not respond to, or experience negative side effects with, opioid medications.

Pharmacology. We believe there is a strong pharmacologic rationale for the use of Sativex in cancer pain. Cannabinoid receptors have been found in all of the principal pain transmission pathways, including the dorsal horn of the spinal cord, the descending tracts from the peri-aqueductal grey and rostral-ventral medulla and within the cortical structures, the medial thalamus, amygdala and limbic cortex. In animal models, not only does local administration of endogenous cannabinoids produce pain relief, but THC and CBD also produce pain relief in animal models of both nociceptive and neuropathic pain.

In this context, the CB1 receptor, of which THC is a partial agonist, has been identified as being most implicated in cannabinoid-induced pain relief. CBD is a potent inhibitor of adenosine uptake, and it is also known to be an agonist at the TRPV-1 (vanilloid) receptor. Both of these activities may produce pain relief. Furthermore, CBD has anti-inflammatory activity in standard animal models of inflammation and is a potent inhibitor of neutrophil chemotaxis. Finally, CBD also has an anxiolytic effect, is anti-psychotic and is believed to mitigate some of the undesirable side effects of THC.

Cancer Pain Clinical Program

Phase 2 Clinical Data. We have completed two Phase 2 multinational, randomized, placebo-controlled trials for Sativex in patients with advanced cancer who experienced inadequate pain relief from the use of optimized chronic opioid therapy. In each of the two trials, patients received Sativex or placebo as add-on treatment to strong opioid therapy while remaining on stable doses of their background optimized opioid therapy.

In both Phase 2 trials, pain was assessed daily by the patient using a 0 to 10 Numeric Rating Scale, or NRS. The change in pain severity was measured by comparing pain scores at the end of the trial with baseline scores at the beginning of the trial. There are two primary approaches to analyzing these changes in pain, either by assessing the mean numeric change in NRS or by responder analyses which assess percentage improvements.

Historically, application of responder analyses required choosing a specific cut-off point on the NRS, or alternatively a percentage threshold, deemed to be clinically meaningful. More recently, an alternative approach to responder analyses, known as the Cumulative Proportion of Responders Analysis, or CPR Analysis, has been proposed as an improvement to previous approaches. This analysis was first published by John Farrar, et al. in the November 2001 issue of Pain and was proposed to overcome concerns with previous approaches which had required a pre-determined choice of the level of response which would be considered clinically meaningful. The CPR Analysis is one of the key efficacy parameters discussed in the FDA-approved package insert of the analgesic medications pregabalin and duloxetine and analyzes the full range of responses achieved across the entire patient population within a trial. We believe the CPR Analysis offers several advantages over using a single cut-off response rate, including:

- because it employs more available data, it provides greater statistical power with the same number of patients;
- it permits an analysis of the totality of response across a patient population, rather than focusing solely on a single, pre-defined, cut-off response rate; and
- if included in labeling, it provides more comprehensive information to the prescriber on the range of responses that patients may experience if treated with the product.

The specific method used is to analyze the cumulative proportion of patients who reach each level of response rate, calculated and displayed up to the response rate cut-off point. The CPR Analysis graph displays patient data in order of the calculated level of response for both active treatment and placebo. For each level of response, it shows the proportion of the total number of patients that equaled or exceeded that level of response.

Results of our Phase 2 trials have been analyzed using three methodologies—mean change in NRS scores, analysis of patients with a response of 30% or more, and the CPR Analysis. Following our end of Phase 2 discussions with FDA, we chose to employ the CPR Analysis as the primary efficacy analysis in the first two of our Phase 3 trials.

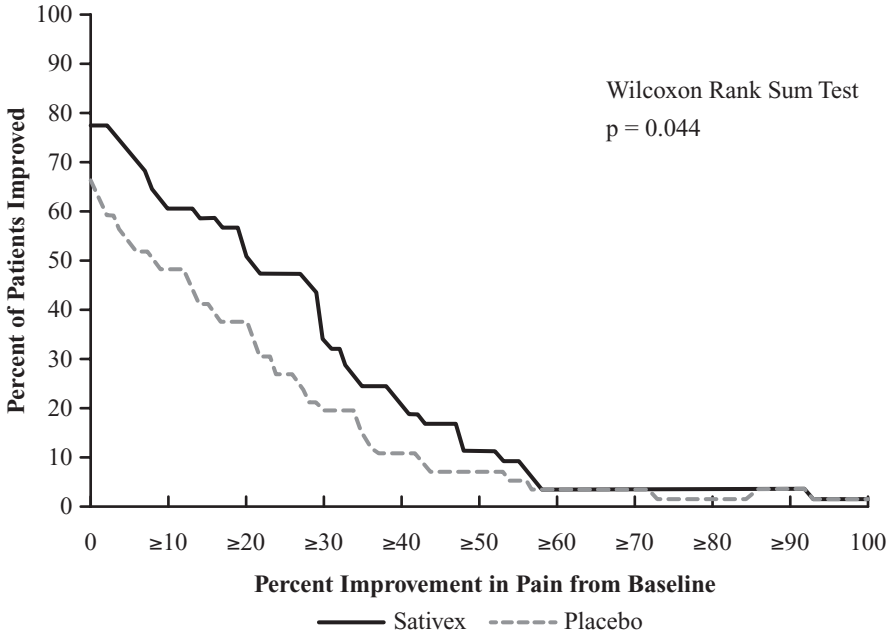
Phase 2a Data

Results from a Phase 2a trial in 177 patients were published by Jeremy Johnson, et al. in the February 2010 issue of Journal of Pain and Symptom Management, the official journal of the American Academy of Hospice and Palliative Medicine, the National Hospice and Palliative Care Organization, and the U.S. Cancer Pain Relief Committee. This three-arm trial compared the efficacy and safety of Sativex to a THC-only extract spray formulation and placebo as add-on treatments to strong opioid therapy administered over a two-week period. A co-primary efficacy endpoint of the trial was the change in mean pain score (on the 0 to 10 NRS) from baseline to end of treatment. The results showed a statistically significant improvement of 0.67 points in the Sativex group compared with the placebo group ($p=0.014$). Changes in pain scores using responder analyses not specified in the trial protocol showed the following:

- 43% of patients using Sativex achieved an improvement in their pain score of 30% or greater compared with 21% of patients in the placebo group. This difference was statistically significant ($p=0.006$).

- The CPR Analysis also showed statistically significant improvements of Sativex versus placebo (p=0.044) and is displayed below:

Sativex in Cancer Pain—Phase 2a CPR Analysis



During the trial, patients were permitted to administer between 0-48 sprays per day. The median dose in the Sativex treatment group was 8.15 sprays per day.

While Sativex showed a statistically significant improvement over placebo in the trial, it is noteworthy that the THC-only extract spray showed a smaller improvement of 0.32 points over placebo, which was not statistically significant, providing evidence that the combination of THC and CBD, the main ingredients in Sativex, is an improved cannabinoid formulation for this patient population as compared to THC alone.

Phase 2b Data

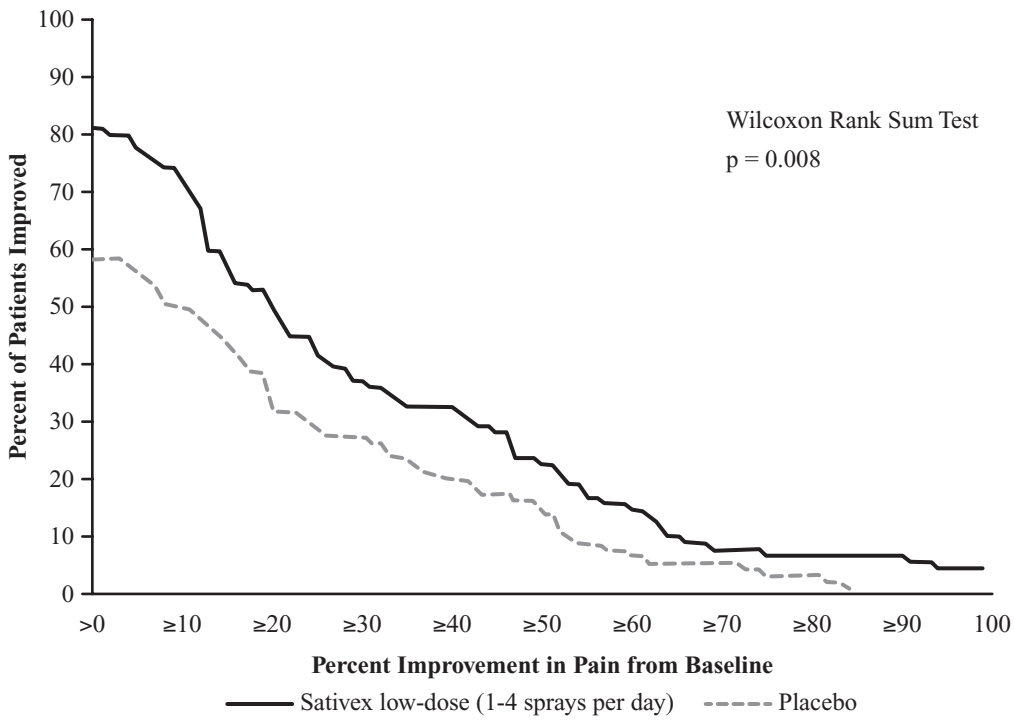
Results from a Phase 2b dose ranging trial were published by Russell Portenoy, et al. in the May 2012 issue of The Journal of Pain, the official journal of the American Pain Society. This randomized, double-blind, placebo-controlled, parallel-group trial recruited a total of 360 patients in 14 countries in North America, Europe, Latin America and South Africa, and evaluated three dose range groups of Sativex—a low-dose (one to four sprays per day), mid-dose (six to ten sprays per day), and high-dose (11 to 16 sprays per day)—and placebo, over a five-week treatment period. The primary objectives of this trial were to determine the effective dose range and to demonstrate a non-effective dose of Sativex in patients with advanced cancer who experience inadequate pain relief during optimized chronic opioid therapy.

The trial provided data to support entry into a Phase 3 program, showing statistically significant differences in favor of Sativex over placebo in two key analyses of pain scores. The trial also provided information sufficient to select a dose range of Sativex in the patient population and confirmed key features of the trial design of our Phase 3 trials.

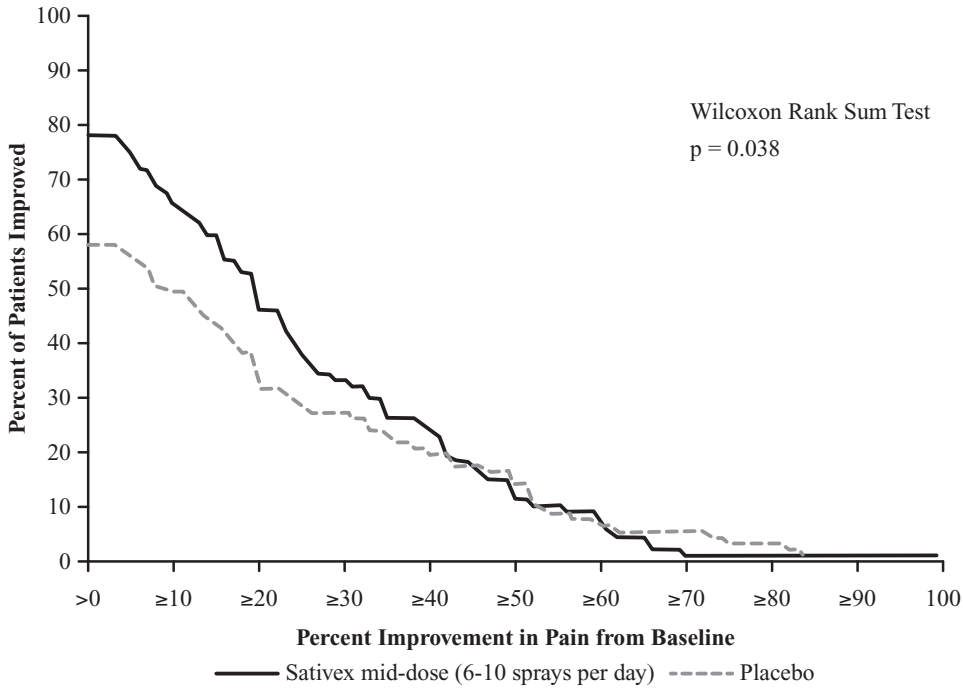
The primary efficacy measure of the trial was a patient assessment of pain using a 0 to 10 NRS. This endpoint was analyzed using a primary and two secondary statistical methodologies, including 30% responder analysis (where a response was defined as a 30% or greater reduction in the NRS score during the last three days of treatment versus the three-day baseline period at the beginning of the trial), CPR Analysis and change from baseline analysis in NRS average pain. The 30% responder analysis was specified as the primary analysis in the protocol. Results of these analyses for the low and mid-dose groups are provided below:

- 30% Responder Analysis. The results of this analysis were numerically in favor of Sativex for the low and mid dose groups but did not show a statistically significant difference in pain scores compared to placebo.
- Change from Baseline Analysis in NRS Average Pain. This analysis showed statistically significant differences in favor of Sativex for the low-dose group compared to placebo (treatment difference 0.75 points, p=0.006). While no statistical difference was seen for the mid-dose group and placebo, the low and mid-dose Sativex groups, when combined, were also statistically significantly superior to placebo (treatment difference 0.55 points, p=0.019).
- CPR Analysis. This analysis showed statistically significant results in favor of Sativex for each of the Sativex low and mid-dose groups compared to placebo (p=0.008 and p=0.038, respectively). The low and mid-dose Sativex groups, when combined, were also significantly superior to placebo (p=0.006). Following the End of Phase 2 meetings with the FDA, we decided to use this analysis as the primary efficacy analysis in our Phase 3 program and to employ a single dose group of three to ten sprays per day, reflecting the data from combining the low and mid-dose groups in the Phase 2b trial. The CPR Analyses for the low-dose group, the mid-dose group, and the combined low and mid-dose groups are displayed in the charts below:

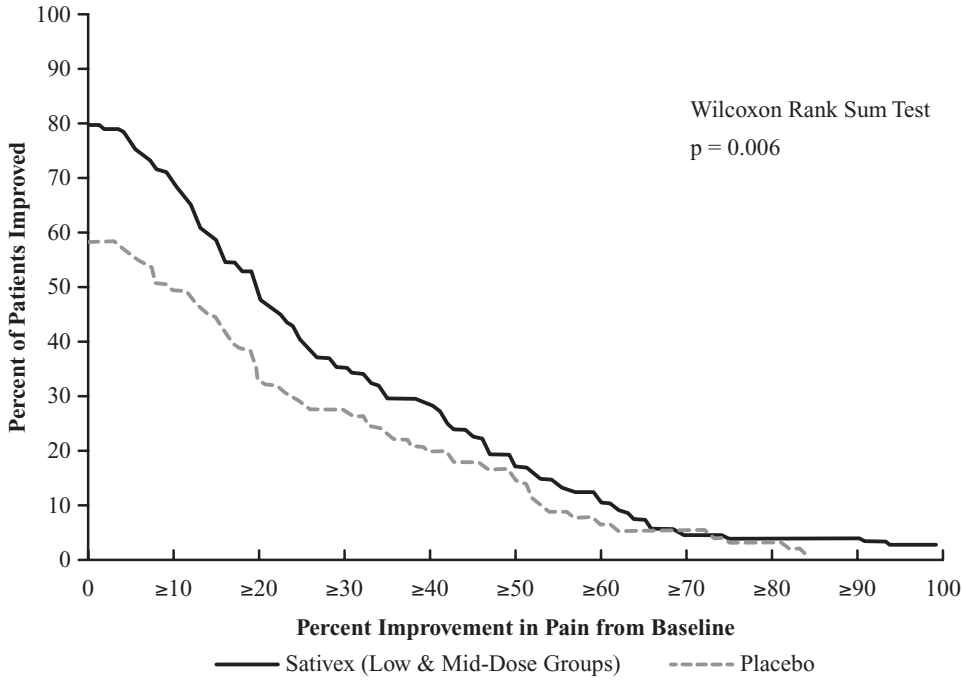
Sativex in Cancer Pain—Phase 2b
CPR Analysis for Low-Dose Group



Sativex in Cancer Pain—Phase 2b
CPR Analysis for Mid-Dose Group



Sativex in Cancer Pain—Phase 2b
CPR Analysis for Combined Low and Mid-Dose Groups



The Sativex high-dose level did not show superior efficacy to placebo. While tolerability does not completely account for this lack of efficacy, it is noteworthy that discontinuation due to adverse events was 28% in the high-dose group and was substantially higher than the rates of discontinuation in the placebo group (18% discontinuation), the low-dose group (14% discontinuation) and in the mid-dose group (17% discontinuation). In addition, 34% of patients in the high-dose group took their medication below their target dose at the end of the treatment period.

The trial included several secondary endpoints, including sleep disruption, which is identified in the Phase 3 trials as the key secondary endpoint. In the Phase 2b trial, the Sativex low-dose group showed a statistically significant difference compared to placebo in reducing sleep disruption (treatment difference 0.88 points, p=0.003). While the mid-dose group showed no improvement over placebo, the low and mid-dose Sativex groups, when combined, did show a statistically significant reduction in sleep disruption compared to placebo (treatment difference 0.61 points, p=0.016).

Phase 2 Safety Profile

The safety profile of Sativex in the two Phase 2 trials was consistent. In the Phase 2a trial, the most common treatment-related adverse events (occurring at a rate greater than or equal to 10% for the Sativex population) reported for the Sativex treatment group were somnolence (13% vs. 10% for placebo), dizziness (12% vs. 5% for placebo) and nausea (10% vs. 7% for placebo). In the Phase 2b trial, the most common treatment-related adverse events (occurring at a rate greater than 10% for the combined Sativex population) reported for the Sativex treatment groups were dizziness (17% vs. 10% for placebo), nausea (11% vs. 8% for placebo) and somnolence (12% vs. 4% for placebo). An analysis of treatment-related severe adverse events showed that such events occurred at a similarly low rate in the mid-dose and low-dose Sativex groups as in the placebo group (3% and 3% vs. 1%). More patients in the high-dose Sativex group experienced treatment-related severe adverse events, with 17% of subjects doing so. The most severe treatment related events observed in the Sativex arm (occurring in more than two patients for the combined Sativex population) were disturbance in attention, dizziness, sedation, anorexia, vomiting, nausea and vertigo.

Phase 2 Key Findings

The Phase 2 trials provided us data sufficient to support entry into Phase 3 trials of Sativex in cancer pain, to determine the optimum dose range to be used in Phase 3 trials, and determine the choice of primary efficacy analysis to be used in the first two Phase 3 trials.

Dose Range

We believe that the Phase 2b trial achieved one of its key objectives in determining the effective dose range for Sativex and demonstrating a non-effective dose range. Efficacy was observed in both the low (one to four sprays per day) and mid-dose (six to ten sprays per day) groups and these groups were also associated with a lower or similar rate of adverse events to placebo, and a low rate of withdrawal from the trial due to adverse events. In contrast, the data suggests that a high-dose range of Sativex reaches a maximum tolerated dose without improved efficacy over placebo. These results are consistent with those seen in the Phase 2a trial where the median daily dose taken by the Sativex treatment group was 8.15 sprays per day.

We have therefore concluded that an appropriate approach to dosing in the Phase 3 trials is to employ a single dose range of three to ten sprays per day.

Primary Efficacy Analysis

The table below summarizes Phase 2 results for three statistical analyses of changes in pain scores:

	Phase 2a Trial	Phase 2b Trial
Number of Patients	**Sativex (n=60) vs. placebo (n=59)**	**Sativex low and mid-dose groups (n=179) vs. placebo (n=91)**
CPR Analysis*	p=0.044	p=0.006
NRS Mean Change	p=0.014**	p=0.019
30% Responder Analysis	p=0.006	p=0.38**

* The primary analysis selected for first two Phase 3 trials.

** The primary analysis in Phase 2 trial.

Following our End of Phase 2 discussions with the FDA, we decided to employ the CPR Analysis as the primary efficacy analysis in the first two of our Phase 3 trials. In the third Phase 3 trial, which employs a different 'enriched' trial design, the primary efficacy analysis is the mean change from baseline in NRS scores. These analyses have provided statistically significant results in favor of Sativex in both Phase 2 trials.

Phase 3 Program. As a result of the positive data seen in our Phase 2 program, we and Otsuka held discussions with the FDA regarding the proposed Phase 3 program for the continued development of Sativex for cancer pain. We are now conducting three multi-national, randomized, placebo-controlled, multi-center Phase 3 trials, two of which will employ an identical trial design and endpoints and are expected to support the NDA submission. These two Phase 3 trials include the following key features:

- The patient population is defined as patients with advanced cancer who have failed to gain adequate pain relief from the use of strong opioids. Patients receive active Sativex or placebo as add-on treatment to strong opioid therapy while remaining on stable doses of their background optimized opioid therapy during the trial.
- The primary efficacy endpoint is the CPR Analysis of pain response as measured by patients using a 0 to 10 NRS.
- The duration of treatment during the trial is five weeks with an additional five to 14 day stabilization period at the beginning of the trial and a one-week follow-up at the end of the trial.
- Single dose range of three to ten sprays per day (reflecting a combination of the low and mid dose groups from the Phase 2b trial).
- Each of the studies will include 380 patients randomized equally between active and placebo groups.
- Secondary endpoints include sleep disruption, opiod consumption and constipation.
- Following completion of the randomized phase, all patients are eligible to enter a long-term extension trial.

The ongoing Phase 3 program, is being performed with and funded by Otsuka.

Patients are being recruited into these two trials at hospital sites in the United States, Europe and Mexico. Professor Marie Fallon, Professor of Palliative Care, University of Edinburgh, is the principal investigator of the first trial, and Dr. Russell K. Portenoy, Chairman of the Department of Pain Medicine and Palliative Care, Beth Israel Medical Center in New York City, is the principal investigator of the second trial. We anticipate that top-line results from at least one of these Phase 3

trials will be available towards the end of 2014, with top-line results from the second Phase 3 trial following shortly thereafter. This program is intended to support the submission of an NDA with the FDA and in other markets around the world.

We are also in the process of conducting a third Phase 3 trial, which we expect to enroll approximately 540 patients, that is designed to provide additional information on the effects of Sativex in treating opioid resistant cancer pain. The results of this third trial are not intended to be included in the initial regulatory filings if the results of the first two pivotal Phase 3 trials provide a sufficient basis to demonstrate the safety and efficacy of Sativex in the target indication. The third Phase 3 trial differs in design from the first two trials, employing a two-part "enriched trial design" akin to that which was successfully employed in the MS spasticity trials program. The trial involves exposing all enrolled patients to Sativex in a two-week single-blind phase, or Phase A, following which responders will be randomized either to stay on Sativex or switch to placebo in a double-blind phase for a five-week treatment period, or Phase B. The primary efficacy analysis will be the mean change from baseline in Phase B as measured using a 0 to 10 NRS. The trial is designed to enroll 216 patients in Phase B. The protocol provides for a pre-planned interim analysis when half the number of planned patients complete the study.

Long-term Safety and Efficacy. Results from a long-term, open-label, follow-up trial in 43 cancer pain patients who had previously participated in the Phase 2a trial were published by Jeremy Johnson, et al. in the November 2012 issue of Journal of Pain and Symptom Management. These results showed that the long-term use of Sativex was generally well tolerated, with no evidence of a loss of effect for the relief of pain with long-term use. Furthermore, patients who kept using Sativex did not seek to increase their dose of Sativex or other pain-relieving medication over time.

Abuse Liability. A study published in the June 2011 issue of Human Psychopharmacology by Kerri Schoedel, et al. compared the abuse liability of Sativex at three dose levels (four sprays taken consecutively, eight sprays taken consecutively and 16 sprays taken consecutively) with placebo and two doses of dronabinol (synthetic THC) capsules (20mg and 40mg) in a randomized, double-blind, crossover study in 23 healthy subjects with a history of non-dependent but regular recreational cannabis use. The subjective effects of 20 and 40mg dronabinol were consistently and significantly greater than placebo, demonstrating that it has measurable abuse potential. The effects of Sativex were consistently lower than dronabinol. Four sprays of Sativex taken consecutively (containing 10.8mg of THC) was not significantly different from placebo with regard to changes in primary variables, suggesting low abuse potential at this dosage. Eight sprays of Sativex taken consecutively had a mixed profile of effects suggesting modest abuse potential, while 16 sprays of Sativex taken consecutively was significantly different from placebo in most outcome measures suggesting significant abuse potential. In contrast to this abuse liability study in which Sativex doses were administered together, patients in the Phase 3 trials administer between three and ten sprays over a 24-hour period.

If Sativex receives FDA approval, it will be a controlled substance, as is the case with opioids, and the U.S. Drug Enforcement Administration, or DEA, will place it in a schedule under the Controlled Substances Act of 1970, or CSA, in order for it to be able to be prescribed to patients in the United States. The schedule into which a product is placed reflects the DEA's determination of its potential for abuse or dependence. We expect Sativex to be listed by the DEA as a Schedule II or III controlled substance. As part of the NDA, we will submit information on abuse liability which will be reviewed by the Controlled Substances Staff at the FDA in consultation with the National Institute on Drug Abuse. Ultimately, the Assistant Secretary for Health will transmit the findings and scheduling recommendation to the DEA.

In February 2013, the Advisory Council on the Misuse of Drugs, which is the advisory body to the U.K. government with respect to controlled substances, confirmed its recommendation to the U.K. government that it deems Sativex to have low abuse potential and low risk of diversion, and that

Sativex thereafter should be scheduled as a Schedule IV substance. Legislation placing Sativex into Schedule IV came into effect in April 2013.

Potential Expansion of Cancer Pain Market. Following successful completion of the development of Sativex in the treatment of pain in patients with advanced cancer, we may consider, together with Otsuka, expanding the target market of Sativex by conducting Phase 3 trials in the treatment of pain in patients with earlier stage cancer. A future submission of a supplemental NDA in this expanded indication would represent a significant additional market opportunity for Sativex in the United States and the rest of the world. Under the terms of our Otsuka collaboration, such additional development costs would be fully funded by Otsuka.

Sativex for MS Spasticity

The approved label for Sativex is as a "treatment for symptom improvement in patients with moderate to severe MS spasticity who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy".

We recently initiated the commercialization of Sativex for MS spasticity in 11 countries outside the United States. We have also received regulatory approval in an additional 11 countries, and we anticipate commercial launches in the majority of these countries during 2014. Two additional countries have recommended approval for Sativex and regulatory filings are ongoing in eight other countries, principally in the Middle East where we expect approvals during 2014.

We believe that MS spasticity represents a significant market opportunity for the United States and we intend to commence a required Phase 3 clinical trial of Sativex for MS spasticity in 2014 intended to lead to submission of an NDA to the FDA for this indication. Although Sativex has been approved for the treatment of MS spasticity in 22 countries outside the United States, we believe that from a commercial and regulatory perspective, Sativex for cancer pain represents the optimal entry point into the United States market. This is because we believe the size of the commercial opportunity for the cancer pain indication in the United States is larger than the MS spasticity opportunity. Moreover, because patients with MS spasticity would typically use Sativex for an extended treatment duration, we expect that additional pre-clinical carcinogenicity data will be required as part of the submission of an NDA in this indication. While the carcinogenicity studies are now underway, the timing of the availability of such data is expected to follow the expected timing of the submission of an NDA in the cancer pain indication potentially allowing us to obtain U.S. approvals for this indication before we would be able to obtain U.S. approvals in MS spasticity. The initial development of Sativex focused on the European MS spasticity market, hence pre-clinical carcinogenicity data was originally generated prior to our first interactions with the FDA.

We held our first meeting with the FDA in December 2012 to discuss the MS spasticity indication. This pre-IND meeting led to the submission and acceptance of an IND in mid-2013 with an investigational plan that includes a Phase 3 trial protocol. The FDA provided initial feedback on design features necessary for the study to serve as a pivotal study in our development program. Consistent with the FDA's recommendations, we expect to request Special Protocol Assessment, or SPA, for the proposed Phase 3 trial and expect this trial to commence in 2014. Under the SPA process, a sponsor may reach an agreement with the FDA as to the required design and size of clinical trials intended to form the primary basis of an efficacy claim.

Regulatory Status of Sativex for MS Spasticity

Launched	Approved (pending launch)	Recommended for approval	Regulatory submission filed
Austria	Australia	Ireland	Bahrain
Canada	Belgium	France	Egypt
Denmark	Czech Republic		Malaysia
Germany	Finland		Morocco
Israel	Iceland		Oman
Italy	Kuwait		Qatar
Norway	Luxembourg		Saudi Arabia
Poland	Netherlands		South Africa
Spain	New Zealand		Switzerland
Sweden	Portugal		United Arab Emirates
United Kingdom	Slovakia		

MS Spasticity Opportunity. MS is the most common disabling neurological condition affecting young adults. According to the World Health Organization, MS affects more than 1.3 million people worldwide, of which over 400,000 are in the United States and over 600,000 are in Europe. MS affects twice as many women as men and typically develops between the ages of 20 and 40 years. The hallmark pathology of MS is patchy demyelination, leading to nerve damage, which in most cases causes symptoms that adversely affect quality of life. Spasticity is one of the most common, chronic, and disabling of these symptoms, affecting up to 80% of MS patients over their lifetimes. Spasticity refers to an abnormal, involuntary tightness of muscles, which increases when the muscles are rapidly stretched, so that the associated joint appears to resist movement. Some of the features of spasticity include muscle stiffness, difficulty straightening joints, reduced mobility, limb weakness, shaking, intermittent spasms and pain. As a result of the increased muscle tone due to spasticity, "simple," everyday movements become difficult or impossible altogether. In addition, painful muscle spasms can lead to difficulty with sleeping, sitting in a chair or lying in bed. Occasionally, spasms may be triggered by fairly minor irritations such as tight clothing, a full bladder or bowel, urinary tract infection or skin irritation, such as from a pressure sore. Moderate to severe spasticity can lead to significant impairment.

There is no cure for spasticity, and it is widely recognized that currently available oral treatments afford only partial relief and have unpleasant side effects. Sativex offers the prospect of treating patients who have failed existing oral therapies and who might otherwise require invasive and costly alternative treatment options such as intrathecal baclofen or surgery.

Pharmacology. Sativex has been investigated for anti-spasticity effects in chronic relapsing experimental allergic encephalomyelitis, or CREAE, the accepted animal model of MS spasticity. In this model, Sativex rapidly reduces spasticity in a dose-dependent way, achieving the same overall reduction in spasticity as baclofen, the standard first line treatment for MS spasticity, without causing as much disability in the animals.

Each of the two principal cannabinoids within Sativex, THC and CBD, possess pharmacological properties that provide a rationale to support the efficacy of Sativex in MS spasticity. In animal models of MS, the CB1 receptor plays a key role in the modulation of spasticity and spasms. While CBD has little activity at cannabinoid receptors, it does have neuroprotective properties, which are most likely mediated by its ability to modulate intra-cellular calcium. The key pharmacology of CBD in MS likely relates to its role as an agonist at TRP channels, critical for maintaining calcium homeostasis and as an inhibitor of adenosine uptake, providing a non-cannabinoid receptor mechanism for its anti-inflammatory properties. In addition, CBD has an anxiolytic effect, is anti-psychotic and is believed to mitigate some of the undesirable side effects of THC.

MS Spasticity Clinical Program. In clinical trials, Sativex has been shown to provide effective relief of spasticity symptoms, including reduced spasms, improved sleep and improved function, in patients for whom existing anti-spasticity treatments have failed. During the course of the development program for Sativex in MS spasticity, we have conducted Phase 2 and Phase 3 double-blind, randomized, placebo-controlled trials involving 1,294 patients. These trials have all been published in peer-reviewed journals. In each trial, patients were permitted to remain on stable doses of their background oral anti-spasticity medication and spasticity was measured using a 0 to 10 NRS. This scale has been validated for use in spasticity clinical trials.

The largest and most recent of the Phase 3 trials, published by A. Novotna, et al. in the April 2011 issue of European Journal of Neurology, was a two-part trial and employed an enriched trial design. During the first four-week period, all patients received Sativex single-blind. This was followed by a 12-week, double-blind period in which patients who had achieved a pre-determined level of response at the end of the prior four-week period were randomized to Sativex or placebo in a conventional parallel group design. We designed this trial to demonstrate the size of clinical benefit achieved from Sativex in patients who had previously shown a capacity to respond to treatment.

The primary efficacy endpoint of the trial was the difference between Sativex and placebo in the mean change in spasticity as measured by the patient using a 0 to 10 NRS in the 12-week period from randomization to the end of treatment. There were a number of functional secondary measures that are important in contributing to an assessment of the clinical relevance of a change in the primary outcome measure. In particular, the objective view of the physician was considered important by regulatory authorities and was therefore included as a secondary endpoint.

After the four-week, single-blind period in 572 patients, Sativex reduced the mean score for spasticity on the NRS scale by 3.01 points from a baseline of 6.91 points, or 44%. In addition, 48% of patients' NRS score improved by 20% or more during this initial period, the pre-defined level of response required to be included in the randomized phase.

As a result, 241 patients proceeded into the 12-week, randomized, placebo-controlled trial phase. The primary endpoint, the mean difference between treatment groups at the end of the randomized treatment period was statistically significant in favor of Sativex ($p=0.0002$). Furthermore, 74% of Sativex responders experienced a reduction of 30% or more in their spasticity score from their original pre-treatment baseline, which represents a meaningful clinical improvement in this patient population.

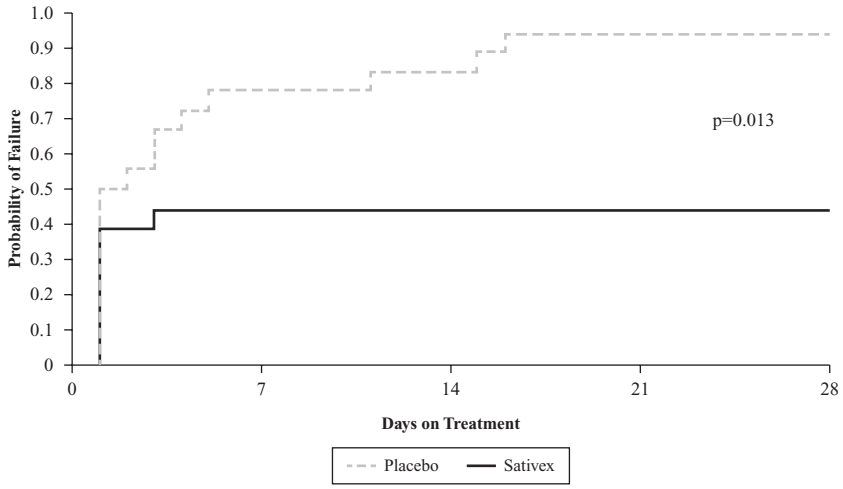
The secondary efficacy measures were in line with the primary outcome of the trial. In particular, the functional measures added to the existing evidence that patients achieve a benefit that is apparent to both their caregiver and their physician. The following secondary efficacy measures showed statistically significant improvements of Sativex over placebo: spasm score ($p=0.0046$), sleep disturbance ($p<0.0001$), Subject Global Impression of Change ($p=0.023$), Physician Global Impression of Change ($p=0.005$), Carer Global Impression of Function ($p=0.005$) and Barthel Activities of Daily Living ($p=0.007$). Of the other secondary efficacy measures, the timed ten meter walk and Modified Ashworth Scale approached statistical significance ($p=0.069$ and $p=0.094$, respectively).

The safety profile of Sativex across placebo-controlled trials conducted in MS patients shows that the drug is generally well tolerated, with the most commonly occurring individual adverse events (occurring at a rate greater than 10%) being dizziness (25% vs. 8% for placebo), fatigue (13% vs. 8% for placebo) and nausea (10% vs. 6% for placebo). Adverse events were typically mild or moderate in severity and the pattern of common adverse events is similar in both short-term and long-term exposure to Sativex. The most common adverse events tend not to be recurrent, occurring in the first four weeks of treatment and much less commonly thereafter.

In August 2013, we opened an IND with the FDA for the MS spasticity indication which includes a proposed Phase 3 clinical trial. The FDA provided initial feedback on design features necessary for the study to serve as a pivotal study in our development program. Consistent with the FDA's recommendations, we expect to request a SPA for the proposed Phase 3 trial and expect this trial to commence in 2014. We expect the trial design will be consistent in some respects with the most recent Phase 3 trial conducted in Europe and published by A. Novotna, et al., in 2011. The U.S. Phase 3 trial is expected to employ an enriched study design, but is expected to employ two co-primary endpoints: spasticity as measured on the Modified Ashworth Scale, and the Physician Global Impression of Change to provide evidence that the observed treatment difference is clinically meaningful. We believe FDA will also require that we establish a dose-response using a multiple fixed dose design.

Long-Term Efficacy. We have demonstrated the long-term efficacy of Sativex in a placebo-controlled trial published by William Notcutt, et al. in the February 2011 issue of Multiple Sclerosis. This randomized withdrawal trial recruited 36 patients with MS that had been receiving Sativex on prescription for a mean duration of 3.6 years. Patients were randomized to continue with Sativex or switched to placebo in a double-blind, four-week treatment period. The primary efficacy endpoint of the trial was the time to treatment failure, with treatment failure being defined as cessation of the randomized treatment before the end of the trial, a worsening of spasticity (defined as an increase in the mean spasticity NRS over the last seven days of the treatment period of at least 20% and at least one unit from the treatment baseline), or a clinically relevant increase in or addition to anti-spasticity drugs or disease modifying medications after randomization.

Kaplan-Meier Plot: Time to Treatment Failure



The primary efficacy endpoint was statistically significant in favor of Sativex (p=0.013). Of the key secondary measures, both the Subject Global Impression of Change (p=0.017) and the Carer Global Impression of Functional Ability (p=0.0011) were also statistically significant.

In addition to this controlled trial, there is a significant body of evidence from long-term open label extension trials to support the evidence of maintenance of efficacy in long-term use of Sativex, many of which have been published in peer-reviewed journals.

The withdrawal rate from open-label, long-term extension trials is low, and withdrawals due to a lack of efficacy are uncommon. For those patients who remained in open-label, long-term extension trials for a year, the symptom score for spasticity remained low, providing supportive evidence that continued use of Sativex is associated with long-term maintenance of efficacy.

The pattern of adverse events seen in long-term use of Sativex is very similar to that seen in the short-term placebo-controlled trials. Since Sativex first became commercially available, there has been an estimated additional 20,000 patient-years of exposure to Sativex outside of clinical trials and no new significant safety issues have been identified.

Post-Approval Evidence of Sativex Clinical Benefits. Since launch, two studies have been completed which support the commercialization efforts of our partners. An independent survey of Sativex prescription use in the United Kingdom has been the subject of a paper published by William Notcutt in the July 2012 issue of the peer-reviewed publication Primary Health Care Research and Development. In this survey of 124 Sativex patients with a mean duration of treatment of 30 months, the majority of respondents and their caregivers reported improvements across a range of daily functional activities, alongside a reduction in the use of concomitant anti-spasticity medication and other health care resources.

A formal prospective trial of prescription use in Germany was presented in October 2012 at the 28th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Lyon, France. This trial involved 300 patients and showed that the clinical response rate on Sativex is with consistent with, and somewhat better than, that seen in the Phase 3 trials.

Post-Approval Evidence of Sativex Safety Profile. In August 2013, we announced the results from a 12-month multicenter, double-blind, randomized parallel group, placebo-controlled study in 121 patients with MS spasticity. The study was required as a post-approval commitment by the UK regulatory authority, the Medicines and Healthcare products Regulatory Agency, or MHRA, with the primary objective of evaluating whether Sativex may have long-term adverse effects on cognitive function or mood. The primary endpoint was the change in cognitive function as assessed by the total Paced Auditory Serial Addition Test, or PASAT, score from baseline to end of treatment. Mood was assessed by the Beck Depression Inventory-II. There was a slight improvement in the PASAT score from the beginning to the end of the study in both the Sativex and placebo groups, thus confirming that the effects of Sativex on long-term cognitive impairment were the same as the effects of placebo. Similarly, the change in mood over the 12 month period was more or less identical in the Sativex and the placebo group, confirming no untoward effect on mood. Of the efficacy secondary endpoints, each of the global impression of change scores as assessed by the patient, physician and carer was highly significantly in favour of Sativex ($p<0.0001$, $p=0.001$ and $p=0.004$ respectively). Detailed data from this study was presented at the 29th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in October 2013.

Sativex in Neuropathic Pain and Other Indications

Sativex is approved to treat MS neuropathic pain in Israel and Canada (under a Notice of Compliance with conditions, or NOC/c, policy) and also has an NOC/c approval in Canada for cancer pain. The NOC/c policy applies to drugs that show promising Phase 2 evidence of efficacy in a patient population with a high, unmet medical need for which there is currently no approved treatment. NOC/c approvals are granted subject to the completion of subsequent Phase 3 confirmatory trials. Although we are not actively pursuing the following indications, we have generated positive Phase 2 data and believe that there may be potential for the use of Sativex to be expanded into the following areas:

- We have studied Sativex in a number of Phase 2 trials in neuropathic pain involving over 1,000 patients. Many of these trials show promising efficacy and are published in peer-reviewed journals. Neuropathic pain is a chronic, debilitating and widespread condition with an estimated prevalence of 1% of the general population. Neuropathic pain arises as a consequence of damage to, or dysfunction in, the nervous system, either peripheral, central or both. Neuropathic pain may be triggered by a variety of diseases and conditions, including MS, stroke, cancer, spinal cord injury, physical trauma or peripheral neuropathy resulting from diabetes.

Neuropathic pain is one of the most difficult types of chronic pain to treat, and relief is often unsatisfactory or short-term.

- In a Phase 2 trial published by R.B.C. Kavia, et al. in the November 2010 issue of Multiple Sclerosis, Sativex showed positive results in the management of bladder problems in people with MS. Bladder problems are a very common feature in up to 75% of people with MS experiencing dysfunction including increased frequency and urgency of urination and increased incontinence.
- In a Phase 2, placebo-controlled trial published by D.R. Blake, et al. in the January 2006 issue of Rheumatology, Sativex showed positive results in treating pain due to rheumatoid arthritis, or RA, as well as treating the underlying disease. RA is the most common form of inflammatory arthritis and afflicts up to 1% of the population of Western countries.

Our Strategic Alliances and Collaborations

We have entered into five separate collaboration agreements for Sativex with major pharmaceutical companies. Each agreement provides the respective partner with exclusive rights in a defined geographic territory to commercialize Sativex in all indications, while we retain the exclusive right to manufacture and supply Sativex to such partner on commercial supply terms for the duration of the commercial life of the product. These agreements typically carry a 15-year initial term, with automatic renewal periods. However, our agreement with Novartis continues on a country-by-country basis for the commercial life of the products. Our partners have the right, under certain circumstances, to terminate their agreements with us, and three of our partners, Almirall, Otsuka and Novartis, have the right to terminate their agreements with us without cause.

Each of our collaboration agreements for Sativex incorporates different supply and royalty terms. With the exception of the Novartis agreement, described below, each of our supply agreements requires us to supply fully labeled Sativex vials at a price that is expressed as a percentage of a partner's in-market net sales revenue. In some cases, part of this revenue is structured as a combination of product supply price plus a royalty, although both types of revenue are accounted for similarly. Sativex supply revenue is invoiced when product inventory is delivered to or collected by the marketing partner. Royalties will be received in arrears based upon quarterly in-market net sales declarations from partners.

The price charged for Sativex in the market is controlled by our marketing partners. However, our contracts do not anticipate us being obligated to supply Sativex at a loss. In such event, if the in-market supply price would cause us to supply Sativex at a loss we would have the right to renegotiate supply terms to prevent this. For example, following the price reduction in Germany in March 2013, the resultant supply price would have led to us providing Sativex to our partner, Almirall, at a loss. We are now completing discussions on an amendment to the supply terms with Almirall which provide for us to generate a margin on supply of product for countries in which a price reduction would otherwise have led to us supplying product at a loss.

Please see Note 3 to our audited consolidated financial statements included as part of this Annual Report for a breakdown of our revenue by geographic location.

Sativex in the United States

In 2007, we entered into a strategic alliance with Otsuka, the second largest Japanese pharmaceutical company based on global sales and the developer of Abilify® (aripiprazole), one of the world's highest selling antipsychotic medications. This alliance is comprised of two separate agreements—a Sativex U.S. license agreement and a global cannabinoid research collaboration agreement.

Under the terms of the Sativex U.S. license agreement, we granted Otsuka an exclusive license to develop and market Sativex in the United States. We are responsible for the manufacture and supply of Sativex to Otsuka. Both companies jointly oversee all U.S. clinical development and regulatory activities for the first cancer pain indication. We will be the holder of the IND until the filing of an NDA, which will be in Otsuka's name. Otsuka will assume development and regulatory responsibility for the second and any subsequent indications. Otsuka will bear the costs of all U.S. development activities for Sativex in the treatment of cancer pain, additional indications and future formulations.

The financial terms of this agreement include total milestone payments and license fees to us of up to $272.0 million, of which approximately $18.0 million relates to license fees, $54.0 million are linked to regulatory milestones, such as initiation of Phase 3 trials, submission of an NDA to the FDA and other regulatory approvals, and $200.0 million are linked to various commercial milestones, as well as revenue from the supply of products and royalties on product sales. Our combined supply price and royalty to Otsuka equates to a percentage in the mid-twenties of Otsuka's in-market net sales revenue. Otsuka paid us the license fee of $18.0 million upfront and has since paid an additional milestone payment of $4.0 million upon commencing the first Phase 3 clinical trial in cancer pain.

Sativex in Asia, the Middle East and Africa

Novartis Pharma AG. In 2011, we entered into an exclusive agreement with Novartis to commercialize Sativex in Australia and New Zealand, Asia (excluding Japan, China and Hong Kong), the Middle East (excluding Israel) and Africa.

Under the terms of this agreement, Novartis has exclusive commercialization rights to Sativex in the above-mentioned territories and will act as the marketing authorization holder for Sativex. We will be responsible for the manufacture and supply of Sativex to Novartis.

The financial terms of the agreement included an upfront fee of $5.0 million from Novartis. In addition, we are eligible to receive additional payments of up to $28.8 million, of which $12.0 million is linked to achievement of regulatory approvals and $16.8 million is linked to commercial performance targets. We will also receive revenue from the supply of products and royalties on net sales of Sativex. Our supply terms to Novartis are structured differently from those of our other partners. We supply batches of unlabeled Sativex vials and Novartis completes the labeling and packaging process. Our supply price is structured as cost of goods plus a margin plus a further royalty that is expected to grow with volume. Over the long-term, we expect our revenue to average a percentage in the teens of Novartis' Sativex in-market net sales revenue.

Australia represents the largest potential market in the territory licensed to Novartis. To date, the Australian reimbursement authorities have not agreed to grant public reimbursement for Sativex in the MS spasticity indication and therefore the product is not yet launched in that country. We expect the position in Australia to impact Novartis' commercialization strategy for its licensed territory and this may lead to Novartis waiting for the cancer pain indication to be approved prior to commencing commercialization of the product.

Neopharm Group. Under an agreement signed in 2010, Neopharm, an Israeli pharmaceutical company, holds exclusive commercial rights to Sativex in Israel. The financial terms of this agreement did not include a license fee and we are not entitled to any milestone payments. We will receive revenue from the supply of products to Neopharm, expected to equate to a percentage equal to forty to fifty of Neopharm's in-market net sales revenue. To date, we have received less than $300,000 under this collaboration agreement.

Under the terms of this agreement, Neopharm acts as market authorization holder in the territory. We are responsible for commercial product supply to Neopharm for which we generate sales revenue.

Sativex in the European Union

Almirall S.A. In 2005, we entered into an exclusive agreement with Almirall, an international pharmaceutical company with headquarters in Spain and 2011 global sales of €768.0 million, to commercialize Sativex in the European Union (excluding the United Kingdom) and E.U. accession countries, as well as Switzerland, Norway and Turkey. In 2012, this agreement was amended to add Mexico to the licensed territory. In countries where Almirall has no direct presence at the time of product launch, we will jointly agree on the appointment of distribution partners. In such countries, we may elect to distribute the product ourselves.

Under the agreement, we are the marketing authorization holder for Sativex in all countries in the territory except where local regulations require a locally registered entity to assume this responsibility. In addition, we are responsible for commercial product supply to Almirall. The financial terms of the agreement included an upfront fee of £12.0 million. In addition, milestone payments are payable to us upon the successful completion of certain development activities, as well as on regulatory approvals and the achievement of specified sales targets. Since its initial execution in 2005, the agreement has been the subject of various amendments, two of which included the provision of new milestone payments. Since 2005, in total, we have received £20.8 million of milestone payments from Almirall. We have the potential to receive a further £19.5 million in future milestone payments in the event that the relevant milestones are achieved. Of such £19.5 million in potential future milestone payments, £6.5 million are linked to regulatory and clinical milestones and £13.0 million are linked to commercial milestones. We also receive revenue from the supply of Sativex, currently equating to a percentage in the low to mid-twenties of Almirall's in-market net sales revenue, a percentage which, following an amendment currently under discussion, is expected to be subject to a floor price equal to cost of goods plus a margin. This percentage is expected to increase to the mid-thirties if Sativex is approved for cancer pain in Europe.

Bayer HealthCare AG. In 2003, we entered into an agreement with Bayer whereby we granted Bayer an exclusive license to market Sativex in the United Kingdom. This agreement was amended later in 2003 to include Canada.

Under the agreement, we are the marketing authorization holder for Sativex in the United Kingdom and Canada. In addition, we are responsible for commercial product supply to Bayer.

The financial terms of the agreement included an upfront fee of £5.0 million. In addition, milestone payments are payable on the successful completion of certain development activities, as well as on regulatory approvals and the achievement of specified sales targets. Since its initial execution in 2003, the agreement has been the subject of various amendments, one of which included the provision of new milestone payments. In total, we have received £14.8 million in milestone payments from Bayer. We have the potential to receive a further £9.0 million in milestone payments in the event that the relevant milestones are achieved, all of which are related to future regulatory approvals. We also receive revenue from supply of Sativex, equating to a percentage in the mid-thirties to forty of Bayer's in-market net sales revenue.

Research Collaboration with Otsuka

Under a six-year research collaboration agreement with Otsuka which ended in June 2013, we jointly conducted pre-clinical research on a range of our cannabinoids, both alone and in combination, as potential new drug candidates for the treatment of CNS disorders and oncology. At the end of the agreement, global rights to all product candidates were automatically exclusively licensed back to us from Otsuka.

This collaboration yielded promising data and new intellectual property with particular focus on epilepsy, schizophrenia and various oncology indications, including glioma. These efforts were focused

on a few cannabinoid drug candidates, which include CBD, THCV, CBG, CBDV, alone and/or in combination. With global rights now licensed back to us, we are now progressing the development of a number of these product candidates. Otsuka is entitled to a small royalty on sales of product candidates protected by patents filed during the term of the collaboration.

Pipeline Research and Development

There are over 70 cannabinoid compounds, and our research explores their potential therapeutic applications across a broad range of disease areas, including in the treatment of epilepsy, type-2 diabetes, ulcerative colitis, schizophrenia, cancer and neurodegenerative disease.

Pipeline Programs

Our pipeline of orphan drug programs include the following:

- Epidiolex, a liquid formulation of highly purified CBD extract, as a treatment for various orphan pediatric epilepsy syndromes;
- Combinations of GWP42002 and GWP42003, which feature THC and CBD as the primary cannabinoids, in Phase 1a trials for the treatment of glioma; and
- Intravenous GWP42003, which features CBD as the primary cannabinoid, in pre-clinical development for the treatment of Neonatal Hypoxic-Ischemic Encephalopathy, or NHIE.

Our additional lead pipeline programs comprise distinct product candidates with the following primary cannabinoid components:

- GWP42006, which features CBDV as the primary cannabinoid, in Phase 1 clinical trials for the treatment of epilepsy for which data is expected in the first half of 2014;
- GWP42004, which features THCV as the primary cannabinoid, is expected to begin Phase 2 clinical trials for the treatment of type-2 diabetes in the first half of 2014;
- GWP42003, which features CBD as the primary cannabinoid, is in Phase 2 clinical trials for the treatment of ulcerative colitis for which data is expected in the first half of 2014; and
- GWP42003, which features CBD as the primary cannabinoid and is expected to enter Phase 2 trials for the treatment of schizophrenia in the first half of 2014.

In addition to these programs, we are conducting pre-clinical research into the potential application of our cannabinoids in several examples of neuroprotection, nausea and anorexia/cachexia.

Our early clinical development activities are conducted outside of the United States and we generally expect to submit INDs in the United States for our product candidates at a later stage in their development. For orphan product candidates, we generally expect to submit INDs in the United States at an earlier stage of clinical development.

Orphan Pediatric Epilepsy Program

Market Overview

Epilepsy is one of the most common neurological disorders in children. According to Russ in the February 2012 edition of Pediatrics, there is a point prevalence of 6.3 per 1,000 children currently diagnosed with epilepsy. Based on these findings, we estimate that 466,000 childhood patients in the United States and 765,000 patients in Europe are currently diagnosed with epilepsy.

Specialists estimate that up to 20% of these cases show pharmacoresistance to current treatment (i.e., seizures that persist despite accurate diagnosis and carefully monitored treatment with multiple

antiepileptic drugs) and are deemed "medically intractable". Furthermore it is recognized that some of those that do find relief often suffer side effects severe enough with their current medication that an alternative or adjunct is often sought.

In total, therefore, we believe the size of the intractable pediatric epilepsy population is 93,200 patients in the United States and 153,000 in Europe.

Epidiolex Development Strategy in Pediatric Epilepsy

Many cases of epilepsy are able to be classified and have clearly defined natural histories providing important information on the likelihood of seizure control and chance of remission. Some of the rarer electroclinical syndromes have very poor responses to treatment and negligible remission rates such as Ohtahara in neonates, Dravet in infants, Lennox-Gastaut in young children and progressive myoclonic epilepsies in adolescence.

Our strategy for the development of Epidiolex in pediatric epilepsy is to initially concentrate on two orphan indication syndromes—Dravet Syndrome and Lennox-Gastaut Syndrome. We expect to further expand the market opportunity by either targeting additional orphan seizure disorders and/or by seeking approval for a wider indication of pediatric epilepsy refractory to current treatments.

Dravet Syndrome

Dravet syndrome is a severe infantile-onset, genetic, drug-resistant epilepsy syndrome with a distinctive but complex electroclinical presentation. Onset of Dravet syndrome occurs during the first year of life with clonic and tonic-clonic seizures in previously healthy and developmentally normal infants. Symptoms peak at about five months of age, and the latest onset beginning by 15 months of use. Other seizures develop between one and four years of age such as prolonged focal dyscognitive seizures and brief absence seizures, and duration of these seizures decreases during this period, but their frequency increases. Prognosis is poor and approximately 14% of children die during a seizure, because of infection, or suddenly due to uncertain causes, often because of the relentless neurological decline. Patients develop intellectual disability and life-long ongoing seizures. Intellectual impairment varies from severe in 50% patients, to moderate and mild intellectual disability each accounting for 25% cases. Patients may rarely return to normal intellect.

According to Forsgren L.et al in the 2004 edition of Epilepsy in Children, the incidence of epilepsy in the first year of life is 1.5 per 1,000 people, or, by our estimate, 6,450 new epilepsies per year. Dravet et al in the 2012 edition of Epileptic Syndromes in Infancy, Childhood and Adolescence, up to 5% of epilepsies diagnosed in the first year of life are Dravet syndrome, equating to 320 new cases per year in the United States. With a mortality rate that studies have shown may be as high as 15% in the first 20 years of life, or, by our estimate, 5,440 patients with Dravet in the United States under the age of 20 years. Applying the same assumptions in Europe, we believe there are an estimated 6,710 Dravet patients in the European Union. It is likely that these figures are a low estimate as this syndrome is reportedly underdiagnosed.

A large percentage of cases of Dravet syndrome have a family history for epilepsy or convulsions. Heterozygous de novo mutations of the alpha 1 (α-1) subunit of the SCN1A gene, which encodes a voltage-gated sodium channel, are the major cause of Dravet syndrome and are found in approximately 75% of patients and more than 500 SCN1A mutations have been reported to be associated with this disorder.

There are currently no FDA approved treatments specifically indicated for Dravet syndrome. The standard of care usually involves a combination of the following anticonvulsants: clobazam, clonazepam, leviteracetam, topirimate, valproic acid, ethosuximide, or zonisamide. Stiripentol is approved in Europe for the treatment of Dravet syndrome in conjunction with clobazam and valproate. In the United States, stiripentol was granted an Orphan Drug Designation for the treatment of Dravet syndrome in 2008; however, the drug is not FDA approved.

Potent sodium channel blockers used to treat epilepsy actually increase seizure frequency in patients with Dravet Syndrome. The most common are phenytoin, carbamazepine and lamotrigine and rufinamide.

Management of this disease may also include a ketogenic diet, and physical and communication therapy. In addition to anti-convulsive drugs, many patients with Dravet syndrome are treated with anti-psychotic drugs, stimulants, and drugs to treat insomnia.

Lennox-Gastaut Syndrome

Lennox-Gastaut syndrome, or LGS, is a rare disorder characterized by multiple types of seizures with slow spike wave complexes on EEG, such seizures usually beginning before four years of age. The seizure types vary among patients and include: tonic axial, atonic, atypical absence, and myoclonic. Tonic axial seizures are the characteristic type of seizure seen in LGS and consist of flexion of the neck and body, extension of the arms and legs and contraction of the facial muscles. Other effects that may be associated include apnea, eye rolling and facial flushing. Although they only last for seconds, they can occur day or night and usually impair consciousness. Atypical absence seizures also occur in a majority of cases and although generally subtle, they are often accompanied by loss of muscle tone, myoclonic jerks and drooling.

According to Trevathan et al in the December 1997 edition of Epilepsia, the estimated prevalence of Lennox-Gastaut syndrome is between 3 and 4% of childhood epilepsy, or, by our estimate, 14,000 to 18,500 patients in the United States and 23,000 to 31,000 patients in the European Union under the age of eighteen years.

Drug resistance is one of the main features of LGS. Generally, treatment often requires broad spectrum anti-epileptic drugs and/or polypharmacy. Treatment will also depend on the seizure type as some treatments that are effective for one type of seizure may worsen another. The treatments already approved by the FDA for LGS and used as adjunctive therapy with existing medications are: Onfi (clobazam); Banzel (rufinamide); Lamictal (lamotrigine); Topamax (topirimate); and Felbatol (felbamate). Although these medicines, when used with other particular anti-epileptic drugs, show a level of efficacy, many also have severe undesirable side effects. Furthermore, several of these medicines are based on the same mechanism of action of traditional anti-epileptic drugs. As patients with LGS generally need to take several treatments to gain any change to their seizure frequency, we believe there is a need for further pharmacological treatments, particularly those with a different mechanism of action, to give prescribers more options in treating this rare, pharmacoresistant syndrome.

Cannabinoid Rationale for Treating Epilepsy

Several features of the pharmacology of certain cannabinoids suggest that they may be candidates for investigation as anti-epileptic drugs. A series of validated laboratory experiments have shown that certain cannabinoids can modulate neurotransmission, can reduce neuro-inflammation, and can affect oxidative stress.

These cannabinoids may simultaneously modulate a number of endogenous systems to attenuate and/or prevent epileptic neuronal hyperexcitability. These include ion channel control, inflammation, modulation of oxidative stress and inhibition of gene expression of epilepsy associated genes.

Several different ion channels influence epileptogenesis (the process by which a normal brain develops epilepsy) including both ligand-gated and voltage-gated ion channels. It is the former to which a proportion of the actions of plant cannabinoids can be attributed, for example through agonism and antagonism of G-protein coupled receptors, including orphan receptors as well as modulation of transient receptor potential (TRP) channels (differentially activated, repressed and desensitized by different plant cannabinoids). Additionally it is now recognized that there is a role for inflammation in epilepsy. Some cannabinoids possess anti-inflammatory properties including inhibition of pro-inflammatory cytokine release and modulation of glial cell/neuronal interactions. Furthermore they modulate oxidative stress and production of toxic nitric oxide. Research shows that other than THC, plant cannabinoids have little or no affinity for the cannabinoid receptors, and therefore do not share the unwanted psychoactivity that goes along with stimulation of the CB1 receptor in particular.

Finally, certain cannabinoids may possess disease modifying potential through regulation of epilepsy related genes, as well as up-regulation of endogenous anti-convulsant neuropeptides and/or compensatory systems.

We continue to conduct research into the mechanism of action of the anti-epileptic cannabinoids.

CBD pharmacology in epilepsy

The epilepsy relevant pharmacology of CBD can be summarized as follows: inhibition of neutrophil and microglial migration, anti-inflammatory effects in conventional animal models; inhibition of adenosine uptake and indirect agonism of the neuroprotective and anti-inflammatory A2a receptor; other neuroprotective effects (TNF inhibition and anti-oxidant activity); antipsychotic activity; agonism at the orphan receptor GPR55; Desensitizer of TRP channels; anticonvulsant activity in all laboratory models tested; ion channel modulation; reduction of acetylcholine turnover at neuro-muscular junctions; and perturbation of the negative effects of THC (opposes euphoric, cognitive and psychotropic effects) via one or more of the above mechanisms.

CBD has negligible binding at the CB1 receptor, and so shares neither the pharmacology of CB1 agonists such as THC nor that of CB1 antagonists such as Rimonabant. CBD's mechanism for treating seizures is not fully understood but is believed to involve a combination of beneficial effects stacking upon one another (polypharmacology).

Preclinical models suggest a broad role for CBD in generalized and absence seizures, and clinical reports of benefit extend into other congenital seizure disorders.

Our CBD Research in Pediatric Epilepsy

We have conducted pre-clinical research of CBD in epilepsy for several years and have reported significant anti-epileptiform and anticonvulsant activity using a variety of in vitro and in vivo models. This research has shown the ability of CBD to treat seizures in acute models of epilepsy with significantly fewer side effects than existing anti-epileptic drugs.

Our cannabinoid research compounds were screened in electrically discharging hippocampal brain slices cause by the omission of Mg^{2+} ions from, or addition of the K^+ channel blocker, 4-aminopyridine (4-AP) to the bathing solution. In these models, 100μM of CBD decreased epileptiform amplitude and duration as well as burst frequency; importantly this compound exerted no effect upon the propagation of epileptiform activity.

Subsequently, the anti-convulsant actions of 1, 10 and 100 mg/kg CBD were examined in three different *in* vivo seizure rodent models. In the PTZ-induced acute, generalized seizures model, 100 mg/kg CBD significantly decreased mortality rate and the incidence of tonic-clonic seizures. In the acute pilocarpine model of temporal lobe seizures all doses of CBD significantly reduced the percentage of animals experiencing the most severe seizures. In this model of partial seizures, 10 and 100 mg/kg CBD significantly decreased the percentage of animals dying as a result of seizures and all doses of CBD also decreased the percentage of animals experiencing the most severe tonic—clonic seizures.

CBD Clinical Data in Pediatric Epilepsy

Although there are no placebo-controlled clinical studies reported in the literature for CBD in the treatment of pediatric epilepsy, study results in an article published in the December 2013 edition of Epilepsy and Behavior by Jacobson and Porter of Stanford University provides evidence of promising effects. The method of the study consisted of surveying parents of children in the United States who reported using CBD-enriched cannabis to control their intractable epilepsy. The parents were identified by their membership in an internet-based group dedicated to sharing information about the use of CBD-enriched cannabis to treat their children's seizures. These parents were using a variety of non-approved and non-standardized "artisanal" CBD preparations to control their children's drug resistant seizures. Nineteen parents were surveyed to determine the effects of CBD-enriched cannabis on their children's seizure frequency. Of the 19 children in the survey, 13 children had Dravet syndrome, four had Doose syndrome, and one each had LGS and idiopathic epilepsy. The average number of antiepileptic drugs tried before using CBD was 12. Sixteen (84%) of the 19 parents reported a reduction in their child's seizure frequency while taking CBD. Of these, two (11%) reported complete seizure freedom, eight (42%) reported a greater than 80% reduction in seizure frequency, and six (32%) reported a 25-60% seizure reduction. Other beneficial effects included increased alertness, better mood, and improved sleep. Side effects included drowsiness and fatigue.

Results from this study are displayed in the graphs below:

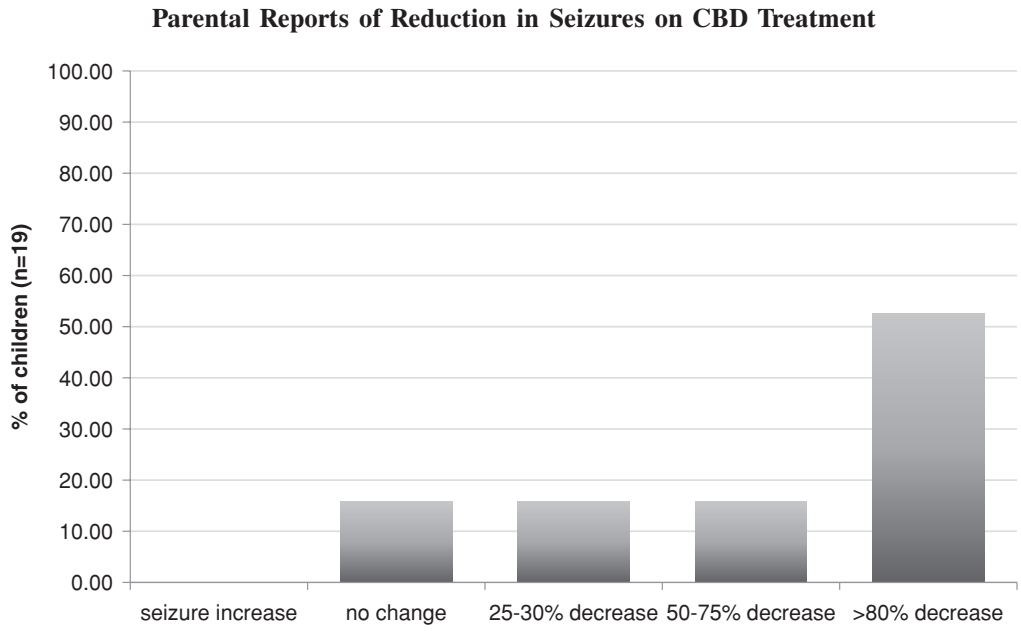


Figure 1. Response to CBD

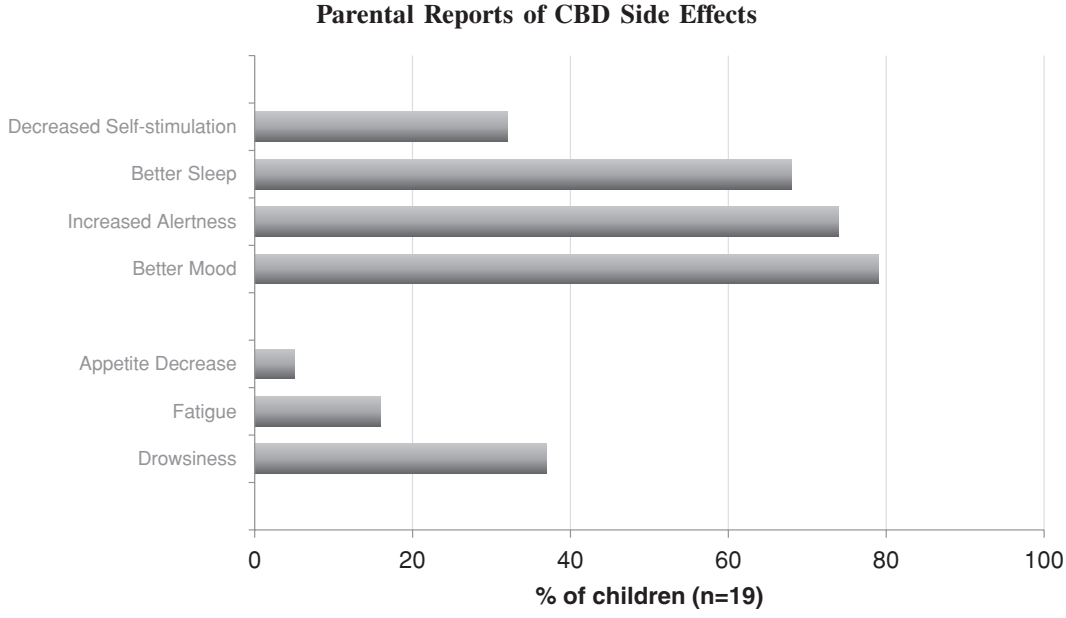


Figure 2. Reports of Side Effects Due to CBD

CBD Published Clinical Data in Epilepsy

In addition to the above survey, there is a published literature of small-scale academic placebo-controlled studies, observational studies and case reports evaluating CBD in epilepsy, which suggest positive clinical signals.

Our Clinical Research

During 2013, we have received increasing interest amongst U.S. pediatric epilepsy specialists and patient organizations in the potential role of CBD in treating intractable childhood epilepsy, in particular Dravet syndrome. This interest led to a medical conference organized by the New York University School of Medicine on October 4th 2013 entitled: "Cannabidiols: Potential Use in Epilepsy and Other Neurological Disorders". Epilepsy specialists at the meeting viewed CBD as attractive for the treatment of these disorders for a variety of reasons, including:

- Case reports of its efficacy in severe, refractory patients consistently provide encouraging signals; and
- CBD's "natural" profile and safety data generated to date suggest that it could be an attractive treatment option without the unwanted side-effects of other anti-seizure drugs.

In addition, specialists at this conference concluded the following:

- Only a pharmaceutical formulation of CBD which could meet FDA requirements for standardization and quality control would be appropriate for administering to children; and
- Placebo-controlled studies should be performed as a matter of urgency in order to provide robust evidence of the safety and efficacy of CBD.

Although no such placebo-controlled trials have yet been initiated, in 2013, a total of seven expanded access INDs have been granted by the FDA to outside investigators to allow treatment of approximately 125 pediatric epilepsy patients with Epidiolex. These patients suffer from Dravet syndrome, LGS, and other pediatric epilepsy syndromes. A small number of patients are already being treated and the majority are expected to commence treatment in the coming months after receipt of the necessary DEA site licenses. We are aware of further interest from additional U.S. and ex-U.S. physicians to host similar INDs for Epidiolex. We are requesting that the physicians collect regular treatment data on seizure frequency, Epidiolex dosing, concomitant anti-epileptic medication, adverse events and other clinical measures.

In November 2013, we received Orphan Drug Designation for Epidiolex for the treatment of Dravet syndrome. With advice from pediatric epilepsy specialists, we have proposed an investigational plan to the FDA for Epidiolex in Dravet syndrome and expect to hold a pre-IND meeting in the near future. Following this, we expect to submit an IND to the FDA and commence clinical development in 2014. We expect to apply to the FDA to obtain Orphan Drug Designation for Epidiolex for the treatment of LGS.

CBD Safety Profile

CBD is one of the two principal cannabinoids in Sativex. Sativex has over 19,000 patient years of exposure in real world use, during which a favorable safety profile and positive benefit-risk balance has continued to be established.

The administration of CBD alone in clinical studies is presently more limited, with 206 patients in GW-sponsored early phase comparative studies having been treated either with CBD alone or with CBD as the major cannabinoid in a combination that included other GW cannabinoids. These studies have included a range of conditions, including inflammatory bowel disease, multiple sclerosis and dyslipidemia. During these Phase 1 and 2 clinical trials, 10 patients reported a total of 12 Serious Adverse Events (SAEs), none of which occurred in more than a single patient. The most common adverse events (i.e., those observed in greater than 10% of subjects) were diarrhea, headache and nausea.

GWP42006 (CBDV) in Epilepsy

In addition to CBD, we have a second product candidate, GWP42006, which features CBDV as the primary cannabinoid, which has also shown anti-convulsant effects across a range of in vitro and in vivo models of epilepsy.

In a paper published in the September 2012 issue of The British Journal of Pharmacology by scientists with whom we collaborate at the University of Reading, United Kingdom, GWP42006 was reported to have the potential to prevent more seizures, with few of the side effects caused by many existing anti-epileptic drugs, such as uncontrollable shaking. In the study, GWP42006 strongly suppressed seizures in six different experimental models commonly used in epilepsy treatment. GWP42006 was also found to provide additional efficacy when combined with drugs currently used to control epilepsy. Genetic biomarkers for response have been identified.

We initiated a Phase 1 trial for GWP42006 in the second half of 2013. This trial is due to report results in the first half of 2014.

GWP42006 has the potential for development in the field of pediatric epilepsy as well as the broader epilepsy market.

Epilepsy is estimated to affect 50 million people worldwide including, according to the Centers for Disease Control and Prevention, 2.2 million people in the United States. Drug therapy remains ineffective for seizure control in up to 30% of patients with epilepsy because either the drugs do not control the seizures or the patients cannot tolerate the side effects. Currently available drugs can cause significant side effects to individuals' movement and cognitive abilities that can adversely affect the quality of life for epileptic patients.

Glioma

Market Overview

Glioma describes any tumor that arises from the glial tissue of the brain. Glioblastoma, or GBM, is a particularly aggressive tumor that forms from abnormal growth of glial tissue. According to the New England Journal of Medicine, GBM accounts for approximately 46% of the 22,500 new cases of brain cancer diagnosed in the United States each year. Treatment options are limited and expected survival is a little over one year. GBM is considered a rare disease by the FDA and the European Medicines Agency, or EMA.

Our Research

In pre-clinical models, we have shown cannabinoids to be orally active in the treatment of gliomas and, in addition, have shown tumor response to be positively associated with tissue levels of cannabinoids. We have identified the putative mechanism of action for our cannabinoid product candidates, where autophagy and programmed cell death are stimulated via inhibition of the akt/mTORC1 axis. We have shown in *in vivo* studies that cannabinoids have a synergistic effect with temozolomide, the standard chemotherapeutic agent used in the treatment of glioma.

In light of this promising pre-clinical research, we commenced an early proof of concept Phase 1b clinical trial in 20 patients with recurrent GBM in October 2013. The trial compares a combination of GWP42002 and GWP42003 with placebo, in each case in combination with temozolomide, the current standard of care. This study is a two part study with an open-label phase to assess safety and tolerability and a double blind, randomised, placebo-controlled phase with patients randomized to receive active or placebo. Data from the open label phase is expected in 2014. The primary outcome measure is 6 month progression free survival.The principal cannabinoids we have studied in pre-clinical models of glioma are GWP42002 and GWP42003 in various ratios, and this first trial will employ an

equal ratio of GWP42002 and GWP42003 to establish a proof of principle. It is anticipated that subsequent development would focus on a product candidate with a different ratio of GWP42002 and GWP42003.

We have also generated promising pre-clinical data to suggest that our cannabinoids could have benefits in other cancers, notably breast cancer, colon cancer and prostate cancer. In particular, in a model of Her2 positive breast cancer, we have shown cannabinoids to have the ability to inhibit not only local metastases, but also the occurrence of distant metastases. Our efforts are now focused on identifying the precise molecular mechanism of action of cannabinoids in breast cancer, and to define the optimum cannabinoid treatment regimen.

Neonatal Hypoxic-Ischemic Encephalopathy

Disease Background

Neonatal hypoxic-ischemic encephalopathy, or NHIE, is acute or sub-acute brain injury due to asphyxia caused during birth resulting from deprivation of oxygen during birth (hypoxia) as a result of a sentinel event such as ruptured placenta, parental shock and even increased heart rate. Hypoxic damage can occur to most of the infant's organs, but brain damage is the most serious and least likely to heal, resulting in encephalopathy. This can later manifest itself as either mental retardation (including developmental delay and/or intellectual disability) or physical disabilities such as spasticity, blindness and deafness. Indeed, spastic diplegia and the other forms of cerebral palsy almost always feature asphyxiation during the birth process as a contributing factor.

The exact timing and underlying causes of these outcomes remains unknown but it is widely recognized that interventions need to be administered within six hours of hypoxic insult.

Market Overview

According to Kurinczuk et al in the 2010 edition of Early Human Development, the incidence of NHIE is 1.5 to 2.8 per 1,000 births in the United States, or, by our estimate, 6,500 to 12,000 cases per year. Of these, 35% are expected to die in early life and 30% will end up with permanent disability. However, at time of diagnosis of NHIE, it is unclear what the prognosis may be, even for cases that are mild, and therefore the whole population is presumed to require treatment.

There are currently no FDA approved medicines specifically indicated for NHIE. The only FDA approved treatment is the Olympic Cool-Cap System and treatment guidelines in many European countries also support use of whole body hypothermia. Clinical studies have shown the Cool-Cap to reduce the occurrence of disability due to NHIE but not death while whole body hypothermia had a more marginal effect on disability but is able to reduce mortality.

There are academic initiatives looking to develop treatments in this area. In addition, one intervention being investigated by the pharmaceutical industry is an IV infusion of 2-Iminobiotin. Neurophyxia attained orphan drug designation for this treatment in both Europe and the United States and is conducting a Phase 2 study in Eastern Europe.

Cannabinoid Rationale for Treating NHIE

The pathophysiology of NHIE includes processes such as apoptosis, oxidative stress, inflammation and excitotoxicity, and may involve not only the brain, but also other organs. Some plant cannabinoids are able to influence all of these processes, but unlike other therapeutic compounds under development, can combine these neuroprotective strategies within a single molecule. Firstly they can act on transcription factors and nuclear receptors that control neuronal homeostasis and survival. Secondly, not only do they have important free radical scavenging actions, but may also upregulate and activate endogenous antioxidant defenses. Thirdly, they influence the immune network and modulate

phenomena associated with infection or inflammation, via inhibition of macrophage and neutrophil migration, natural killer cell proliferation, and by their ability to inhibit harmful cytokine production. . It has been widely reported that endocannabinoids are able to protect the glial cell, an, effect that may be independent of CB receptors. Finally, the endocannabinoid system, or ECS, has been shown to be neuroprotective in animal models—the levels of endogenous cannabinoids become enhanced in the brains of newborn rats after acute injury, acting as a protective response, and it has been proposed that one additional mechanism by which plant cannabinoids work is by preventing theenzymatic degradation of endocannabinoids., thus enhancing endogenous defense mechanisms.

Recent research into the neuroprotection that has been shown by cannabinoids in animal models of neonatal hypoxia has also suggested a role for the 5HT1A receptor, since some of the beneficial effects can be blocked by 5HT1A receptor blockers.

CBD as the Primary Cannabinoid Product Candidate in NHIE

In addition to its other properties, the possible neuroprotective effects of CBD have been examined. These neuroprotective effects are thought to be based mainly on the potent anti-inflammatory and anti-oxidant properties of CBD, although other actions of CBD that might also account for CBD-induced neuroprotection including: inhibition of calcium transport across membranes; inhibition of anandamide uptake and enzymatic hydrolysis; inhibition of iNOS protein expression and NF-κB activation; and inhibition of adenosine uptake. In a similar fashion to endocannabinoids, adenosine is thought to be part of a natural neuroprotective system, because adenosine levels rise in response to hypoxic insult in the brain and increasing extracellular adenosine acts as a neuroprotectant. It has been demonstrated that CBD enhances adenosine signaling through the inhibition of adenosine re-uptake and therefore indirectly activates the A_{2A} receptor.

Previously, it was demonstrated that CBD reduces brain damage after ischemic injury in adult animals. In a piglet model of NHIE, CBD improved brain activity as measured by an EEG and reduced the numbers of seizures by half, while histological analysis of brain tissues showed that neuron degeneration was reduced. Neurological exams showed improved neurobehavioral performance up to three days after insult. There were also significant beneficial extra cerebral effects and the dose of dopamine needed by the animals to maintain blood pressure was less than half of what was required in vehicle treated animals.

Our NHIE Research

In a paper by Castillo, reporting results from our collaboration, CBD protected newborn mice forebrain slices from oxygen and glucose deprivation. Prevention of necrotic and apoptotic cell death and reductions in excitotoxicity, inflammation and nitrous oxide production was mediated by CB_2 and adenosine receptors. Another study from our collaboration with Lafuente showed that administration of CBD to newborn piglets at doses much lower than those reported in the literature protects brain cells, preserves brain activity, prevents seizures and improves neurobehavioral performance. These neuroprotective effects were not only free from side effects but also associated with some cardiac, hemodynamic, and ventilatory benefits unlike other promising compounds with neuroprotective activity. These data support the view of CBD as a possible therapy for asphyxiated newborns.

During 2014, we are planning to consult with regulatory authorities on the development program for an intravenous CBD formulation in the treatment of NHIE.

Type-2 Diabetes

Market Overview

According to the American Diabetes Association, 25.8 million individuals in the United States, or 8.3% of the population, have diabetes, of which at least 90% have the type-2 form. According to the World Health Organization, between 2010 and 2030, diabetes rates in developing countries will increase by 70% and by 20% in developed countries.

Type-2 diabetes is associated with two pathological features—insulin resistance in peripheral tissues causing an increase in the insulin requirement and a failure of the insulin producing cells in the pancreas to meet this increased demand. Insulin resistance is driven by obesity, as well as a genetic predisposition, age and lack of exercise. Insulin resistance causes elevated blood glucose levels, which is associated with various complications of diabetes, including increased risk of cardiovascular disease, kidney damage, nerve damage, and eye disease.

There is no cure for diabetes, so treatments are aimed primarily at controlling blood glucose levels. There is recognition that advances in the treatment of type-2 diabetes should focus not merely on glucose control but in protecting the overworked pancreatic islet cells from failure. Thus, there is an unmet need for improved insulin sensitizer drugs and oral treatments that result in a restoration of normal insulin production and glucose-dependent release of insulin from pancreatic islets.

Our Research

We have completed a Phase 2a trial in the treatment of dyslipedemia in patients with type-2 diabetes. This five-arm trial was a 13 week randomized, double blind, placebo controlled, parallel group, pilot trial of GWP42004 (5mg), GWP42003 (100mg) and two separate ratios (5mg:5mg and 100mg:5mg) of GWP42003 and GWP42004. Each treatment was delivered in the form of oral capsules and administered twice daily. The trial enrolled a total of 62 type-2 diabetes patients, such that each treatment group had 11 to 14 patients.

Although GWP42004 showed no benefit in lipid control, the trial showed that GWP42004, an oral cannabinoid treatment, produced the following desirable anti-diabetic effects: reduced fasting plasma glucose levels ($p=0.04$), with an increase in fasting insulin ($p=0.289$), and improved pancreatic beta-cell function ($p=0.0074$). Other trends of interest included increased serum adiponectin ($p=0.0024$), reduced systolic blood pressure ($p=0.099$), reduced serum IL-6 levels ($p=0.076$), and reduced serum C-Reactive Protein (CRP) levels ($p=0.107$). GWP42004 also showed numerical improvement in increased insulin sensitivity ($p=0.275$), improvements in both glucose and insulin response to glucose load (OGTT) ($p=0.889$ and $p=0.417$, respectively), and raised GLP-1 (glucagon-like peptide-1) ($p=0.254$). In this small study, GWP42004 was numerically better than placebo in reduction of HbA1c, the standard primary endpoint for Phase 3 diabetes studies, but failed to demonstrate significance ($p=0.278$). Because baseline HbA1c levels were normal, a significant reduction would not be expected. We are designing future studies of GWP42004 to focus on patients with elevated baseline HbA1c levels. The trial did not show meaningful effects in the other treatment arms.

Several of these findings are consistent with pre-clinical data generated in collaboration with Professor Mike Cawthorne at the GW Metabolic Research Laboratory, University of Buckingham. In particular, pre-clinical data suggests that GWP42004 protects the insulin-producing cells of the pancreatic islets, a highly desirable feature of a new anti-diabetic medicine, increases insulin sensitivity, and reduces fasting plasma glucose levels.

We are now planning a larger placebo-controlled Phase 2 dose ranging trial of GWP42004 which is expected to start in the first half of 2014.

Ulcerative Colitis

Market Overview

Ulcerative colitis, or UC, is a chronic, relapsing inflammatory disease affecting the colon which can cause pain, urgent diarrhea, severe tiredness and loss of weight. In addition, patients with chronic intestinal inflammation have an increased risk of developing bowel cancers. According to the Crohn's & Colitis Foundation of America, UC may affect as many as 700,000 Americans.

Medical treatment for UC has two main goals: achieving remission (the near absence of symptoms) and, once that is accomplished, maintaining remission (prevention of flare-ups). To accomplish these goals, treatment is aimed at controlling the ongoing inflammation in the intestine. The four major classes of medication used today to treat ulcerative colitis are aminosalicylates (5-ASA), steroids, immune modifiers and antibiotics. According to the Centers for Disease Control and Prevention, in one-quarter to one-third of patients with ulcerative colitis, medical therapy is not completely successful or complications arise. Under these circumstances, surgical removal of the colon may be considered.

Our Research

We have shown that GWP42003 has anti-inflammatory properties in a number of accepted animal models of inflammation, notably of the gut and the joints. In addition, we have shown the capacity of GWP42003 to inhibit the production in tissues of chemical mediators of inflammation, such as Tumor Necrosis Factor alpha, or TNFα. In particular, we have demonstrated efficacy in the treatment of UC in standard in vivo models.

We have initiated a 62-patient Phase 2a trial to investigate the efficacy and safety of GWP42003 compared with placebo for the treatment of UC in patients refractory to 5-ASA. This trial is due to report results in the first half of 2014.

Schizophrenia

Market Overview

Schizophrenia is a chronic disease that manifests through disturbances of perception, thought, cognition, emotion, motivation and motor activity. Over a lifetime, about 1% of the population will develop schizophrenia.

All antipsychotic treatments for schizophrenia rely primarily upon their antagonistic action at the dopamine D2 receptor for their antipsychotic effect. They produce a wide range of adverse events, and are often poorly tolerated by patients resulting in poor compliance with treatment.

Current antipsychotics also have little or no effect upon the 'negative' symptoms (blunted mood and lack of pleasure, motivation and movement) of schizophrenia or the associated cognitive deficit. Furthermore, the 'positive' symptoms (such as hallucinations, delusions and thought disorder) of at least one third of patients fail to respond adequately to current treatments.

Our Research

GWP42003 has shown notable anti-psychotic effects in accepted pre-clinical models of schizophrenia and importantly has also demonstrated the ability to reduce the characteristic movement disorders induced by currently available anti-psychotic agents. The mechanism of GWP42003 does not appear to rely on the D2 receptor augmentation of standard antipsychotics and therefore has the potential to offer a novel treatment option in this therapeutic area. We are currently preparing to commence a Phase 2a trial of GWP42003 in the treatment for schizophrenia in the first half of 2014.

Additionally, our pre-clinical research findings suggest that a range of other psychiatric conditions may be promising targets for cannabinoid therapeutics.

Intellectual Property and Technology Licenses

Our success depends in significant part on our ability to protect the proprietary nature of Sativex, our product candidates, technology and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing on our proprietary rights. We have sought, and

plan to continue to seek, patent protection in the United States and other countries for our proprietary technologies. Our intellectual property portfolio includes 46 patent families with issued and/or pending claims directed to plants, plant extracts, extraction technology, pharmaceutical formulations, drug delivery and the therapeutic uses of cannabinoids, as well as plant variety rights, know-how and trade secrets. As of September 30, 2013, we own 318 pending patent applications worldwide. Within the United States, we already have 17 issued patents with a further 25 pending patent applications under active prosecution. There are an additional 192 issued patents outside of the United States. Our policy is to seek patent protection for the technology, inventions and improvements that we consider important to the development of our business, but only in those cases where we believe that the costs of obtaining patent protection is justified by the commercial potential of the technology, and typically only in those jurisdictions that we believe present significant commercial opportunities.

We also rely on trademarks, trade secrets, know-how and continuing innovation to develop and maintain our competitive position.

Our strategy is to seek and obtain patents related to Sativex across all major pharmaceutical markets around the world. In the United States, our patents and/or pending applications (if they were to issue) relating to Sativex would expire on various dates between 2021 and 2026, excluding possible patent term extensions. We have at least seven different patent families containing one or more pending and/or issued patents directed to the Sativex formulation, the extracts from which Sativex is composed, the extraction technique used to produce the extracts and the therapeutic use of Sativex. In the key indication, treatment of cancer pain, we have obtained a patent in the United States, entitled "Pharmaceutical Compositions for the Treatment of Pain", which would expire in September 2026. This patent is specific to the United States, and we will not seek to file, or obtain corresponding rights under, this patent in other countries.

Under the 2007 research collaboration agreement with Otsuka, which expired in June 2013, all intellectual property (including both patents and non-manufacturing related know-how) that was conceived by either Otsuka or us during the course of the collaboration is jointly owned by Otsuka and us, and is referred to as "collaboration IP". Since no product/product candidate(s) were licensed by Otsuka at the end of the collaboration, we have an exclusive sub-licensable royalty-bearing license to use collaboration IP both outside and within the fields of CNS and oncology.

Under the collaboration agreement, we are responsible for the filing, prosecution, maintenance and defense of any patents filed on the jointly owned collaboration IP, and Otsuka is responsible for all out-of-pocket expenses associated therewith. In the event Otsuka no longer wishes to reimburse us for our out-of-pocket costs associated with any of the jointly owned patents, Otsuka is required to assign its rights to the patents in question back to us. Otsuka has the first right to bring and control any action for infringement of any joint patent rights in the research field, and we have the right to join such action at our own expense. In the event Otsuka fails to bring such an action, we have the right to bring and control any such action at our own expense. Neither party shall have the right to settle any infringement litigation regarding the joint patent rights inside the research field without the prior written consent of the other party.

We have a portfolio of intellectual property relating to CBD and CBDV in epilepsy. This portfolio includes four distinct patent families which are either granted or filed, protecting the use of these product candidates and five further patent families which protect other aspects of their manufacture and formulation. The latest expiry date of these families runs to September 2032. Several of these patent families are collaboration IP derived from the now expired Otsuka research collaboration, and to which we have an exclusive sub-licensable royalty-bearing license. These patent families include claims to use of CBD and/or CBDV in the treatment of epilepsy as well as other families which provide protection for compositions, extraction techniques, CBD and CBDV extracts and highly purified CBD. We anticipate additional patent applications being filed as new data is generated. The

trademark Epidiolex is registered in the United Kingdom and approved for publication in the United States.

The term of individual patents depends upon the countries in which they are obtained. In most countries in which we have filed, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or PTO, in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent.

The term of a patent that covers an FDA-approved drug may also be eligible for extension, which permits term restoration as compensation for the term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits an extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Extensions cannot extend the remaining term of a patent beyond 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions to extend the term of a patent that covers an approved drug are available in Europe and other non-U.S. jurisdictions; indeed Supplementary Protection Certificates have been applied for such that the European formulation patent for Sativex will be extended to 2025 in Europe. In the future, if and when our pharmaceutical product candidates receive FDA approval, we may apply for extensions on patents covering those products.

To protect our rights to any of our issued patents and proprietary information, we may need to litigate against infringing third parties, avail ourselves of the courts or participate in hearings to determine the scope and validity of those patents or other proprietary rights.

We also rely on trade secret protection for our confidential and proprietary information, and it is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us.

Manufacturing

We are responsible for the manufacture and supply of our products for commercial and clinical trial purposes. We operate under GMP manufacturing licenses issued by the Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom and our facilities have been audited by the MHRA on several occasions. We have personnel with extensive experience in production of botanical raw material, pharmaceutical production, quality control, quality assurance and supply chain.

For commercial Sativex production, the BRM is currently contracted to an external third party, although our staff is at the contract site to monitor activity and production quality on a weekly basis. All other steps in the commercial production process for Sativex are performed in-house. We routinely hold significant inventories of Sativex BRM and BDS, both of which have extended shelf lives that enable us to manufacture finished product on demand. We believe that these inventories are currently sufficient to enable us to continue to meet anticipated commercial demand for Sativex in the event of an interruption in our supply of BRM.

We are in the process of expanding and upgrading parts of our manufacturing facilities in order to meet future demand and FDA requirements. Over the next two years, we will construct a new BDS production facility at our current site and install new BDS processing equipment. Construction work for this new facility commenced in September 2013. Longer term, depending on volume requirements, we anticipate the need to construct a new BDP facility.

We have successfully exported cannabinoid commercial or research materials to 34 countries and have the necessary in-house expertise to manage the import/export process worldwide. We have

substantial expertise in, and experience with, relevant international and national regulations in relation to the research, distribution and commercialization of cannabinoid therapeutics. We have formed relationships with relevant international and national agencies in order to enable licensing of research sites, establishing appropriate product distribution channels and securing licensed storage, obtaining import/export licenses, and facilitating amendments to relevant legislation if required prior to commercialization.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our scientific knowledge, technology and development experience provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

A synthetic THC (dronabinol) oral capsule has been approved and distributed in the United States for anorexia associated with weight loss in patients with AIDS. Dronabinol and nabilone (a synthetic molecule similar to THC) capsules have been approved and distributed in the United States for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. We are also aware of exploratory research into the effects of THC formulations in other areas.

We are aware of discovery research within the pharmaceutical industry into synthetic agonists and antagonists of CB1 and CB2 receptors. We are also aware of companies that supply synthetic cannabinoids and cannabis extracts to researchers for pre-clinical and clinical investigation. We are also aware of various companies that cultivate cannabis plants with a view to supplying herbal cannabis or non-pharmaceutical cannabis-based formulations to patients. These activities are generally not compliant with national and international legislation and have not been approved by the FDA.

In both MS spasticity and cancer pain, Sativex aims to treat patients who do not respond adequately to standard of care. In MS spasticity, such treatments include baclofen and tizanidine and in cancer pain, such treatments include morphine and other opioids. In cancer pain, the principal focus of ongoing clinical research by our potential competitors is in the development of alternative formulations of opioids.

With respect to CBD, a number of non-approved and non-standardized "artisanal" CBD preparations derived from crude herbal cannabis have been made available in limited quantities by producers of "medical marijuana" in the United States. In addition, certain pharmaceutical companies that currently manufacture synthetic THC are likely to have the capability to manufacture synthetic CBD and may already be doing so.

We have never endorsed or supported the idea of distributing or legalizing crude herbal cannabis, or preparations derived from crude herbal cannabis, for medical use and do not believe prescription cannabinoids are the same, and therefore competitive, with crude herbal cannabis. We have consistently maintained that only a cannabinoid medication, one that is standardized in composition, formulation, and dose, administered by means of an appropriate delivery system, and tested in properly controlled pre-clinical and clinical studies, can meet the standards of regulatory authorities around the world, including those of the FDA. We have also repeatedly stressed that these regulatory processes provide important protections for patients, and we believe that any cannabinoid medication must be subjected to, and satisfy, such rigorous scrutiny.

The prospect for cannabinoid therapeutics to be approved through the FDA approval pathway has been the subject of statements from the White House, Congress and the Drug Enforcement Administration, or DEA. The White House Office of National Drug Control Policy states on its "Facts and Answers to the Frequently Asked Questions about Marijuana" on the White House website that the FDA has recognized and approved the medicinal use of isolated components of the marijuana plant and related synthetic compounds, and it specifically references Sativex as a product that is currently in late-stage clinical trials with the FDA. In its June 2012 report entitled "Reducing the U.S. Demand for Illegal Drugs," the U.S. Senate Caucus on International Narcotics Control expresses the view that the development of marijuana-based therapeutics through an approved FDA process is the best route to explore and references Sativex as a promising product currently in the final phase of the FDA's trials for approved use in the United States. In that report, the Senate Caucus urged the FDA to complete a careful review of Sativex in a timely manner. In its April 2013 report entitled "The DEA Position on Marijuana," the DEA expresses support for ongoing research into potential medicinal uses of marijuana's active ingredients, and specifically references Sativex.

Government Regulation and Product Approval

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development in the United States typically involves pre-clinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate, well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of pre-clinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations, (ii) in compliance with Good Clinical Practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors, and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome, and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all pre-clinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2,169,000, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently exceeding $104,000 per product and $554,000 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten to twelve months, while most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for drugs intended to treat

a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee, which is typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices, or cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for health care professionals, and elements to assure safe use, or 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. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Information related to the product, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed until the product or new indication being studied has been approved. Competitors may use this publicly-available information to gain knowledge regarding the design and progress of our development programs.

Fast Track Designation and Accelerated Approval

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of

the IND for the drug candidate. FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program and FDA's accelerated approval regulations, FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with FDA, FDA may initiate review of sections of a fast track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the fast track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

The Hatch-Waxman Act

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement, certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use, rather than certify to a listed method-of-use patent.

If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approval an ANDA for a generic drug that includes the change.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

For a botanical drug, FDA may determine that the active moiety is one or more of the principle components or the complex mixture as a whole. This determination would affect the utility of any 5-year exclusivity as well as the ability of any potential generic competitor to demonstrate that it is the same drug as the original botanical drug.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase—the time between IND submission and NDA submission—and all of the review phase—the time between NDA submission and approval up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the PTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Advertising and Promotion

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including

standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse Event Reporting and GMP Compliance

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Pediatric Exclusivity and Pediatric Use

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include a determination by the FDA that information relating to the use of a new drug in the pediatric population may produce health benefits in that population; a written request by the FDA for pediatric studies; and agreement by the applicant to perform the requested studies and the submission to the FDA, and the acceptance by the FDA, of the reports of the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications.

In addition, under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective, unless the sponsor has received a deferral or waiver from the FDA. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. The required pediatric assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data need to be collected before the pediatric studies begin. Under PREA, the FDA must send a non-compliance letter requesting a response with 45 days to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Special Protocol Assessment

A company may reach an agreement with the FDA under the Special Protocol Assessment, or SPA, process as to the required design and size of clinical trials intended to form the primary basis of an efficacy claim. According to its performance goals, the FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the administrative record. Under the FDC Act and FDA guidance implementing the statutory requirement, an SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, public health concerns emerge that were unrecognized at the time of the protocol assessment, the sponsor and FDA agree to the change in writing, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA.

Controlled Substances

The federal Controlled Substances Act of 1970, or CSA, and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the U.S. Drug Enforcement Administration, or DEA. The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s). For example, separate registrations are required for importation and manufacturing activities, and each registration authorizes which schedules of controlled substances the registrant may handle. However, certain coincident activities are permitted without obtaining a separate DEA registration, such as distribution of controlled substances by the manufacturer that produces them.

The DEA categorizes controlled substances into one of five schedules—Schedule I, II, III, IV, or V—with varying qualifications for listing in each schedule. Schedule I substances by definition have a

high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. They may be used only in federally-approved research programs and may not be marketed or sold for dispensing to patients in the United States. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. The regulatory requirements are more restrictive for Schedule II substances than Schedule III substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist in most situations, and cannot be refilled.

The DEA inspects all manufacturing facilities to review security, record keeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. An application for a manufacturing registration as a bulk manufacturer (not a dosage form manufacturer or a repacker/relabeler) for a Schedule I or II substance must be published in the Federal Register, and is open for 30 days to permit interested persons to submit comments, objections, or requests for a hearing. A copy of the notice of the Federal Register publication is forwarded by DEA to all those registered, or applicants for registration, as bulk manufacturers of that substance. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. As with applications for registration as a bulk manufacturer, an application for an importer registration for a Schedule I or II substance must also be published in the Federal Register, which remains open for 30 days for comments. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary to ensure that the United States complies with its obligations under international drug control treaties.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. This limited aggregate amount of cannabis that the DEA allows to be produced in the United States each year is allocated among individual companies, which, in turn, must annually apply to the DEA for individual manufacturing and procurement quotas. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State Authorities, including Boards of Pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with

applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the European Union member states resulting from the national implementation of underlying E.U. legislation. In all cases, the clinical trials are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under E.U. regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the European Union by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures. The initial Sativex approvals were a consequence of an application under the De-Centralized Procedure, or DCP, to the E.U. member states of the United Kingdom and Spain.

The EMA implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing authorization granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated "orphan drugs" (drugs used for rare human diseases) and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used for human drugs which do not fall within the above mentioned categories if the human drug (a) contains a new active substance which, on the date of entry into force of this Regulation, was not authorized in the Community; or (b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in the centralized procedure is in the interests of patients or animal health at European Community level.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions

asked by the Committee for Medicinal Products for Human Use, or CHMP), with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: the seriousness of the disease to be treated; the absence of an appropriate alternative therapeutic approach, and anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

The mutual recognition procedure, or MRP, for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the European Union. Basically, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products, and is based on the principle of recognition of an already existing national marketing authorization by one or more member states. Since the first approvals for Sativex were national approvals in the United Kingdom and Spain (following a DCP), the only route open to us for additional marketing authorizations in the European Union was the MRP.

The characteristic of the MRP is that the procedure builds on an already existing marketing authorization in a member state of the E.U. that is used as reference in order to obtain marketing authorizations in other E.U. member states. In the MRP, a marketing authorization for a drug already exists in one or more member states of the E.U. and subsequently marketing authorization applications are made in other European Union member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states.

The MRP is based on the principle of the mutual recognition by European Union member states of their respective national marketing authorizations. Based on a marketing authorization in the reference member state, the applicant may apply for marketing authorizations in other member states. In such case, the reference member state shall update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any Member State refuse to recognize the marketing authorization by the reference member state, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, member states shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the Commission, for the start of the decision making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products or Veterinary Medicinal Products, as appropriate. Since the initial approvals of Sativex in the United Kingdom and Spain, there have been three "waves" of additional approvals under three separate MRPs. Each of these procedures have been completed without any referral, and therefore without any delay.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

In addition, 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 marketing approval for 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 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 that case, we would be unable to market our products in those countries in the near future or perhaps at all.

Reimbursement

Sales of pharmaceutical products in the United States will depend, in part, on the extent to which the costs of the products will be covered by third-party payers, such as government health programs, commercial insurance and managed health care organizations. These third-party payers are increasingly challenging the prices charged for medical products and services. Additionally, the containment of health care costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries and included a major expansion of the prescription drug benefit under Medicare Part D. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

On February 17, 2009, President Obama signed into law The American Recovery and Reinvestment Act of 2009. This law provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and

the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear how such a result could be avoided and what if any effect the research will have on the sales of our product candidates, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our product candidates. Decreases in third-party reimbursement for our product candidates or a decision by a third-party payer to not cover our product candidates could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the ACA) enacted in March 2010, is expected to have a significant impact on the health care industry. The ACA is expected to expand coverage for the uninsured while at the same time contain overall health care costs. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare D program. We cannot predict the impact of the ACA on pharmaceutical companies as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred. In addition, although the United States Supreme Court has upheld the constitutionality of most of the ACA, some states have stated their intentions to not implement certain section of ACA and some members of Congress are still working to repeal ACA. These challenges add to the uncertainty of the changes enacted as part of ACA. In addition, the current legal challenges to the ACA, as well as Congressional efforts to repeal the ACA, add to the uncertainty of the legislative changes enacted as part of the ACA.

In addition, in some foreign countries, 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. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Other Health Care Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), or CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, or VHCA, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the VHCA, drug

companies are required to offer certain drugs at a reduced price to a number of federal agencies including U.S. Department of Veteran Affairs and U.S. Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to require that discounted prices be offered for certain U.S. Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities or register their sales representatives. Other legislation has been enacted in certain states prohibiting pharmacies and other health care entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and prohibiting certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Legal Proceedings and Related Matters

From time to time, we may be party to litigation that arises in the ordinary course of our business. We do not have any pending litigation that, separately or in the aggregate, would, in the opinion of management, have a material adverse effect on our results of operations, financial condition or cash flows.

C. Organizational Structure

The following is a list of our significant subsidiaries:

Name of undertaking	Country of registration	Activity	% holding
GW Pharma Limited	England and Wales	Research and Development	100
GW Research Limited	England and Wales	Research and Development	100
Cannabinoid Research Institute Limited	England and Wales	Research and Development	100
Guernsey Pharmaceuticals Limited	Guernsey	Research and Development	100
GWP Trustee Company Limited	England and Wales	Employee Share Ownership	100
G-Pharm Trustee Company Limited	England and Wales	Dormant	100
G-Pharm Limited	England and Wales	Dormant	100
GW Pharmaceuticals Inc.	United States	Clinical Research	100

D. Property Plant and Equipment.

Type	Location	Size	Expiry
Executive office	Wiltshire, United Kingdom	2,942	July 2014
Executive office	London, United Kingdom	2,680	September 2015
Executive office	Cambridge, United Kingdom	12,120	May 2021
Research and manufacturing	Southern United Kingdom	69,356	January 2019
Research and manufacturing	Southern United Kingdom	14,560	December 2023
Research and manufacturing(1)	Southern United Kingdom	3,847	October 2013

(1) The lease for 3,847 square feet expired in October 2013 but we have agreed terms for a six year extension and are currently in the process of finalizing the detailed terms of this extension.

All of our property is leased. We believe that our office, research and manufacturing facilities are sufficient to meet our current needs. However, in anticipation of future commercial and research demand, in October 2013 we entered into contracts for the construction, fit out and lease for a new bespoke 10,000 square feet manufacturing facility and we are in the process of agreeing lease terms for an additional 3,261 square feet of manufacturing facility space in the south of the United Kingdom.

We are not aware of any environmental issues that may affect our utilization of our property.

Further details of our Plant and Equipment are given in Note 13 to our consolidated financial statements set out on page F-28.

Item 4A. Unresolved Staff Comments

There are no written comments from the staff of the U.S. Securities and Exchange Commission which remain unresolved before the end of the fiscal year to which the annual report relates.

Item 5. Operating and Financial Review and Prospects

The following discussion of our financial condition and results of operations should be read in conjunction with "Selected Financial Data," and our consolidated financial statements included elsewhere in this Annual Report. We present our consolidated financial statements in pounds sterling and in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, and as adopted by the European Union, or EU.

The statements in this discussion regarding industry outlook, our expectations regarding our future performance, liquidity and capital resources and other non-historical statements are forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, the risks and uncertainties described in "Risk Factors" and "Forward-Looking Statements" in this Annual Report. Our actual results may differ materially from those contained in or implied by any forward-looking statements.

Solely for the convenience of the reader, unless otherwise indicated, all pound sterling amounts as at and for the year ended September 30, 2013 have been translated into U.S. dollars at the rate at September 30, 2013, of £0.6181 to $1.00. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as at that or any other date.

A. Operating Results

Important Financial and Operating Terms and Concepts

Revenue

We generate revenue from product sales, license fees, collaboration fees, technical access fees, development and approval milestone fees, research and development fees and royalties. Agreements with our commercial partners generally include a non-refundable upfront fee (attributed to separately identifiable components including license fees, collaboration fees and technical access fees), milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones, royalties on product sales of licensed products if and when such product sales occur and revenue from the supply of products. For these agreements, total arrangement consideration is attributed to separately identifiable components on a reliable basis that reasonably reflects the selling prices that might be achieved in stand-alone transactions. The allocated consideration is recognized as revenue in accordance with our accounting policies for each revenue stream.

Product sales

We recognize revenue from the sale of products when we have transferred the significant risks and rewards of ownership of the goods to the buyer, when we no longer have effective control over the goods sold, when the amount of revenue and costs associated with the transaction can be measured reliably, and when it is probable that we will receive future economic benefits associated with the transaction. Product sales have no rights of return. Provisions for rebates are established in the same period that the related sales are recorded.

License fees

License fees are upfront payments received under our product out-licensing agreements from our commercial partners for the right to commercialize products. Such fees are generally received upfront, are non-refundable and are deferred and recognized over the period of the expected license term.

Collaboration fees

Collaboration fees are amounts received from our commercial partners for our participation in joint development activities. Such fees are generally received upfront, are non-refundable and are deferred and recognized as services are rendered based on the percentage of completion method.

Technical access fees

Technical access fees represent amounts charged to licensing partners to provide access to, and allow them to commercially exploit, data that we possess or that can be expected to result from our research programs that are in progress. Non-refundable technical access fees that involve the delivery of data that we possess and that permit our licensing partners to use the data freely and where we have no remaining obligations to perform are recognized as revenue upon delivery of the data. Non-refundable technical access fees relating to data where the research program is ongoing are recognized based on the percentage of completion method.

Development and approval milestone fees

Development and approval milestones represent amounts received from our commercial partners, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones. We recognize development and approval milestone fees as revenue based on the percentage of completion method on the assumption that all stages will be completed successfully, but with

cumulative revenue recognized limited to non-refundable amounts already received or reasonably certain to be received.

Research and development fees

Research and development fees represent amounts chargeable to our development partners relating to the conduct of our joint research plans. Revenue from development partner-funded contract research and development agreements is recognized as research and development services are rendered. Where services are in-progress at period end, we recognize revenue proportionately, in line with the percentage of completion of the service. Where such in-progress services include the conduct of clinical trials, we recognize revenue in line with the stage of completion of each trial so that revenue is recognized in line with the expenditures.

Royalties

Royalty revenue arises from our contractual entitlement to receive a fixed percentage of our commercial partner's in-market net product sales revenue. Royalty revenue is recognized on an accrual basis in accordance with the substance of the relevant agreement provided that it is probable that the economic benefits will flow to us and the amount of revenue can be measured reliably.

Costs of sales

Costs of sales principally includes the cost of materials, direct labor, depreciation of manufacturing assets and overhead associated with our manufacturing facilities.

Research and development expenditure

Expenses on research and development activities are recognized as an expense in the period in which the expense is incurred.

An internally-generated intangible asset arising from our development activities is recognized only when an asset is created that can be identified, it is probable that the asset created will generate future economic benefits and the development cost of the asset can be measured reliably.

We have determined that regulatory approval is the earliest point at which the probable threshold for the creation of an internally generated intangible asset can be achieved. All research and development expenditure incurred prior to achieving regulatory approval is therefore expensed as incurred.

GW-funded research and development expenditure

GW-funded research and development expenditure consists of costs associated with our research activities. These costs include costs of conducting our pre-clinical studies or clinical trials, payroll costs associated with employing our team of research and development staff, share-based payment expenses, property costs associated with leasing laboratory and office space to accommodate our research teams, costs of growing botanical raw material, costs of consumables used in the conduct of our in-house research programs, payments for research work conducted by sub-contractors and sponsorship of work by our network of academic collaborative research scientists, costs associated with safety studies and costs associated with the development of further Sativex data.

We expect to increase our investment in GW-funded research and development in the future as we seek to advance our most promising pipeline product candidates through further clinical development.

Development partner-funded research and development expenditure

Development partner-funded research and development expenditure represent costs incurred by us in conducting the joint research plans under our collaborations. These costs include (i) costs incurred under our Phase 3 cancer pain program and other Sativex related U.S. market development activities that are chargeable to Otsuka under the terms of the 2007 Sativex U.S. development license, (ii) costs incurred in carrying out our pre-clinical toxicology, pharmacology and both in vitro and in vivo pre-clinical models in the fields of CNS disease and oncology, which were chargeable to our partner Otsuka under the terms of the research collaboration agreement until its conclusion on June 30, 2013 and (iii) costs that we incur in providing support to the regulatory and research activities of our other Sativex development partners, which are recoverable under the terms of our agreements.

Management and administrative expenses

Management and administrative expenses consist primarily of salaries and benefits related to our executive, finance, business development and support functions. Other management and administrative expenses include costs associated with managing our commercial activities and the costs of compliance with the day-to-day requirements of being a listed public company in both the United Kingdom and the United States, including insurance, general administration overhead, legal and professional fees, audit fees and fees for taxation services. We expect that management and administrative expenses will increase in the future as we expand our operating activities.

Interest expense and income

Interest expense consists primarily of interest expense incurred on two finance leases which expire in 2018 and 2027, respectively.

Interest income consists primarily of interest earned by investing our cash reserves in short-term interest-bearing deposit accounts.

Taxation

As a U.K. resident trading entity, we are subject to U.K. corporate taxation. Our tax recognized represents the sum of the tax currently payable or recoverable, and deferred tax. Deferred tax liabilities are generally recognized for all taxable temporary differences and deferred tax assets are recognized only to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilized.

As a company that carries out extensive research and development activities, we benefit from the U.K. research and development tax credit regime, whereby our principal research subsidiary company, GW Research Ltd., is able to surrender the trading losses that arise from its research and development activities for a cash rebate of up to 24.75% of eligible research and development expenditures. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects. Subcontracted research expenditures are eligible for a cash rebate of up to 16%. The majority of our pipeline research, clinical trials management and the Sativex chemistry and manufacturing controls development activities, all of which are being carried out by GW Research Ltd., are eligible for inclusion within these tax credit cash rebate claims. The Sativex Phase 3 cancer pain clinical trials program, which is fully funded by Otsuka, and certain other Sativex safety studies are being carried out by GW Pharma Ltd., our principal commercial trading subsidiary. As GW Pharma Ltd. is currently profitable, it is currently unable to surrender trading losses to seek a research and development tax credit cash rebate.

We also expect to benefit in the future from the new "patent box" initiative in the United Kingdom. This effectively allows profits attributable to revenues from patented products to be taxed at

a lower rate than other revenue that over time will be reduced to 10%. As we have many different patents covering our products, we expect that future upfront fees, milestone fees, product revenues and royalties will be taxed at this favorably low tax rate. When taken in combination with the enhanced relief available on our research and development expenditure, we expect that this will result in a long-term low rate of corporation tax. As such, we consider that the United Kingdom is a favorable location for us to continue to conduct our business for the long-term.

Critical Judgments in Applying our Accounting Policies

In the application of our accounting policies, we are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

Our estimates and assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revisions and future periods if the revision affects both current and future periods.

The following are our critical judgments, except those involving estimation uncertainty, that we have made in the process of applying our accounting policies and that have the most significant effect on the amounts recognized in our consolidated financial statements included elsewhere in this prospectus.

Recognition of clinical trials expenses

We recognize expenses incurred in carrying out clinical trials during the course of conduct of each clinical trial in line with the state of completion of each trial. This involves the calculation of clinical trial accruals at each period end to account for incurred expenses. This requires estimation of the expected full cost to complete the trial as well as the current stage of trial completion.

Clinical trials usually take place over extended time periods and typically involve a set-up phase, a recruitment phase and a completion phase which ends upon the receipt of a final report containing full statistical analysis of trial results. Accruals are prepared separately for each in-process clinical trial and take into consideration the stage of completion of each trial including the number of patients that have entered the trial, the number of patients that have completed treatment and whether we have received the final report. In all cases, the full cost of each trial is expensed by the time we have received the final report.

Revenue recognition

We recognize revenue from product sales, license fees, collaboration fees, technical access fees, development and approval milestone fees, research and development fees and royalties. Agreements with our commercial partners generally include a non-refundable upfront fee (attributed to separately identifiable components including license fees, collaboration fees and technical access fees), milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones, royalties on product sales of licensed products if and when such product sales occur and revenue from the supply of products to our commercial partners. For these agreements, we are required to apply judgment in the allocation of total agreement consideration to the separately identifiable components on a reliable basis that reasonably reflects the selling prices that might be expected to be achieved in stand-alone transactions.

Product revenue received is based on a contractually agreed percentage of our commercial partner's in-market net sales revenue. The commercial partner's in-market net sales revenue is the price per vial charged to end customers, less set defined deductible overheads incurred in distributing the product. In developing estimates, we use monthly unit sales and in-market sales data received from commercial partners during the course of the year. For certain markets, where negotiations are ongoing with local reimbursement authorities, an estimated in-market sales price is used, which requires the application of judgement in assessing whether an estimated in-market sales price is reliably measurable. In our assessment, we consider, inter alia, identical products sold in similar markets and whether the agreed prices for those identical products support the estimated in-market sales price. In the event that we consider there to be significant uncertainty with regards to the in-market sales price to be charged by the commercial partner as a result of, as an example, ongoing pricing negotiations with local health authorities, such that it is not possible to reliably measure the amount of revenue that will flow to us, we would not recognize revenue until that uncertainty has been resolved.

We apply the percentage of completion revenue recognition method to certain classes of revenue. The application of this approach requires our judgment with regards to the total costs incurred and total estimated costs expected to be incurred over the length of the agreement.

Key Sources of Estimation Uncertainty

The key assumptions concerning the future, and other key sources of estimation uncertainty at the balance sheet date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next year, are discussed below.

Provision for inventories

We maintain inventories which, based upon current sales levels and the current regulatory status of the product in each indication, are in-excess of the amount that is expected to be utilized in the manufacture of finished product for future commercial sales. Provision is therefore made to reduce the carrying value of the excess inventories to their expected net realizable value.

Our provision for inventories, and adjustments thereto, are estimated based on evaluation of the status of the regulatory approval, projected sales volumes and growth rates. The timing and extent of future provision adjustments will be contingent upon the timing and extent of future regulatory approvals and post-approval in-market sales demand, which remain uncertain at this time.

Deferred taxation

At September 30, 2013, we have accumulated tax losses of £33.6 million, which are available to offset against future profits. Our policy is to recognize deferred tax assets only to the extent that it is probable that future taxable profits, feasible tax-planning strategies and deferred tax liabilities will be available against which the brought forward trading losses can be utilized. Estimation of the level of future taxable profits is therefore required in order to determine the appropriate carrying value of the deferred tax asset at each balance sheet date. We recognize the value of certain tax losses as deferred tax assets on the balance sheet. A deferred tax asset of £0.9 million was recognized on our balance sheet at September 30, 2013.

If the value of the remaining losses and certain other timing differences were recognized within our balance sheet at the balance sheet date, we would be carrying a further deferred tax asset of £6.1 million as at September 30, 2013.

Rebate provision

We maintain a rebate provision for expected reimbursements to our commercial partners in circumstances in which actual net revenue per vial differs from expected net revenue per vial as a consequence of, as an example, ongoing pricing negotiations with local health authorities.

The amount of our rebate provision is based on, amongst other things, monthly unit sales and in-market sales data received from commercial partners and represents our best estimate of the rebate expected to be required to settle the present obligation at the end of the reporting period.

Pricing decisions made by local health authorities, including revisions and clarifications that have retroactive application can result in changes to management's estimates of the rebates reported in prior periods.

Aggregate rebate provision accruals at September 30, 2013 were £1.2 million.

Segments

We operate through three reportable segments, Sativex Commercial, Sativex Research and Development and Pipeline Research and Development.

Sativex Commercial. The Sativex Commercial segment promotes Sativex through strategic collaborations with major pharmaceutical companies for the currently approved indication of MS spasticity. We entered into agreements with: Otsuka in the United States; Almirall in Europe (excluding the United Kingdom) and Mexico; Novartis in Australia and New Zealand, Asia (excluding Japan, China and Hong Kong), the Middle East (excluding Israel) and Africa; Bayer in the United Kingdom and Canada; and Neopharm Group in Israel.

Sativex Research and Development. The Sativex R&D segment seeks to maximize the potential of Sativex through the development of new indications. The current focus for this segment is the Phase 3 clinical development program of Sativex for use in the treatment of cancer pain. We also believe that MS spasticity represents an attractive indication for the United States and we intend to pursue an additional clinical development program for this significant market opportunity. In addition, Sativex has shown promising efficacy in Phase 2 trials in other indications such as neuropathic pain, but these areas are not currently the subject of full development programs.

Pipeline Research and Development. The Pipeline R&D segment seeks to develop cannabinoid medications other than Sativex across a range of therapeutic areas using our proprietary cannabinoid product platform. The Group's product pipeline includes an orphan childhood epilepsy program as well as other product candidates in Phase 1 and 2 clinical development for glioma, ulcerative colitis, type-2 diabetes and schizophrenia.

Results of Operations

Comparison of Years Ended September 30, 2013 and 2012

The following table summarizes the results of our operations for the years ended September 30, 2013 and 2012, together with the changes to those items.

	Year Ended September 30,			Change 2013 vs. 2012	
	2013	2013	2012	Increase/(Decrease)	
	$	£	£	£	%
	(in thousands, except for percentages)				
Revenue	44,158	27,295	33,120	(5,825)	(18)%
Cost of sales	(2,064)	(1,276)	(839)	437	52%
Research and development expenditure	(52,897)	(32,697)	(27,578)	5,119	19%
Management and administrative expenses	(6,135)	(3,792)	(3,660)	132	4%
Operating (loss)/profit	(16,938)	(10,470)	1,043	(11,513)	(1,104)%
Interest expense	(104)	(64)	(1)	63	—
Interest income	288	178	200	(22)	(11)%
(Loss)/profit before tax	(16,754)	(10,356)	1,242	(11,598)	(934)%
Tax	9,395	5,807	1,248	4,559	365%
(Loss)/profit for the year	(7,359)	(4,549)	2,490	(7,039)	(283)%

Revenue

The following table summarizes our revenue for the years ended September 30, 2013 and 2012, together with the changes to those items.

	Year Ended September 30,			Change 2013 vs. 2012	
	2013	2013	2012	Increase/ (Decrease)	
	$	£	£	£	%
	(in thousands, except for percentages)				
Product sales	3,490	2,157	2,514	(357)	(14)%
Research and development fees	38,172	23,594	19,500	4,094	21%
License, collaboration and technical access fees	2,094	1,294	1,294	—	—
Development and approval milestone fees	402	250	9,812	(9,562)	(97)%
Total revenue	44,158	27,295	33,120	(5,825)	(18)%

Total revenue decreased by 18% to £27.3 million for the year ended September 30, 2013, compared to £33.1 million for the year ended September 30, 2012. This reduction was driven by a variety of factors, as explained below.

Sativex product sales revenue declined by £0.4 million, or 14%, to £2.2 million for the year ended September 30, 2013 compared to £2.5 million for the year ended September 30, 2012. This decline was primarily due to the recognition of a £1.1 million rebate provision in 2013 for amounts expected to be paid to Almirall following an adverse German pricing decision in March 2013 coupled with a decline in the supply price charged to Almirall as a result of the amended supply agreement, which was effective from March 2012. These declines were partially offset by a 51% increase in the sales volumes of Sativex shipped to partners.

Research and development fees increased by £4.1 million, or 21%, to £23.6 million for the year ended September 30, 2013 compared to £19.5 million for the year ended September 30, 2012. This

increase was due to increased charges to our partners, principally Otsuka, for fees we have incurred in conducting our joint research plans, for which our partners reimburse us under the terms of our license and collaboration agreements. Further discussion regarding the joint research plan activities is included within the "research and development expenditure" section below.

License, collaboration and technical access fees of £1.3 million were consistent with the £1.3 million recorded in the year ended September 30, 2012.

Development and approval milestone fees decreased by £9.5 million, or 97%, to £0.3 million for the year ended September 30, 2013 compared to £9.8 million for the year ended September 30, 2012. Development and approval milestone fees consist of milestone payments due to us from Sativex partners under the terms of our agreements. Development and approval milestone payments of £0.3 million during the year ended September 30, 2013 resulted from a single milestone payment received from Almirall upon agreement of Italian pricing and reimbursement approval for Sativex.

During the year ended September 30, 2012, development and approval milestone fees of £9.8 million resulted from a milestone payment received from Almirall upon achievement of an agreed Phase 3 cancer pain trial patient recruitment target.

Cost of sales

Cost of sales increased by £0.4 million, or 52%, to £1.2 million for the year ended September 30, 2013 compared to £0.8 million for the year ended September 30, 2012. This increase was due to a 51% increase in the volume of Sativex vials shipped to partners during the year ended September 30, 2013 compared to 2012 as previously discussed. Costs of sales per unit shipped remained consistent across periods.

Research and development expenditure

The following table summarizes our research and development expenditure for the years ended September 30, 2013 and 2012, together with the changes to those items.

	Year Ended September 30,			Change 2013 vs. 2012	
	2013	2013	2012	Increase/ (Decrease)	
	$	£	£	£	%
	(in thousands, except for percentages)				
GW-funded research and development	14,725	9,103	8,078	1,025	13%
Development partner-funded research and development	38,172	23,594	19,500	4,094	21%
Total research and development expenditure	**52,897**	**32,697**	**27,578**	**5,119**	**19%**

Research and development expenditure increased by £5.1 million, or 19%, to £32.7 million for the year ended September 30, 2013, from £27.6 million for year ended September 30, 2012. As shown in the table above, research and development expenditure consists of two elements, GW-funded research and development expenditure and development partner-funded research and development expenditure.

The £1.0 million increase in GW-funded research and development expenditure was due principally to:

- £0.7 million of costs relating to a Phase 1 clinical trial with GWP42006, one of our epilepsy product candidates, plus costs associated with our collaborative work with U.S. epileptologists at New York University and the University of California—San Francisco to establish a program of investigator IND's to explore the use of our other epilepsy product candidate, Epidiolex, to treat pediatric epilepsy syndromes.

- £0.1 million of costs associated with new Phase 2 clinical studies in the fields of glioma, schizophrenia and diabetes.
- a £0.2 million increase in payroll costs for research staff, share based payment expenses, property related overhead and other internal overhead costs associated with GW-funded research activities.

We track all research and development expenditures against detailed budgets but do not seek to allocate and monitor all research and development costs by individual project. As noted in the segmental analysis below, we do analyze GW-funded research and development into Sativex related expenditures and pipeline related expenditures. External third-party costs of running clinical trials totaling £1.4 million for the year ended September 30, 2013 and £1.5 million for the year ended September 30, 2012 were tracked by individual project while the remaining £7.7 million for the year ended September 30, 2013 and £6.6 million for the year ended September 30, 2012 consisting largely of internal overhead costs were not allocated to individual projects. We believe that our existing liquidity is sufficient to complete our currently ongoing GW-funded research and development projects.

Development partner-funded research and development projects are funded in advance by our development partners, which involves the receipt of advanced funds every three months, sufficient to cover projected expenditure for the next three months. For further information on the risks our research and development program face, see "Risk Factors—Risks Related to Development and Regulatory Approval of Sativex and Our Product Candidates".

Development partner-funded research and development expenditure was made up of two principal elements, as follows:

	Year Ended September 30,			Change 2013 vs. 2012	
	2013	2013	2012	Increase/ (Decrease)	
	$	£	£	£	%
	(in thousands, except for percentages)				
Sativex U.S. development program	31,278	19,333	14,080	5,253	37%
Otsuka research collaboration expenses	6,894	4,261	5,420	(1,161)	(21)%
Total development partner-funded research and development	**38,172**	**23,594**	**19,500**	**4,094**	**21%**

Sativex U.S. development expenses increased by £5.3 million, or 37%, to £19.3 million during the year ended September 30, 2013 as compared to the year ended September 30, 2012. This reflects increased patient recruitment into the first two Sativex Phase 3 trials, geographic expansion of the trials into new territories and commencement of the third Phase 3 cancer pain trial.

Otsuka research collaboration expenses decreased by £1.2 million, or 21%, to £4.3 million during the year ended September 30, 2013 as compared to £5.4 million for the year ended September 30, 2012. These charges to Otsuka included charges for the cost of employing staff to work on our joint research plan, plus the cost of subcontracted pre-clinical studies and sponsorship of our network of academic scientists. The decrease reflects the fact that the Otsuka research collaboration term ended on June 30, 2013. Most of the pre-clinical programs that Otsuka were funding are now proceeding into Phase 1/2 clinical trials as part of the GW-funded clinical programs.

Management and administrative expenses

Management and administrative expenses increased by £0.1 million, or 4%, to £3.8 million for the year ended September 30, 2013 compared to £3.7 million for the year ended September 30, 2012. This reflected the combined effects of increases in management and administrative expenses of £0.3 million, driven by incremental costs associated with being a U.S. publicly listed company offset by a reversal of

£0.2 million of share-based payment charges previously recognized as a result of management not having met a non-market vesting condition linked to 25% of the long term incentive plan grants that were due to vest in July 2013.

Interest expense

Interest expense of £0.1 million for the year ended September 30, 2013 represents a £0.1 million increase compared to the year ended September 30, 2012. This expense relates to a finance lease arrangement we entered into in June 2013 to fund the fit-out of new research and development laboratory space.

Interest income

Interest income of £0.2 million for the year ended September 30, 2013 was consistent with the £0.2 million for the year ended September 30, 2012.

Tax

Our tax credit increased by £4.6 million, or 365%, to £5.8 million for the year ended September 30, 2013 compared to £1.2 million for the year ended September 30, 2012. This credit consists of:

- Recognition of a £2.0 million research and development tax credit claimed and received in early 2013 from the UK tax authority in respect of the year ended September 30, 2012. This resulted from Her Majesty's Revenue and Customs, or HMRC, agreeing that our principal research subsidiary company, GW Research Ltd., was able to surrender trading losses that arise from its research and development activity for a tax credit cash rebate. The majority of our pipeline research, clinical trials management and the Sativex chemistry and manufacturing controls development activities, all of which are being carried out by GW Research Ltd., are eligible for inclusion within the tax credit cash rebate claims.
- Accrual for an expected research and development tax credit claim of £2.9 million in respect of the year ended September 30, 2013 for GW Research Ltd. We expect to submit this claim in by the quarter ended March 31, 2014 and this claim is subject to agreement by HMRC.
- Recognition of a deferred tax asset of £0.9 million arising from the expected utilization of brought forward corporation tax trading losses which we intend to utilize to offset against future trading profits by GW Pharma Ltd., our principal commercial trading subsidiary.

Research and development tax credits recognized vary depending on our available tax losses, the eligibility of our research and development expenditure and the level of certainty relating to the recoverability of the claim.

Segmental review

Sativex Commercial segment

The following table summarizes the results of our operations for our Sativex Commercial segment for the years ended September 30, 2013 and 2012, together with the changes to those items.

	Year Ended September 30,			Change 2013 vs. 2012 Increase/ Decrease	
	2013	2013	2012		
	$	£	£	£	%
	(in thousands, except for percentages)				
Product sales	3,490	2,157	2,514	(357)	(14)%
License, collaboration and technical access fees	2,094	1,294	1,294	—	—
Development and approval milestone fees	402	250	9,812	(9,562)	97%
Total revenue	5,986	3,701	13,620	(9,919)	73%
Cost of sales	(2,064)	(1,276)	(839)	437	52%
Research and development credit	966	597	1,300	(703)	(54)%
Segmental result	**4,888**	**3,022**	**14,081**	**(11,059)**	**(79)%**

We classify all revenue from Sativex collaboration partners, with the exception of research and development fees, as Sativex Commercial segment revenue. The principal variances in these revenue streams are summarized in the table above. An explanation of the principal movements in the revenue streams is provided in the revenue section above.

Cost of sales increased by £0.5 million, or 52%, to £1.3 million for the year ended September 30, 2013 compared to £0.8 million for the year ended September 30, 2012 driven by a 51% year on year increase in the volume of Sativex vials shipped to partners as previously discussed.

For the Sativex Commercial segment, the research and development credit represents the movement in the provision against inventories manufactured prior to the regulatory approval of Sativex. All inventories manufactured prior to regulatory approval were capitalized as an asset but provided for, with the charge recognized in the research and development expenditure line, until there was a high probability of regulatory approval. When we determined that there was a high probability of regulatory approval of Sativex, the provision was revised to adjust the carrying value of Sativex inventories to the expected net realizable value, which may not exceed original cost. The provision for inventories release of £0.6 million for the year ended September 30, 2013 was lower than the £1.3 million for the year ended September 30, 2012. The higher provision release in the year ended September 30, 2012 was due to us having reassessed and increased our estimated future sales of Sativex, resulting in release of provision.

The provision release in the year ended September 30, 2013 reflects increased sales of Sativex and a decrease in the volume of inventory expected to expire prior to use.

Sativex Research and Development segment

The following table summarizes the results of our operations for our Sativex R&D segment for the years ended September 30, 2013 and 2012, together with the changes to those items.

	Year Ended September 30,			Change 2013 vs. 2012 Increase/ Decrease	
	2013	2013	2012		
	$	£	£	£	%
	(in thousands, except for percentages)				
Research and development fees	31,278	19,333	14,080	5,253	37%
Research and development expenditure					
GW-funded research and development	(7,125)	(4,404)	(4,335)	69	2%
Development partner-funded research and development	(31,278)	(19,333)	(14,080)	5,253	37%
Total research and development expenditure	(38,403)	(23,737)	(18,415)	5,322	29%
Segmental result	**(7,125)**	**(4,404)**	**(4,335)**	**69**	**2%**

Total research and development expenditure related to Sativex during the year ended September 30, 2013 increased by £5.3 million, or 29%, to £23.8 million as compared to £18.4 million for the year ended September 30, 2012. This growth consisted of a £3.9 million increase due to the expansion of the Phase 3 cancer pain clinical program plus £1.4 million of Phase 1 trials, pre-clinical, regulatory and abuse liability planning activities that are being carried out to support the cancer pain development program and are funded by Otsuka under the terms of the Sativex license and development agreement.

As all of the development partner-funded research and development expenditure is reimbursed to us under the terms of our license agreements, the net result for this segment equals the GW-funded research and development expenditure on Sativex related projects.

Pipeline Research and Development segment

The following table summarizes the results of our operations for our Pipeline R&D segment for the years ended September 30, 2013 and 2012, together with the changes to those items.

	Year Ended September 30,			Change 2013 vs. 2012 Increase/ Decrease	
	2013	2013	2012		
	$	£	£	£	%
	(in thousands, except for percentages)				
Research and development fees	6,894	4,261	5,420	(1,159)	(21)%
Research and development expenditure					
GW-funded research and development	(8,055)	(4,979)	(4,484)	495	11%
Development partner-funded research and development	(6,894)	(4,261)	(5,420)	(1,159)	(21)%
Total research and development expenditure	(14,949)	(9,240)	(9,904)	(664)	(7)%
Segmental result	**(8,055)**	**(4,979)**	**(4,484)**	**495**	**11%**

Pipeline research and development fees are equal to the development partner-funded research and development expenditure incurred by us in conducting our joint pipeline research program and recharged to Otsuka under the terms of our 2007 research collaboration agreement. The 21% year-on-year decrease in pipeline research and development fees reflects the fact that our pre-clinical

research collaboration with Otsuka in the field of CNS disorders and oncology ended on June 30, 2013. GW has a worldwide license to all data and product candidates generated under the collaboration.

GW-funded pipeline research and development expenditure increased by £0.5 million, or 11%, to £5.0 million for the year ended September 30, 2013 as compared to £4.5 million for the year ended September 30, 2012. This reflects the fact that most of the product candidates that have been developed under the pre-clinical collaboration with Otsuka are now starting to enter Phase 1/Phase 2 clinical trials and are being wholly funded internally. Since July 1, 2013 we have initiated a Phase 1 clinical trial with GWP42006, a glioma Phase 2 trial with a THC:CBD product candidate and is in the process of setting up Phase 2 trials in the field of schizophrenia with GWP42003 and in diabetes with GWP42004.

As the development partner-funded research and development expenditure was fully offset by the associated research and development fees, the segmental result equals the GW-funded pipeline research and development expenditure.

Comparison of Years Ended September 30, 2012 and 2011

The following table summarizes the results of our operations for the years ended September 30, 2012 and 2011, together with the changes to those items.

	Year Ended September 30,		Change 2012 vs. 2011 Increase/ (Decrease)	
	2012	2011		
	£	£	£	%
Revenue	33,120	29,627	3,493	12%
Cost of sales	(839)	(1,347)	(508)	(38)%
Research and development expenditure	(27,578)	(22,714)	4,864	21%
Management and administrative expenses	(3,660)	(3,298)	362	11%
Operating profit	1,043	2,268	(1,225)	(54)%
Interest expense	(1)	(3)	(2)	(67)%
Interest income	200	263	(63)	(24)%
Profit before tax	1,242	2,528	(1,286)	(51)%
Tax	1,248	221	1,027	465%
Profit for the year	2,490	2,749	(259)	(9)%

Revenue

The following table summarizes our revenue for the years ended September 30, 2012 and 2011, together with the changes to those items.

	Year Ended September 30,		Change 2012 vs. 2011 Increase/ (Decrease)	
	2012	2011		
	£	£	£	%
Product sales	2,514	4,409	(1,895)	(43)%
Research and development fees	19,500	16,038	3,462	22%
License, collaboration and technical access fees	1,294	3,843	(2,549)	(66)%
Development and approval milestone fees	9,812	5,337	4,475	84%
Total revenue	33,120	29,627	3,493	12%

Total revenue grew by 12% to £33.1 million for the year ended September 30, 2012, compared to £29.6 million for the year ended September 30, 2011. This growth was driven by a variety of factors, as explained below.

Sativex product sales revenue declined by £1.9 million, or 43%, to £2.5 million for the year ended September 30, 2012 when compared to 2011. This decline was driven by two factors. First, at this early stage in the commercialization of Sativex, our deliveries consist principally of launch stock for new countries. During the year ended September 30, 2011, product sales revenue included £1.2 million of launch inventory delivered to Almirall between June and September 2011 in anticipation of a German commercial launch in the first quarter of the year ended September 30, 2012. In comparison, there were no launch stock deliveries during the year ended September 30, 2012. Second, there were lower deliveries of Sativex batches during the year ended September 30, 2012 compared to 2011, as Almirall in Europe and Bayer in the United Kingdom serviced in-market sales principally from their existing inventory. As our partners' level of inventory stabilizes, we expect our revenue from product sales to become more representative of the in-market sales trend. This sales trend will be determined by launches in new countries, the level of pricing charged by our partners in each country and the rate of sales growth.

Total Sativex in-market net sales by our commercial partners rose to £10.0 million, for the year ended September 30, 2012 from £5.3 million for the year ended September 30, 2011. The volume of Sativex 10ml vials sold in-market by our partners increased year on year by 108%, which was driven by increased prescription rates in Spain and Germany as a result of Almirall's marketing efforts.

Research and development fees increased by £3.5 million, or 22%, to £19.5 million for the year ended September 30, 2012 compared to the year ended September 30, 2011. This reflected increased charges to our partners, principally Otsuka, for fees we have incurred in conducting our joint research plans, for which our partners reimburse us under the terms of our license and collaboration agreements. Further discussion regarding the joint research plan activities is included within the research and development expenditure section below.

License, collaboration and technical access fees declined by £2.5 million, or 66%, to £1.3 million for the year ended September 30, 2012 when compared to the year ended September 30, 2011. This variance was due principally to:

- The inclusion in the year ended September 30, 2011 of Novartis technical access fees of £1.9 million, which included a £1.8 million fee to grant access to our MS spasticity dossier. We recognized technical access fee revenue of £1.8 million upon completion and delivery of the dossier during the year ended September 30, 2011.
- A decline in Otsuka collaboration fees of £0.8 million.

Development and approval milestone fees increased by £4.5 million, or 84%, to £9.8 million for the year ended September 30, 2012 compared to £5.3 million for the year ended September 30, 2011. Development and approval milestone fees consist of milestone payments due to us from Sativex partners under the terms of our agreements. Development and approval milestone payments of £9.8 million during the year ended September 30, 2012 resulted from a £9.8 million milestone payment received from Almirall upon achievement of an agreed Phase 3 cancer pain trial patient recruitment target.

During the year ended September 30, 2011, development and approval milestone fees of £5.3 million included:

- £2.5 million from Almirall upon achievement of Spanish reimbursement and pricing approval for Sativex;
- £0.3 million from Almirall upon German commercial launch; and

- £2.5 million from Otsuka upon recruitment of the first patient into our Phase 3 cancer pain clinical program.

Cost of sales

Cost of sales decreased by £0.5 million, or 38%, to £0.8 million for the year ended September 30, 2012 compared to £1.3 million for the year ended September 30, 2011. This decline was primarily driven by higher sales of Sativex to Almirall during the year ended September 30, 2011 as compared to 2012 as it prepared for the German commercial launch of Sativex in the first quarter of the year ended September 30, 2012 and sales of Sativex in 2012 by Almirall and Bayer being serviced out of their existing inventory.

Research and development expenditure

The following table summarizes our research and development expenditure for the years ended September 30, 2012 and 2011, together with the changes to those items.

	Year Ended September 30,		Change 2012 vs. 2011	
			Increase/ (Decrease)	
	2012	2011		
	£	£	£	%
GW-funded research and development	8,078	6,676	1,402	21%
Development partner-funded research and development	19,500	16,038	3,462	22%
Total research and development expenditure	**27,578**	**22,714**	**4,864**	**21%**

Research and development expenditure increased by £4.9 million, or 21%, to £27.6 million for the year ended September 30, 2012, from £22.7 million for year ended September 30, 2011. As shown in the table above, research and development expenditure consists of two elements, GW-funded research and development expenditure and development partner-funded research and development expenditure.

The £1.4 million increase in GW-funded research and development expenditure was due principally to:

- a £0.3 million increase in expenditure on our Phase 2 trials as two of the four trials that were in progress during the year ended September 30, 2012 neared completion. This expense consisted principally of external third party costs incurred in the conduct of these exploratory clinical trials;
- £0.5 million of expenditure on our Sativex regulatory commitments, which includes a 120 patient MS cognition trial as well as patient registry studies being conducted in the United Kingdom, Germany and Sweden. These studies were required by regulators as a post-approval commitment following the regulatory approvals granted during the years ended September 30, 2010 and September 30, 2011 in these countries; and
- a £0.6 million increase in payroll costs for research staff, share based payment expenses, property related overhead and other internal overhead costs associated with GW-funded research activities.

We track all research and development expenditures against detailed budgets but do not seek to allocate and monitor all research and development costs by individual project. As noted in the segmental analysis below, we do analyze GW-funded research and development into Sativex related expenditures and pipeline related expenditures. External third party costs of running clinical trials totaling £1.5 million for the year ended September 30, 2012 and £0.8 million for the year ended

September 30, 2011 were tracked by individual project while the remaining £6.6 million for the year ended September 30, 2012 and £5.9 million for the year ended September 30, 2011 consisting largely of internal overhead costs were not allocated to individual projects. We believe that our existing liquidity is sufficient to complete our GW-funded research and development projects. Development partner-funded research and development projects are funded in advance by our development partners, which involves the receipt of advanced funds every three months, sufficient to cover projected expenditure for the next three months. For further information on the risks our research and development program face, see "Risk Factors—Risks Related to Development and Regulatory Approval of Sativex and Our Product Candidates".

Development partner-funded research and development expenditure was made up of two principal elements, as follows:

	Year Ended September 30,		Change 2012 vs. 2011	
			Increase/ (Decrease)	
	2012	2011		
	£	£	£	%
Sativex U.S. development program	14,080	10,822	3,228	30%
Otsuka research collaboration expenses	5,420	5,216	234	5%
Total development partner-funded research and development	**19,500**	**16,038**	**3,462**	**22%**

Sativex U.S. development expenses increased by £3.2 million, or 30%, to £14.1 million during the year ended September 30, 2012 as compared to the year ended September 30, 2011. This reflected increased patient recruitment into the first two Sativex Phase 3 trials, geographic expansion of the trials into new territories and commencement of the third Phase 3 cancer pain trial.

Otsuka research collaboration expenses increased by £0.2 million, or 5%, to £5.4 million during the year ended September 30, 2012 as compared to the year ended September 30, 2011. These charges to Otsuka included charges for the cost of employing staff to work on our joint research plan, plus the cost of subcontracted pre-clinical studies and sponsorship of our network of academic scientists. The increase reflected a rise in the amount of sub-contracted pre-clinical studies as we started to focus our research upon the product candidates of most interest to Otsuka to demonstrate efficacy in *in vivo* models of disease and to refine our understanding of likely mechanisms of action in an effort to further advance this collaboration.

Management and administrative expenses

Management and administrative expenses increased by £0.4 million, or 11%, to £3.7 million for the year ended September 30, 2012 compared to £3.3 million for the year ended September 30, 2011. This reflected the combined effects of increases in share-based payment charges of £0.2 million and other management and administrative expenses of £0.2 million.

Interest income

Interest income declined by £0.1 million to £0.2 million for the year ended September 30, 2012 compared to £0.3 million for the year ended September 30, 2011, reflecting lower interest rates achieved on our cash deposits during the year ended September 30, 2012, principally due to a tightening of our treasury policy, whereby our board of directors decided to keep our cash deposits on a very short term, typically 30 to 60 days, in order to maximize the liquidity of our funds during a period of economic uncertainty and increased concern about counterparty credit risk. This approach to investing our surplus cash deposits resulted in a reduction to the average interest rates achieved on deposits.

Tax

Our tax credit increased by £1.0 million, or 464%, to £1.2 million for the year ended September 30, 2012 compared to £0.2 million for the year ended September 30, 2011. Research and development tax credits recognized vary depending on our available tax losses, the eligibility of our research and development expenditure and the level of certainty relating to the recoverability of the claim. The significant increase in research and development tax credits recognized in the year ended September 30, 2012 arose following an increase in levels of qualifying expenditure supported by a sustained history of agreement by Her Majesty's Revenue and Customs (UK) with such claims.

Segmental review

Sativex Commercial segment

The following table summarizes the results of our operations for our Sativex Commercial segment for the years ended September 30, 2012 and 2011, together with the changes to those items.

	Year Ended September 30,		Change 2012 vs. 2011	
	2012	2011	Increase/ Decrease	
	£	£	£	%
Product sales	2,514	4,409	(1,895)	(43)%
License, collaboration and technical access fees	1,294	3,843	(2,549)	(66)%
Development and approval milestone fees	9,812	5,337	4,475	(84)%
Total revenue	13,620	13,589	31	0%
Cost of sales	(839)	(1,347)	(508)	(38)%
Research and development credit	1,300	266	1,034	389%
Segmental result	**14,081**	**12,508**	**1,573**	**13%**

We classify all revenue from Sativex collaboration partners, with the exception of research and development fees, as Sativex Commercial segment revenue. The principal variances in these revenue streams are summarized in the table above. An explanation of the principal movements in the revenue streams is provided in the revenue section above.

Cost of sales declined by £0.5 million, or 38%, to £0.8 million for the year ended September 30, 2012 compared to £1.3 million for the year ended September 30, 2011. An explanation of the principal movements in the cost of sales is provided in the cost of sales section above.

For the Sativex Commercial segment, the research and development credit represents the movement in the provision against inventories manufactured prior to the regulatory approval of Sativex. All inventories manufactured prior to regulatory approval were capitalized as an asset but provided for, with the charge recognized in the research and development expenditure line, until there was a high probability of regulatory approval. When we determined that there was a high probability of regulatory approval of Sativex, the provision was revised to adjust the carrying value of Sativex inventories to the expected net realizable value, which may not exceed original cost. The provision for inventories release of £1.3 million for the year ended September 30, 2012 was higher than the £0.3 million for the year ended September 30, 2011 due to higher estimated future sales of Sativex at September 30, 2012.

Sativex Research and Development segment

The following table summarizes the results of our operations for our Sativex Research and Development segment for the years ended September 30, 2012 and 2011, together with the changes to those items.

	Year Ended September 30,		Change 2012 vs. 2011 Increase/ Decrease	
	2012	2011		
	£	£	£	%
Research and development fees	14,080	10,822	3,258	30%
Research and development expenditure				
GW-funded research and development	(4,335)	(3,935)	400	10%
Development partner-funded research and development	(14,080)	(10,822)	3,258	30%
Total research and development expenditure	(18,415)	(14,757)	3,658	25%
Segmental result	**(4,335)**	**(3,935)**	**(400)**	**10%**

Total research and development expenditure related to Sativex during the year ended September 30, 2012 increased by £3.7 million, or 25%, to £18.4 million as compared to the year ended September 30, 2011. This growth was largely attributable to a £3.3 million increase to the expanding Phase 3 cancer pain clinical program and associated development projects that are funded by Otsuka under the terms of the Sativex license and development agreement.

As all of the development partner-funded research and development expenditure is reimbursed to us under the terms of our license agreements, the net result for this segment equals the GW-funded research and development expenditure on Sativex related projects.

Pipeline Research and Development segment

The following table summarizes the results of our operations for our Pipeline R&D segment for the years ended September 30, 2012 and 2011, together with the changes to those items.

	Year Ended September 30,		Change 2012 vs. 2011 Increase/ Decrease	
	2012	2011		
	£	£	£	%
Research and development fees	5,420	5,216	204	4%
Research and development expenditure				
GW-funded research and development	(4,484)	(2,618)	1,866	71%
Development partner-funded research and development	(5,420)	(5.216)	204	4%
Total research and development expenditure	(9,904)	(7,834)	2,070	26%
Segmental result	**(4,484)**	**(2,618)**	**1,866**	**71%**

Pipeline research and development fees are equal to the development partner-funded research and development expenditure incurred by us in conducting our joint pipeline research program and recharged to Otsuka under the terms of our 2007 research collaboration agreement. The 4% year-on-year increase in pipeline research and development fees and development partner-funded research and development fees reflect an increasing amount of in vivo pre-clinical studies as we focused our work on preparing Otsuka's preferred product candidates for potential clinic development.

GW-funded pipeline research and development expenditure increased by £1.9 million, or 71%, to £4.5 million for the year ended September 30, 2012 as compared to £2.6 million for the year ended September 30, 2011. This increase was attributable to us having made progress with the recruitment of our Phase 2 trials, with the result that there was a year-on-year increase in Phase 2 clinical expenses.

As the development partner-funded research and development expenditure was fully offset by the associated research and development fees, the segmental result equals the GW-funded pipeline research and development expenditure.

B. Liquidity & Capital Resources

In recent years, we have largely funded our operations and growth from research and development fees and milestone payments from our development partners. We have also funded our operations and growth with cash flow from operations including Sativex revenue, research and development tax credits, interest income and issuances of equity securities. Our cash flows may fluctuate, are difficult to forecast and will depend on many factors including:

- the rate of growth of our Sativex revenue, which relies upon the marketing efforts of our commercial partners and factors such as the timing of further national approvals, the price levels achieved by our partners in each country, and the availability of reimbursement in countries in which the product is able to be marketed;
- the extent to which we seek to retain development rights to our pipeline of new product candidates or whether we seek to out-license them to a partner who will fund future research and development expenditure in return for a right to share in future commercial revenue;
- the extent of success in our early pre-clinical and clinical stage research programs which will determine the amount of funding required to further the development of our product candidates;
- the timing of achievement of the milestones receivable if Sativex is approved and launched in the United States;
- the terms and timing of new strategic collaborations;
- the number and characteristics of the product candidates that we seek to develop;
- the outcome, timing and cost of regulatory approvals of Sativex and our other product candidates;
- the costs involved in constructing larger, FDA-compliant manufacturing facilities for Sativex and our other product candidates;
- the costs involved in filing and prosecuting patent applications and enforcing and defending potential patent claims; and
- the costs of hiring additional skilled employees to support our continued growth.

We believe that our cash and cash equivalents as at September 30, 2013 of £38.1 million coupled with cash flow from operating activities will be sufficient to fund our operations, including currently anticipated research and development activities and planned capital expenditures, for the foreseeable future, including for at least the next twelve months.

Cash Flows

The following table summarizes the results of our cash flows for the years ended September 30, 2013, 2012 and 2011.

	Year Ended September 30,			
	2013	2013	2012	2011
	$	£	£	£
		(in thousands)		
Net cash (outflow)/inflow from operating activities	(12,080)	(7,468)	1,801	2,361
Net cash outflow from investing activities	(3,359)	(2,076)	(1,060)	(647)
Net cash inflow from financing activities	29,529	18,253	73	1,393
Cash and cash equivalents at end of the year	61,588	38,069	29,335	28,319

Operating activities

Net cash flow from operating activities decreased by £9.3 million to a £7.5 million outflow for the year ended September 30, 2013 compared to a £1.8 million inflow for the year ended September 30, 2012. This decrease was primarily driven by a £9.5 million reduction in development milestone receipts, a £0.3 million reduction in Sativex product sales, a £1.1 million increase in GW-funded research and development expenditure, a £0.9 million increase in cash used for working capital partially offset by a £2.4 million increase in research and development tax receipts.

Net cash inflow from operating activities decreased by £0.6 million, or 24%, to £1.8 million for the year ended September 30, 2012 compared to £2.4 million for the year ended September 30, 2011. This decrease was primarily driven by a £3.1 million reduction in receipts of license and technical access fees, a £1.4 million reduction in Sativex product sales and a £1.8 million increase in GW-funded research and development expenditure and management and administrative expenditure, being only partially offset by an increase in milestone payments received of £4.5 million, a £1.0 million reduction in working capital growth and a £0.2 million increase in tax credit receipts.

Investing activities

The net cash outflow from investing activities increased by £1.0 million to £2.1 million for the year ended September 30, 2013 from £1.1 million for the year ended September 30, 2012, reflecting an increase in capital expenditure of £0.9 million during the year ended September 30, 2013 as we invested in expanding and upgrading our manufacturing and research laboratory facilities.

The net cash outflow from investing activities increased by £0.5 million to £1.1 million for the year ended September 30, 2012 from £0.6 million for the year ended September 30, 2011, principally reflecting an increase in capital expenditure of £0.4 million during the year ended September 30, 2012 as we invested in expanding and upgrading our manufacturing facilities.

Financing activities

Net cash inflow from financing activities increased by £18.2 million for the year ended September 30, 2013 primarily as a result of the receipt of £18.1 million of net proceeds from the new equity issuance of ADSs in our U.S. initial public offering in May 2013. In addition, proceeds received on the inception of a new finance lease amounted to £0.2 million.

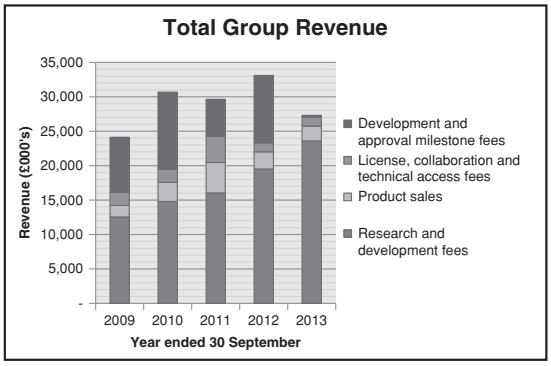
Cash generated by financing activities in the years ended September, 30 2012 and September 30, 2011 relates principally to the proceeds received on exercise of share options. Such cash inflows amounted to £0.1 million in the year ended September 30, 2012 and £1.4 million in the year ended September 30, 2011.

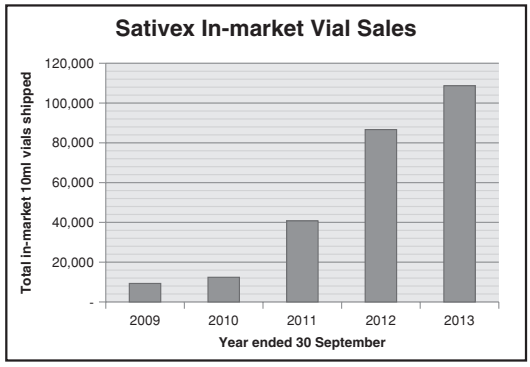
C. Research and development, patents and licenses, etc.

Full details of our research and development activities and expenditures are given in the Business section and Operating and financial review sections above.

D. Trend information.

The following charts illustrate the key financial trends in our business:





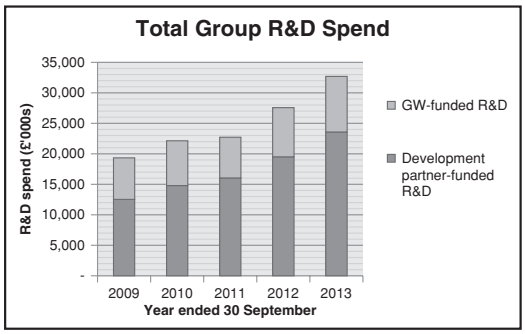
Our revenues consist of research and development fees, product sales revenues, license collaboration and technical access fees and development and approval milestone fees. As illustrated above, in each of the years ended September 30, 2009 to 2012 we received substantial development and approval milestones from our Sativex licensees. During the year ended September 30, 2013, we received only £0.3 million of development and approval milestone income, £9.5 million less than the prior year. The £5.8 million reduction in total revenues from 2012 to 2013 was therefore wholly attributable to the reduction in development and approval milestones earned, offset by increases to research and development fees earned.

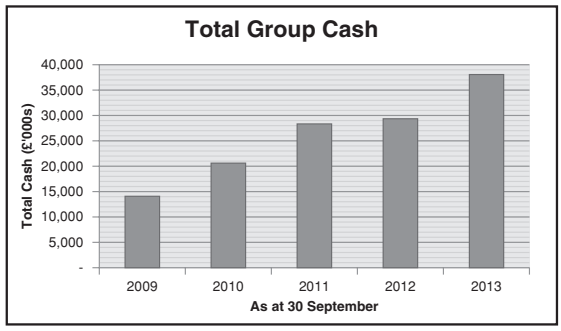
We consider our research and development fees, license and technical access fees and our product sales revenues to be recurring revenues. As illustrated above, over the last five years there has been a consistent growth trend in these revenues. The milestone revenues recognized in each of the years above tend to be individual items linked to specific development milestones achieved in a particular year. These are non-recurring items which tend to have a significant impact upon the profitability and cash flow of our business in each year in which they are received and earned.

The Sativex in-market vial sales graph above illustrates the trend in in-market commercial sales of Sativex by our commercial marketing partners Bayer in UK/Canada, Almirall in Europe and Neopharm in Israel.

In 2009, vial sales consisted entirely of vials sold by Bayer in Canada. In June 2010, Bayer started marketing Sativex in the UK. In 2011, Almirall launched Sativex in Spain, Germany and Denmark and in 2012 started commercial sales of Sativex to private patients in Sweden. In 2013, Almirall commenced sales of Sativex in Norway, Austria, Italy, Poland and Neopharm initiated sales of Sativex in Israel. We expect new launches and increases to the number of prescriptions written in each of the existing markets to continue to drive growth of Sativex sales in the future.

In market sales of Sativex in the year ended September 30, 2013 grew by 25% from the year ended September 30, 2012 to the year ended September 30, 2013. The growth trend in Sativex sales above reflects a compound annual growth rate of 24% per annum over the last five years.





As illustrated above our research and development expenditures have shown a consistent growth trend over the last five years from £19.4 million for the year ended September 30, 2009 to £32.7 million for the year ended September 30, 2013. The growth reflects progress with the Sativex development program and the expansion of the scope of our research to involve a broad range of pipeline product candidates. In the last five years, a significant proportion of the growth of the partner-funded research and development expenditures has been driven by our expanding U.S. Phase 3 Sativex cancer pain clinical trials program, which has evolved from a single Phase 2a trial in 2009 to three pivotal Phase 3 cancer pain trials plus a series of supporting Phase 1 clinical trial and regulatory activities in 2013. All of this clinical activity is funded by our development partner Otsuka.

Over the last five years Otsuka also funded a significant amount of pre-clinical activity as part of our six year pre-clinical research collaboration. This pre-clinical collaboration ended on June 30, 2013, resulting in a £1.2 million decrease in partner-funded pre-clinical expenditures in the year ended September 30, 2013 from the year ended September 30, 2012.

From the year ended September 30, 2009 to the year ended September 30, 2011, GW-funded research and development expenditure remained relatively static. For the year ended September 30, 2009 GW-funded research and development expenditure was £6.8 million, £7.3 million in 2010 and £6.9 million in 2011, increasing to £8.1 million in 2012 and £9.1 million in 2013. This increasing GW-funded research and development expenditure reflects decisions we have taken to progress the cannabinoid product candidates developed under the Otsuka pre-clinical collaboration into Phase 1/2 clinical trials in order to seek proof of concept data in multiple disease areas including epilepsy, glioma, diabetes and schizophrenia.

The cash graph above illustrates the trend in our year-end closing cash and cash equivalents position for each of the last five years in the period ended September 30, 2013.

From the year ended September 30, 2010 to the year ended September 30, 2012, we recorded a positive net operating cash inflow in each year, largely as a result of the substantial milestone receipts in each year. In the year ended September 30, 2013 the lack of milestone receipts and increase in GW-funded research and development expenditure, as previously discussed, resulted in an operating cash outflow for the year of £7.5 million. However, we raised £18.1 million of net new funds from issue of equity securities as part of our Nasdaq initial public offering on May 1, 2013 and we reported a net increase in cash and cash equivalents for the year ended September 30, 2013 of £8.7 million, resulting in closing cash and cash equivalents at September 30, 2013 of £38.1 million.

E. Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

F. Contractual Obligations and Commitments

The following table summarizes our contractual commitments and obligations as at September 30, 2013.

	Payments Due by Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
	£	£	£ (in thousands)	£	£
Operating lease obligations(1)	3,971	1,136	1,637	391	807
Finance lease obligations(2)	2,005	100	282	320	1,303
Purchase obligations(3)	147	147	—	—	—
Total contractual cash obligations(3)	6,123	1,383	1,919	711	2,110

(1) We enter into operating leases in the normal course of business. Most lease arrangements provide us with the option to renew the leases on defined terms. The future operating lease obligations would change if we exercise our renewal options, or if we were to enter into additional new operating leases. See Note 24 to our consolidated financial statements included elsewhere in this Annual Report. In addition, see Note 28 for a discussion of an operating lease arrangement entered into subsequent to September 30, 2013 (which is therefore not reflected in the table above).

(2) We enter into finance leases when beneficial to the Group. See Note 17 to our consolidated financial statements included elsewhere in this Annual Report.

(3) Purchase obligations include signed orders for capital equipment, which have been committed but not yet received at the balance sheet date totaling £0.1 million.

G. Safe Harbor

See the section entitled "Information Regarding Forward-Looking Statements" at the beginning of this Annual Report.

Item 6 Directors, Senior Management and Employees

A. Directors and Senior Management.

The following table sets forth the names, ages and positions of our executive officers and directors:

Name	Age	Position
Executive Officers		
Dr. Geoffrey Guy(3)	58	Chairman of the Board of Directors and member of Board of Directors
Justin Gover	42	Chief Executive Officer and member of Board of Directors
Dr. Stephen Wright	61	Research and Development Director and member of Board of Directors
Adam George	43	Chief Financial Officer and member of Board of Directors
Chris Tovey	47	Chief Operating officer and Member of Board of Directors
Non-Employee Directors		
James Noble(1)(2)(3)(4)	54	Deputy Chairman
Cabot Brown(1)(2)(3)(4)(5)	51	Non-Executive Director
Thomas Lynch(1)(2)(4)	55	Non-Executive Director

(1) Member of the Audit Committee.

(2) Member of the Remuneration Committee.

(3) Member of the Nomination Committee.

(4) An "independent director" as such term is defined in Rule 10A-3 under the Exchange Act.

(5) The board confirmed Mr. Brown's appointment in February 2013.

Executive Officers

Dr. *Geoffrey Guy* is our founder and has served as our Chairman since 1998. Dr. Guy has over 30 years of experience in medical research and global drug development, most recently as Chairman and Chief Executive of Ethical Holdings plc, a Nasdaq-quoted drug delivery company (now Amarin Corporation plc, or Amarin), which he founded in 1985 and led to its Nasdaq listing in 1993. He also founded Phytopharm plc in 1989, of which he was Chairman until 1997. Dr. Guy has been the physician in charge of over 200 clinical studies including first dose in man, pharmacokinetics, pharmacodynamics, dose-ranging, controlled clinical trials and large scale multi-centered studies and clinical surveys. He is also an author on numerous scientific publications and has contributed to six books. Dr. Guy was appointed as Visiting Professor in the School of Science and Medicine at the University of Buckingham in July 2011. He also received the "Deloitte Director of the Year Award in Pharmaceuticals and Healthcare" in 2011. Dr. Guy holds a BSc. in pharmacology from the University of London, an MBBS at St. Bartholomew's Hospital, an MRCS Eng. and LRCP London, an LMSSA Society of Apothecaries and a Diploma of Pharmaceutical Medicine from the Royal Colleges of Physicians.

Justin Gover has served as our Chief Executive Officer since January 1999. He has 17 years' experience in the pharmaceutical industry. As Chief Executive Officer, he has been the lead executive responsible for the running of our company's operations, as well as in leading equity financings and business development activities. Prior to joining our company, Mr. Gover was Head of Corporate Affairs at Ethical Holdings plc from 1995 to 1997 where he was responsible for the company's strategic corporate activities, including mergers and acquisitions, strategic investments, equity financings and investor relations. Mr. Gover holds an M.B.A. from INSEAD and a BSc. (Hons) from Bristol University.

Dr. Stephen Wright has served as our Research and Development Director since January 2004 and as a Director since March 2005. Dr. Wright has more than 20 years of experience in drug development. Prior to joining our company, Dr. Wright was Senior Vice President of Clinical Research & Development and a member of the U.K. Board of Directors at Ipsen Limited, where he led teams responsible for regulatory success in both the United States and the European Union. Dr. Wright also has direct U.S. drug development experience, first as Medical Director of Immunosciences, then as Venture Head of Neuroscience at Abbott Laboratories. Dr. Wright is a Fellow of the Royal College of Physicians of Edinburgh and the Faculty of Pharmaceutical Medicine. Dr. Wright is also a Visiting Professor in the School of Chemistry, Food and Pharmacy at The University of Reading and is the author of more than 100 publications, and several book chapters. Dr. Wright received an M.D. and an M.A. in Social and Political Science from the University of Cambridge and qualified in Medicine (MBBS) at The Royal London Hospital.

Adam George has served as our Chief Financial Officer since June 2012. Mr. George also acts as our Company Secretary. Prior to taking on his current role, Mr. George served as our Financial Controller since 2007. Mr. George has previously occupied several senior finance roles within both public and privately-owned companies, most recently as Finance Director from 2004 to 2007 and as Group Financial Controller from 2001 to 2004 of Believe It Group Limited (now 4Com plc), a telecommunications service provider. Mr. George holds a BSc. in Biology from Bristol University and is qualified as a chartered accountant.

Chris Tovey has served as our Chief Operating Officer since October 2012. Mr. Tovey has over 25 years' experience in the pharmaceutical industry. Prior to joining our Company, Mr. Tovey was at UCB Pharmaceuticals from 2006 to 2012. Most recently, Mr. Tovey was the Vice President of Global

Marketing Operations where he was responsible for worldwide marketing activities on a portfolio of UCB products generating over €2.0 billion in annual sales. Previous experience and roles at UCB included Managing Director Greece and Cyprus, and leader of all UCB activities on the orphan narcotic medication Xyrem®, used in the treatment of narcolepsy. Mr. Tovey previously spent 18 years at GlaxoSmithKline plc in senior commercial roles in both the European and U.K. organizations. These roles included Director Commercial Strategy Distribution Europe, Director European Vaccine Therapy Director Commercial Development U.K., Director Vaccines Business Unit U.K. and Business Unit Manager Oncology U.K. While at GSK, Mr. Tovey worked across a wide range of therapeutic areas including infectious diseases, neurology, oncology, diabetes, respiratory, and immunology. Mr. Tovey holds a BSc. degree in Marine Biology from the University of Liverpool.

Non-Employee Directors

James Noble has served as a Non-Executive Director since January 2007. Mr. Noble has 20 years of experience in the biotech industry. Mr. Noble currently serves as Chief Executive Officer of Immunocore Limited and Adaptimmune Limited, two privately-held companies involved in T-cell receptor technology. Mr. Noble has previously held numerous non-executive director positions, including at CuraGen Corporation, PowderJect Pharmaceuticals plc, Oxford GlycoSciences plc, MediGene AG, and Advanced Medical Solutions plc. Mr. Noble is qualified as a chartered accountant with Price Waterhouse and spent seven years at the investment bank Kleinwort Benson Limited, where he became a director in 1990. He then joined British Biotech plc as Chief Financial Officer and secured the company's IPO on the Nasdaq and London stock exchanges in 1992. Mr. Noble was previously Chief Executive Officer of Avidex Limited, a privately-held biotechnology company. Mr. Noble holds an M.A. from the University of Oxford. Our board of directors believes Mr. Noble's qualifications to serve as a member of our board include his financial expertise, his extensive experience in the pharmaceutical industry and his years of experience in his leadership roles as a director and executive officer.

Cabot Brown has served as a Non-Executive Director since February 2013. Mr. Brown has over 25 years of experience in the financial industry. Mr. Brown is the Founder and Chief Executive Officer of Carabiner LLC, an advisory and private equity firm based in San Francisco and London that specializes in health care and education. Previously, Mr. Brown served as a Managing Director at GCA Savvian Group Corp., an international financial advisory firm, from 2011 to 2012 where he directed the firm's efforts in the health care industry. Before joining GCA Savvian, Mr. Brown worked for ten years at Seven Hills Group, an investment banking group he co-founded where he also directed the firm's health care activities. He also was Managing Director of Brown, McMillan & Co., an investment firm he co-founded that sponsored buy-outs and venture capital investments. From 1987 until 1995, Mr. Brown worked at Volpe, Welty & Company, a boutique investment bank where he co-founded and ran the health care practice and served as a member of its Executive Committee. Mr. Brown started his finance career in New York, working in the investment banking departments of The First Boston Corporation and Lehman Brothers. Mr. Brown holds an M.B.A. from Harvard Business School with high distinction as a George F. Baker Scholar and an A.B. cum laude in Government from Harvard College. Our board of directors believes Mr. Brown's qualifications to serve as a member of our board include his financial expertise, his extensive experience in the health care industry and his years of experience in his leadership roles as a director and executive officer.

Thomas Lynch has served as a Non-Executive Director since July 2010. Mr. Lynch has over 19 years of experience in the biotechnology industry. Mr. Lynch currently serves as Chairman of ICON plc, a clinical research company, and Profectus BioSciences Inc., (a company conducting research into immunological diseases) and is Chairman of Chrontech AB, a Swedish company conducting research in infectious diseases. Previously, Mr. Lynch served as Chairman and Chief Executive Officer of Amarin from 2000 and 2007, respectively, until December 2009. During his tenure as Chief

Executive Officer, Mr. Lynch led the re-positioning of Amarin as a cardiovascular company, over $100 million in equity financings and the de-listing of Amarin's shares from the AIM while maintaining the company's primary listing on Nasdaq. As at December 31, 2012, Amarin's market capitalization had reached over $1.2 billion. Mr. Lynch continues as Chairman of Amarin Pharmaceuticals (Ireland) Limited, having stepped down from its parent board of directors in October 2010. From 1993 to 2004, Mr. Lynch worked in a variety of capacities in Elan Corporation plc, including Chief Financial Officer, Executive Vice-President, Vice-Chairman and senior adviser. Mr. Lynch holds an economics degree from Queen's University Belfast. Our board of directors believes Mr. Lynch's qualifications to serve as a member of our board include his extensive experience in the pharmaceutical industry and his years of experience in his leadership roles as a director and executive officer.

B. Compensation

The following discussion provides the amount of compensation paid, and benefits in kind granted, by us and our subsidiaries to our directors and members of the executive management board for services in all capacities to us and our subsidiaries for the year ended September 30, 2013, as well as the amount contributed by us or our subsidiaries into money purchase plans for the year ended September 30, 2013 to provide pension, retirement or similar benefits to, our directors and members of the executive management board.

Directors and Executive Management Board Compensation

Directors Compensation

For the year ended September 30, 2013, the table below sets forth the compensation paid to our directors, and in the case of Messrs. Guy, Gover, Wright and George, reflects the compensation paid for their services as our executives.

Year Ended September 30, 2013 Directors Compensation(1)

Name	Salary/Fees	Annual Bonus	Benefit(3) Excluding Pension	Pension Benefit	Total
	£	£	£	£	£
Dr. Geoffrey Guy *Executive Director* *Chairman*	354,383	112,761	5,542	56,204	528,890
Justin Gover *Executive Director* *Chief Executive Officer*	286,770	92,725	3,905	47,405	430,805
Dr. Stephen Wright *Executive Director* *Research and Development Director*	241,232	77,234	8,845	39,486	366,797
Adam George *Executive Director* *Chief Financial Officer*	162,163	43,750	3,646	22,109	231,668
Chris Tovey(4) *Executive Director* *Chief Operating Officer*	214,988	17,063	3,656	34,893	270,600
James Noble *Non-Executive Director* *Deputy Chairman*	52,934	—	—	—	52,934
Cabot Brown(5) *Non-Executive Director*	28,863	—	—	—	28,863
Richard Forrest(6) *Non-Executive Director*	22,712	—	—	—	22,712
Thomas Lynch(7) *Non-Executive Director*	—	—	—	—	—

(1) For the year ended September 30, 2013, the compensation of all our Non-Executive and Executive Directors was set, and paid, in pounds sterling (£).

(2) For our Executive Directors, these amounts represent the value of the personal benefits granted to our senior management for the year ended September 30, 2013, which include car allowance and medical and life insurance.

(3) These amounts represent our contribution into money purchase plans.

(4) Mr. Tovey was appointed on October 1, 2012.

(5) Mr. Brown was appointed on February 19, 2013.

(6) Mr. Forrest retired on January 18, 2013.

(7) Mr. Lynch has waived his right to receive remuneration for his service as a Non-Executive Director.

Executive Management Compensation

The compensation for each member of our executive management board is comprised of the following elements: base salary, annual bonus, personal benefits, and long-term incentives. The total amount of compensation paid and benefits in kind granted to the members of our executive management board, whether or not a director, for the year ended September 30, 2013 was £1.9 million.

Bonus Plans

The discussion set forth below describes each bonus plan pursuant to which compensation was paid to our directors and members of our executive management board for our last full year.

Executive Directors are eligible for an annual bonus at the discretion of the Remuneration Committee. Bonus awards are reviewed at the end of each calendar year and any such awards are determined by the performance of the individual and the Group as a whole based upon the achievement of strategic objectives set at the beginning of the year. The awards are normally limited to a maximum of 50% of basic salary, however in exceptional circumstances the annual maximum may increase up to 100% of basic salary.

Outstanding Equity Awards, Grants and Option Exercise

During the year ended September 30, 2013, 1,616,261 options to purchase ordinary shares were awarded to the directors. As of September, 2013, directors held options to purchase 9,140,952 ordinary shares. None of the Directors exercised any options during the year ended September 30, 2013.

We periodically grant share options to employees, including executive officers, to enable them to share in our successes and to reinforce a corporate culture that aligns employee interests with that of our shareholders. Since September 30, 2010, we have granted a number of additional options to purchase ordinary shares to 160 employees who are not members of our executive management board.

Options issued under our Long Term Incentive Plan have an exercise price of £0.001 per share, a three-year vesting period and expire ten years from the date of grant. These options are also subject to a number of different performance conditions. If the relevant performance conditions are not achieved by the three-year vesting date, the options lapse. In addition, generally, an optionholder must remain an employee throughout the relevant vesting period or the options will lapse. Options issued under the other share option schemes were all issued with an exercise price equal to the closing market price on the day prior to grant, a three-year vesting period and expire ten years from date of grant. The only performance condition linked to these awards was continued employment throughout the vesting period.

Pension, Retirement and Similar Benefits

For the year ended September 30, 2013, we and our subsidiaries contributed a total of £0.2 million into money purchase plans to provide pension, retirement or similar benefits to our directors and members of the executive management board.

Employment Agreements

Dr. Geoffrey Guy

On March 14, 2013, GW Research Limited entered into a service agreement with Dr. Guy, our Chairman and Founder. Dr. Guy's service agreement provides that his service will continue until either party provides no less than 12 months' written notice. Upon notice of termination, GW Research Limited may require Dr. Guy not to attend work for all or any part of the period of notice, during which time he will continue to receive his salary and other contractual entitlements. GW Research

Limited may terminate Dr. Guy's employment with immediate effect at any time by notice in writing for certain circumstances as described in his service agreement, including bankruptcy, criminal convictions, gross misconduct or serious or repeated breaches of obligations of his service.

Dr. Guy's service agreement provides for a base salary of £322,174 per annum (to be reviewed annually), a car allowance of £24,960 per annum, plus a monthly pension contribution of 17.5% of salary, permanent health insurance coverage, life assurance coverage and private health insurance, and a bonus on such terms and of such amount as approved from time to time by the Remuneration Committee in its sole discretion. Dr. Guy's service agreement provides that for a 12 months following termination of his employment with GW Research Limited, he will not entice, induce or encourage any customer or employee to end their relationship with GW Research Limited or any other member of the Group, solicit or accept business from customers or engage in competitive acts more fully described in his service agreement.

Justin Gover

On February 26, 2013, GW Research Limited entered into a service agreement with Mr. Gover, our Chief Executive Officer. Mr. Gover's service agreement provides that his service will continue until either party provides no less than 12 months' written notice. Upon notice of termination, GW Research Limited may require Mr. Gover not to attend work for all or any part of the period of notice, during which time he will continue to receive his salary and other contractual entitlements. GW Research Limited may terminate Mr. Gover's employment with immediate effect at any time by notice in writing for certain circumstances as described in his service agreement, including bankruptcy, criminal convictions, gross misconduct or serious or repeated breaches of obligations of his service.

Mr. Gover's service agreement provides for a base salary of £272,875 per annum (to be reviewed annually), plus a monthly pension contribution of 17.5% of salary, car allowance of £15,600 per annum, permanent health insurance coverage, life assurance coverage and private health insurance, and a bonus on such terms and of such amount as approved from time to time by the Remuneration Committee in its sole discretion.

Mr. Gover's service agreement provides that for 12 months following termination of his employment with GW Research Limited, he will not entice, induce or encourage any customer or employee to end their relationship with GW Research Limited or any other member of the Group, solicit or accept business from customers or engage in competitive acts more fully described in his service agreement.

Dr. Stephen Wright

On January 18, 2013, GW Research Limited entered into a service agreement with Dr. Stephen Wright, our Research and Development Director. The service agreement provides that his service will continue until either party provides no less than twelve months' written notice. Upon notice of termination, GW Research Limited may require Dr. Wright not to attend work for all or any part of the period of notice, during which time he will continue to receive his salary and other contractual entitlements. GW Research Limited may terminate Dr. Wright's employment with immediate effect at any time by notice in writing for certain circumstances as described in his service agreement, including bankruptcy, criminal convictions, gross misconduct or serious or repeated breaches of obligations of his service.

Dr. Wright's service agreement provide for a base salary of £227,287 per annum (to be reviewed annually), plus a monthly pension contribution of 17.5% of salary, a car allowance of £15,600 per annum, life assurance coverage, the cost of membership for Dr. Wright, his spouse and children in a private patients medical plan, access to a permanent health insurance plan, and a bonus on such terms

and of such amount as approved from time to time by the Remuneration Committee in its sole discretion.

Dr. Wright's service agreement provides that for 12 months following termination of his employment with GW Research Limited, he will not entice, induce or encourage any customer or employee to end their relationship with GW Research Limited or any other member of the Group, solicit or accept business from customers or engage in competitive acts more fully described in his service agreement.

Adam George

On June 1, 2012, GW Pharma Limited entered into a service agreement with Mr. George, our Chief Financial Officer. The service agreement provides for a base salary of £185,000 per annum (to be reviewed annually), plus a monthly pension contribution of 17.5% of salary, a car allowance of £15,600 per annum, life assurance coverage, the cost of membership for Mr. George, his spouse and children in a private patients medical plan, access to a permanent health insurance plan, and a discretionary bonus on such terms and of such amount as decided from time to time by the Remuneration Committee in its sole discretion.

Mr. George's service agreement provides that his service will continue until either party provides no less than six months' written notice. The notice period is expected to increase to 12 months after two years' service, subject to approval by the Remuneration Committee. During the first two years of service, the notice period required from GW Pharma Limited will increase to 12 months if notice is given during the three month period immediately following a change of control of the company. Upon notice of termination, GW Pharma Limited may require Mr. George not to attend work for all or any part of the period of notice, during which time he will continue to receive his salary and other contractual entitlements. GW Pharma Limited may terminate Mr. George's employment with immediate effect at any time by notice in writing for certain circumstances as described in his service agreement, including bankruptcy, criminal convictions, gross misconduct or serious or repeated breaches of obligations of his service.

Mr. George's service agreement provides that for a period of 12 months following termination of his employment with GW Pharma Limited, he will not entice, induce or encourage any customer or employee to end their relationship with GW Pharma Limited or any member of the Group, solicit or accept business from customers or engage in competitive acts more fully described in his service agreement.

Chris Tovey

On July 11, 2012, GW Pharma Limited entered into a service agreement with Mr. Tovey, our Chief Operating Officer. The service agreement provides for a base salary of £200,850 per annum (to be reviewed annually), plus a monthly pension contribution of 17.5% of salary, a car allowance of £15,600 per annum, life assurance coverage, the cost of membership for Mr. Tovey, his spouse and children in a private patients medical plan, access to a permanent health insurance plan, and a discretionary bonus on such terms and of such amount as decided from time to time by the Remuneration Committee in its sole discretion.

Mr. Tovey's service agreement provides that his service will continue until either party provides no less than six months' written notice. Upon notice of termination, GW Pharma Limited may require Mr. Tovey not to attend work for all or any part of the period of notice, during which time he will continue to receive his salary and other contractual entitlements. GW Pharma Limited may terminate Mr. Tovey's employment with immediate effect at any time by notice in writing for certain circumstances as described in his employment agreement, including bankruptcy, criminal convictions, gross misconduct, or serious or repeated breaches of obligations to his service.

Mr. Tovey's service agreement provides that for a period of 12 months following termination of his employment with GW Pharma Limited, he will not entice, induce or encourage any customer or employee to end their relationship with GW Pharma Limited or any other member of the Group, solicit or accept business from customers or engage in competitive acts more fully described in his service agreement.

James Noble

On January 19, 2007, GW Pharmaceuticals plc appointed Mr. Noble Deputy Chairman and Non-Executive Director with effect from January 26, 2007. On February 26, 2013, GW Pharmaceuticals plc entered into an appointment letter with Mr. Noble, which continues for no specific duration. The appointment letter provides for Director's fees of £52,934 per annum plus reimbursement for all reasonable out-of-pocket expenses incurred on GW Pharmaceutical plc business and director's and officer's liability insurance, subject to the provisions governing such insurance and on such terms as our Board of Directors may from time to time decide. Mr. Noble's agreement provides that he is not entitled to participate in any pension or employee share schemes and is not eligible for any other benefits.

Mr. Noble's appointment letter provides that his appointment will continue until either party provides no less than three months' written notice and that he should be prepared to spend at least 12 days per year on company business. Mr. Noble's appointment may be automatically terminated if he is removed from office by a resolution of the shareholders, is not re-elected to office, vacates his office, commits any act that would justify summary termination of an employment contract or if he is unable to perform his duties under his appointment for six months consecutively or in aggregate in any period of one year. Mr. Noble's agreement provides that GW Pharmaceuticals plc may, during any period of notice, ask Mr. Noble not to attend any Board or General meetings or to perform any other services on its behalf. The agreement includes a non-compete clause, to take effect on termination, for 12 months following termination of his office.

Cabot Brown

We originally appointed Mr. Brown as a Non-Executive Director on February 19, 2013. Mr. Brown serves as a member of the Audit Committee, the Remuneration Committee and Nominations Committee.

On November 7, 2013, Mr. Brown entered into a new employment contract with GW Pharmaceuticals Inc., the terms of which provide for an agreed salary plus reimbursement for all reasonable out of pocket expenses incurred on GW Pharmaceuticals Inc.'s business and director's and officer's liability insurance, subject to the provisions governing such insurance and on such terms as GW Pharmaceuticals Inc.'s Board of Directors may from time to time decide. The contract provides that he is not entitled to participate in any pension and will not be eligible for other benefits.

Mr. Brown's contract also provides that his employment will continue until either party provides no less than three months' written notice and that he should be prepared to spend at least 12 days per year attending board and general meetings of GW Pharmaceuticals plc representing GW Pharmaceuticals Inc.'s business interests. Mr. Brown's appointment may be automatically terminated if he is removed from office as a director of GW Pharmaceuticals plc by a resolution of the shareholders, is not re-elected to office, vacates his office, commits any act that would justify summary termination of an employment contract or if he is unable to perform his duties under his appointment for six months consecutively or in aggregate in any period of one year. Mr. Brown's employment contract provides that GW Pharmaceuticals Inc. may, during any period of notice, ask Mr. Brown not to attend any Board or General meetings or to perform any other services on its behalf. The contract includes a non-compete clause, to take effect on termination, for one year.

Thomas Lynch

On July 22, 2010, GW Pharmaceuticals plc appointed Mr. Lynch, a Non-Executive Director. On February 26, 2013, Mr. Lynch entered into an updated appointment letter with GW Pharmaceuticals plc, which continues for no specific duration. Mr. Lynch has waived his right to receive remuneration for this role. Mr. Lynch's agreement provides for reimbursement for all reasonable out-of-pocket expenses incurred on GW Pharmaceutical plc business and director's and officer's liability insurance, subject to the provisions governing such insurance and on such terms as our Board of Directors may from time to time decide. Mr. Lynch's agreement provides that he is not entitled to participate in any pension or employee share schemes and is not eligible for any other benefits.

Mr. Lynch's agreement provides that his appointment will continue until either party provides no less than three months' written notice and that he should be prepared to spend at least 12 days per year on company business. Mr. Lynch's appointment may be automatically terminated if he is removed from office by a resolution of the shareholders, is not re-elected to office, vacates his office, commits any act that would justify summary termination of an employment contract or if he is unable to perform his duties under his appointment for six months consecutively or in aggregate in any period of one year.

Mr. Lynch's agreement provides that GW Pharmaceuticals plc may, during any period of notice, ask Mr. Lynch not to attend any Board or General meetings or to perform any other services on its behalf. The agreement includes a non-compete clause, to take effect on termination, for 12 months following termination of his office.

Equity Compensation Plans

GW Pharmaceuticals plc Long-Term Incentive Plan

Our board of directors adopted and our shareholders approved the GW Pharmaceuticals plc Long-Term Incentive Plan, or the Long-Term Incentive Plan, on March 18, 2008. The Long-Term Incentive Plan permits participating employees to purchase Investment Shares and provides for the grant of Matching Awards and Performance Awards, or, collectively, Awards, all summarized below.

Investment Shares. The Remuneration Committee may invite any eligible employee to participate in the Long-Term Incentive Plan by purchasing ordinary shares, which are referred to as Investment Shares in this Annual Report. The invitation will specify the maximum amount of Investment Shares which can be purchased, the procedure for purchasing the Investment Shares, the maximum number of ordinary shares which may be received as a Matching Award and other terms of the award. A "Return Date" will also be specified which is the date by which the invitation to participate must be accepted. As soon as practicable after the Return Date, we procure the Investment Shares. The participant will have full rights with respect to the Investment Shares. Any ordinary shares subject to a Matching Award with respect to Investment Shares will be transferred to the participant when the Matching Award vests.

Matching Awards and Performance Awards. Under the Long-Term Incentive Plan, the Remuneration Committee may grant Matching Awards or Performance Awards and will designate the type of award prior to the date on which the award is granted. The Remuneration Committee will also specify whether an Award is a Conditional Award or an option to purchase our ordinary shares, referred to in this Annual Report as an Option; provided, however, that if the Remuneration Committee does not specify the type of Award, the Award will be in the form of an Option. Awards may be granted only within the six weeks beginning with the dealing date after the date on which we announce our results for any period or at any other time that the Committee determines that the circumstances justify the grant. The Remuneration Committee may determine that any Conditional Award or Option may be settled in cash rather than ordinary shares unless it would be unlawful to do

so or if it would cause adverse tax or social security contribution consequences for the participant or us or our affiliates.

Vesting of Awards. Awards generally vest on the later of the date on which the Remuneration Committee determines whether any applicable performance conditions or other vesting condition have been met or the third anniversary of the grant date (or such other date as the Remuneration Committee may determine prior to the grant of the applicable Award). In addition, a Matching Award will lapse on the date on which the participant does any act in breach of the terms relating to Investment Shares or loses his entitlement to, transfers, charges or otherwise disposes of the Investment Shares to which the Matching Award relates and the lapse shall be pro rata to the number of the affected Investment Shares.

If a participant ceases to be a director or employee of us or our affiliates before the normal vesting date of an Award by reason of (i) death, (ii) retirement with the agreement of the Remuneration Committee (in the case of our executive directors or senior management) or the employer (in the case of other participants), (iii) ill health, injury or disability, (iv) redundancy, (v) his office or employment is with a company that ceases to be one of our affiliates or relating to a business or part of a business which is transferred to an unrelated third party, or (vi) or for any other reason that the Remuneration Committee determines, then the Award will vest on the normal vesting date unless the Remuneration Committee decides that the Award will vest on the date specified in paragraphs (i) through (vi) above (and an Option could be exercised for six months thereafter). If a participant ceases to be a director or employee in other circumstances, the Award will lapse immediately upon cessation of service. Special rules apply to determine the number of ordinary shares that will vest in any specified circumstances, including application of any performance conditions.

Limits on Ordinary Shares and Awards. No Award may be made under the Long-Term Incentive Plan in any calendar year if, at the time of the proposed grant date, it would cause the number of our ordinary shares allocated on or after June 28, 2001 and in the period of ten calendar years ending with that calendar year under the Long-Term Incentive Plan, any other employee share plan operated by us or any other share incentive arrangement operated by us for the benefit of directors or consultants to any participating company to exceed ten percent of our ordinary share capital in issue at that time. Ordinary shares are generally considered to be allocated if they are subject to outstanding options to acquire unissued shares or treasury shares, if they are issued or transferred from treasury otherwise than pursuant to an option or other right to acquire the ordinary shares or, in certain circumstances, if they are issued or may be issued to any trustees to satisfy the grant of an option or other contractual right. Existing shares other than treasury shares that are transferred or over which options or other contractual rights are granted are not treated as allocated. Special rules apply to the determination of whether shares are allocated in the case of awards that expire or are settled in cash or where institutional investor guidelines cease to require the shares to be counted as allocated. In addition, the aggregate number of shares in relation to which Awards may be made pursuant to the Long-Term Incentive Plan after March 14, 2013 shall not exceed 15 million.

Except as otherwise determined by the Committee for exceptional circumstances (such as recruitment or retention), the maximum total market value of our ordinary shares over which Award may be granted to any employee during any year is 100% of the employee's base salary.

Takeovers and Corporate Events. If a person or group obtains control of us pursuant to a general offer to acquire our ordinary shares or has obtained control of us and then makes such an offer or such an offer becomes unconditional in all respects, then the Remuneration Committee will notify all participants and all Awards will vest on the date determined by the Remuneration Committee (but no later than the date of the change in control or offer becoming unconditional) and any Option can be exercised within one month after such early vesting date. Special vesting rules apply in the context of a winding up of us or in the event of a demerger, special dividends or other events which, in the opinion

of the Remuneration Committee would affect the market price of our ordinary shares to a material extent. In certain cases, the Remuneration Committee, with the consent of an acquiring company if applicable, may decide before the change of control that an Award will not vest under the special vesting provisions but shall instead be surrendered in consideration for the grant of a new award which the Remuneration Committee determines is equivalent in value to the Award that it replaces. Special rules apply to determine the numbers of ordinary shares that will vest in any specified circumstances, including application of any performance conditions.

Adjustment of Awards. In the event that there is any variation in our share capital or any demerger, special dividend or other similar event which affects the market price of our ordinary shares to a material extent, the Remuneration Committee may make such adjustments as it considers appropriate, taking into account where relevant, any adjustment to the related holding of Investment Shares. Any such adjustments may be made to one or more of the number of ordinary shares subject to an Award, the option price or the number of ordinary shares that may be transferred pursuant to a vested Award which has not yet been settled. Limitations apply to the extent that any such adjustments may reduce the price at which ordinary shares may be purchased pursuant to the exercise of an Option.

Transferability. No award under the Long-Term Incentive Plan may be transferred, assigned, charged or otherwise disposed of (except on death to the recipient's personal representatives) and will lapse immediately upon an attempt to do so. In addition, an award under the Long-Term Incentive Plan will lapse immediately if the recipient of an award is declared bankrupt.

Amendment and Termination. The Long-Term Incentive Plan will expire ten years after the date that it was approved by our shareholders and no awards may be granted thereunder after the expiration date. The Committee may, at any time, alter the Long-Term Incentive Plan or the terms of any Award; provided, however, that no alteration to the benefit of a participant or potential participants will be made to the provisions relating to the individual limits on participation, the overall limits on the issue of ordinary shares or transfer of treasury shares, the overall limit on the number of ordinary shares which may be subject to Awards or the foregoing restrictions without approval of our ordinary shareholders. Minor alterations to benefit the administration of the Long-Term Incentive Plan, to take into account changes in law or obtain or maintain favorable tax treatment, exchange control or regulatory treatment for participants or us and our affiliates or alterations to performance conditions are not subject to shareholder approval. Alterations to the disadvantage of participants (other than changes to performance conditions) may not be made unless all participants have the opportunity to approve the change and the change is approved by a majority of the participants. Although performance conditions can generally be altered by the Committee, we have undertaken to consult with our major shareholders prior to altering any performance conditions existing as of January 18, 2008.

GW Pharmaceuticals All Employee Share Scheme

GW Pharma Ltd. (then GW Pharmaceuticals Ltd.) adopted the GW Pharmaceuticals All Employee Share Scheme, or the Share Scheme, on August 16, 2000 and it was approved by the U.K.'s Inland Revenue on August 25, 2000 as what is now known as an approved share incentive plan. The Share Scheme provides for the grant of awards of our ordinary shares, which may be Free Shares, Matching Shares or Partnership Shares, or, collectively, Share Scheme Awards, all summarized below, in a tax advantageous manner. Dividends payable in relation to Share Scheme Awards may be reinvested as Dividend Shares subject to the scheme. Shares awarded are held by the trustees of the scheme, or the Trustees, in a specially established trust on behalf of the participants. The scheme originally operated over ordinary shares in GW Pharma Ltd, but following our acquisition of GW Pharma Ltd the scheme was amended so that it operated over our ordinary shares.

Eligibility. Generally, employees of GW Pharma or certain of its subsidiaries are eligible to receive Share Scheme Awards under the Plan. In order to satisfy certain U.K. tax rules, certain

participants, referred to in this Annual Report as Qualifying Employees, must be invited to participate in the Share Scheme if they are otherwise eligible.

Generally, all Qualifying Employees who are required to be invited (or who have been invited) to participate in an Share Scheme Award under the Share Scheme will participate on the same terms. We may, however, make awards of Free Shares to Qualifying Employees which vary by reference to their remuneration, length of service or hours worked or by reference to their performance.

Free Shares. The Trustees, with the prior consent of GW Pharma Ltd., may award Free Shares. The number of Free Shares to be awarded to each Qualifying Employee will be determined by GW Pharma Ltd. and the initial market value of any such Share Scheme Award in any tax year will not exceed £3,000. The number of Free Shares granted to a Qualifying Employee on any date may be determined by reference to performance allowances. If such performance allowances are used, they will apply to all Qualifying Employees. The Share Scheme sets forth methodologies for determining how to calculate the number of Free Shares that are awarded to a Qualifying Employee by reference to performance allowances. With respect to the grant of Free Shares, a holding period is specified through which a participant who has been granted Free Shares must be bound by the terms of a Free Share agreement. The length of the holding period will not be less than three nor more than five years beginning on the award date and will be the same for all participants who receive a grant at the same time.

Partnership Shares. GW Pharma Ltd. may invite every Qualifying Employee to enter into an agreement with respect to the grant of Partnership Shares. Partnership Shares are subject to the terms and conditions of the Share Scheme and are not subject to any forfeiture provisions. Participants are required to have amounts deducted from their compensation to pay for Partnership Shares, such amounts referred to in this Annual Report as Partnership Share Money; provided, however, that the maximum amount of Partnership Share Money for any month cannot exceed £125 or such lower figure that may be specified and the total Partnership Share Money for any period during which contributions are accumulated to purchase Partnership Shares such period referred to in this Annual Report as the Accumulation Period, cannot exceed 10% of the payments of salary made to the participant over the Accumulation Period. There may also be a minimum amount of Partnership Share Money for any month (applied uniformly to all participants), which minimum cannot exceed £10. Any Partnership Share Money that is deducted in excess of the limitations, less applicable taxes, will be paid to the participant as soon as practicable.

If there is an Accumulation Period, the maximum number of Partnership Shares that may be acquired for that Accumulation Period will be determined by reference to the lower of the value of our shares at the beginning of the Accumulation Period or the value of ordinary shares on the acquisition date. Any excess Partnership Share Money remaining after purchase of the ordinary shares may, with the agreement of the participant, be carried over to the next Accumulation Period or in other cases be paid to the participant less applicable taxes. The number of Partnership Shares that may be purchased as of any date may be reduced if the applications to purchase exceed the permitted limits.

An employee may withdraw from purchasing Partnership Shares at any time. Unless otherwise specified by the employee, the withdrawal will take effect 30 days after we receive the notice. In the event of a withdrawal, any Partnership Purchase Money held on behalf of the withdrawing employee, less applicable taxes, will be returned to the employee as soon as practicable.

If approval of the Share Scheme is withdrawn or if the Share Scheme is terminated, all Partnership Share Money, less applicable taxes, will be repaid to employees as soon as practicable.

Matching Shares. Matching Shares are granted on the basis set forth in the Partnership Agreement relating to the grant of Partnership Shares. No payment is made by the participants in

relation to Matching Shares. Generally, Matching Shares are awarded to all participants on the same basis. In no event will the ratio of Matching Shares to Partnership Shares exceed 2:1.

Dividend Shares. If any dividends are paid in relation to ordinary shares held pursuant to the Share Scheme for participants, GW Pharma Ltd may specify that some or all of those dividends shall be applied to purchase Dividend Shares or they may give the participants the choice between such dividends being applied to purchase Dividend Shares or being paid in cash. Special rules apply to reinvestment of dividends. Dividend Shares are subject to a three year holding period.

Limits on Shares and Awards. No ordinary shares will be issued under the Share Scheme if the issue would result in the aggregate number of our ordinary shares which have been allocated under the Share Scheme, any other employees' share plan adopted by us or any other share incentive arrangements for employees, directors, officers and consultants of our affiliates during the period of ten years ending on the date of the issue to exceed 10% of our ordinary shares then in issue. "Allocated" for these purposes means the grant of options or other rights to acquire ordinary shares which may be satisfied by the issue of new shares, or, where no such rights are granted, the issue of ordinary shares. Rights which have lapsed are no longer taken into account.

Amendment. GW Pharma Ltd. may, with the Trustees' written consent, amend the Share Scheme, provided that no amendment which may increase the limits described in the preceding paragraph may be made without the approval of our shareholders. In addition, no amendment may be made which would adversely prejudice to a material extent the rights attached to any ordinary shares awarded, and certain amendments would require the approval of the UK tax authorities.

Reconstructions and Rights Issues. The Share Scheme sets forth special rules that apply in the case of reconstructions and rights issues.

GW Pharmaceuticals Unapproved Share Option Scheme 2001

Our shareholders approved and adopted the GW Pharmaceuticals Unapproved Share Option Scheme 2001, or the Executive Option Scheme, on May 31, 2001. In the United Kingdom, generally, an "unapproved" share option scheme means that it does not qualify for certain tax breaks since it has not been "approved" by the U.K. tax authority. It is typical for U.K. companies to have both "approved" and "unapproved" share options schemes due, in part, to the individual participation limits found in "approved" schemes. Under the Executive Option Scheme, Options were granted to our employees, such employees referred to in this Annual Report as eligible employees. The scheme terminated on May 31, 2011, and no further options will be granted under the scheme. Termination of the scheme did not affect the rights of existing participants.

Options granted under the Executive Option Scheme may be designated as "EMI Options" which are intended to qualify for advantageous tax treatment as enterprise management incentives under applicable UK tax law. Generally, EMI Options are subject to the same terms and conditions as apply to Options. Other terms and conditions may also apply to EMI Options, particularly where the Committee determines that such alternative treatment is appropriate to obtain, protect or maximize beneficial tax or national insurance treatment of the participant, us or our affiliates.

Exercise of Options. Options generally may not be exercised prior to the third anniversary of the grant, however all outstanding options are currently exercisable. If applicable, any performance targets and other conditions on exercise must also be satisfied. Vesting provisions and performance targets may be waived only to the extent provided in the grant terms or, in the case of a performance target, an event occurs which makes the condition more onerous to achieve.

Generally, Options must be exercised while the participant is an eligible employee. In the event, however, that a participant ceases to be an eligible employee as the result of injury, illness or disability,

redundancy or retirement on or after attaining his normal retirement age (age 60 or such other date on which he is required to retire pursuant to his employment contract) or at the specific request of his employer, the Option may be exercised during the period of six months (or such longer period as the Committee may specify) commencing on the date he ceases to be an eligible employee. If a participant dies while he is an eligible employee or during the extended exercise period described in the preceding sentence, the participant's personal representatives may exercise the Option for twelve months after the participant's death. In all other cases, the Remuneration Committee may permit post-cessation exercise during such period from the date of cessation as they may notify to the participant. All Options lapse upon the tenth anniversary of the date of grant.

Takeovers and Corporate Events. If any person obtaining control of us (as determined in accordance with specified U.K. tax law) as the result of making an offer to acquire all of our issued share capital that is either unconditional or which is made on a condition which, if satisfied will cause the person making the offer to have control of us or a general offer to acquire all of our ordinary shares, any such offer referred to in this document as a Takeover Offer, Options may be exercised within the relevant period after the time the person has obtained control and any conditions subject to which the Takeover Offer have been satisfied. Options may also be exercisable for the relevant period in the event of certain court sanctioned restructurings or amalgamations of us or if another company becomes bound or entitled to acquire our ordinary shares pursuant to certain provisions of U.K. corporate law. If the Remuneration Committee determines that it is likely that we will come under the control of another company such that our ordinary shares will cease to satisfy specified conditions of U.K. tax law, the Remuneration Committee may permit exercise of the Options prior to the change of control.

In the event of a Takeover Offer or court sanctioned restructuring or amalgamation, the participant, by agreement with the other company, release Options in consideration for the grant of a new option with respect to the acquiring company's shares and subject to certain other terms and conditions. The Remuneration Committee may also permit exercise of the Options within a relevant period following the date on which we pass a resolution for voluntary winding up or certain other transactions involving a change in control of us.

With respect to any event, the "relevant period" is generally the period of three months or such different period not less than 30 days and not more than six months that the Remuneration Committee may determine in connection with a relevant particular event which may allow Options to be exercised. Options not exercised by the end of that period will lapse.

Adjustment of Awards. In the event that there is any variation in our share capital the Remuneration Committee may make adjustments as it considers fair and reasonable to preserve the participant's position to the number of ordinary shares subject to an Option and/or the acquisition price and/or the aggregate maximum number of ordinary shares. Limitations apply to the extent to which any such adjustments may reduce the price at which ordinary shares may be purchased pursuant to the exercise of an Option.

Transferability. No Option under the Executive Option Scheme may be transferred, assigned, charged or otherwise disposed of (except on death to the recipient's personal representatives) and will lapse immediately upon an attempt to do so. In addition, an award under the Executive Option Scheme will lapse immediately if the recipient of an award is declared bankrupt or if there is a compulsory winding up of us.

Amendment. The Committee may, at any time, alter the Executive Option Scheme.

GW Pharmaceuticals Approved Share Option Scheme 2001

Our shareholders approved and adopted the GW Pharmaceuticals Approved Share Option Scheme 2001, or the "Company Option Scheme", on May 31, 2001 and it was approved by the U.K.'s Inland Revenue on July 3, 2001. Under the Company Option Scheme, Options were granted to our employees who were not ineligible to participate in the Company Option Scheme under applicable U.K. tax law and who, in the case of a director, is required to work not less than 25 hours per week, such individuals referred to in this Annual Report as Option Scheme eligible employees. The scheme terminated on May 31, 2011, and no further options will be granted under the scheme. Termination of the scheme did not affect the rights of existing participants.

Exercise of Options. Options generally may not be exercised prior to the third anniversary of the grant. All outstanding options, however, are currently exercisable. If applicable, any performance targets and other conditions on exercise must also be satisfied. Vesting provisions and performance targets may be waived only to the extent provided in the grant terms or, in the case of a performance target, an event occurs which makes the condition more onerous to achieve.

Generally, Options must be exercised while the participant is an Option Scheme eligible employee. In the event, however, that a participant ceases to be an Option Scheme eligible employee as the result of injury, illness or disability, redundancy or retirement on or after attaining his normal retirement age (age 60 or such other date on which he is required to retire pursuant to his employment contract) or at the specific request of his employer, the Option may be exercised during the period commencing on the date he ceases to be an Option Scheme eligible employee and ending on the later of six months thereafter or three years and six months after the date of grant. If a participant dies while he is an Option Scheme eligible employee or during the extended exercise period described in the preceding sentence, the participant's personal representatives may exercise the Option for twelve months after the participant's death (unless the participant would have been precluded from exercising the option during that period under applicable U.K. tax law). In all other cases, the Remuneration Committee may permit post-cessation exercise for up to six months from the date of cessation or, if later three years and six months after the date of grant. All Options lapse upon the tenth anniversary of the date of grant.

Takeovers and Corporate Events. If any person obtains control of us (as determined in accordance with specified U.K. tax law) as a result of making a Takeover Offer, any Options may be exercised within the relevant period after the time the person has obtained control and any conditions subject to which the Takeover Offer have been satisfied. Options may also be exercisable for the relevant period in the event of certain court sanctioned restructurings or amalgamations of us or if another company becomes bound or entitled to acquire our ordinary shares pursuant to certain provisions of U.K. corporate law. If the Remuneration Committee determines that it is likely that we will come under the control of another company such that our ordinary shares will cease to satisfy the conditions of applicable U.K. tax law, the Remuneration Committee may permit exercise of the Options prior to the change of control.

In the event of a Takeover Offer or court sanctioned restructuring or amalgamation, the participant may, by agreement with the other company, release Options in consideration for the grant of a new option with respect to the acquiring company's shares and subject to certain other terms and conditions, in such a manner as to preserve the tax advantages applicable to the Options.

The Remuneration Committee may also permit exercise of the Options within a relevant period following the date on which we pass a resolution for voluntary winding up or certain other transactions involving a change in control of us.

With respect to any event, the "relevant period" is generally the period of three months or such different period not less than 30 days and not more than six months that the Remuneration Committee

may determine in connection with a relevant particular event which may allow Options to be exercised. Options not exercised by the end of that period will lapse.

Adjustment of Awards. In the event that there is any variation in our share capital the Remuneration Committee may make adjustments as it considers fair and reasonable to preserve the participant's position to the number of ordinary shares subject to an Option and/or the acquisition price and/or the aggregate maximum number of ordinary shares. Limitations apply to the extent to which any such adjustments may reduce the price at which ordinary shares may be purchased pursuant to the exercise of an Option and no adjustment will take effect until it has been approved by the United Kingdom tax authorities in accordance with applicable U.K. tax law.

Transferability. No Option under the Company Option Scheme may be transferred, assigned, charged or otherwise disposed of (except on death to the recipient's personal representatives) and will lapse immediately upon an attempt to do so. In addition, an award under the Company Option Scheme will lapse immediately if the recipient of an award is declared bankrupt or if there is a compulsory winding up of us.

Amendment. The Remuneration Committee may, at any time, alter the Company Option Scheme provided that no alterations shall be effective unless approved by the U.K. tax authorities in accordance with applicable U.K. tax law.

Options granted to non-employees

Our consultants and non-executive directors, who are not employees of companies in the Group, are not eligible to participate in our equity compensation plans described above. Certain of these consultants and non-executive directors have been granted options to acquire our shares pursuant to separate option agreements. These options are generally on comparable terms to options granted under the Executive Option Scheme.

Limitations on Liability and Indemnification Matters

To the extent permitted by the Companies Act 2006, we shall indemnify our directors against any liability. We maintain directors and officers insurance to insure such persons against certain liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us under the foregoing provisions, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and therefore is unenforceable.

C. Board Practices

Board Composition

Our business affairs are managed under the direction of our board of directors, which is currently composed of eight members. As a foreign private issuer, we have elected to follow home country practices in lieu of Nasdaq's requirement that a majority of our board qualify as independent directors. Three of our directors qualify as independent directors under Rule 5605(a)(2) of the Nasdaq Marketplace Rules.

Committees of the Board of Directors and Corporate Governance

Subject to certain exceptions, the rules of the Nasdaq permit a foreign private issuer to follow its home country practice in lieu of the listing requirements of Nasdaq.

The committees of our board of directors consist of an audit committee, a remuneration committee and a nominations committee. Each of these committees has the responsibilities described below. Our board of directors may also establish other committees from time to time to assist in the discharge of its responsibilities.

Audit Committee

The members of our audit committee comprise our three non-executive directors, Mr. James Noble, Mr. Cabot Brown and Mr. Thomas Lynch, and each of the members is an "independent director" as such term is defined in Rule 10A-3 under the Exchange Act. Mr. Noble serves as chair of the audit committee. Our board of directors has determined that Mr. Noble is a financial expert as contemplated by the rules of the SEC implementing Section 407 of the Sarbanes Oxley Act of 2002. Our Audit Committee meets at least three times per year and oversees the monitoring of our internal controls, accounting policies and financial reporting and provides a forum through which our external auditors and independent registered public accounting firm reports. Our Audit Committee meets at least once a year with the external auditors and our independent registered public accounting firm without executive Board members present. The audit committee is also responsible for overseeing the activities of the external auditors and our independent registered public accounting firm, including their appointment, reappointment, or removal as well as monitoring of their objectivity and independence. The Audit Committee also considers the fees paid to the external auditors and independent registered public accounting firm and determines whether the fee levels for non-audit services, individually and in aggregate, relative to the audit fee are appropriate so as not to undermine their independence.

Remuneration Committee

The members of the Remuneration Committee comprise our three non-executive directors, Mr. James Noble, Mr. Cabot Brown and Mr. Thomas Lynch, and each of the members is an "independent director" as such term is defined in Rule 10A-3 under the Securities Exchange Act of 1934. Mr. Lynch serves as chair of the remuneration committee. Our Remuneration Committee reviews, among other things, the performance of the Executive Directors and sets the scale and structure of their remuneration and the basis of their service agreements with due regard to the interests of the shareholders. The Remuneration Committee also determines the allocation of awards under the Long-Term Incentive Plan, or LTIP to our executive directors. No director has a service agreement with a notice period exceeding one year. During the year ended September 30, 2012, there were three meetings of the Remuneration Committee. It is a policy of the Remuneration Committee that no individual participates in discussions or decisions concerning his own remuneration.

Nominations Committee

As permitted for foreign private issuers, we have elected to follow our home country's practice in lieu of Nasdaq's requirement for U.S. listed companies that a nominating committee must be comprised of independent directors. The members of the nominations committee comprise Dr. Geoffrey Guy, Mr. James Noble and Cabot Brown, with Mr. Noble and Mr. Brown being independent directors. Dr. Guy serves as chair of the nominations committee and oversees the evaluation of the board's performance. Dr. Guy's performance as Chairman is reviewed by Mr. Noble, in his capacity as senior independent director, taking into account feedback from other members of the board of directors. The nominations committee meets at least twice a year and reviews the structure, size and composition of the board of directors, supervising the selection and appointment process of directors, making recommendations to the board of directors with regard to any changes and using an external search consultancy if considered appropriate. For new appointments, the nominations committee will make a final recommendation to the board of directors, and the board has the opportunity to meet the candidate prior to approving the appointment. Once appointed, the

nominations committee oversees the induction of new directors and provides the appropriate training to the board during the course of the year in order to ensure that they have the knowledge and skills necessary to operate effectively. The nominations committee is also responsible for annually evaluating the performance of the board, both on an individual basis and for the board as a whole, taking into account such factors as attendance record, contribution during board meetings and the amount of time that has been dedicated to board matters during the course of the year.

Code of Business Conduct and Ethics

Our Code of Business Conduct and Ethics is applicable to all of our employees, officers and directors and is available on our website at http://www.gwpharm.com. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this document, and you should not consider information on our website to be part of this document.

D. Employees

The number of employees by function and geographic location as of the end of the period for our fiscals ended September 30, 2013, 2012 and 2011 was as follows:

	2013	2012	2011
By Function:			
Research and development	108	109	118
Manufacturing and operations	43	39	24
Quality control and assurance	23	20	18
Management and administrative	20	16	14
Total	194	194	174
By Geography:			
United Kingdom	194	184	174
North America	—	—	—
Rest of the World	—	—	—
Total	194	184	174

We have never had a work stoppage and none of our employees are covered by collective bargaining agreements or represented by a labor union. We believe our employee relations are good.

E. Share Ownership

Item 7 Major Shareholders and Related Party Transactions

A. Major Shareholders.

The following table and related footnotes set forth information with respect to the beneficial ownership of our ordinary shares, as of September 30, 2013, by:

- each of our directors and members of the executive board; and
- each person known to us to own beneficially more than 5% of our ordinary shares as of September 30, 2013.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of ordinary shares owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security.

These ordinary shares, however, are not included in the computation of the percentage ownership of any other person. Ownership of our ordinary shares by the "principal shareholders" identified above has been determined by reference to our share register, which provides us with information regarding the registered holders of our ordinary shares but generally provides limited, or no, information regarding the ultimate beneficial owners of such ordinary shares. As a result, we may not be aware of each person or group of affiliated persons who beneficially owns more than 5% of our ordinary shares.

This table assumes no exercise of the underwriters' option to purchase additional ADSs.

Unless otherwise indicated, the address for each of the shareholders in the table below is c/o GW Pharmaceuticals plc, Porton Down Science Park, Salisbury, Wiltshire, SP4 0JQ, United Kingdom.

	Ordinary Shares Beneficially Owned(2)	
Name of Beneficial Owner(1)	**Number**	**Percent**
Greater than 5% Shareholders		
Prudential plc group of companies(3)	26,241,389	14.8%
VHCP Management LLC(4)	10,053,600	5.7%
Dr. Brian Whittle(5)	8,428,722	6.3%
Named Executive Officers and Directors		
Dr. Geoffrey Guy(6)	18,711,986	10.5%
Mr. Justin Gover(7)	5,258,554	3.0%
Mr. Thomas Lynch	236,344	*
Mr. James Noble	72,500	*
Mr. Adam George(8)	288,761	*
Dr. Stephen Wright(9)	1,274,172	*
Mr. Chris Tovey	10,000	*
Mr. Cabot Brown	—	*
All Named Executive Officers and Directors as a Group (8 persons)	25,852,317	14.6%

* Indicates beneficial ownership of less than one percent of our ordinary shares.

(1) The business addresses for the listed beneficial owners are as follows: Prudential plc group of companies—Laurence Pountney Hill, London, EC4R 0HH, VHCP Management LLC—3340 Hillview Avenue, Palo Alto, CA 94304 and Dr. Brian Whittle c/o Graybrowne Limited, The Counting House, 13 Nelson Street, Hull, HU1 1XE.

(2) Number of shares owned as shown both in this table and the accompanying footnotes and percentage ownership is based on 177,521,287 ordinary shares outstanding on September 30, 2013.

(3) Includes (i) 26,241,389 ordinary shares indirectly held by Prudential plc, (ii) 26,241,389 ordinary shares indirectly held by M&G Group Limited, a wholly owned subsidiary of Prudential plc, (iii) 26,241,389 ordinary shares indirectly held by M&G Limited, a wholly owned subsidiary of M&G Group Limited, (iv) 26,241,389 ordinary shares indirectly held by M&G Investment Management Limited, a wholly owned subsidiary of M&G Limited and (v) 26,241,389 ordinary shares held of record by M&G Securities Limited, a wholly owned subsidiary of M&G Limited.

(4) VHCP Management LLC holds these shares in the form of American Depositary Shares.

(5) Includes options to purchase 341,231 ordinary shares that have vested.

(6) Includes 25,000 ordinary shares beneficially owned by Dr. Guy's immediate family, 1,174,958 shares held by his personal pension plan and options to purchase 1,524,332 ordinary shares that have vested.

(7) Includes 33,147 ordinary shares beneficially owned by Mr. Gover's spouse and options to purchase 1,274,886 ordinary shares that have vested.

(8) Includes 21,696 shares held by his personal pension plan and options to purchase 267,065 ordinary shares that have vested.

(9) Includes 5,000 ordinary shares beneficially owned by Dr. Wright's spouse and options to purchase 1,269,172 ordinary shares that have vested.

Our major shareholders do not have different voting rights. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Citibank, N.A. is the holder of record for the company's ADR program, whereby each ADS represents twelve ordinary. As of September 30, 2013, Citibank, N.A. held 43,741,692 ordinary shares representing 24.6% of the issued share capital held at that date. As of September 30, 2013, we had a further 1,016,523 ordinary shares held by 11 U.S. resident shareholders of record, representing less than one percent of total voting power. Certain of these ordinary shares and ADSs were held by brokers or other nominees. As a result, the number of holders of record or registered holders in the U.S. is not representative of the number of beneficial holders or of the residence of beneficial holders.

To our knowledge, there has been no significant change in the percentage ownership held by the principal shareholders listed above since September 30, 2013.

B. Related Party Transactions

During the three year period ended September 30, 2013, there has not been, nor is there currently proposed, any material transaction or series of similar material transactions to which we were or are a party in which any of our directors, members of our executive management board, associates, holders of more than 10% of any class of our voting securities, or any affiliates or member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest, other than the compensation and shareholding arrangements we describe where required in "Management."

We have adopted a related person transaction policy which sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any employee, director or beneficial owner of more than 3% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third-party or to or from employees

generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related person transactions and to effectuate the terms of the policy. In addition, under our Code of Business Conduct and Ethics, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

C. Interests of experts and counsel

Not applicable.

Item 8 Financial Information.

A. Consolidated Statements and Other Financial Information.

See "Item 18. Financial Statements."

B. Significant Changes

Except as disclosed in Note 28 to our consolidated financial statements included as part of this Annual Report, there have been no significant changes since September 30, 2013.

Item 9 The Offer and Listing.

A. Offer and Listing Details

Price History of Stock

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ordinary shares on the AIM in pounds sterling and U.S. dollars. U.S. dollar per ordinary share amounts have been translated into U.S. dollars at $1.00 = £0.6181 based on the certified foreign exchange rates published by Federal Reserve Bank of New York on September 30, 2013.

	Price Per Ordinary Share		Price Per Ordinary Share	
	£		$	
	High	Low	High	Low
Annual (Year Ended September 30):				
2008	1.04	0.35	1.68	0.56
2009	1.07	0.26	1.73	0.42
2010	1.56	0.80	2.52	1.29
2011	1.33	0.83	2.15	1.34
2012	1.03	0.66	1.66	1.06
2013	0.90	0.40	1.46	0.65
Quarterly:				
First Quarter 2010	1.03	0.80	1.66	1.29
Second Quarter 2010	1.41	0.86	2.27	1.39
Third Quarter 2010	1.56	1.06	2.52	1.71
Fourth Quarter 2010	1.24	0.90	2.00	1.45
First Quarter 2011	1.15	0.83	1.86	1.34
Second Quarter 2011	1.19	0.93	1.92	1.50
Third Quarter 2011	1.30	0.93	2.10	1.50
Fourth Quarter 2011	1.33	0.86	2.15	1.39
First Quarter 2012	1.03	0.76	1.66	1.23
Second Quarter 2012	1.00	0.81	1.61	1.31
Third Quarter 2012	0.94	0.72	1.52	1.16
Fourth Quarter 2012	0.78	0.66	1.26	1.06
First Quarter 2013	0.75	0.54	1.21	0.87
Second Quarter 2013	0.63	0.40	1.02	0.65
Third Quarter 2013	0.70	0.46	1.13	0.74
Fourth Quarter 2013	0.87	0.47	1.41	0.76
Most Recent Six Months:				
May 2013	0.62	0.48	1.00	0.78
June 2013	0.49	0.46	0.79	0.74
July 2013	0.57	0.47	0.92	0.76
August 2013	0.63	0.54	1.02	0.87
September 2013	0.87	0.63	1.41	1.02
October 2013	1.73	0.83	2.80	1.34
November 2013 (through November 20, 2013)	1.83	1.44	2.96	2.33

On September 30, 2013, the last reported sales price of our ordinary shares on AIM was £0.87 per share ($1.00 per share).

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ADSs on Nasdaq in U.S. dollars.

	Price Per Ordinary Share	
	$	
	High	Low
Annual (Year Ended September 30):		
2013	17.95	8.46
2014 (through November 20, 2013)	17.95	8.46
Quarterly:		
Third Quarter 2013	9.20	8.46
Fourth Quarter 2013	17.95	8.50
Most Recent Six Months:		
May 2013	9.20	8.72
June 2013	9.08	8.46
July 2013	11.50	8.50
August 2013	12.50	9.87
September 2013	17.95	12.50
October 2013	35.00	16.60

On September 30, 2013, the last reported sales price of our ADSs on Nasdaq was $17.34 per ADS.

B. Plan of Distribution

Not applicable.

C. Markets

3,645,141 of our ADSs of GW Pharmaceuticals PLC are listed on Nasdaq. The Depositary for the ADSs holds twelve ordinary share for every ADS. Our ADSs are listed on Nasdaq under the symbol "GWPH". 133,779,595 of our ordinary shares are listed on the AIM. Our ordinary shares have been trading on the AIM under the symbol "GWP" since June 28, 2001.

D. Selling Shareholders

Not applicable

E. Dilution

Not applicable

F. Expenses of the Issue

Not applicable.

Item 10 Additional Information

A. Share Capital

The following describes our issued share capital, summarizes the material provisions of our articles of association and highlights certain differences in corporate law in the United Kingdom and the United States.

Issued Share Capital

Our issued share capital as at the date of this report is 177,521,287 ordinary shares, par value £0.001 per share. Each issued ordinary share is fully paid.

Ordinary Shares

The holders of ordinary shares are entitled to receive, in proportion to the number of ordinary shares held by them and according to the amount paid up on such ordinary shares (excluding amounts paid up in advance of a call) during any portion or portions of the period in respect of which the dividend is paid, all of our profits paid out as dividends. Holders of ordinary shares are entitled, in proportion to the number of ordinary shares held by them and to the amounts paid up thereon, to share in any surplus in the event of the winding up of our company. The holders of ordinary shares are entitled to receive notice of, attend either in person or by proxy or, being a corporation, by a duly authorized representative, and vote at general meetings of shareholders.

As at September 30, 2013, there were options to purchase 12,740,180 ordinary shares outstanding. All options granted are exercisable at the market value on the date of the grant, with the exception of options issued under our Long Term Incentive Plan, which are issued with an exercise price equivalent to the par value of the shares under option. The vesting period for all options granted is three years from the date of grant and the options lapse after ten years.

As at September 30, 2013, there were warrants to subscribe for 3,776,960 ordinary shares outstanding. These warrants can be exercised at any time prior to August 13, 2014. The exercise price for warrants exercisable for 1,888,480 of the ordinary shares is £1.05 per ordinary share and the exercise price for the remaining warrants is £1.75 per ordinary share.

B. Memorandum and articles of association

The information called for by this item has been reported previously in our Registration Statement on form F-1 (File No. 333-187356), filed with the SEC March 19, 2013, as amended, under the heading "Description of Share Capital" and is incorporated by reference into this Annual Report.

C. Material contracts

There are no material contracts other than those entered to in the ordinary course of business.

All material contracts are listed on Part III

D. Exchange controls

There are no governmental laws, decrees, regulations or other legislation in the United Kingdom that may affect the import or export of capital, including the availability of cash and cash equivalents for use by us, or that may affect the remittance of dividends, interest, or other payments by us to non-resident holders of our ordinary shares or ADSs, other than withholding tax requirements. There is no limitation imposed by English law or our articles of association on the right of non-residents to hold or vote shares.

E. Taxation

U.S. Federal Income Taxation

The following discussion describes the material U.S. federal income tax consequences of the purchase, ownership and disposition of the ADSs by a holder that is a citizen or resident of the United States, a U.S. domestic corporation or a person or entity that otherwise will be subject to U.S. federal income tax on a net income basis in respect of our ADSs (a "U.S. Holder"). This discussion does not

purport to be a comprehensive description of all tax considerations that may be relevant to a decision to purchase, hold or dispose of the ADSs. In particular, this discussion does not address tax considerations applicable to a U.S. Holder that may be subject to special tax rules, including, without limitation, a dealer in securities or currencies, a trader in securities that elects to use a mark-to-market method of accounting for securities holdings, banks, thrifts, or other financial institutions, an insurance company, a tax-exempt organization, a person that holds the ADSs as part of a hedge, straddle or conversion transaction for tax purposes, a person whose functional currency for tax purposes is not the U.S. dollar, certain former citizens or residents of the United States, a person subject to the U.S. alternative minimum tax, or a person that owns or is deemed to own 10% or more of the company's voting stock (including ADSs). In addition, the discussion does not address tax consequences to an entity treated as a partnership for U.S. federal income tax purposes that holds the ADSs, or a partner in such partnership. This summary applies only to U.S. Holders that hold the ADSs as capital assets for U.S. federal income tax purposes.

This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, in effect as of the date of this Annual Report and on U.S. Treasury regulations in effect or, in some cases, proposed, as of the date of this Annual Report, as well as judicial and administrative interpretations thereof available on or before such date. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below. This summary does not address any tax consequences under the laws of any state or locality of the United States.

YOU ARE URGED TO CONSULT YOUR TAX ADVISORS ABOUT THE APPLICATION OF THE U.S. FEDERAL INCOME TAX RULES TO YOUR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF THE ADSs.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms.

If you hold ADSs, you should be treated as the holder of the underlying ordinary shares represented by those ADSs for U.S. federal income tax purposes.

Taxation of Dividends and Other Distributions on the ADSs

Subject to the passive foreign investment company rules discussed below, the gross amount of cash distributions made by us to you with respect to the ADSs will generally be includable in your gross income as dividend income on the date of receipt by the depositary, but only to the extent that the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent, if any, that the amount of the distribution exceeds our current and accumulated earnings and profits, it will be treated first as a tax-free return of your tax basis in your ADSs, and to the extent the amount of the distribution exceeds your tax basis, the excess will be taxed as capital gain. We do not intend to calculate our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Holder should expect that a distribution will generally be treated as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. U.S. Holders should consult their own tax advisors regarding the tax consequences to them if we pay dividends in any non-U.S. currency. A dividend in respect of the ADSs will not be eligible for the dividends-received deduction allowed to corporations in respect of dividends received from other U.S. corporations.

With respect to non-corporate U.S. Holders, including individual U.S. Holders, dividends will generally be taxed at the preferential rate applicable to qualified dividend income, provided that (i) the ADSs are readily tradable on an established securities market in the United States, or we are eligible for the benefits of an approved qualifying income tax treaty with the United States that includes an

exchange of information program, (ii) we are not a passive foreign investment company (as discussed below) for either our taxable year in which the dividend is paid or the preceding taxable year, (iii) certain holding period requirements are met and (iv) you are not under any obligation to make related payments with respect to positions in substantially similar or related property. Under U.S. Internal Revenue Service authority, common or ordinary shares, or ADSs representing such shares, are considered for purpose of clause (i) above to be readily tradable on an established securities market in the United States if they are listed on Nasdaq. You should consult your tax advisors regarding the availability of the preferential rate for dividends paid with respect to the ADSs.

Dividends generally will constitute income from sources outside the United States for U.S. foreign tax credit purposes. However, if 50% or more of our stock is treated as held by U.S. persons, we will be treated as a "U.S.-owned foreign corporation." In that case, dividends may be treated for U.S. foreign tax credit purposes as income from sources outside the United States to the extent paid out of our non-U.S. source earnings and profits, and as income from sources within the United States to the extent paid out of our U.S. source earnings and profits. We cannot assure you that we will not be treated as a U.S.-owned foreign corporation. If the dividends are taxed as qualified dividend income (as discussed above), the amount of the dividend taken into account for purposes of calculating the U.S. foreign tax credit limitation will generally be limited to the gross amount of the dividend, multiplied by the preferential rate divided by the highest rate of tax normally applicable to dividends. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to the ADSs will generally constitute "passive category income."

Taxation of Dispositions of ADSs

Subject to the passive foreign investment company rules discussed below, you will recognize taxable gain or loss on any sale, exchange or other taxable disposition of an ADS equal to the difference between the amount realized (in U.S. dollars) for the ADS and your tax basis (in U.S. dollars) in the ADS. The gain or loss will generally be capital gain or loss. If you are a non-corporate U.S. Holder, including an individual U.S. Holder, who has held the ADS for more than one year, you will be eligible for preferential tax rates. The deductibility of capital losses is subject to limitations. Any such gain or loss that you recognize will generally be treated as U.S. source income or loss for U.S. foreign tax credit purposes.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds will be subject to an additional 3.8% Medicare tax on some or all of such U.S. Holder's "net investment income." Net investment income generally includes interest on, and gain from the disposition of, the ADSs unless such interest income or gain is derived in the ordinary course of the conduct of a trade or business (other than a trade or business that consists of certain passive or trading activities). You should consult your tax advisors regarding the effect this Medicare tax may have, if any, on your acquisition, ownership or disposition of the ADSs.

Passive Foreign Investment Company

Special U.S. tax rules apply to companies that are considered to be passive foreign investment companies or PFICs. We will be classified as a PFIC in a particular taxable year if either (i) 75% or more of our gross income for the taxable year is passive income; or (ii) on average at least 50% of the value of our assets produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income.

In making this determination, we will be treated as earning our proportionate share of any income and owning our proportionate share of any assets of any corporation in which we hold a 25% or greater interest (by value). Based on current estimates of our gross income and gross assets, the nature of our business and our current business plan (all of which are subject to change), we believe that we will not be classified as a PFIC, but the PFIC tests must be applied each year, and it is possible that we may become a PFIC in a future year. In the event that, contrary to our expectation, we are classified as a PFIC in any year in which you hold the ADSs, and you do not make one of the elections described in the following paragraph, any gain recognized by you on a sale or other disposition (including a pledge) of the ADSs would be allocated ratably over your holding period for the ADSs. The amounts allocated to the taxable year of the sale or other disposition and to any year before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an interest charge would be imposed. Further, to the extent that any distribution received by you on your ADSs were to exceed 125% of the average of the annual distributions on the ADSs received during the preceding three years or your holding period, whichever is shorter, that distribution would be subject to taxation in the same manner as gain on the sale or other disposition of shares if we were a PFIC, described above. Classification as a PFIC may also have other adverse tax consequences, including, in the case of individuals, the denial of a step-up in the basis of your ADSs at death.

You can avoid the unfavorable rules described in the preceding paragraph by electing to mark your ADSs to market, but only if the ADSs are treated as "marketable stock." If you make this mark-to-market election, you will be required in any year in which we are a PFIC to include as ordinary income the excess of the fair market value of your ADSs at year-end over your basis in those ADSs. In addition, the excess, if any, of your basis in the ADSs over the fair market value of your ADSs at year-end is deductible as an ordinary loss in an amount equal to the lesser of (i) the amount of the excess or (ii) the amount of the net mark-to-market gains that you have included in income in prior years. Any gain you recognize upon the sale of your ADSs will be taxed as ordinary income in the year of sale. Amounts treated as ordinary income will not be eligible for the preferential tax rate applicable to qualified dividend income or long-term capital gains.

The U.S. federal income tax rules relating to PFICs are complex. You are urged to consult your tax advisors with respect to the purchase, ownership and disposition of the ADSs, any elections available with respect to such ADSs and the U.S. Internal Revenue Service information reporting obligations with respect to the purchase, ownership and disposition of the ADSs.

Information Reporting and Backup Withholding

Distributions with respect to ADSs and proceeds from the sale, exchange or disposition of ADSs may be subject to information reporting to the U.S. Internal Revenue Service and possible U.S. backup withholding. Backup withholding will not apply, however, to a U.S. Holder who furnishes a correct taxpayer identification number and makes any other required certification or who is otherwise exempt from backup withholding. U.S. Holders who are required to establish their exempt status generally must provide such certification on U.S. Internal Revenue Service Form W-9. You should consult your tax advisors regarding the application of the U.S. information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against your U.S. federal income tax liability, and you may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the U.S. Internal Revenue Service and furnishing any required information.

United Kingdom Tax Considerations

The following is a general summary of certain U.K. tax considerations relating to the ownership and disposal of the ordinary shares or the ADSs and does not address all possible tax consequences relating to an investment in the ordinary shares or the ADSs. It is based on current U.K. tax law and published HM Revenue & Customs, or HMRC, practice as at the date of this Annual Report, both of which are subject to change, possibly with retrospective effect.

Save as provided otherwise, this summary applies only to persons who are resident (and, in the case of individuals, domiciled) in the United Kingdom for tax purposes and who are not resident for tax purposes in any other jurisdiction and do not have a permanent establishment or fixed base in any other jurisdiction with which the holding of the ordinary shares or ADSs is connected ("U.K. Holders"). Persons (a) who are not resident (or, if resident are not domiciled) in the United Kingdom for tax purposes, including those individuals and companies who trade in the United Kingdom through a branch, agency or permanent establishment in the United Kingdom to which the ordinary shares or the ADSs are attributable, or (b) who are resident or otherwise subject to tax in a jurisdiction outside the United Kingdom, are recommended to seek the advice of professional advisors in relation to their taxation obligations.

This summary is for general information only and is not intended to be, nor should it be considered to be, legal or tax advice to any particular investor. It does not address all of the tax considerations that may be relevant to specific investors in light of their particular circumstances or to investors subject to special treatment under U.K. tax law. In particular:

- this summary only applies to the absolute beneficial owners of the ordinary shares or the ADSs and any dividends paid in respect of the ordinary shares where the dividends are regarded for U.K. tax purposes as that person's own income (and not the income of some other person);
- this summary: (a) only addresses the principal U.K. tax consequences for investors who hold the ordinary share or ADSs as capital assets, (b) does not address the tax consequences that may be relevant to certain special classes of investor such as dealers, brokers or traders in shares or securities and other persons who hold the ordinary shares or ADSs otherwise than as an investment, (c) does not address the tax consequences for holders that are financial institutions, insurance companies, collective investment schemes, pension schemes, charities and tax-exempt organizations, (d) assumes that the holder is not an officer or employee of the company (or of any related company) and has not (and is not deemed to have) acquired the ordinary shares or ADSs by virtue of an office or employment, and (e) assumes that the holder does not control or hold (and is not deemed to control or hold), either alone or together with one or more associated or connected persons, directly or indirectly (including through the holding of the ADSs), an interest of 10% or more in the issued share capital (or in any class thereof), voting power, rights to profits or capital of the company, and is not otherwise connected with the company.

This summary further assumes that a holder of ADSs is the beneficial owner of the underlying ordinary shares for U.K. direct tax purposes.

POTENTIAL INVESTORS IN THE ADSs SHOULD SATISFY THEMSELVES PRIOR TO INVESTING AS TO THE OVERALL TAX CONSEQUENCES, INCLUDING, SPECIFICALLY, THE CONSEQUENCES UNDER U.K. TAX LAW AND HMRC PRACTICE OF THE ACQUISITION, OWNERSHIP AND DISPOSAL OF THE ORDINARY SHARES OR ADSs, IN THEIR OWN PARTICULAR CIRCUMSTANCES BY CONSULTING THEIR OWN TAX ADVISERS.

Taxation of dividends

Withholding Tax

Dividend payments in respect of the ordinary shares or ADSs may be made without withholding or deduction for or on account of U.K. tax.

Income Tax

Dividends received by individual U.K. Holders will be subject to U.K. income tax on the gross amount of the dividend paid (including the amount of the non-refundable U.K. dividend tax credit referred to below).

An individual holder of ordinary shares or ADSs who is not a U.K. Holder will not be chargeable to U.K. income tax on dividends paid by the company, unless such holder carries on (whether solely or in partnership) a trade, profession or vocation in the United Kingdom through a branch or agency in the United Kingdom to which the ordinary shares or ADSs are attributable. In these circumstances, such holder may, depending on his or her individual circumstances, be chargeable to U.K. income tax on dividends received from the company.

The rate of U.K. income tax that is chargeable on dividends received in the tax year 2013/2014 by (i) additional rate taxpayers is 37.5%, (ii) higher rate taxpayers is 32.5%, and (iii) basic rate taxpayers is 10%. Individual U.K. Holders will be entitled to a non-refundable tax credit equal to one-ninth of the full amount of the dividend received from the company, which will be taken into account in computing the gross amount of the dividend that is chargeable to U.K. income tax. The tax credit will be credited against such holder's liability (if any) to U.K. income tax on the gross amount of the dividend. After taking into account the tax credit, the effective rate of tax for the 2013/2014 tax year (i) for additional rate taxpayers will be 30.6% of the dividend paid (ii) for higher rate taxpayers will be 25% of the dividend paid, and (iii) for basic rate taxpayers will be nil. An individual holder who is not subject to U.K. income tax on dividends received from the company will not generally be entitled to claim repayment of the tax credit in respect of such dividends. An individual's dividend income is treated as the top slice of their total income that is chargeable to U.K. income tax.

Corporation Tax

A U.K. Holder within the charge to U.K. corporation tax may be entitled to exemption from U.K. corporation tax in respect of dividend payments. If the conditions for the exemption are not satisfied, or such U.K. Holder elects for an otherwise exempt dividend to be taxable, U.K. corporation tax will be chargeable on the gross amount of any dividends. If potential investors are in any doubt as to their position, they should consult their own professional advisers.

A corporate holder of ordinary shares or ADSs that is not a U.K. Holder will not be subject to U.K. corporation tax on dividends received from the company, unless it carries on a trade in the United Kingdom through a permanent establishment to which the ordinary shares or ADSs are attributable. In these circumstances, such holder may, depending on its individual circumstances and if the exemption from U.K. corporation tax discussed above does not apply, be chargeable to U.K. corporation tax on dividends received from the company.

Taxation of disposals

U.K. Holders

A disposal or deemed disposal of ordinary shares or ADSs by an individual U.K. Holder may, depending on his or her individual circumstances, give rise to a chargeable gain or to an allowable loss for the purpose of U.K. capital gains tax. The principal factors that will determine the capital gains tax

position on a disposal of ordinary shares or ADSs are the extent to which the holder realizes any other capital gains in the tax year in which the disposal is made, the extent to which the holder has incurred capital losses in that or any earlier tax year and the level of the annual allowance of tax-free gains in that tax year (the "annual exemption"). The annual exemption for the 2013/2014 tax year is £10,900. If, after all allowable deductions, an individual U.K. Holder's total taxable income for the year exceed the basic rate income tax limit, a taxable capital gain accruing on a disposal of ordinary shares or ADSs will be taxed at 28%. In other cases, a taxable capital gain accruing on a disposal of ordinary shares or ADSs may be taxed at 18% or 28% or at a combination of both rates.

A disposal of ordinary shares or ADSs by a corporate U.K. Holder may give rise to a chargeable gain or an allowable loss for the purpose of U.K. corporation tax. Such a holder should be entitled to an indexation allowance, which applies to reduce capital gains to the extent that such gains arise due to inflation. The allowance may reduce a chargeable gain but will not create or increase an allowable loss.

Any gains or losses in respect of currency fluctuations over the period of holding the ADSs would also be brought into account on the disposal.

Non-U.K. Holders

An individual holder who is not a U.K. Holder will not be liable to U.K. capital gains tax on capital gains realized on the disposal of his or her ordinary shares or ADSs unless such holder carries on (whether solely or in partnership) a trade, profession or vocation in the United Kingdom through a branch or agency in the United Kingdom to which the ordinary shares or ADSs are attributable. In these circumstances, such holder may, depending on his or her individual circumstances, be chargeable to U.K. capital gains tax on chargeable gains arising from a disposal of his or her ordinary shares or ADSs.

A corporate holder of ordinary shares or ADSs that is not a U.K. Holder will not be liable for U.K. corporation tax on chargeable gains realized on the disposal of its ordinary shares or ADSs unless it carries on a trade in the United Kingdom through a permanent establishment to which the ordinary shares or ADSs are attributable. In these circumstances, a disposal of ordinary shares or ADSs by such holder may give rise to a chargeable gain or an allowable loss for the purposes of U.K. corporation tax.

Inheritance Tax

If for the purposes of the Taxes on Estates of Deceased Persons and on Gifts Treaty 1978 between the United States and the United Kingdom an individual holder is domiciled in the United States and is not a national of the United Kingdom, any ordinary shares or ADSs beneficially owned by that holder will not generally be subject to U.K. inheritance tax on that holder's death or on a gift made by that holder during his/her lifetime, provided that any applicable United States federal gift or estate tax liability is paid, except where (i) the ordinary shares or ADSs are part of the business property of a U.K. permanent establishment or pertain to a U.K. fixed base used for the performance of independent personal services; or (ii) the ordinary shares or ADSs are comprised in a settlement unless, at the time the settlement was made, the settlor was domiciled in the United States and not a national of the U.K. (in which case no change to U.K. inheritance tax should apply).

Stamp Duty and Stamp Duty Reserve Tax

Issue and transfer of ordinary shares

No U.K. stamp duty or stamp duty reserve tax or SDRT, is payable on the issue of the ordinary shares.

The transfer on sale of ordinary shares by a written instrument of transfer will generally be liable to U.K. stamp duty at the rate of 0.5% of the amount or value of the consideration for the transfer. The purchaser normally pays the stamp duty.

An agreement to transfer ordinary shares will generally give rise to a liability on the purchaser to SDRT at the rate of 0.5% of the amount or value of the consideration. Such SDRT is payable on the seventh day of the month following the month in which the charge arises, but where an instrument of transfer is executed and duly stamped before the expiry of a period of six years beginning with the date of that agreement, (i) any SDRT that has not been paid ceases to be payable, and (ii) any SDRT that has been paid may be recovered from HMRC, generally with interest.

UK legislation does provide for stamp duty (in the case of transfers) or SDRT to be payable at the rate of 1.5% on the amount or value of the consideration (or, in some cases, the value of the ordinary shares) where ordinary shares are issued or transferred to a person (or a nominee or agent of a person) whose business is or includes issuing depositary receipts or the provision of clearance services.

However, following litigation on the subject, HMRC has confirmed that it will no longer seek to apply the 1.5% SDRT charge when new shares are issued to a clearance service or depositary receipt system on the basis that the charge is not compatible with EU law. In HMRC's view, the 1.5% SDRT or stamp duty charge will continue to apply to transfers of shares into a clearance service or depositary receipt system unless they are an integral part of an issue of share capital. The law in this area may still be susceptible to change. We therefore recommend that advice is sought in relation to paying the 1.5 per cent SDRT or stamp duty charge in any circumstances.

Transfer of ADSs

No U.K. stamp duty will be payable on a written instrument transferring an ADS or on a written agreement to transfer an ADS provided that the instrument of transfer or the agreement to transfer is executed and remains at all times outside the United Kingdom. Where these conditions are not met, the transfer of, or agreement to transfer, an ADS could, depending on the circumstances, attract a charge to U.K. stamp duty at the rate of 0.5% of the value of the consideration given in connection with the transfer.

No SDRT will be payable in respect of an agreement to transfer an ADS.

F. Dividends and paying agents

Not applicable.

G. Statement by experts

Not applicable.

H. Documents on Display

You may read and copy any reports or information that we file at the SEC's Public Reference Room at 100 F Street, N.E.,Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling at the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet website that contains reports and other about issuers, like us, that file electronically with the SEC. The address of that site is "www.sec.gov".

We also make available on our website, free of charge, our annual reports on Form 20-F and the text of our reports on Form 6-K, including any amendments to these reports, as well as cretins other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the

SEC. Our website address is "www.gwpharm.com". The information contained on our website is not incorporated by reference in this document.

I. Subsidiary information

Not applicable

Item 11 Quantitative & Qualitative Disclosures About Market Risk

Market risk arises from our exposure to fluctuation in interest rates and currency exchange rates. These risks are managed by maintaining an appropriate mix of cash deposits in various currencies, placed with a variety of financial institutions for varying periods according to expected liquidity requirements.

Interest Rate Risk

We are exposed to interest rate risk as we place surplus cash funds on deposit to earn interest income. We seek to ensure that we consistently earn commercially competitive interest rates by using the services of an independent broker to identify and secure the best commercially available interest rates from those banks that meet our stringent counterparty credit rating criteria. In doing so, we manage the term of cash deposits, up to 365 days, in order to maximize interest earnings while also ensuring that we maintain sufficient readily available cash in order to meet short-term liquidity needs.

At September 30, 2013, our cash and cash equivalents consisted of very short-term cash deposits with maturities of less than 90 days, in order to maximize the liquidity of our funds during a period of economic uncertainty and increased concern about counterparty credit risk.

We do not have any balance sheet exposure to assets or liabilities that would increase or decrease in fair value with changes to interest rates.

Currency Risk

Our functional currency is pounds sterling and the majority of our transactions are denominated in that currency. However, we receive revenue and incur expenses in other currencies and are exposed to the effects of exchange rates. We seek to minimize this exposure by passively maintaining other currency cash balances at levels appropriate to meet foreseeable expenses in these other currencies, converting surplus currency balances of these other currencies into pounds sterling as soon as they arise. We do not use forward exchange contracts to manage exchange rate exposure.

For additional information about our quantitative and qualitative risks, see Note 19 to the consolidated financial statements.

Item 12 Description of Securities Other Than Equity Securities

A. Debt Securities

Not Applicable

B. Warrant and Rights

As at September 30, 2013, there were warrants to subscribe for 3,776,960 ordinary shares outstanding. These warrants can be exercised at any time prior to August 13, 2014. The exercise price for warrants exercisable for 1,888,480 of the ordinary shares is £1.05 per ordinary share and the exercise price for the remaining warrants is £1.75 per ordinary share.

C. Other Securities

Not Applicable

D. American Depositary Shares

Fees and Charges

The following table shows the fees and charges that a holder of our ADSs may have to pay, either directly or indirectly. The majority of these costs are set by the Depositary and are subject to change:

Service	Fees
Issuance of ADSs	Up to U.S. 5¢ per ADS issued
Cancellation of ADSs	Up to U.S. 5¢ per ADS canceled
Distribution of cash dividends or other cash distributions	Up to U.S. 5¢ per ADS held
Distribution of ADSs pursuant to stock dividends, free stock distributions or exercise of rights	Up to U.S. 5¢ per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs	Up to U.S. 5¢ per ADS held
Depositary Services	Up to U.S. 5¢ per ADS held on the applicable record date(s) established by the depositary bank

ADS holders may also be responsible to pay certain fees and expenses incurred by the depositary bank and certain taxes and governmental charges such as:

- Fees for the transfer and registration of Shares charged by the registrar and transfer agent for the Shares in England and Wales (i.e., upon deposit and withdrawal of Shares).
- Expenses incurred for converting foreign currency into U.S. dollars.
- Expenses for cable, telex and fax transmissions and for delivery of securities.
- Taxes and duties upon the transfer of securities (i.e., when Shares are deposited or withdrawn from deposit).
- Fees and expenses incurred in connection with the delivery or servicing of Shares on deposit.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

None

Item 14. Material Modifications To The Rights of Security Holders and Use of Proceeds.

Not applicable

Item 15. Controls & Procedures.

We have carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) under the supervision and the participation of the Executive Management Board, which is responsible for the management of the internal controls, and which includes the Chief Executive Officer and the Chief Financial Officer. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation as of September 30, 2013, the Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures (i) were effective at a reasonable level of assurance as of the end of the period covered by this Annual Report in ensuring that information required to be recorded, processed, summarized and reported in the reports that are filed or submitted under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) were effective at a reasonable level of assurance as of the end of the period covered by this Annual Report in ensuring that information to be disclosed in the reports that are filed or submitted under the Exchange Act is accumulated and communicated to the management of the Company, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosure.

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

During the period covered by this Annual Report, we have not made any changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

Our board of directors has determined that Mr. Noble is a financial expert as contemplated by the rules of the SEC implementing Section 407 of the Sarbanes Oxley Act of 2002.

Item 16B. Code of Ethics

Our Code of Business Conduct and Ethics is applicable to all of our employees, officers and directors and is available on our website at http://www.gwpharm.com. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this document, and you should not consider information on our website to be part of this document.

Item 16C. Principal Accountant Fees and Services

The aggregate fees billed by our principal accountants, Deloitte LLP, for the years ended September 30, 2013, 2012, and 2011 are further described in Note 6 to the consolidated financial statements.

Pre-Approval policies and procedures

The Audit Committee recognizes it is important that the independence of the external auditors, real or perceived, is not impaired through the provision of non-audit services. To ensure the independence and objectivity of the external auditors, all service are pre- approved by the Audit Committee.

Item 16D. Exemptions From The Listing Standards For Audit Committees

Not Applicable

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not Applicable

Item 16F. Change in the Registrants Certifying Accountant

Not Applicable

Item 16G. Corporate Governance

We rely on a provision in Nasdaq's Listed Company Manual that allows us to follow English corporate law and the Companies Act 2006 with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on Nasdaq.

For example, we are exempt from Nasdaq regulations that require a listed U.S. company to:

- have a majority of the board of directors consist of independent directors;
- require non-management directors to meet on a regular basis without management present;
- promptly disclose any waivers of the code for directors or executive officers that should address certain specified items;
- have an independent nominating committee;
- solicit proxies and provide proxy statements for all shareholder meetings; and
- seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares.

As a foreign private issuer, we are permitted to, and we will, follow home country practice in lieu of the above requirements.

In accordance with our Nasdaq listing, our Audit Committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and Rule 10A-3 of the Exchange Act, both of which are also applicable to Nasdaq-listed U.S. companies. Because we are a foreign private issuer, however, our Audit Committee is not subject to additional Nasdaq requirements applicable to listed U.S. companies, including an affirmative determination that all members of the Audit Committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer.

Item 16H. Mine Safety Disclosure

Not Applicable

PART III

Item 17 Financial Statements

We have elected to provide financial statements pursuant to Item 18.

Item 18 Financial Statements

The financial statements are filed as part of this Annual Report beginning on page F-1.

Item 19 Exhibits

Exhibit Number	Description of Exhibit
1.1*	Memorandum & Articles of Association of GW Pharmaceuticals plc. (incorporated by reference to Exhibit 3.1 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
2.1*	Form of specimen certificate evidencing ordinary shares (incorporated by reference to Exhibit 4.1 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
2.2(1)*	Form of Deposit Agreement among GW Pharmaceuticals plc, Citibank, N.A., as the depositary bank and all Holders and Beneficial Owners of ADSs issued thereunder (incorporated by reference to Exhibit 4.2 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
2.3(1)*	Form of American Depositary Receipt (included in Exhibit 4.2) (incorporated by reference to Exhibit 4.3 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
2.4*	Share Warrant to subscribe for ordinary shares issued to Biomedical Value Fund, L.P. dated August 2009 (incorporated by reference to Exhibit 4.4 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
2.5*	Share Warrant to subscribe for ordinary shares issued to Biomedical Value Fund, L.P. dated August 2009 (incorporated by reference to Exhibit 4.5 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
2.6*	Share Warrant to subscribe for ordinary shares issued to Biomedical Offshore Value Fund, L.P. dated August 2009 (incorporated by reference to Exhibit 4.6 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
2.7*	Share Warrant to subscribe for ordinary shares issued to Biomedical Offshore Value Fund, L.P. dated August 2009 (incorporated by reference to Exhibit 4.7 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.1†*	License and Distribution Agreement between Bayer AG Division Pharma and GW Pharma Ltd., dated May 20, 2003 (incorporated by reference to Exhibit 10.1 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.2†*	Amendment Number 1 to the License and Distribution Agreement, dated November 4, 2003 (incorporated by reference to Exhibit 10.2 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).

Exhibit Number	Description of Exhibit
4.3*	Amendment Number 2 to the License and Distribution Agreement between GW Pharma Ltd. and Bayer Healthcare AG Division Pharma, dated January 14, 2004 (incorporated by reference to Exhibit 10.3 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.4†*	Amendment Number 3 to the License and Distribution Agreement between GW Pharma Ltd. and Bayer Healthcare AG Division Pharma, dated March 1, 2005 (incorporated by reference to Exhibit 10.4 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.5†*	Amendment Number 4 to the License and Distribution Agreement between GW Pharma Ltd. and Bayer Healthcare AG Division Pharma, dated May 10, 2005 (incorporated by reference to Exhibit 10.5 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.6*	Amendment Number 5 to the License and Distribution Agreement between GW Pharma Ltd. and Bayer Schering Pharma AG (f/k/a Bayer AG, Bayer HealthCare, Division Pharma), dated March 10, 2010 (incorporated by reference to Exhibit 10.6 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.7†*	Supply Agreement between Bayer AG and GW Pharma Ltd., dated May 20, 2003 (incorporated by reference to Exhibit 10.7 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.8†*	Amendment Number 1 to the Supply Agreement between GW Pharma Ltd. and Bayer Healthcare AG, dated November 4, 2003 (incorporated by reference to Exhibit 10.8 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.9†*	Amendment Number 2 to the Supply Agreement between GW Pharma Ltd. and Bayer Healthcare AG, dated May 10, 2005 (incorporated by reference to Exhibit 10.9 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.10†*	Amendment Number 3 to the Supply Agreement between GW Pharma Ltd. and Bayer Schering Pharma AG (f/k/a Bayer AG, Bayer HealthCare, Division Pharma), dated March 10, 2010 (incorporated by reference to Exhibit 10.10 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.11†*	Product Commercialisation and Supply Consolidated Agreement between GW Pharma Limited and Almirall Prodesfarma, S.A., dated June 6, 2006 (incorporated by reference to Exhibit 10.11 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.12†*	Amendment No. 1 to the Product Commercialisation and Supply Consolidated Agreement between GW Pharma Ltd. and Laboratorios Almirall S.A., dated March 4, 2009 (incorporated by reference to Exhibit 10.12 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.13†*	Amendment to the Product Commercialisation and Supply Consolidated Agreement, dated June 6, 2006 between GW Pharma Ltd. and Almirall S.A., dated July 23, 2010 (incorporated by reference to Exhibit 10.13 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).

Exhibit Number	Description of Exhibit
4.14†*	Supplementary Agreement to the Product Commercialisation and Supply Consolidated Agreement, dated June 6, 2006 between GW Pharma Ltd. and Almirall S.A., dated November 17, 2011 (incorporated by reference to Exhibit 10.14 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.15†*	Amendment and Supplementary Agreement to the Product Commercialisation and Supply Consolidated Agreement, dated June 6, 2006 between GW Pharma Ltd. and Almirall S.A., dated March 13, 2012 (incorporated by reference to Exhibit 10.15 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.16†*	Research Collaboration and Licence Agreement between GW Pharma Ltd. and GW Pharmaceuticals plc and Otsuka Pharmaceutical Co., Ltd., dated July 9, 2007 (incorporated by reference to Exhibit 10.16 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.17†*	Amendment No. 1 to Research Collaboration and Licence Agreement, dated March 14, 2008 (incorporated by reference to Exhibit 10.17 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.18†*	Amendment No. 2 to Research Collaboration and Licence Agreement, dated June 29, 2010 (incorporated by reference to Exhibit 10.18 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.19†*	Development and License Agreement between GW Pharma Ltd. and GW Pharmaceuticals Plc and Otsuka Pharmaceutical Co., Ltd., dated February 14, 2007 (incorporated by reference to Exhibit 10.19 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.20†*	Amendment No. 1 to Development and License Agreement, dated November 1, 2008 (incorporated by reference to Exhibit 10.20 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.21†*	Letter amending Development and License Agreement, dated October 21, 2010 (incorporated by reference to Exhibit 10.21 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.22†*	Distribution and License Agreement, dated April 8, 2011, by and between GW Pharma Ltd. and Novartis Pharma AG (incorporated by reference to Exhibit 10.22 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.23†*	Manufacturing and Supply Agreement, dated November 9, 2011, by and between Novartis Pharma AG and GW Pharma Ltd. (incorporated by reference to Exhibit 10.23 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.24†*	Production Supply Agreement, dated March 7, 2007 (incorporated by reference to Exhibit 10.24 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.25†*	Lease, dated July 6, 2009 (incorporated by reference to Exhibit 10.25 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).

Exhibit Number	Description of Exhibit
4.26†*	Lease, dated October 9, 2009 (incorporated by reference to Exhibit 10.26 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.27†*	Lease, dated April 6, 2011 (incorporated by reference to Exhibit 10.27 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.28†*	Lease, dated October 12, 2011 (incorporated by reference to Exhibit 10.28 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.29†*	Lease, dated January 6, 2012 (incorporated by reference to Exhibit 10.29 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.30†*	Agreement for Lease, dated April 4, 2012 (incorporated by reference to Exhibit 10.30 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.31*	Occupational Underlease, dated August 11, 2010 (incorporated by reference to Exhibit 10.31 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.32*	Lease, dated May 24, 2011 (incorporated by reference to Exhibit 10.32 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.33*	Tenancy Agreement, dated November 19, 2012 (incorporated by reference to Exhibit 10.33 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.34*	Service Agreement by and between GW Pharma Ltd., and Adam George, dated June 1, 2012 (incorporated by reference to Exhibit 10.34 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.35†*	Service Agreement by and between GW Pharma Ltd., and Chris Tovey, dated July 11, 2012 (incorporated by reference to Exhibit 10.35 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.36*	Service Agreement by and between GW Research Ltd. and Dr. Geoffrey Guy, dated March 14, 2013 (incorporated by reference to Exhibit 10.36 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.37*	Service Agreement by and between GW Research Ltd. and Justin Gover, dated February 26, 2013 (incorporated by reference to Exhibit 10.37 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.38*	Service Agreement by and between GW Research Ltd. and Dr. Stephen Wright, dated January 18, 2013 (incorporated by reference to Exhibit 10.38 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).

Exhibit Number	Description of Exhibit
4.39*	Letter of Appointment by and between GW Pharmaceuticals plc and James Noble, dated February 26, 2013 (incorporated by reference to Exhibit 10.39 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.40*	Letter of Appointment by and between GW Pharmaceuticals plc and Tom Lynch, dated February 26, 2013 (incorporated by reference to Exhibit 10.40 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.41	Service Agreement by and between GW Pharmaceuticals Inc. and Cabot Brown, dated November 7, 2013.
4.42*	Long Term Incentive Plan (incorporated by reference to Exhibit 10.42 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.43*	GW Pharmaceuticals All Employee Share Scheme (incorporated by reference to Exhibit 10.43 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.44*	GW Pharmaceuticals Approved Share Option Scheme 2001 (incorporated by reference to Exhibit 10.44 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.45*	GW Pharmaceuticals Unapproved Share Option Scheme 2001 (incorporated by reference to Exhibit 10.45 to our Registration Statement on Form F-1 (file no. 333-187356), as amended, initially filed with the SEC on March 19, 2013).
4.46†	Lease, dated May 24, 2013.
4.47†	Lease, dated May 24, 2013.
4.48†	Lease, dated May 24, 2013.
4.49	Lease, dated August 1, 2013.
4.50†	Lease, dated July 16, 2013.
8.1	List of Subsidiaries.
12.1	Section 302 Certificate.
12.2	Section 302 Certificate.
13.1	Section 906 Certificate.
13.2	Section 906 Certificate.

* Previously filed.

† Confidential treatment requested.

(1) Incorporated by reference to the Registration Statement on Form F-6 (File No. 333-187978), filed with the Securities and Exchange Commission with respect to ADSs representing ordinary shares.

Signature

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

GW PHARMACEUTICALS PLC

By: /s/ JUSTIN GOVER

Name: Justin Gover
Title: *Chief Executive Officer*

Date: November 25, 2013

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of GW Pharmaceuticals plc

We have audited the accompanying consolidated balance sheets of GW Pharmaceuticals plc and subsidiaries (the "Group") as at 30 September 2013 and 2012, and the related consolidated income statements, consolidated statements of changes in equity, and consolidated cash flow statements for each of the three years in the period ended 30 September 2013. These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Group is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of GW Pharmaceuticals plc and subsidiaries as at 30 September 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended 30 September 2013, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

/s/ DELOITTE LLP
Reading, United Kingdom
18 November 2013

Consolidated Income Statements

For the year ended 30 September

	Notes	2013	2012	2011
		£000's	£000's	£000's
Revenue	3	27,295	33,120	29,627
Cost of sales		(1,276)	(839)	(1,347)
Research and development expenditure	4	(32,697)	(27,578)	(22,714)
Management and administrative expenses		(3,792)	(3,660)	(3,298)
Operating (loss)/profit		(10,470)	1,043	2,268
Interest expense	9	(64)	(1)	(3)
Interest income	9	178	200	263
(Loss)/profit before tax	5	(10,356)	1,242	2,528
Tax	10	5,807	1,248	221
(Loss)/profit for the year		(4,549)	2,490	2,749
(Loss)/earnings per share—basic	11	(3.0)p	1.9p	2.1p
(Loss)/earnings per share—diluted	11	(3.0)p	1.8p	2.0p

All activities relate to continuing operations.

The Group has no recognised gains or losses other than the gains and losses shown above and therefore no separate consolidated statements of comprehensive income have been presented.

The accompanying notes are an integral part of these consolidated income statements.

Consolidated Statements of Changes in Equity

For the year ended 30 September

Group	Share capital	Share premium account	Other reserves	Accumulated deficit	Total
	£000's	£000's	£000's	£000's	£000's
At 1 October 2010	131	64,433	20,184	(72,075)	12,673
Exercise of share options	2	1,433	—	—	1,435
Share-based payment transactions	—	—	—	795	795
Profit for the year	—	—	—	2,749	2,749
Balance at 30 September 2011	**133**	**65,866**	**20,184**	**(68,531)**	**17,652**
Exercise of share options	—	81	—	—	81
Share-based payment transactions	—	—	—	1,009	1,009
Profit for the year	—	—	—	2,490	2,490
Balance at 30 September 2012	**133**	**65,947**	**20,184**	**(65,032)**	**21,232**
Issue of share capital	45	19,725	—	—	19,770
Expenses associated with new equity issue	—	(1,670)	—	—	(1,670)
Exercise of share options	—	3	—	—	3
Share-based payment transactions	—	—	—	616	616
Loss for the year	—	—	—	(4,549)	(4,549)
Balance at 30 September 2013	**178**	**84,005**	**20,184**	**(68,965)**	**35,402**

The accompanying notes are an integral part of these consolidated statements of changes in equity.

Consolidated Balance Sheets

As at 30 September

	Notes	Group 2013 £000's	Group 2012 £000's
Non-current assets			
Intangible assets—goodwill	12	**5,210**	5,210
Property, plant and equipment	13	**5,476**	2,432
		10,686	7,642
Current assets			
Inventories	14	**4,661**	3,537
Deferred tax asset		**895**	—
Taxation recoverable	10	**2,900**	820
Trade receivables and other current assets	15	**1,733**	1,588
Cash and cash equivalents	19	**38,069**	29,335
		48,258	35,280
Total assets		**58,944**	42,922
Current liabilities			
Trade and other payables	16	**(9,440)**	(9,114)
Obligations under finance leases	17	**(100)**	—
Deferred revenue	18	**(3,181)**	(2,449)
		(12,721)	(11,563)
Non-current liabilities			
Obligations under finance leases	17	**(1,905)**	—
Deferred revenue	18	**(8,916)**	(10,127)
Total liabilities		**(23,542)**	(21,690)
Net assets		**35,402**	21,232
Equity			
Share capital	20	**178**	133
Share premium account		**84,005**	65,947
Other reserves	23	**20,184**	20,184
Accumulated deficit		**(68,965)**	(65,032)
Total equity		**35,402**	21,232

The accompanying notes are an integral part of these consolidated balance sheets.

Consolidated Cash Flow Statements

For the year ended 30 September

	Group		
	2013	2012	2011
	£000's	£000's	£000's
(Loss)/profit for the year	**(4,549)**	2,490	2,749
Adjustments for:			
Interest expense	**64**	1	3
Interest income	**(178)**	(200)	(263)
Tax	**(5,807)**	(1,248)	(221)
Depreciation of property, plant and equipment	**989**	754	589
Net foreign exchange (gains)/losses	**(25)**	(202)	7
(Decrease)/increase in allowance for doubtful debts	**(26)**	26	—
Decrease in provision for inventories	**(530)**	(1,300)	(425)
Share-based payment charge	**616**	1,009	795
	(9,446)	1,330	3,234
Increase in inventories	**(594)**	(813)	(219)
(Increase)/decrease in trade receivables and other current assets	**(108)**	609	(1,043)
(Decrease)/increase in trade and other payables and deferred revenue	**(152)**	247	168
Cash (used in)/generated by operations	**(10,300)**	1,373	2,140
Research and development tax credits received	**2,832**	428	221
Net cash (outflow)/inflow from operating activities	**(7,468)**	1,801	2,361
Investing activities			
Interest received	**167**	258	244
Purchase of property, plant and equipment	**(2,243)**	(1,318)	(891)
Net cash outflow from investing activities	**(2,076)**	(1,060)	(647)
Financing activities			
Proceeds on exercise of share options	**3**	81	1,435
Proceeds of new equity issue	**19,770**	—	—
Expenses of new equity issue	**(1,670)**	—	—
Interest paid	**(64)**	(1)	(3)
Proceeds from finance leases	**225**	—	—
Capital element of finance leases	**(11)**	(7)	(39)
Net cash inflow from financing activities	**18,253**	73	1,393
Net increase in cash and cash equivalents	**8,709**	814	3,107
Cash and cash equivalents at the beginning of the year	**29,335**	28,319	25,219
Effect of foreign exchange rate changes	**25**	202	(7)
Cash and cash equivalents at end of the year	**38,069**	29,335	28,319

The accompanying notes are an integral part of these consolidated cash flow statements.

1. General Information

GW Pharmaceuticals plc (the "Company") and its subsidiaries (the "Group") are primarily involved in the development of cannabinoid prescription medicines using botanical extracts derived from the *Cannabis Sativa* plant. The Group are developing a portfolio of cannabinoid medicines, of which the lead product is Sativex®, an oromucosal spray for the treatment of MS symptoms, cancer pain and neuropathic pain.

The Company is a public limited company, which has been listed on the Alternative Investment Market ("AIM"), which is a market operated by London Stock Exchange plc, since 28 June 2001. The Company is incorporated and domiciled in the United Kingdom. The address of the Company's registered office and principal place of business is Porton Down Science Park, Salisbury, Wiltshire.

In addition, the Company has American Depository Receipts ("ADRs") registered with the U.S. Securities and Exchange Commission ("SEC") and is listed on NASDAQ.

2. Significant Accounting Policies

The principal Group accounting policies are summarised below.

Basis of Accounting

The financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS"). The financial statements have also been prepared in accordance with IFRS as endorsed by the European Union and as issued by the International Accounting Standards Board ("IASB"). The Group financial statements also comply with Article 4 of the EU IAS regulation.

The financial statements have been prepared under the historical cost convention, except for the revaluation of financial instruments. Historical cost is generally based on the fair value of the consideration given in exchange for the assets. The principal accounting policies are set out below.

The financial statements were approved for issuance by the Board on 18 November 2013.

Going Concern

The Directors have considered the financial position of the Group, its cash position and forecast cash flows for the twelve month period from the date of signing these financial statements when considering going concern. They have also considered the Group's business activities, the key policies for managing financial risks and the key factors affecting the likely development of the business in 2014. In the light of this review, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing these financial statements.

Basis of Consolidation

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company (its subsidiaries) made up to 30 September each year. Subsidiaries are all entities over which the Group has the power to govern the financial and operating policies of the entity concerned, generally accompanying a shareholding of more than one half of the voting rights.

The results of subsidiaries acquired or disposed of during the year are included in the consolidated income statement from the effective date of acquisition or up to the effective date of disposal, as appropriate. Where necessary, adjustments are made to the financial statements of subsidiaries to bring

2. Significant Accounting Policies (Continued)

the accounting policies used into line with those used by the Group. All intra-group transactions, balances, income and expenses are eliminated on consolidation. Acquisitions are accounted for under the acquisition method.

In future business combinations, if a non-controlling interest in a subsidiary arises, such non-controlling interest will be identified separately from the Group's equity therein. The interests of non-controlling shareholders that are present ownership interests entitling their holders to a proportionate share of net assets upon liquidation may initially be measured at fair value or at the non-controlling interests' proportionate share of the fair value of the acquiree's identifiable net assets. The choice of measurement is made on an acquisition-by-acquisition basis. Other non-controlling interests are initially measured at fair value. Subsequent to acquisition, the carrying amount of non-controlling interests is the amount of those interests at initial recognition plus the non-controlling interests' share of subsequent changes in equity. Total comprehensive income is attributed to non-controlling interests even if this results in the non-controlling interests having a deficit balance.

Changes in the Group's interests in subsidiaries that do not result in a loss of control are accounted for as equity transactions. The carrying amount of the Group's interests and the non-controlling interests are adjusted to reflect the changes in their relative interests in the subsidiaries. Any difference between the amount by which the non-controlling interests are adjusted and the fair value of the consideration paid or received is recognised directly in equity and attributed to the owners of the Company.

When the Group loses control of a subsidiary, the profit or loss on disposal is calculated as the difference between (i) the aggregate of the fair value of the consideration received and the fair value of any retained interest and (ii) the previous carrying amount of the assets (including goodwill), less liabilities of the subsidiary and any non-controlling interests. Amounts previously recognised in other comprehensive income in relation to the subsidiary are accounted for (i.e. reclassified to profit or loss or transferred directly to accumulated deficit) in the same manner as would be required if the relevant assets or liabilities are disposed of. The fair value of any investment retained in the former subsidiary at the date when control is lost is regarded as the fair value on initial recognition for subsequent accounting under IAS 39 Financial Instruments: Recognition and Measurement or, when applicable, the costs on initial recognition of an investment in an associate or jointly controlled entity.

Intangible Assets—Goodwill

Goodwill arising in a business combination is recognised as an asset at the date that control is acquired. Goodwill is measured as the excess of the sum of consideration transferred, the amount of any non-controlling interest in the acquiree and the fair value of the acquirer's previously held equity interest (if any) in the entity over the net of the acquisition date amounts of the identifiable assets and liabilities assumed.

Goodwill is not amortised but is tested for impairment at least annually. For the purpose of impairment testing, goodwill is allocated to each of the Group's cash-generating units expected to benefit from the synergies of the combination. Cash-generating units to which goodwill has been allocated are tested for impairment annually, or more frequently when there is an indication that the unit may be impaired. If the recoverable amount of the cash-generating unit is less than the carrying amount of the unit, the impairment loss is allocated first to reduce the carrying amount of any goodwill allocated to the unit and then to the other assets of the unit pro-rata on the basis of the carrying

2. Significant Accounting Policies (Continued)

amount of each asset in the unit. An impairment loss recognised for goodwill is not reversed in a subsequent period.

On disposal of a subsidiary, the attributable amount of goodwill is included in the determination of the profit or loss on disposal.

Revenue

Revenue is measured at the fair value of the consideration received or receivable and represents amounts receivable for goods and services provided in the normal course of business net of value added tax and other sales-related taxes. The Group recognises revenue when the amount can be reliably measured; when it is probable that future economic benefits will flow to the Group; and when specific criteria have been met for each of the Group's activities, as described below.

The Group's revenue arises from product sales, licensing fees, collaboration fees, technical access fees, development and approval milestone fees, research and development fees and royalties. Agreements with commercial partners generally include non-refundable up-front license and collaboration fees, milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones, as well as royalties on product sales of licensed products, if and when such product sales occur, and revenue from the supply of products. For these agreements, total arrangement consideration is attributed to separately identifiable components on a reliable basis that reasonably reflects the selling prices that might be expected to be achieved in stand-alone transactions. The then allocated consideration is recognised as revenue in accordance with the principles described below.

The percentage of completion method is used for a number of revenue streams of the Group. For each of the three years ended 30 September 2013, there were no discrete events or adjustments which caused the Group to revise its previous estimates of completion associated with those revenue arrangements accounted for under the percentage of completion method.

Product Sales

Revenue from the sale of products is recognised when the Group has transferred to the buyer the significant risks and rewards of ownership of the goods, the Group no longer has effective control over the goods sold, the amount of revenue and costs associated with the transaction can be measured reliably, and it is probable that the Group will receive future economic benefits associated with the transaction. Product sales have no rights of return.

The Group maintains a rebate provision for expected reimbursements to our commercial partners in circumstances in which actual net revenue per vial differs from expected net revenue per vial as a consequence of, as an example, ongoing pricing negotiations with local health authorities.

The amount of our rebate provision is based on, amongst other things, monthly unit sales and in-market sales data received from commercial partners and represents management's best estimate of the rebate expected to be required to settle the present obligation at the end of the reporting period. Provisions for rebates are established in the same period that the related sales are recorded.

2. Significant Accounting Policies (Continued)

Licensing Fees

License fees received in connection with product out-licensing agreements, even where such fees are non-refundable, are deferred and recognised over the period of the license term.

Collaboration Fees

Collaboration fees are deferred and recognised as services are rendered based on the percentage of completion method.

Technical Access Fees

Technical access fees represent amounts charged to licensing partners to provide access to, and to commercially exploit data that the Group possesses or which can be expected to result from Group research programmes that are in progress. Non-refundable technical access fees that involve the delivery of data that the Group possesses and that permit the licensing partner to use the data freely and where the Group has no remaining obligations to perform are recognised as revenue upon delivery of the data. Non-refundable technical access fees relating to data where the research programme is on-going are recognised based on the percentage of completion method.

Development and Approval Milestone Fees

Development and approval milestone fees are recognised as revenue based on the percentage of completion method on the assumption that all stages will be completed successfully, but with cumulative revenue recognised limited to non-refundable amounts already received or reasonably certain to be received.

Research and Development Fees

Revenue from partner funded contract research and development agreements is recognised as research and development services are rendered. Where services are in-progress at period end, the Group recognises revenues proportionately, in line with the percentage of completion of the service. Where such in-progress services include the conduct of clinical trials, the Group recognises revenue in line with the stage of completion of each trial so that revenues are recognised in line with the expenditures.

Royalties

Royalty revenue is recognised on an accrual basis in accordance with the substance of the relevant agreement, provided that it is probable that the economic benefits will flow to the Group and the amount of revenue can be measured reliably.

Research and Development

Expenditure on research and development activities is recognised as an expense in the period in which it is incurred.

An internally generated intangible asset arising from the Group's development activities is recognised only if the following conditions are met:

- an asset is created that can be identified

2. Significant Accounting Policies (Continued)

- it is probable that the asset created will generate future economic benefits, and
- the development cost of the asset can be measured reliably.

The Group has determined that regulatory approval is the earliest point at which the probable threshold can be achieved. All research and development expenditure incurred prior to achieving regulatory approval is therefore expensed as incurred.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, net of accumulated depreciation and any recognised impairment loss. Depreciation is provided so as to write off the cost of assets, less their estimated residual values, over their useful lives using the straight line method, as follows:

Motor vehicles	4 years
Plant, machinery and lab equipment	3 - 10 years
Office and IT equipment	4 years
Leasehold improvements	5 - 15 years or term of the lease if shorter

Assets under finance leases are depreciated over their expected useful lives on the same basis as owned assets or, where shorter, over the term of the relevant lease.

No depreciation is provided on assets under the course of construction.

The gain or loss arising on disposal or scrappage of an asset is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognised in operating profit.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is calculated using the weighted average cost method. Cost includes materials, direct labour, depreciation of manufacturing assets and an attributable proportion of manufacturing overheads based on normal levels of activity. Net realisable value is the estimated selling price, less all estimated costs of completion and costs to be incurred in marketing, selling and distribution.

If net realisable value is lower than the carrying amount, a write down provision is recognised for the amount by which the carrying amount exceeds its net realisable value.

Inventories manufactured prior to regulatory approval are capitalised as an asset but provided for until there is a high probability of regulatory approval of the product. At the point when a high probability of regulatory approval is obtained, the provision is adjusted appropriately to adjust the carrying value to expected net realisable value, which may not exceed original cost.

Adjustments to the provision against inventories manufactured prior to regulatory approval are recorded as a component of research and development expenditure. Adjustments to the provision against commercial product related inventories manufactured following achievement of regulatory approval are recorded as a component of cost of goods.

Taxation

The tax expense represents the sum of the tax currently payable or recoverable and deferred tax.

2. Significant Accounting Policies (Continued)

The tax payable or recoverable is based on taxable profit for the year. Taxable profit differs from net profit as reported in the consolidated income statement because it excludes items of income or expense that are taxable or deductible in other years and it further excludes items that are never taxable or deductible. The Group's liability for current tax is calculated using tax rates and laws that have been enacted or substantively enacted by the balance sheet date.

Deferred tax is the tax expected to be payable or recoverable on differences between carrying amounts of assets and liabilities in the financial statements and the corresponding tax bases used in the computation of taxable profit, and is accounted for using the balance sheet liability method. Deferred tax liabilities are generally recognised for all taxable temporary differences and deferred tax assets are recognised only to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilised. Such assets and liabilities are not recognised if the temporary difference arises from the initial recognition of goodwill or from the initial recognition (other than in a business combination) of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit.

Deferred tax liabilities are recognised for taxable temporary differences arising on investments in subsidiaries and associates, and interests in joint ventures, except where the Group is able to control the reversal of the temporary difference and it is probable that the temporary difference will not reverse in the foreseeable future.

The carrying amount of deferred tax assets is reviewed at each balance sheet date and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Deferred tax is calculated at the tax rates that are expected to apply in the period when the liability is settled or the asset is realised based on tax laws and rates that have been enacted at the balance sheet date. Deferred tax is charged or credited in the income statement, except when it relates to items charged or credited in other comprehensive income, in which case the deferred tax is also dealt with in other comprehensive income.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income taxes levied by the same taxation authority and the Group intends to settle its current tax assets and liabilities on a net basis.

(Loss)/earnings per Share

Basic earnings or loss per share represents the profit or loss for the year, divided by the weighted average number of ordinary shares in issue during the year, excluding the weighted average number of ordinary shares held in the GW Pharmaceuticals All Employee Share Scheme (the "ESOP") during the year to satisfy employee share awards.

Diluted earnings or loss per share represents the profit or loss for the year, divided by the weighted average number of ordinary shares in issue during the year, excluding the weighted average number of shares held in the ESOP during the year to satisfy employee share awards, plus the weighted average number of dilutive shares resulting from share options or warrants where the inclusion of these would not be antidilutive.

2. Significant Accounting Policies (Continued)

Retirement Benefit Costs

The Group does not operate any pension plans, but makes contributions to personal pension arrangements of its Executive Directors and employees. The amounts charged to the consolidated income statement in respect of pension costs are the contributions payable in the year. Differences between contributions payable in the year and contributions paid are shown as either accruals or prepayments in the consolidated balance sheet.

Foreign Currency

The individual financial statements of each group company are presented in the currency of the primary economic environment in which it operates (its functional currency), which for all companies forming part of the Group, is pounds sterling. The presentation currency of the consolidated financial statements is also pounds sterling.

In preparing the financial statements of the individual companies, transactions in currencies other than the entity's functional currency (foreign currencies) are recorded at the rate of exchange at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are retranslated at the rates of exchange prevailing at that date. Non-monetary items carried at fair value that are denominated in foreign currencies are translated at the rates prevailing at the date when the fair value was determined. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

Any gain or loss arising from a change in exchange rates subsequent to the date of the transaction is included as an exchange gain or loss in the income statement as a component of operating loss.

Share-based Payment

Equity-settled share-based payments to employees and others providing similar services are measured at fair value (excluding the effect of non-market based vesting conditions) at the date of grant.

The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the Group's estimate of shares that will eventually vest. At each balance sheet date, the Group revises its estimate of the number of equity instruments expected to vest as a result of the effect of non-market based vesting conditions. The impact of the revision of the original estimates, if any, is recognised in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to equity reserves.

Equity-settled share-based payment transactions with parties other than employees are measured at the fair value of the goods or services received, except where that fair value cannot be estimated reliably, in which case they are measured at the fair value of the equity instruments granted, measured at the date of grant.

Warrants

Warrants issued by the Group are recognised and classified as equity when upon exercise, the Company would issue a fixed amount of its own equity instruments (ordinary shares) in exchange for a fixed amount of cash or another financial asset.

2. Significant Accounting Policies (Continued)

Consideration received, net of incremental costs directly attributable to the issue of such new warrants, is shown in equity.

Changes in fair value of such warrants are not recognised in the consolidated financial statements.

When the warrants are exercised, the Company issues new shares. The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

Leases

Leases are classified as finance leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. All other leases are classified as operating leases.

Rentals under operating leases are charged on a straight-line basis over the term of the relevant lease except where another more systematic basis is more representative of the time pattern in which economic benefits from the lease are consumed. Contingent rentals arising under operating leases are recognised as an expense in the period in which they are incurred.

In the event that lease incentives are received to enter into operating leases, such incentives are recognised as a liability. The aggregate benefit of incentives is recognised as a reduction of rental expense on a straight-line basis, except where another systematic basis is more representative of the time pattern in which economic benefits from the leased asset are consumed.

Assets held under finance leases are recognised as assets of the Group at their fair value or, if lower, the present value of the minimum lease payments, each determined at the inception of the lease. The corresponding liability to the lessor is included in the balance sheet as a finance lease obligation. Lease payments are apportioned between finance charges and reduction of the finance lease obligation so as to achieve a constant rate of interest on the remaining balance of the liability. Finance expenses are recognised immediately in profit or loss, unless they are directly attributable to qualifying assets, in which case they are capitalised in accordance with the Group's general policy on borrowing costs. Contingent rentals are recognised as an expense in the periods in which they are incurred.

Financial Instruments

Financial assets and liabilities are recognised in the Group's balance sheet when the Group becomes party to the contractual provisions of the instrument.

All financial assets are recognised and derecognised on a trade date where the purchase or sale of a financial asset is under a contract whose terms require delivery of the financial asset within the timeframe established by the market concerned, and are initially measured at fair value, plus transaction costs, except for those financial assets classified as at fair value through profit or loss, which are initially measured at fair value.

Financial assets are classified into the following specified categories: financial assets 'at fair value through profit or loss', 'held-to-maturity' investments, 'available-for-sale' financial assets and 'loans and receivables'. The classification depends on the nature and purpose of the financial assets and is determined at the time of initial recognition.

For each reporting period covered herein, the Group's financial assets were restricted to 'loans and receivables'.

2. Significant Accounting Policies (Continued)

Loans and Receivables

Trade receivables that have fixed or determinable payments that are not quoted in an active market are classified as 'loans and receivables'. Loans and receivables are measured at amortised cost, less any impairment. Interest income is recognised by applying the effective interest rate, except for short-term receivables when the recognition of interest would be immaterial.

Trade receivables are assessed for indicators of impairment at each balance sheet date. Trade receivables are impaired where there is objective evidence that, as a result of one or more events that occurred after initial recognition, the estimated future cash flows of the receivables have been affected. Appropriate allowances for estimated irrecoverable amounts are recognised in the income statement. The allowance recognised is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows discounted at the effective interest rate computed at initial recognition.

Cash and Cash Equivalents

Cash and cash equivalents comprise cash in hand and on-call deposits held with banks and other short-term highly liquid investments with a maturity of three months or less.

Financial Liabilities

Financial liabilities are classified as either financial liabilities 'at Fair Value Though Profit and Loss' or 'other financial liabilities'. For each reporting period covered herein, the Group's financial liabilities were restricted to 'other financial liabilities'.

Other Financial Liabilities

Trade payables are initially measured at fair value, net of transaction costs, and are subsequently measured at amortised cost, using the effective interest rate method.

The effective interest method is a method of calculating the amortised cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments through the expected life of the financial liability, or, where appropriate, a shorter period, to the net carrying amount on initial recognition.

Critical Judgements in Applying the Group's Accounting Policies

In the application of the Group's accounting policies, which are described above, the Board of Directors are required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period or in the period of the revisions and future periods if the revision affects both current and future periods.

2. Significant Accounting Policies (Continued)

The following are the critical judgements, apart from those involving estimations (which are dealt with separately below), that the Directors have made in the process of applying the Group's accounting policies and that have the most significant effect on the amounts recognised in the financial statements.

Recognition of Clinical Trials Expenditure

The Group recognises expenditure incurred in carrying out clinical trials during the course of conduct of each clinical trial in line with the state of completion of each trial. This involves the calculation of clinical trial accruals at each period end to account for expenditure which has been incurred. This requires estimation of the expected full cost to complete the trial and also estimation of the current stage of trial completion.

Clinical trials usually take place over extended time periods and typically involve a set-up phase, a recruitment phase and a completion phase which ends upon the receipt of a final report containing full statistical analysis of trial results. Accruals are prepared separately for each in-process clinical trial and take into consideration the stage of completion of each trial including the number of patients that have entered the trial, the number of patients that have completed treatment and whether the final report has been received. In all cases, the full cost of each trial is expensed by the time the final report has been received.

Revenue Recognition

The Group recognises revenue from product sales, licensing fees, collaboration fees, technical access fees, development and approval milestone fees, research and development fees and royalties. Agreements with commercial partners generally include a non-refundable up-front fee, milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones, as well as royalties on product sales of licensed products, if and when such product sales occur. For these agreements, the Group is required to apply judgement in the allocation of total agreement consideration to the separately identifiable components on a reliable basis that reasonably reflects the selling prices that might be expected to be achieved in stand-alone transactions.

Product revenue received is based on a contractually agreed percentage of our commercial partner's in-market net sales revenue. The commercial partner's in-market net sales revenue is the price per vial charged to end customers, less set defined deductible overheads incurred in distributing the product. In developing estimates, the Group uses monthly unit sales and in-market sales data received from commercial partners during the course of the year. For certain markets, where negotiations are ongoing with local reimbursement authorities, an estimated in-market sales price is used, which requires the application of judgement in assessing whether an estimated in-market sales price is reliably measurable. In the Group's assessment, the Group considers, inter alia, identical products sold in similar markets and whether the agreed prices for those identical products support the estimated in-market sales price. In the event that the Group considers there to be significant uncertainty with regards to the in-market sales price to be charged by the commercial partner as a result of, as an example, ongoing pricing negotiations with local health authorities, such that it is not possible to reliably measure the amount of revenue that will flow to the Group, the Group would not recognize revenue until that uncertainty has been resolved.

The Group applies the percentage of completion revenue recognition method to certain classes of revenue. The application of this approach requires the judgement of the Group with regards to the total costs incurred and total estimated costs expected to be incurred over the length of the agreement.

2. Significant Accounting Policies (Continued)

Key Sources of Estimation Uncertainty

The key assumptions concerning the future, and other key sources of estimation uncertainty at the balance sheet date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are discussed below.

Rebate provision

The Group maintains a rebate provision for expected reimbursements to our commercial partners in circumstances in which actual net revenue per vial differs from expected net revenue per vial as a consequence of, as an example, ongoing pricing negotiations with local health authorities.

The amount of the rebate provision is based on, amongst other things, monthly unit sales and in-markets sales data received from commercial partners and represents management's best estimate of the rebate expected to be required to settle this present obligation at the end of the reporting period.

Pricing decisions made by local health authorities, including revisions and clarifications that have retroactive application can result in changes to management's estimates of the rebates reported in prior periods.

Aggregate rebate provision accruals as at 30 September 2013 and 2012 were £1.2 and £0.2 million, respectively.

Provision for inventories

The Group maintains inventories which, based upon current sales levels and the current regulatory status of the product in each indication, is in-excess of the amount that is expected to be utilised in the manufacture of finished product for future commercial sales.

Provision is therefore made to reduce the carrying value of the excess inventories to their expected net realisable value.

The provision for inventories and adjustments thereto, are estimated based on evaluation of the status of the regulatory approval, projected sales volumes and growth rates. The timing and extent of future provision adjustments will be contingent upon timing and extent of future regulatory approvals and post-approval in-market sales demand, which remain uncertain at this time.

Deferred taxation

At the balance sheet date, the Group has accumulated tax losses of £33.6m (2012: £40.9m) available to offset against future profits. If the value of these losses were recognised within the Group's balance sheet at the balance sheet date, the Group would be carrying a deferred tax asset of £6.1m (2012: £9.7m). However, as explained in the tax accounting policy note, the Group's policy is to recognise deferred tax assets only to the extent that it is probable that future taxable profits, feasible tax-planning strategies, and deferred tax liabilities will be available against which the brought forward trading losses can be utilised. Estimation of the level of future taxable profits is therefore required in order to determine the appropriate carrying value of the deferred tax asset at each balance sheet date.

2. Significant Accounting Policies (Continued)

Adoption of New and Revised Standards

In the current year, the following revised standards have been adopted in these financial statements. Adoption has not had a significant impact on the amounts reported in these financial statements but may impact the accounting for future transactions and arrangements.

IFRS 10 Consolidated Financial Statements
IFRS 11 Joint Arrangements
IFRS 12 Disclosure of Interests in Other Entities
IFRS 13 Fair Value Measurement
IAS 19 (revised June 2011) Employee Benefits
IAS 27 (revised May 2011) Separate Financial Statements
IAS 28 (revised May 2011) Investments in Associates and Joint Ventures
Amendments to IAS 1 (June 2011) Presentation of Items of Other Comprehensive Income

At the date of authorisation of these financial statements, the following Standards and Interpretations which have not been applied in these financial statements were issued by the IASB but not yet effective:

Amendments to IFRS 10, IFRS 12 and IAS 27 (Oct 2012) Investment Entities
Amendments to IAS 32 (Dec 2011) Offsetting Financial Assets and Financial Liabilities
Amendments to IAS 36 (May 2013) Recoverable Amount Disclosures for Non-Financial Assets
Amendments to IAS 39 (Jun 2013) Novation of Derivatives and Continuation of Hedge Accounting
Amendments to IFRS 1 (Mar 2012) Government Loans
Amendments to IFRS 7 (Dec 2011) Disclosures—Offsetting Financial Assets and Financial Liabilities
Annual Improvements to IFRSs: 2009-2011 Cycle (May 2012)
Consolidated Financial Statements, Joint Arrangements and Disclosure of Interests in Other Entities: Transition Guidance (June 2012)
IFRS 9 Financial Instruments
IFRIC 20 Stripping Costs in the Production Phase of a Surface Mine
IFRIC 21 Levies

The Directors do not expect that the adoption of these Standards and Interpretations in future periods will have a material impact on the financial statements of the Group.

3. Segmental Information

Information reported to the Company's Board of Directors, the chief operating decision maker for the Group, for the purposes of resource allocation and assessment of segment performance is focused on the stage of product development. The Group's reportable segments are as follows:

- **Sativex Commercial:** The Sativex Commercial segment promotes Sativex through strategic collaborations with major pharmaceutical companies for the currently approved indication of spasticity due to multiple sclerosis. The Group has licensing agreements for the commercialization of Sativex with Almirall S.A. in Europe (excluding the United Kingdom) and Mexico, Otsuka Pharmaceutical Co. Ltd. (''Otsuka'') in the United States, Novartis Pharma AG in Australia, New Zealand, Asia (excluding Japan, China and Hong Kong), the Middle East and Africa, Bayer HealthCare AG in the United Kingdom and Canada and Neopharm Group in Israel. Sativex Commercial segment revenues include product sales, license, collaboration, and technical access fees, and development and approval milestone fees.

3. Segmental Information (Continued)

- **Sativex Research and Development:** The Sativex Research and Development segment seeks to maximize the potential of Sativex through the development of new indications. The current focus for this segment is the Phase III clinical development program of Sativex for use in the treatment of cancer pain. The Group also believe that MS spasticity represents an attractive indication for the United States and we intend to pursue an additional clinical development program for this significant market opportunity. In addition, Sativex has shown promising efficacy in Phase 2 trials in other indications such as neuropathic pain, but these areas are not currently the subject of full development programs. Sativex Research and Development segment revenues consist of research and development fees charged to Sativex licensees.
- **Pipeline Research and Development:** The Pipeline Research and Development segment seeks to develop cannabinoid medications other than Sativex across a range of therapeutic areas using the Group's proprietary cannabinoid technology platform. The Group's product pipeline includes an orphan childhood epilepsy program as well as other product candidates in Phase 1 and 2 clinical development for glioma, ulcerative colitis, type-2 diabetes and schizophrenia. Pipeline Research and Development segment revenues consist of research and development fees charged to Otsuka under the terms of our pipeline research collaboration agreement.

The accounting policies of the reportable segments are consistent with the Group's accounting policies described in Note 2. Segment result represents the result of each segment without allocation of share-based payment expenses, and before management and administrative expenses, interest expense, interest income and tax.

No measures of segment assets and segment liabilities are reported to the Company's Board of Directors in order to assess performance and allocate resources. Intersegment activity has been eliminated. There are no intersegment sales and all revenue is generated from external customers.

3. Segmental Information (Continued)

Segment Results

For the Year Ended 30 September 2013

	Sativex Commercial	Sativex R&D	Pipeline R&D	Total reportable segments	Unallocated costs(1)	Consolidated
	£'000	£'000	£'000	£'000	£'000	£'000
Revenue:						
Product sales	2,157	—	—	2,157	—	2,157
Research and development fees	—	19,333	4,261	23,594	—	23,594
License, collaboration and technical access fees	1,294	—	—	1,294	—	1,294
Development and approval milestone fees	250	—	—	250	—	250
Total revenue	3,701	19,333	4,261	27,295	—	27,295
Cost of sales	(1,276)	—	—	(1,276)	—	(1,276)
Research and development credit/(expenditure)	597	(23,737)	(9,240)	(32,380)	(317)	(32,697)
Segmental result	3,022	(4,404)	(4,979)	(6,361)	(317)	(6,678)
Management and administrative expenses						(3,792)
Operating loss						(10,470)
Interest expense						(64)
Interest income						178
Loss before tax						(10,356)
Tax						5,807
Loss for the year						(4,549)

The following is an analysis of depreciation and the movement in the provision for inventories by segment for the year ended 30 September 2013:

	Sativex Commercial	Sativex R&D	Pipeline R&D	Total reportable segments	Unallocated costs(1)	Consolidated
	£'000	£'000	£'000	£'000	£'000	£'000
Depreciation	—	(560)	(429)	(989)	—	(989)
Decrease/(increase) in provision for inventories	597	(67)	—	530	—	530

(1) Unallocated costs represent the portion of share-based payment expenditures which is included in research and development expenditure, but which is not allocated to segments. The remaining share-based payment expenditure is included within management and administrative expenses, which is similarly excluded from segmental result.

3. Segmental Information (Continued)

Segment Results

For the Year Ended 30 September 2012

	Sativex Commercial	Sativex R&D	Pipeline R&D	Total reportable segments	Unallocated costs(1)	Consolidated
	£'000	£'000	£'000	£'000	£'000	£'000
Revenue:						
Product sales	2,514	—	—	2,514	—	2,514
Research and development fees	—	14,080	5,420	19,500	—	19,500
License, collaboration and technical access fees	1,294	—	—	1,294	—	1,294
Development and approval milestone fees	9,812	—	—	9,812	—	9,812
Total revenue	13,620	14,080	5,420	33,120	—	33,120
Cost of sales	(839)	—	—	(839)	—	(839)
Research and development credit/ (expenditure)	1,300	(18,415)	(9,904)	(27,019)	(559)	(27,578)
Segmental result	14,081	(4,335)	(4,484)	5,262	(559)	4,703
Management and administrative expenses						(3,660)
Operating profit						1,043
Interest expenses						(1)
Interest income						200
Profit before tax						1,242
Tax						1,248
Profit for the year						2,490

The following is an analysis of depreciation and the movement in the provision for inventories by segment for the year ended 30 September 2012:

	Sativex Commercial	Sativex R&D	Pipeline R&D	Total reportable segments	Unallocated costs(1)	Consolidated
	£'000	£'000	£'000	£'000	£'000	£'000
Depreciation	—	(394)	(360)	(754)	—	(754)
Decrease in provision for inventories	1,300	—	—	1,300	—	1,300

(1) Unallocated costs represent the portion of share-based payment expenditures which is included in research and development expenditure, but which is not allocated to segments. The remaining share-based payment expenditure is included within management and administrative expenses, which is similarly excluded from segmental result.

3. Segmental Information (Continued)

Segment Results

For the Year Ended 30 September 2011

	Sativex Commercial	Sativex R&D	Pipeline R&D	Total reportable segments	Unallocated costs(1)	Consolidated
	£'000	£'000	£'000	£'000	£'000	£'000
Revenue:						
Product sales	4,409	—	—	4,409	—	4,409
Research and development fees	—	10,822	5,216	16,038	—	16,038
License, collaboration and technical access fees	3,843	—	—	3,843	—	3,843
Development and approval milestone fees	5,337	—	—	5,337	—	5,337
Total revenue	13,589	10,822	5,216	29,627	—	29,627
Cost of sales	(1,347)	—	—	(1,347)	—	(1,347)
Research and development credit/ (expenditure)	266	(14,757)	(7,834)	(22,325)	(389)	(22,714)
Segmental result	12,508	(3,935)	(2,618)	5,955	(389)	5,566
Management and administrative expenses						(3,298)
Operating profit						2,268
Interest expense						(3)
Interest income						263
Profit before tax						2,528
Tax						221
Profit for the year						2,749

The following is an analysis of depreciation and the movement in the provision for inventories by segment for the year ended 30 September 2011:

	Sativex Commercial	Sativex R&D	Pipeline R&D	Total reportable segments	Unallocated costs(1)	Consolidated
	£'000	£'000	£'000	£'000	£'000	£'000
Depreciation	—	(248)	(341)	(589)	—	(589)
Decrease in provision for inventories	266	159	—	425	—	425

(1) Unallocated costs represent the portion of share-based payment expenditures which is included in research and development expenditure, but which is not allocated to segments. The remaining share-based payment expenditure is included within management and administrative expenses, which is similarly excluded from segmental result.

3. Segmental Information (Continued)

Segment Results

Revenues from the Group's largest customer, the only customer where revenues amount for more than 10% of the Group's revenues, are included within the above segments as follows:

	Sativex Commercial	Sativex R&D	Pipeline R&D	Total
	£'000	£000's	£000's	£000's
Year ended 30 September 2013	—	19,333	4,261	23,594
Year ended 30 September 2012	—	13,994	5,420	19,414
Year ended 30 September 2011	3,687	10,729	5,216	19,632

Geographical Analysis of Revenue by Destination of Customer:

	2013	2012	2011
	£000's	£000's	£000's
UK	**577**	248	1,469
Europe (excluding UK)	**2,290**	12,712	10,317
United States	**19,508**	14,274	11,830
Canada	**587**	436	795
Asia	**4,333**	5,450	5,216
	27,295	33,120	29,627

All revenue, profits and losses before tax originated in the UK. All assets and liabilities are held in the UK.

4. Research and Development Expenditure

	2013	2012	2011
	£000's	£000's	£000's
GW-funded research and development	**9,103**	8,078	6,676
Development partner-funded research and development	**23,594**	19,500	16,038
	32,697	27,578	22,714

GW-funded research and development consists of payroll costs for research staff and associated overhead, cost of growing botanical raw material, research work and sponsorship of collaborative scientists, and external third party costs incurred in conducting clinical trials.

Development partner-funded research and development expenditures include the costs of employing staff to work on joint research and development plans, plus the costs of subcontracted pre-clinical studies and sponsorships of academic scientists who collaborate with the Group. These expenditures are charged to the Group's commercial partners, principally Otsuka. The Group is the primary obligor for these activities and under the terms of the Sativex development agreements and the Otsuka research collaboration agreement, the Group uses both its internal resources and third party contractors to provide contract research and development services to its commercial partners.

5. (Loss)/profit before Tax

(Loss)/profit before tax is stated after charging/(crediting):

	2013	2012	2011
	£000's	£000's	£000's
Operating lease rentals—land and buildings	**1,186**	1,036	782
Depreciation of property, plant and equipment—owned	**947**	744	541
Depreciation of property, plant and equipment—leased	**42**	10	48
Provision for inventories	**(530)**	(1,300)	(425)
Allowance for doubtful debts—trade receivables	**(26)**	26	—
Foreign exchange loss/(gain)	**237**	301	(96)
Staff costs (see note 7)	**10,686**	10,098	8,532

6. Auditor's remuneration

	2013	2012	2011
	£000's	£000's	£000's
The auditor for the years ended 30 September 2013, 2012 and 2011 were Deloitte LLP			
Audit fees:			
—Audit of the Company's annual accounts(1)	**70**	51	8
—Audit of the Company's subsidiaries pursuant to legislation	**40**	42	37
Total audit fees	**110**	93	45
Other services			
—Audit-related assurance(2)	**40**	5	5
—Other assurance services(3)	**306**	—	—
—All other services(4)	**—**	13	—
Total non-audit fees	**346**	18	5

(1) For the years ended 30 September 2013 and 2012, the audit fees include amounts for the audit of the Group in accordance with the PCAOB standards.

(2) Audit related assurance fees relate to fees for the performance of interim reviews.

(3) Other assurance services represents assurance reporting on historical financial information included in the Company's initial US registration statement.

(4) All other services represent other assurance services provided to the Group.

7. Staff Costs

The average number of Group employees (including Executive Directors) for the year ended 30 September was:

	2013 Number	2012 Number	2011 Number
Research and development	**170**	162	136
Management and administration	**18**	15	16
	188	177	152

	2013 £000's	2012 £000's	2011 £000's
Their aggregate remuneration comprised:			
Wages and salaries	**8,442**	7,700	6,443
Social security costs	**1,103**	926	865
Other pension costs	**525**	463	429
Share-based payment	**616**	1,009	795
	10,686	10,098	8,532

8. Directors' Remuneration

Directors' remuneration and other benefits for the year ended 30 September were as follows:

	2013 £000's	2012 £000's	2011 £000's
Emoluments	**1,733**	1,692	1,426
Money purchase contributions to Directors' pension arrangements	**200**	158	171
Gain on exercise of share options	**—**	122	225
	1,933	1,972	1,822

During 2013, five Directors were members of defined contribution pension schemes (2012 and 2011: four).

9. Interest

	2013 £000's	2012 £000's	2011 £000's
Interest expense—Finance lease interest	**(64)**	(1)	(3)
Interest income—Bank interest	**178**	200	263

10. Tax

a) Analysis of tax credit for the year

	2013	2012	2011
	£000's	£000's	£000's
Current year research and development tax credit	**(2,900)**	(820)	—
Adjustment in respect of prior year tax credit	**(2,012)**	(428)	(221)
Recognition of previously unrecognized deferred tax asset	**(2,872)**	—	—
Current year utilization of deferred tax assets	**1,977**	—	—
Tax credit	**(5,807)**	(1,248)	(221)

Tax credits relate to UK research and development tax credits claimed under the Finance Act 2000.

The Group has historically recognised uncertain benefits of enhanced research and development deductions and the resulting tax credits when certain acceptances of the claim has been reached with Her Majesty's Revenue and Customs (UK)("HMRC"), resulting in prior year adjustments to the tax credit as shown above. There is now a sustained history of agreeing such claims with HMRC, resulting in the recognition in the year ended 30 September 2013 of the full estimated benefit for qualifying current year research and development expenditures. Any difference in the credit ultimately received is recorded as an adjustment in respect of prior year.

During the current year, the Group reached an agreement with HMRC regarding the tax returns submitted for the year ended 30 September 2012. Pursuant to this agreement, HMRC agreed that the Group's principal research subsidiary company, GW Research Ltd., was able to surrender trading losses that arise from its research and development activity for a tax benefit. This agreement with HMRC resulted in an additional tax benefit being recorded in the current year due to: (i) the recognition of an additional £2.0m of research and development tax credits in respect of the year ended 30 September 2012 by GW Research Ltd. and (ii) the recognition of a £2.9m deferred tax asset in respect of cumulative trading losses which are utilisable against current and future trading profits by GW Pharma Ltd.

At 30 September 2013 the Group had tax losses available for carry forward of approximately £33.6m (2012: £40.9m, 2011: £46.0m). The Group has recognised a deferred tax asset in respect of £4.1m (2012: £nil) of such losses. The Group has not recognised deferred tax assets relating to the remaining carried forward losses, of approximately £29.5m (2012: £40.9m, 2011: £11.4m). In addition, the Group has not recognised deferred tax assets relating to other temporary differences of £1.7m (2012: £1.3m, 2011: £0.4m). These deferred tax assets have not been recognised as the Group's management considers that there is insufficient future taxable income, taxable temporary differences and feasible tax-planning strategies to utilise all of the cumulative losses and therefore it is probable that the deferred tax assets will not be realised in full. If future income differs from current projections, this could significantly impact the tax charge or benefit in future periods.

10. Tax (Continued)

b) Factors affecting the tax credit for the year

The tax credit for the year can be reconciled to the tax (credit)/charge on the Group (loss)/profit at the standard UK Corporation tax rate as follows:

	2013	2012	2011
	£000's	£000's	£000's
(Loss)/profit before tax	**(10,356)**	1,242	2,528
Tax charge on Group (loss)/profit at standard UK Corporation tax rate of 23.5% (2012: 25%, 2011: 27%)	**(2,434)**	311	682
Effects of:			
Expenses not deductible in determining taxable profit	**44**	—	3
Income not taxable in determining taxable profit	**(8)**	(4)	(45)
Current year research and development tax credit	**(2,900)**	(820)	—
R&D enhanced tax relief and surrender of losses	**2,225**	88	(1,275)
Effect of unrecognised losses and temporary differences	**2,150**	(395)	635
Recognition of previously unrecognized deferred tax asset	**(2,872)**	—	—
Adjustment in respect of prior year tax credit	**(2,012)**	(428)	(221)
Tax	**(5,807)**	(1,248)	(221)

The following are the major deferred tax liabilities and assets recognised by the Group and movements thereon during the current and prior reporting periods:

	Accelerated tax depreciation	Other temporary differences	Tax losses	Total
	£000's	£000's	£000's	£000's
At 1 October 2010	(149)	71	78	—
(Charged)/credited to profit or loss	(53)	131	(78)	—
At 1 October 2011	(202)	202	—	—
(Charged)/credited to profit or loss	(75)	75	—	—
At 1 October 2012	(277)	277	—	—
(Charged)/credited to profit or loss	(463)	(277)	1,635	895
At 30 September 2013	**(740)**	**—**	**1,635**	**895**

Deferred tax assets and liabilities have been offset where the Group has a legally enforceable right to do so, and intends to settle on a net basis. All entities in the Group operate in the same taxation jurisdiction and the taxing authority permits the Group to make or receive a single net payment.

On 2 July 2013, the UK Government substantively enacted a reduction in the main rate of corporation tax from 23% to 21% with effect from 1 April 2014. The rate will reduce further to 20% from 1 April 2015.

11. (Loss)/earnings Per Share

The calculations of (loss)/earnings per share are based on the following data:

	2013	2012	2011
	£000's	£000's	£000's
(Loss)/profit for the year—basic and diluted	**(4,549)**	2,490	2,749

	Number of shares		
	2013	2012	2011
	m	m	m
Weighted average number of ordinary shares	**151.5**	133.2	131.9
Less ESOP trust ordinary shares(1)	**—**	(0.2)	(0.2)
Weighted average number of ordinary shares for purposes of basic earnings per share	**151.5**	133.0	131.7
Effect of potentially dilutive shares arising from share options	**—**	4.5	3.9
Effect of potentially dilutive shares arising from warrants(2)	**—**	—	0.2
Weighted average number of ordinary shares for purposes of diluted earnings per share	**151.5**	137.5	135.8
(Loss)/earnings per share—basic	**(3.0p)**	1.9p	2.1p
(Loss)/earnings per share—diluted	**(3.0p)**	1.8p	2.0p

(1) As at 30 September 2013, 34,706 ordinary shares were held in the ESOP trust. The financial effect is less than 0.1m, and consequently these have not been presented above.

(2) We incurred a loss in the year ended 30 September 2013. As a result, the inclusion of potentially dilutive share options in the diluted loss per share calculation would have an antidilutive effect on the loss per share for the period. Therefore, the impact of 6.7 million share options have been excluded from the diluted loss per share calculation for the year ended 30 September 2013.

12. Intangible Assets—Goodwill

Group:	2013	2012
	£000's	£000's
Cost—As at 1 October	**5,210**	5,210
Accumulated impairment losses	**—**	—
Net book value—As at 30 September	**5,210**	5,210

Goodwill arose upon the acquisition of GW Research Ltd (formerly G-Pharm Ltd) by GW Pharma Limited in 2001. For impairment testing purposes, all goodwill has been allocated to the Sativex Commercial segment as a separate cash generating unit. The Group tests goodwill annually for impairment or more frequently if there are indications that goodwill might be impaired.

The recoverable amount of this cash-generating unit is determined based on a value in use calculation which uses cash flow projections based on financial budgets covering a five year period and a discount rate of 12% per annum (2012: 12% per annum). These projections take into account projected future product sales revenues. The Group models expected sales based upon the current in-market run rate. Expectations of future growth and timing of new launches are modelled based upon guidance from our marketing partners.

12. Intangible Assets—Goodwill (Continued)

Any reasonably possible change in the key assumptions on which recoverable amount is based would not cause the carrying amount to exceed the recoverable amount of the cash-generating unit. An impairment loss is recognised only if the carrying value of the cash generating unit exceeds the recoverable amount.

13. Property, Plant and Equipment

Group	Motor vehicles	Assets under the course of construction	Plant, machinery and lab equipment	Office and IT equipment	Leasehold improvements	Total
	£000's	£000's	£000's	£000's	£000's	£000's
Cost						
At 1 October 2011	11	—	3,545	1,122	1,110	5,788
Additions	—	—	500	235	583	1,318
Disposals	(11)	—	(403)	(490)	(504)	(1,408)
At 1 October 2012	—	—	3,642	867	1,189	5,698
Additions	—	1,164	630	225	2,014	4,033
At 30 September 2013	**—**	**1,164**	**4,272**	**1,092**	**3,203**	**9,731**
Accumulated depreciation						
At 1 October 2011	11	—	2,396	669	844	3,920
Charge for the year	—	—	392	195	167	754
Disposals	(11)	—	(403)	(490)	(504)	(1,408)
At 1 October 2012	—	—	2,385	374	507	3,266
Charge for the year	—	—	477	237	275	989
At 30 September 2013	**—**	**—**	**2,862**	**611**	**782**	**4,255**
Net book value						
At 30 September 2013	**—**	**1,164**	**1,410**	**481**	**2,421**	**5,476**
At 30 September 2012	—	—	1,257	493	682	2,432

The net book value of property, plant and equipment at 30 September 2013 includes £1.9m in respect of assets held under finance leases (2012: nil).

14. Inventories

	2013	2012
	£000's	£000's
Raw materials	**180**	312
Work in progress	**4,101**	2,951
Finished goods	**380**	274
	4,661	3,537

Inventory with a carrying value of £3.5m is considered to be recoverable after more than one year from the balance sheet date, but within the Group's normal operating cycle (2012: £2.3m).

14. Inventories (Continued)

The provision for inventories relates to inventories expected to expire before being utilised by the Group. The movement in the provision for inventories is as follows:

	2013	2012
	£000's	£000's
Opening balance—as at 1 October	**2,131**	3,431
Decrease in provision for inventories	**(530)**	(1,300)
As at 30 September	**1,601**	2,131

15. Financial Assets

Trade and Other Receivables

	Group	
	2013	2012
	£000's	£000's
Amounts falling due within one year		
Trade receivables	**621**	784
Provision for impairment—trade receivables	**—**	(26)
	621	758
Prepayments and accrued income	**763**	595
Other receivables	**349**	235
	1,733	1,588

Trade receivables disclosed above are classified as loans and receivables and are therefore measured at amortised cost.

Trade receivables at 30 September 2013 represent 8 days of sales (2012: 8 days). The average trade receivable days during the year ended 30 September 2013 was 34 days (2012: 31 days). The credit period extended to customers is 30 to 60 days.

The provision for impairment—trade receivables is £nil at 30 September 2013. £26,000 was considered to be impaired at 30 September 2012. This was subsequently reversed during the year ended 30 September 2013 following recovery in full of the related receivable. All trade receivables, aside from this individual receivable in the year ended 30 September 2012, were current at the balance sheet date as at 30 September 2013 and 2012.

	Group	
	2013	2012
	£000's	£000's
Movement in the allowance for doubtful debts		
Balance at the beginning of the period	**26**	—
Impairment losses recognised	**—**	26
Amounts recovered during the year	**(26)**	—
Balance at the end of the period	**—**	26

15. Financial Assets (Continued)

The trade receivables balance at 30 September 2013 consisted of balances due from seven customers (2012: six customers) with the largest single customer representing 35% (2012: 38%) of the total amount due. Given that the Group's customers consist of a small number of large pharmaceutical companies, counterparty credit risk is considered to be low. The Group seeks to mitigate credit risk by seeking payments in advance from pharmaceutical partners for expenditure to be incurred on their behalf.

No interest is charged on trade receivables.

The Directors consider that the carrying value of trade receivables approximates to their fair value.

16. Financial Liabilities

Trade and Other Payables

	Group	
	2013	2012
	£000's	£000's
Amounts falling due within one year		
Other creditors and accruals	**5,302**	4,437
Trade payables	**3,393**	4,090
Other taxation and social security	**745**	587
	9,440	9,114

Trade payables principally comprise amounts outstanding for trade purchases and on-going costs.

Trade payables at 30 September 2013 represent the equivalent of 36 days purchases (2012: 51 days).

The average credit period taken for trade purchases during the year ended 30 September 2013 was 39 days (2012: 31 days).

For most suppliers, no interest is charged on invoices that are paid within a pre-agreed trade credit period. The Group has procedures in place to ensure that invoices are paid within agreed credit terms so as to ensure that interest charges by suppliers are minimised.

The Directors consider that the carrying value of trade payables approximates to their fair value.

17. Obligations under Finance Leases

	Minimum lease payments	
	2013	2012
	£000's	£000's
Amounts payable under finance leases:		
Within one year	**177**	—
In the second to fifth years inclusive	**861**	—
After five years	**1,559**	—
	2,597	—
Less: future finance charges	**592**	—
Present value of lease obligations	**2,005**	—

	Present value of lease payments	
	2013	2012
	£000's	£000's
Amounts payable under finance leases:		
Amounts due for settlement within 12 months	**100**	—
Amounts due for settlement after 12 months	**1,905**	—
	2,005	—

It is the Group's policy to lease certain of its property, plant and equipment under finance leases. The weighted average lease term remaining is 13.9 years (2012: nil). For the year ended 30 September 2013, the average effective borrowing rate was 4% (2012: nil). Interest rates are fixed at the contract date. All leases to date have been on a fixed repayment basis and no arrangements have been entered into for contingent rental payments.

All lease obligations are denominated in sterling.

The carrying value of the Group's lease obligations as at 30 September 2013 approximates to their fair value.

The Group's obligations under finance leases are generally secured by the lessors' rights over the leased assets.

18. Deferred Revenue

	Group	
	2013	2012
	£000's	£000's
Amounts falling due within one year		
Deferred license, collaboration, and technical access fee income(1) .	**1,294**	1,378
Advance research and development fees(2)	**1,887**	1,071
	3,181	2,449
Amounts falling due after one year		
Deferred license, collaboration and technical access fee income(1) . .	**8,916**	10,127

(1) These deferred revenues result mainly from up-front license fees received in 2005 of £12.0 million from Almirall S.A. (deferred revenue balance as at 30 September 2013—£5.9 million and 30 September 2012—£6.6 million) and collaboration and technical access fees from other Sativex licensees. Amounts deferred under each agreement will be recognised in revenue as discussed in Note 2.

(2) Advance payments received represents payments for research and development activities to be carried out in the next year on behalf of Otsuka. These amounts will be recognised as revenue in future periods as the services are rendered.

19. Financial Instruments

The Group manages its capital to ensure that entities in the Group will be able to continue as going concerns while maximising return to shareholders. The Group's overall strategy remains unchanged from 2012.

Group senior management are responsible for monitoring and managing the financial risks relating to the operations of the Group, which include credit risk, market risks arising from interest rate risk and currency risk, and liquidity risk. The Board of Directors and the Audit Committee review and approve the internal policies for managing each of these risks, as summarised below. The Group is not subject to any externally imposed capital requirements.

19. Financial Instruments (Continued)

The Group's financial instruments, as at 30 September, are summarised below:

Categories of Financial Instruments

	2013	2012
	£000's	£000's
Financial assets		
Cash and cash equivalents	**38,069**	29,335
Taxation recoverable	**2,900**	820
Trade receivables—at amortised cost	**621**	758
Prepayments and accrued income	**763**	595
Other receivables	**349**	235
Total financial assets	**42,702**	31,743
Financial liabilities		
Other creditors and accruals	**5,302**	4,437
Trade payables—at amortised cost	**3,393**	4,090
Other taxation and social security	**745**	587
Obligations under finance leases	**2,005**	—
Total financial liabilities	**11,445**	9,114

All financial assets and financial liabilities, other than the non-current element of £1.9m in respect of the obligations under finance leases (2012: £nil), are current in nature. In all instances, the fair value of financial assets and financial liabilities approximates the carrying value due to the short-term nature of these instruments.

It is, and has been throughout the period under review, the Group's policy that no speculative trading in financial instruments shall be undertaken.

Credit Risk:

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in financial loss to the Group. The Group has a policy of only dealing with creditworthy counterparties, principally involving the major UK clearing banks and their wholly owned subsidiaries, when placing cash on deposit. In addition the Group operates a treasury policy that dictates the maximum cash balance that may be placed on deposit with any single institution or group. This policy is reviewed and approved from time to time by the Audit Committee and the Board of Directors.

Trade receivables represent amounts due from customers for the sale of commercial product and research funding from development partners, consisting primarily of a small number of major pharmaceutical companies where the credit risk is considered to be low. The Group seeks to minimise credit risk by offering only 30 days credit to commercial customers and by requesting payment in advance from its development partners for the majority of its research activities.

At the balance sheet date the maximum credit risk attributable to any individual counterparty was £11.2m (2012: £13.0m).

Trade receivables at 30 September 2013 to the value of £nil (2012: £26,000) were past their due date and were provided against in full.

19. Financial Instruments (Continued)

The carrying amount of the financial assets recorded in the financial statements represents the Group's maximum exposure to credit risk as no collateral or other credit enhancements are held.

Market Risk:

The Group's activities expose it primarily to financial risks of changes in interest rates and foreign currency exchange rates. These risks are managed by maintaining an appropriate mix of cash deposits in various currencies, placed with a variety of financial institutions for varying periods according to the Group's expected liquidity requirements. There has been no material change to the Group's exposure to market risks or the manner in which it manages and measures risk.

i) Interest Rate Risk

The Group is exposed to interest rate risk as it places surplus cash funds on deposit to earn interest income. The Group seeks to ensure that it consistently earns commercially competitive interest rates by using the services of an independent broker to identify and secure the best commercially available interest rates from those banks that meet the Group's stringent counterparty credit rating criteria. In doing so the Group manages the term of cash deposits, up to a maximum of 365 days, in order to maximise interest earnings while also ensuring that it maintains sufficient readily available cash in order to meet short-term liquidity needs.

Interest income of £0.2m (2012: £0.2m; 2011: £0.3m) during the year ended 30 September 2013 was earned from deposits with a weighted average interest rate of 0.97% (2012: 1.00%; 2011: 0.86%). Therefore, a 100 basis point increase in interest rates would have increased interest income, and reduced the loss for the year, by £0.2m (2012: increased profit by £0.2m; 2011: increased profit by £0.3m).

The Group does not have any balance sheet exposure to assets or liabilities which would increase or decrease in fair value with changes to interest rates.

ii) Currency Risk

The functional currency of the Company, and each of its subsidiaries, is pounds sterling and the majority of transactions in the Group are denominated in that currency. However, the Group receives revenues and incurs expenditures in foreign currencies and is exposed to the risks of foreign exchange rate movements, with the impacted recognised which are recorded in the consolidated income statement. The Group seeks to minimise this exposure by passively maintaining foreign currency cash balances at levels appropriate to meet foreseeable foreign currency expenditures, converting surplus foreign currency balances into pounds as soon as they arise. The Group does not use derivative contracts to manage exchange rate exposure.

19. Financial Instruments (Continued)

The table below shows an analysis of the sterling equivalent of the year end cash and cash equivalents balances by currency:

	2013	2012
	£000's	£000's
Cash at bank and in hand:		
Sterling	**4,312**	7,779
Euro	**776**	683
US Dollar	**5,201**	4,600
Canadian Dollar	**227**	228
Total	**10,516**	13,290
Short-term deposits:		
Sterling	**27,553**	16,045
Total cash and cash equivalents	**38,069**	29,335

The table below shows those transactional exposures that give rise to net currency gains and losses recognised in the consolidated income statement. Such exposures comprise the net monetary assets and monetary liabilities of the Group that are not denominated in the functional currency of the relevant Group entity. As at 30 September these exposures were as follows:

Net Foreign Currency Assets/(Liabilities):

	2013	2012
	£000's	£000's
US Dollar	**2,424**	355
Euro	**710**	396
Canadian Dollar	**432**	464
Other	**(51)**	(24)
	3,515	1,191

Foreign Currency Sensitivity Analysis:

The most significant currencies in which the Group transacts, other than Sterling, are the US Dollar and the Euro. The Group also trades in the Canadian Dollar; the Czech Crown and the Polish Zloty. The following table details the Group's sensitivity to a 10% change in the key foreign currency exchange rates against sterling:

Year Ended 30 September 2013	Euro	US Dollar	Can Dollar	Other
	£'000	£'000	£'000	£'000
Profit before tax	**71**	**242**	**43**	**(5)**
Equity	**71**	**242**	**43**	**(5)**

19. Financial Instruments (Continued)

Year Ended 30 September 2012	Euro	US Dollar	Can Dollar	Other
	£'000	£'000	£'000	£'000
Profit before tax	40	36	46	(2)
Equity	40	36	46	(2)

Year Ended 30 September 2011	Euro	US Dollar	Can Dollar	Other
	£'000	£'000	£'000	£'000
Profit before tax	90	99	22	(4)
Equity	90	99	22	(4)

Liquidity Risk:

Responsibility for liquidity risk management rests with the Board of Directors, which has built a liquidity risk management framework to enable the monitoring and management of short, medium and long term cash requirements of the business.

The Board of Directors actively monitor Group cash flows and regularly review projections of future cash requirements to ensure that appropriate levels of liquidity are maintained. The Group manages its short term liquidity primarily by planning the maturity dates of cash deposits in order to time the availability of funds as liabilities fall due for payment. The Group does not maintain any borrowing facilities.

Cash deposits, classified as cash and cash equivalents on the balance sheet, comprise deposits placed on money markets for periods of up to three months and on call. The weighted average time for which the rate was fixed was 38 days (2012: 50 days).

All of the Group's financial liabilities at each balance sheet date have maturity dates of less than 12 months from the balance sheet date, other than the long-term obligations under finance leases of £1.9m (2012: £nil) which will be repaid over a weighted average 13.9 year term. There have been no material changes to the Group's exposure to liquidity risks or the manner in which it manages and measures liquidity risk.

20. Share Capital

As at 30 September 2013 the share capital of the Company allotted, called-up and fully paid was as follows:

	2013	2012
	£000's	£000's
Allotted, called-up and fully paid	**178**	133

20. Share Capital (Continued)

Changes to the number of ordinary shares in issue have been as follows:

	Number of shares	Total nominal value	Total share premium	Total consideration
		£000's	£000's	£000's
As at 1 October 2011	133,055,154	133	65,866	65,999
Exercise of share options	315,200	—	81	81
As at 30 September 2012	133,370,354	133	65,947	66,080
Issue of new shares	44,136,000	45	18,055	18,100
Exercise of share options	14,933	—	3	3
As at 30 September 2013	**177,521,287**	**178**	**84,005**	**84,183**

During the year ended 30 September 2013 the Group completed an Initial Public Offering on the NASDAQ Global Market, issuing 44,136,000 shares for net consideration of £18.1 million. This took the form of 3,678,000 American depositary shares ("ADSs") at a price to the public of $8.90 per ADS. Each ADS represents 12 ordinary shares of 0.1p each in the capital of the Company.

The Company has one class of ordinary shares which carry no right to fixed income.

Equity-settled share option schemes

The Company operates various equity-settled share option schemes for employees of the Group. In addition, options have been issued to a small number of expert consultants in return for services provided to the Group.

All options granted under these schemes are exercisable at the share price on the date of the grant, with the exception of options issued under the GW Pharmaceuticals Long Term Incentive Plan ("LTIP") which are issued with an exercise price equivalent to the par value of the shares under option.

The vesting period for all options granted is three years from the date of grant and options lapse after 10 years.

Options generally also lapse if the employee leaves the Group before the options vest. However, at the discretion of the Remuneration Committee, under the "Good Leaver" provisions of the share option scheme rules, employees may be allowed to retain some or all of the share options upon ceasing employment by the Group. Vested options usually need to be exercised within six months of leaving.

Under the terms of the LTIP employees are awarded options to subscribe for the Company's ordinary shares at an exercise price equivalent to the par value of the shares under option. These options are subject to performance conditions which must be achieved before the options vest and become exercisable. In the event that the performance conditions are not achieved within the required three year vesting period these options lapse. Once vested, an LTIP award may be exercised at any time prior to the tenth anniversary of the date of grant.

21. Share-based payments

LTIP awards granted to Executive Directors are subject to performance conditions which are determined by the Remuneration Committee. These are usually a mixture of market-based and

21. Share-based payments (Continued)

non-market based performance conditions which are intended to link executive compensation to the key value drivers for the business whilst aligning the interests of the Executive Directors with those of shareholders and employees.

2010 awards

The vesting period of the 2010 awards completed on 19 July 2013. These awards were subdivided into four equal tranches, dependent upon four separate performance conditions. Two of the performance conditions were met. One unmet performance conditions was a marked-based performance condition, and therefore no reversal of the charge is permitted. The remaining unmet performance condition was a non-market-based performance condition. The reversal of this charge was £0.3m.

2011 awards

In the year ended 30 September 2011, all awards granted were LTIP awards.

The 2011 LTIP awards are subject to a performance condition whereby the number of options vesting on the third anniversary of the date of grant will be determined according to the performance of the Company share price relative to a comparator group consisting of the constituents of the FTSE small cap index. LTIP awards will vest if the Company is ranked at median or above in relation to the group. 25% of the award vests if the Company achieves median ranking, with 100% vesting if an upper quartile ranking is achieved. A straight line approach is used to calculate the percentage vesting between these two extremes.

2012 awards

In the year ended 30 September 2012, all awards granted were LTIP awards.

The 2012 LTIP awards are subdivided into four equal tranches, each of which vests on 6 June 2015 upon achievement of the following performance conditions:

- one quarter of the award vests upon achievement of first positive cancer pain clinical trial results;
- one quarter of the award vests upon filing of a New Drug Application ("NDA") for Sativex with the US Food and Drug Administration ("FDA");
- one quarter of the award vests upon signature of a new non-Sativex product license agreement; and
- one quarter of the award vests subject to the Company share price performance over the three year vesting period. This will be ranked against the share price performance of a comparator group made up of the constituents of the FTSE Smallcap index. Awards will only vest if the Company is ranked at Median or above. 25% of this element of the award will vest if the Company achieves a Median ranking and 100% will vest if the Company achieves an Upper Quartile ranking, with a straight line approach used to calculate the percentage vesting between these two extremes.

21. Share-based payments (Continued)

2013 awards

In the year ended 30 September 2013, all awards granted were LTIP awards.

The 2013 LTIP awards are subject to performance conditions whereby 100% of the awards vest on the third anniversary of the date of the grant if the ADS price has increased by 75% or more during the three year vesting period ended 24 September 2016. 25% of the awards vests if 25% growth is achieved, with a straight line basis of calculation being used to calculate the number of options vesting between these two extremes. No options vest if the share price growth is below 25% over the three year vesting period.

The starting price for the growth calculation for the 2013 award is based on the US dollar equivalent of the average closing mid-market price of twelve AIM listed Ordinary shares, as calculated over the last 30 trading days prior to the Nasdaq IPO on 1 May 2013. This price of $10.37, equivalent to 56.6 pence per UK Ordinary share, will be compared to the US dollar denominated average mid-market closing price of the ADS, calculated by reference to the last 30 trading days of the 3 year vesting period.

The number of outstanding options under each scheme can be summarised as follows:

	30 Sept 2013 Number of share options	30 Sept 2012 Number of share options
Employee share option schemes	**5,535,581**	6,462,379
Employee LTIP awards	**6,778,743**	4,591,765
Consultant share options	**425,856**	612,456
Options outstanding at 30 September	**12,740,180**	11,666,600

The movement in share options in each scheme during the year can be summarised as follows:

	Employee options		Employee LTIP		Consultant options		Total options	
	Number of share options	Weighted average exercise price	Number of share options	Weighted average exercise price	Number of share options	Weighted average exercise price	Number of share options	Weighted average exercise price
		£		£		£		£
Outstanding at 1 October 2011	**6,867,829**	**1.23**	**3,458,345**	**0.001**	**714,956**	**1.32**	**11,041,130**	**0.85**
Granted during the year	—	—	1,326,770	0.001	—	—	1,326,770	0.001
Exercised during the year	(95,200)	0.76	(190,000)	0.001	(30,000)	0.29	(315,200)	0.26
Expired during the year	(310,250)	1.14	(3,350)	0.001	(72,500)	1.22	(386,100)	1.15
Outstanding at 1 October 2012	**6,462,379**	**1.24**	**4,591,765**	**0.001**	**612,456**	**0.76**	**11,666,600**	**0.76**
Granted during the year	—	—	2,679,374	0.001	—	—	2,679,374	0.001
Exercised during the year	(5,800)	0.54	(9,133)	0.001	—	—	(14,933)	0.21
Expired during the year	(920,998)	1.71	(483,263)	0.001	(186,600)	1.61	(1,590,861)	1.34
Outstanding at 30 September 2013	**5,535,581**	**1.16**	**6,778,743**	**0.001**	**425,856**	**1.28**	**12,740,180**	**0.57**

21. Share-based payments (Continued)

Share options outstanding at 30 September 2013 can be summarised as follows:

Range of exercise prices	Employee options Number of share options	Weighted average remaining contractual life/years	Employee LTIP Number of share options	Weighted average remaining contractual life/years	Consultant options Number of share options	Weighted average remaining contractual life/years	Total options Number of share options	Weighted average remaining contractual life/years
£0.01 - £0.50	**10,000**	**5.0**	**6,778,743**	**8.5**	**30,000**	**6.2**	**6,818,743**	**8.5**
£0.51 - £1.00	**3,016,817**	**2.5**	**—**	**—**	**35,000**	**0.9**	**3,051,817**	**2.5**
£1.01 - £1.50	**1,656,372**	**1.7**	**—**	**—**	**288,496**	**1.5**	**1,944,868**	**1.7**
£1.51 - £2.00	**852,392**	**0.3**	**—**	**—**	**72,360**	**0.3**	**924,752**	**0.3**
Outstanding at 30 September 2013	**5,535,581**	**1.9**	**6,778,743**	**8.5**	**425,856**	**1.6**	**12,740,180**	**5.4**
Exercisable at 30 September 2013	**5,535,581**	**1.9**	**2,342,099**	**5.8**	**425,856**	**1.6**	**8,303,536**	**3.0**

Share options outstanding at 30 September 2012 can be summarised as follows:

Range of exercise prices	Employee options Number of share options	Weighted average remaining contractual life/years	Employee LTIP Number of share options	Weighted average remaining contractual life/years	Consultant options Number of share options	Weighted average remaining contractual life/years	Total options Number of share options	Weighted average remaining contractual life/years
£0.01 - £0.50	**10,000**	**6.0**	**4,591,765**	**7.9**	**30,000**	**7.2**	**4,631,765**	**7.9**
£0.51 - £1.00	**3,025,117**	**3.5**	**—**	**—**	**85,000**	**0.8**	**3,110,117**	**3.4**
£1.01 - £1.50	**1,656,372**	**2.8**	**—**	**—**	**375,096**	**2.6**	**2,031,468**	**2.8**
£1.51 - £2.00	**918,498**	**0.3**	**—**	**—**	**72,360**	**0.8**	**990,858**	**0.3**
£2.01 - £2.50	**852,392**	**1.3**	**—**	**—**	**50,000**	**0.8**	**902,392**	**1.3**
Outstanding at 30 September 2012	**6,462,379**	**2.6**	**4,591,765**	**7.9**	**612,456**	**1.9**	**11,666,600**	**4.7**
Exercisable at 30 September 2012	**6,462,379**	**2.6**	**1,443,132**	**6.1**	**612,456**	**1.9**	**8,517,967**	**3.1**

Charges for share based payments have been allocated to the research and development expenditure and management and administrative expenses in the consolidated income statements as follows:

	2013 £000's	2012 £000's
Research and development expenditure	**317**	559
Management and administrative expenses	**299**	450
	616	1,009

In the year ended 30 September 2013, options were granted on 30 November 2012, 20 February 2013, 28 March 2013 and 24 September 2013. The aggregate of the estimated fair values of the options granted on those dates is £1.5m and the weighted average fair value of the awards made during 2013 was £0.57 per option.

In the year ended 30 September 2012, options were granted on 15 December 2011, 23 March 2012, 31 May 2012, 6 June 2012 and 1 July 2012. The aggregate of the estimated fair values of the options

21. Share-based payments (Continued)

granted on those dates is £1.1m and the weighted average fair value of the awards made during 2012 was £0.82 per option.

Fair values were calculated using the Black-Scholes share option pricing model for grants with non-market based performance conditions. The Monte Carlo share option pricing model has been used for grants with market based performance conditions. The following weighted average assumptions were used in calculating these fair values:

	2013	2012
Weighted average share price	**55p**	83p
Weighted average exercise price	**0.1p**	0.1p
Expected volatility	**44%**	52%
Expected life	**5.0 Years**	5.0 Years
Risk-free rate	**0.5%**	0.5%
Expected dividend yield	**Nil**	Nil

Expected volatility was determined by calculating the historical volatility of the Group's share price over the previous three years. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, performance conditions and behavioural considerations.

22. Warrants

Warrants to subscribe for ordinary shares in the Company are as shown below:

	At 1 Oct 2012 Number	Warrants granted Number	Warrants exercised Number	Warrants lapsed Number	At 30 Sept 2013 Number	Date of issue	Exercise price	Date of expiry
Warrant Holder								
Great Point Partners	1,888,480	—	—	—	**1,888,480**	13/08/09	105.0p	13/08/14
Great Point Partners	1,888,480	—	—	—	**1,888,480**	13/08/09	175.0p	13/08/14
Total	3,776,960	—	—	—	**3,776,960**			

The above warrants were issued to Great Point Partners on 13 August 2009 at a time when the mid-market price for ordinary shares of the Company was 78.0 pence. The warrant issue was concurrent with the issue of 7,553,920 new ordinary shares to Great Point partners at 78.0 pence per share.

The warrants can be exercised at any time prior to their expiry on 13 August 2014.

23. Other Reserves

Other reserves of £20.2m relate to a £19.3m merger reserve and a £0.9m warrants reserve. The warrants reserve is discussed in note 22. The merger reserve was created as a result of the acquisition by the Company of the entire issued share capital of GW Pharma Ltd in 2001. This acquisition was effected by a share for share exchange which was merger accounted under UK Generally Accepted Accounting Practice, or UK GAAP, in accordance with the merger relief provisions of section 131 of the Companies Act 1985 (as amended) relating to the accounting for business combinations involving the issue of shares at a premium. In preparing consolidated financial statements, the amount by which

23. Other Reserves (Continued)

the fair value of the shares issued exceeded their nominal value was recorded in a merger reserve on consolidation, rather than in a share premium account. The merger reserve was retained upon transition to IFRS, as allowed under UK law. This reserve is not considered to be distributable.

ESOP Reserve

The Group's "ESOP" is an Inland Revenue approved all employee share scheme constituted under a trust deed. The trust holds shares in the Company for the benefit of and as an incentive for the employees of the Group. The trustee of the ESOP is GWP Trustee Company Limited, a wholly owned subsidiary of the Company. Costs incurred by the trust are expensed in the Group's financial statements as incurred. Distributions from the trust are made in accordance with the scheme rules and on the recommendation of the Board of Directors of the Company.

Shares held in trust represent issued and fully paid up 0.1 pence ordinary shares and remain eligible to receive dividends. The shares held by the ESOP were originally acquired in 2000 for nil consideration by way of a gift from a shareholder and hence the balance on the ESOP reserve is nil (2012: nil).

As at 30 September the ESOP held the following shares:

	2013 Number	2012 Number
Unconditionally vested in employees	**374,408**	228,607
Conditionally gifted to employees	**—**	173,951
Shares available for future distribution to employees	**34,706**	34,706
Total	**409,114**	437,264

The valuation methodology used to compute the share-based payment charge related to the ESOP is based on fair value at the grant date, which is determined by the application of a Black-Scholes share option pricing model. The assumptions underlying the Black-Scholes model for the ESOP shares are as detailed in Note 21 relating to the LTIP awards. The exercise price for shares granted under the ESOP is nil, and the vesting conditions include employment by the Group over the three year vesting period from the date of grant. The share-based payment charge for shares granted under the ESOP plan amounted to £nil in the year ended 30 September 2013 (2012: £33,441).

As at 30 September 2013 the number and market value of shares held by the trust which have not yet unconditionally vested in employees is 34,706 (2012: 208,657) and £nil (2012: £0.2m) respectively.

24. Financial Commitments

The Group had capital commitments for property, plant and equipment contracted but not provided for at 30 September 2013 of £0.1m (2012: £0.1m).

24. Financial Commitments (Continued)

At the balance sheet date the Group had outstanding commitments for future minimum lease payments under non-cancellable operating leases, which fall due as follows:

	Group	
	2013	2012
	£000's	£000's
—within one year	**1,136**	987
—between two and five years	**2,028**	2,375
—after five years	**807**	—
	3,971	3,362

The minimum lease payments payable under operating leases recognised as an expense in the year were £1.2m (2012: £1.0m).

Operating lease payments represent rentals payable by the Group for certain of its leased properties. Manufacturing and laboratory facilities are subject to 10 to 15 year leases with a lease break three years prior to the conclusion of the lease at the Group's option. Office properties are usually leased for one year or less with the exception of the London property, which is on a five year lease and the Histon property which is on a ten year lease with a five year break.

25. Contingent Liabilities

The Group may, from time to time, be involved in legal proceedings that are incidental to the Group operations. The Group is not currently involved in any legal or arbitration proceedings which may have, or have had in the 12 months preceding the date of this report, a material effect on the consolidated financial position, results of operations or liquidity of the Group.

26. Related Party Transactions

Remuneration of Key Management Personnel:

The remuneration of the Directors, who are the key management personnel of the Group, is set out below in aggregate for each of the categories specified in IAS 24 Related Party Disclosures.

	2013	2012	2011
	£000's	£000's	£000's
Short term employee benefits	**1,733**	1,664	1,426
Post-employment benefits	**200**	158	171
Share-based payments	**539**	831	625
	2,472	2,653	2,222

Other Related Party Transactions:

During the year the Group purchased services in the ordinary course of business from Brian Whittle Associates Limited, a company controlled by Brian Whittle, a former Director and substantial shareholder of the Company, at a cost of £4,000 (2012: £3,000; 2011: £19,000). As at 30 September 2013 there was no amount due to Brian Whittle Associates Limited (2012: nil; 2011: nil).

26. Related Party Transactions (Continued)

Upon the retirement of David Kirk from the Board of Directors of the Company, on 1 June 2012, the Remuneration Committee agreed that, in accordance with the "Good Leaver" provisions of the share option scheme rules, David Kirk would be allowed to retain all of his outstanding share options after leaving the employment of the Group.

This includes:

- 1.2m share options, with a weighted average exercise price of £1.48 and a weighted average time to expiry of 1.9 years.
- 0.3m of vested LTIP awards with a 0.1 pence exercise price and a weighted average time to expiry of 6.0 years.
- 0.3m of unvested LTIP award, with a 0.1 pence exercise price and weighted average time to expiry of 8.25 years.

Subsequently, 0.5 m of the share options and 0.1m of the unvested LTIP award have lapsed. The remaining unvested options remain subject to the performance conditions and shall only become exercisable if the Group achieves the performance conditions before the vesting date. All vested options shall remain available to exercise at any time prior to their expiry upon the tenth anniversary of their date of grant.

27. Investments

The Group has investments in the following significant subsidiary undertakings:

Name of undertaking	Country of registration	Activity	% holding
GW Pharma Limited	England and Wales	Research and Development	100
GW Research Limited	England and Wales	Research and Development	100
Cannabinoid Research Institute Limited .	England and Wales	Research and Development	100
Guernsey Pharmaceuticals Limited	Guernsey	Research and Development	100
GWP Trustee Company Limited	England and Wales	Employee Share Ownership	100
G-Pharm Trustee Company Limited	England and Wales	Dormant	100
G-Pharm Limited	England and Wales	Dormant	100

All the subsidiary undertakings are included in the consolidated accounts.

28. Subsequent events

Subsequent to the year-end, on 12 November 2013, the Group entered into an arrangement for the construction of new 10,000 sq. ft. manufacturing lease premises. As part of the agreement of the lease, the landlord will provide up to £7.8m of fit out funding as a finance lease, to be repaid via rentals of £1.0m over the first fifteen years of the twenty year lease term. Construction is expected to start in December 2013 and be completed in 2015.

Corporate Information

Board of Directors

Dr Geoffrey W Guy BSc, MB BS, MRCS Eng, LRCP, LMSSA, Dip Pharm Med
Chairman

James Noble MA, FCA
Non-executive Deputy Chairman

Justin Gover BSc, MBA
Chief Executive Officer

Adam George, BSc, ACA
Chief Financial Officer

Dr Stephen Wright MA, MD, FRCPE, FFPM
Research & Development Director

Chris Tovey, BSc
Operating Officer

Thomas Lynch BSc (Econ), FCA
Non-executive Director

Cabot Brown AB, MBA
Non-executive Director

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Stock Listing

Our shares are traded both on AIM under the symbol "GWP" and on the NASDAQ Global Market under the symbol "GWPH".

Investor Relations

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Forward-looking statements:

This annual report contains forward-looking statements that reflect GW's current expectations regarding future events. Forward-looking statements involve risks and uncertainties. Actual results and events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the success of GW's research strategies, the applicability of the discoveries made therein, the successful and timely completion of uncertainties related to the regulatory process, and the acceptance of Sativex and other products by consumer and medical professionals. A further list and description of risks, uncertainties and other risks associated with an investment in GW can be found in GW's filings with the U.S. Securities and Exchange Commission, including the Company's 20-F as filed on November 25, 2013. 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.

SEC Form 20-F

A copy of our annual report filed with the Securities and Exchange Commission on Form 20-F is available without charge by calling or writing to our registered office address provided above.

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