Capstone Therapeutics Corp. Form S-8
June 17, 2014

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM S-8 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

CAPSTONE THERAPEUTICS CORP.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 86-0585310 (IRS Employer Identification No.)

12 75 West Washington Street, Suite 104, Tempe, Arizona, 85281 (Address of principal executive offices) (Zip Code)

CAPSTONE THERAPEUTICS CORP. 2005 EQUITY INCENTIVE PLAN (Full title of the plan)

John M. Holliman, III
Executive Chairman
Capstone Therapeutics Corp.
12 75 West Washington Street, Suite 104
Tempe, Arizona, 85281
(Name and address of agent for service)
(602) 286-5520

(Telephone number, including area code, of agent for service)

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [] Accelerated filer [] Non-accelerated filer [] (Do not check if a smaller reporting company) Smaller reporting company [x]

CALCULATION OF REGISTRATION FEE

Title of securities to be registered

Amount to be registered

Amount to be registered

registered

offering price aggregate per

offering

Common Stock, par value \$.0005 per share (1)	500,000 shares (2)	share \$ 0.26 (3), (4)	price \$130,000 (3)	\$16.74 (5)
(1) The securities to be registed	ered include optio	ons to acquire Cor	mmon Stock.	

- (2) This Registration Statement covers the 500,000 additional shares available for grant under the Capstone Therapeutics Corp. 2005 Equity Incentive Plan (the "2005 Plan") authorized by stockholders at the 2014 Annual Meeting of Stockholders. This Registration Statement shall also cover any additional shares of Common Stock which become issuable under the 2005 Plan by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the Registrant's receipt of consideration which results in an increase in the number of the outstanding shares of the Registrant's Common Stock.
- (3) Estimated solely for the purpose of calculating the amount of the registration fee and, pursuant to Rules 457(c) and 457(h) of the Securities Act of 1933, as amended, based upon the weighted average purchase price of shares subject to outstanding options, and, as to shares not currently subject to outstanding options, the average of the high and low prices as reported on the OTCQB on June 13, 2014, for shares of the Registrant's Common Stock.
- (4) The actual offering price will be determined in accordance with the terms of the 2005 Plan.
- (5)The filing fee of \$16.74 has been previously paid. In connection with Capstone Therapeutics Corp.'s (formerly OrthoLogic Corp.) registration statement on Form S-3 filed August 9, 2005, as amended on August 17, 2005, Commission File No. 333-127356, the Registrant paid a total of \$11,770 in filing fees. The offering was later withdrawn, no securities having been sold thereunder, leaving a balance of \$11,770. The Registrant applied \$708.91 of this balance to its registration statement on Form S-3 filed April 13, 2006, Commission File no. 333-133273, which was later withdrawn, no securities having been sold thereunder, leaving a balance of \$11,770. The Registrant applied \$256.62 to its registration statement on Form S-3 filed April 25, 2006, Commission File no. 333-133530, leaving a balance of \$11,513.38. The Registrant applied \$378.78 to its registration statement on Form S-8 filed June 13, 2006, Commission File no. 333-134980, leaving a balance of \$11,134.60. The Registrant applied \$280.60 to its registration statement on Form S-3 filed October 3, 2006, Commission File no. 333-137754, leaving a balance of \$10,854. The Registrant applied \$41.85 to its registration statement on Form S-8 filed May 14, 2009, Commission File no. 333-159238, leaving a balance of \$10,812.15. It is from this balance that the Registrant wishes to pay the filing fee for this registration statement on Form S-8.

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EXPLANATORY NOTE

This Registration Statement on Form S-8 (this "Registration Statement") registers additional securities of the same class as other securities for which effective registration statements on Form S-8, relating to the Capstone Therapeutics Corp. 2005 Equity Incentive Plan (the "2005 Plan"), have been filed. This Registration Statement covers 500,000 shares of Common Stock, par value \$.0005 per share, which together with the 3,250,000 shares already registered, constitute 3,750,000 shares of Common Stock registered for issuance under the 2005 Plan.

This Registration Statement has been prepared and filed pursuant to and in accordance with the requirements of General Instruction E to Form S-8 for the purpose of effecting the registration under the Securities Act of 1933, as amended, of the additional 500,000 shares of Common Stock subject to issuance under the 2005 Plan. Pursuant to General Instruction E to Form S-8, the contents of the Registration Statements on Form S-8 filed with the Securities and Exchange Commission on June 13, 2006 (No. 333-134980 and May 14, 2009 (No.333-159238)) are hereby incorporated by reference.

PART II

INFORMATION REQUIRED IN THE REGISTRATION STATEMENT

Item 3. Incorporation of Documents by Reference.

Capstone Therapeutics Corp. (the "Registrant") hereby incorporates by reference into this Registration Statement the following documents previously filed with the Securities and Exchange Commission (the "Commission"):

- (a) The Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 filed with the Commission on March 27, 2014;
- (b) All other reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "1934 Act") since the end of the fiscal year covered by the Registrant's Annual Report referred to in (a) above; and
- (c) The description of the Registrant's Common Stock contained in its Registration Statement on Forms 8-A filed with the Commission June 9, 2011, and any further amendment or report updating that description.

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All reports and definitive proxy or information statements filed pursuant to Section 13(a), 13(c), 14 or 15(d) of the 1934 Act after the date of this Registration Statement and prior to the filing of a post-effective amendment which indicates that all securities offered hereby have been sold or which de-registers all securities then remaining unsold shall be deemed to be incorporated by reference into this Registration Statement and to be a part hereof from the date of filing of such documents. Unless expressly incorporated into this Registration Statement, a report furnished on Form 8-K under the 1934 Act shall not be incorporated by reference into this Registration Statement. Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained herein or in any subsequently filed document which also is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Registration Statement.

Item 8. Exhibits.

See the Exhibit Index which is incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Tempe, State of Arizona, on June 17, 2014.

CAPSTONE THERAPEUTICS CORP. (Registrant)

By: /s/ John M. Holliman, III John M. Holliman, III Executive Chairman

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John M. Holliman, III and Les M. Taeger, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, and any other regulatory authority, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Person

Title

Date

/s/ John M. Holliman, III Executive Chairman (Principal June 17, 2014 John M. Holliman, III Executive Officer) and Director

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/s/ Les M. Taeger Les M. Taeger	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	June 17, 2014
/s/ Eric W. Fangmann Eric W. Fangmann	Director	June 17, 2014
/s/ Fredric J. Feldman Fredric J. Feldman, Ph.D.	Director	June 17, 2014
/s/ Elwood D. Howse, Jr. Elwood D. Howse, Jr.	Director	June 17, 2014

CAPSTONE THERAPEUTICS CORP.

EXHIBIT INDEX TO FORM S-8 REGISTRATION STATEMENT

Exhibit	Description	Incorporated Herein by	Filed Herewith
Number		Reference To	
5.1	Opinion of Quarles & Brady LLP		X
23.1	Consent of Moss Adams LLP,		X
	Independent Registered Public		
	Accounting Firm		
23.2	Consent of Quarles & Brady LLP		Included in Exhibit 5.1 of
	•		this Registration Statement
24.1	Powers of Attorney		See signature page S-1 of
	·		this Registration Statement
99.1	2005 Equity Incentive Plan	Exhibit 10.1 to the Registrant's	
		Current Report on Form 8-K filed	
		with the Commission on May 18,	
		2006	
99.2	Amendment to 2005 Equity	Exhibit 10.2 to the Registrant's	
	Incentive Plan	Current Report on Form 8-K filed	
		with the Commission on May 14,	
		2009	
99.3	Amendment to 2005 Equity		X
	Incentive Plan		

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E="margin-top:6pt; margin-bottom:0pt; margin-left:12%; font-size:10pt; font-family:Times New Roman">The integrity of our data is essential to success in all stages of the research data lifecycle: design, generation, recording and management, analysis, reporting and storage and retrieval. Our research data is governed by legislation and regulatory requirements.

Research data and supporting documents are core components at various stages of pipeline progression decision-making and also form the content of regulatory submissions. Poor data integrity can compromise our

research efforts.

There are innate complexities and interdependencies required for regulatory filings, particularly given our global research and development footprint. Rapid changes in submission requirements in developing countries continue to increase the complexity of worldwide product registration.

Failure to manage environment, health and safety and sustainability (EHSS) risks consistent with the Group s ethics, objectives, policies and relevant laws and regulations.

Risk impact

Failure to manage EHSS risks could lead to significant harm to people, the environment and communities in which we operate, fines, failure to meet stakeholder expectations and regulatory requirements, litigation or regulatory action, and damage to the Group s reputation and could materially and adversely affect our financial results.

Context

The Group is subject to health, safety and environmental laws of various jurisdictions. These laws impose duties to protect people, the environment and the communities in which we operate as well as potential obligations to remediate contaminated sites. We have also been identified as a potentially responsible party under the US Comprehensive Environmental Response Compensation and Liability Act at a number of sites for remediation costs relating to our use or ownership of such sites. Failure to manage these environmental risks properly could result in litigation, regulatory action and additional remedial costs that may materially and adversely affect our financial results. See Note 45 to the financial statements, Legal proceedings, for a discussion of the environmental related proceedings in which we are involved. We routinely accrue amounts related to our liabilities for such matters.

Risk to the Group s business activity if critical or sensitive computer systems or information are not available when needed, are accessed by those not authorised, or are deliberately changed or corrupted.

Risk impact

Failure to adequately protect critical and sensitive systems and information may result in our inability to maintain patent rights, loss of commercial or strategic advantage, damage to our reputation or business disruption including litigation or regulatory sanction and fines, which could materially and adversely affect our financial results.

Context

We rely on critical and sensitive systems and data, such as corporate strategic plans, sensitive personally identifiable information, intellectual property, manufacturing systems and trade secrets. There is the potential that malicious or careless actions expose our computer systems or information to misuse or unauthorised disclosure.

Inability to recover and sustain critical operations following a disruption or to respond to a crisis incident in a timely manner.

Risk impact

Failure to manage crisis and continuity management (CCM) effectively can lead to prolonged business disruption, greater damage to the Group s assets, and risk of supply disruption to patients of a medicine, any of which could materially and adversely affect our financial results. Delays to operational activities and delivery of our products to consumers and patients who rely on them could also expose us to litigation or regulatory action, materially and adversely affect our financial results and lead to reputational damage.

Context

The Group s international operations, and those of its partners, maintain a vast global footprint exposing our workforce, facilities, operations and information technology to potential disruption resulting from a natural event (e.g., storm or earthquake), a man-made event (e.g., civil unrest, terrorism), or a global emergency (e.g., Ebola outbreak, Flu pandemic). Through effective crisis management and business continuity planning we are committed to providing for the health and safety of our people, minimising damage and impact to the Group, and maintaining functional operations following a natural or man-made disaster, or a public health emergency.

Failure to maintain adequate governance and oversight over third-party relationships; failure of third-parties to meet their contractual, regulatory, confidentiality or other obligations; failure of third-parties to comply with the law or appropriately manage their respective operations to mitigate the Principal Risks to the Group outlined above.

Risk impact

Failure to adequately manage third-party relationships could result in business interruption and exposure to risk ranging from sub-optimal contractual terms and conditions, to severe business sanctions and/or significant reputational damage. Any of these consequences could materially and adversely affect our business operations and financial results.

Context

Third parties are critical to our business delivery and are an integral part of the solution to improve our productivity, quality, service and innovation. We rely on third-parties, including suppliers, distributors, individual contractors,

licensees, and other pharmaceutical and biotechnology collaboration partners for discovery, manufacture, and marketing of our products and important business processes.

However, these business relationships present a material risk. For example, we share critical and sensitive information such as marketing plans, clinical data, and employee data with specific third parties who are conducting the relevant outsourced business operations. Inadequate protection or misuse of this information by third parties could have significant business impact. Similarly, we use distributors and agents in a range of activities such as promotion and tendering which have inherent risks such as inappropriate promotion or corruption. Insufficient internal compliance and controls by the distributors could affect our reputation. These risks are further increased by the complexities of working with large numbers of third parties.

Item 4. **Information on the Company**

4.A History and development of the company The information set forth under the heading:

About GSK on the inside back cover;

Head Office and Registered Office on the outside back cover; and

Note 38 Acquisitions and disposals on pages 183 to 187 of the GSK Annual Report 2014 is incorporated herein by reference.

4.B Business overview

See Item 3D Risk factors above; In addition, the information set forth under the headings:

Overview of 2014 on the inside front cover;

Chairman s statement on pages 2 to 3;

CEO s Statement on pages 4 to 5;

What we do on pages 6 to 7;

Our Global Marketplace on pages 8 to 10;

Our business model on page 11;

Our strategic priorities on pages 12 to 13;

How we performed on pages 14 to 15;

Risk management, on pages 16 to 17;

Deliver within Pharmaceuticals and Vaccines on pages 24 to 26, Viiv Healthcare on page 32 and Consumer Healthcare on page 34;

Pharmaceuticals R&D Approach on pages 26 to 27;

Investment in R&D on page 27;

Vaccines R&D Approach on page 28;

Late-stage pipeline on page 29;

Simplify within Pharmaceuticals and Vaccines on page 30, Viiv Healthcare on page 32 and Consumer Healthcare on page 35;

Responsible business on pages 36 to 47;

Note 6 Segment Information on pages 147 to 151;

Note 38 Acquisitions and disposals on pages 183 to 187;

Pharmaceutical products, competition and intellectual property on pages 229 to 231; and

Consumer Healthcare products and competition on page 231 of the GSK Annual Report 2014 is incorporated herein by reference.

4.C Organizational structure

The information set forth under the heading:

Note 44 Principal Group companies on pages 204 to 205 of the GSK Annual Report 2014 is incorporated herein by reference.

4.D Property, plants and equipment The information set forth under the headings:

Note 6 Segment information on pages 147 to 151; and

Note 17 Property, plant and equipment on pages 158 to 159 of the GSK Annual Report 2014 is incorporated herein by reference.

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Item 4A. **Unresolved Staff Comments** Not applicable.

Item 5. Operating and Financial Review and Prospects

5.A Operating results

The information set forth under the headings:

Pricing and Regulation on pages 8 to 10;

Intellectual Property and patent protection on page 10;

Grow within Pharmaceuticals and Vaccines on pages 21 to 23, Viiv Healthcare on pages 31 to 32 and Consumer Healthcare on page 34;

Group financial review on pages 48 to 60 and 62 to 70; and

Financial record Quarterly trend on pages 218 to 219 of the GSK Annual Report 2014 is incorporated herein by reference.

The following tables reconcile total results to core results. References in the GSK Annual Report 2014 to the reconciliations on page 61 of that report should be read to refer to the information in these tables.

Core results reconciliation 31 December 2014

	Core results £ m	Intangible amortisation £ m	Intangible impairment £ m	Major restructuring £ m	Legal charges £ m	Acquisition accounting and other £ m	Total results £ m
Gross profit	16,471	(503)	(78)	(204)		(3)	15,683
Operating profit	6,594	(575)	(150)	(750)	(548)	(974)	3,597
Profit before taxation	5,978	(575)	(150)	(755)	(548)	(982)	2,968
Profit after taxation	4,806	(366)	(121)	(540)	(522)	(426)	2,831

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Earnings per share	95.4p	(7.6)p	(2.5)p	(11.3)p	(10.9)p	(5.8)p	57.3p
Weighted average number of shares (millions)	4,808						4,808
The following adjustments are made in arriving at core gross profit							
Cost of sales	(6,535)	(503)	(78)	(204)		(3)	(7,323)
The following adjustments are made in arriving at core operating profit							
Selling, general and administration	(7,074)			(430)	(548)	(194)	(8,246)
Research and development	(3,113)	(72)	(72)	(116)		(77)	(3,450)
Other operating income						(700)	(700)
The following adjustments are made in arriving at core profit before tax							
Net finance costs	(646)			(5)		(8)	(659)
The following adjustments are made in arriving at core profit after tax							
Taxation	(1,172)	209	29	215	26	556	(137)

COLE LESUIS LECONCINATION ST DECENIDE 2	Core resu	ts recond	ciliation	31 I	December	2013
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	Core results excluding divestments	vestments		Intangible In	-	Major	a Legal	equisition ecounting and other	Total results
	£ m	£ m	£ m	£ m	£ m	£ m	£ m	£ m	£ m
Gross profit	18,527	429	18,956	(450)	(408)	(178)			17,920
Operating profit	7,771	244	8,015	(547)	(739)	(517)	(252)	1,068	7,028
Profit before taxation	n 7,122	244	7,366	(547)	(739)	(523)	(252)	1,342	6,647
Profit after taxation	5,487	184	5,671	(398)	(513)	(378)	(243)	1,489	5,628
Earnings per share	108.4p	3.8p	112.2p	(8.2)p	(10.7)p	(7.8)p	(5.0)p	32.0p	112.5p
Weighted average number of shares (millions)			4,831						4,831
The following adjustments are made in arriving at core gross profit									
Turnover	25,602	903	26,505						26,505
Cost of sales	(7,075)	(474)	(7,549)	(450)	(408)	(178)			(8,585)
The following adjustments are made in arriving at core operating profit									
Selling, general and administration	(7,749)	(179)	(7,928)			(300)	(252)		(8,480)
Research and development	(3,394)	(6)	(3,400)	(97)	(331)	(39)		(56)	(3,923)
Other operating income								1,124	1,124
The following adjustments are made in arriving at core profit before tax									
Net finance costs	(692)		(692)			(6)		(8)	(706)
Profit on disposal of interest in associates								282	282

and joint ventures

The following									
adjustments are									
made in arriving at									
core profit after tax									
Taxation	(1,635)	(60)	(1,695)	149	226	145	9	147	(1,019)

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Core results reconciliation 31 December 2012

Core results reconcination 311	Core results £ m	Intangible	•	Major restructuring £ m	Legal charges £ m	Acquisition accounting and other £ m	Total results £ m
Gross profit	19,322	(378)	(309)	(128)		(1)	18,506
Operating profit	8,238	(477)	(693)	(557)	(436)	1,225	7,300
Profit before taxation	7,543	(477)	(693)	(558)	(436)	1,221	6,600
Profit after taxation	5,705	(332)	(497)	(843)	(286)	931	4,678
Earnings per share	111.4p	(6.8)p	(7.3)p	(17.4)p	(5.8)p	17.5p	91.6
Weighted average number of shares (millions)	4,912						4,912
The following adjustments are made in arriving at core gross profit							
Cost of sales	(7,109)	(378)	(309)	(128)		(1)	(7,925)
The following adjustments are made in arriving at core operating profit Selling, general and administration	(7,905)			(418)	(436)	(30)	(8,789)
Research and development	(3,485)		(384)	(11)	,		(3,979)
Other operating income						1,256	1,256
The following adjustments are made in arriving at core profit before tax							
Net finance costs	(724)			(1)		(4)	(729)
The following adjustments are made in arriving at core profit after tax							
Taxation	(1,838)	145	196	(285)	150	(290)	(1,922)

Financial review 2014

The Financial review summarises the performance of the Group for the year, in comparison with the results of the previous year. The Financial review also sets out the balance sheet position of the Group at 31 December 2013.

Group performance

Our financial review discusses the operating and financial performance of the Group, the financial outlook and our financial resources. We compare the results for each year primarily with results of the preceding year and on a CER basis. In this review we discuss the results on both a core basis and a total basis.

All growth rates included in this Report are at constant exchange rates (CER) unless otherwise stated. CER growth is discussed below.

Financial review 2013

The discussion that follows on movements in turnover is presented excluding divestments completed in 2013. The 2012 turnover analyses have been presented on a comparable basis.

Group turnover by business

		2012		
	2013	(restated)	Growth	Growth
	£m	£m	CER%*	$\mathfrak{£}\%$
Pharmaceuticals	17,426	17,411	1	
Vaccines	3,420	3,325	2	3
Pharmaceuticals and Vaccines	20,846	20,736	1	1
Consumer Healthcare	4,756	4,747	2	
	25,602	25,483	2	
Divestments completed in 2013	903	948		
	26,505	26,431	1	

^{*} CER% represents growth at constant exchange rates. £% represents growth at actual exchange rates. Total Group turnover for 2013 was £26,505 million, up 1%. Excluding the impact of divestments completed in 2013, turnover increased 2%. Pharmaceuticals and Vaccines turnover grew 1%. Pharmaceuticals turnover grew 1% and, as growth in the US, Japan and Emerging Markets was partially offset by continued pricing pressures and generic competition in Europe. ViiV Healthcare turnover for 2013 was flat. Vaccines turnover grew 2%, despite the adverse comparison with strong *Cervarix* sales in Japan in 2012. Excluding *Cervarix* in Japan, Vaccines sales grew 5%, reflecting the strong growth in the US of *Infanrix/Pediarix* and *Boostrix*, both of which benefited from competitor supply issues, and *Fluarix/FluLaval*, which benefited from the launch of the new Quadrivalent formulation, as well as a better performance by the business in Europe. Consumer Healthcare turnover increased 2% to £4,756 million.

Group turnover by geographic region

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		2012		
	2013	(restated)	Growth	Growth
	£m	£m	CER%	$\mathfrak{£}\%$
US	8,620	8,330	2	3
Europe	6,862	6,675		3
Emerging Markets	6,579	6,629	2	(1)
Japan	1,886	2,219	2	(15)
Other	1,655	1,630	5	2
	25,602	25,483	2	
Divestments completed in 2013	903	948		
_	26,505	26,431	1	

Group sales outside the USA and Europe accounted for 40% of total turnover and reported growth of 2%, adversely impacted by sales declines in China.

Group turnover by segment

		2012		
	2013	(restated)	Growth	Growth
	£m	£m	CER%	$\mathfrak{£}\%$
Pharmaceuticals and Vaccines:				
US	5,817	5,508	4	6
Europe	4,226	3,956	3	7
Emerging Markets	3,370	3,309	3	2
Japan	1,058	1,203	6	(12)
ViiV Healthcare	1,386	1,374		1
Established Products	3,874	4,351	(8)	(11)
Other trading and unallocated	1,115	1,035	11	8
Pharmaceuticals and Vaccines	20,846	20,736	1	1
Consumer Healthcare	4,756	4,747	2	
	25,602	25,483	2	
Divestments completed in 2013	903	948		
	26,505	26,431	1	

Pharmaceuticals turnover

		2012		
	2013	(restated)	Growth	Growth
	£m	£m	CER%	$\mathfrak{£}\%$
Respiratory	7,289	7,044	4	3
Oncology	969	798	22	21
Cardiovascular, metabolic and urology	1,073	1,144	(5)	(6)
Immuno-inflammation	161	70	>100	>100
Other pharmaceuticals	2,674	2,630	5	2
ViiV Healthcare (HIV)	1,386	1,374		1
Established Products	3,874	4,351	(8)	(11)
	17,426	17,411	1	

Respiratory

Respiratory sales in 2013 grew 4% to £7,289 million, with the US up 7%, Europe down 2%, Emerging Markets up 4% and Japan up 10%. *Seretide/Advair* sales were up 4% to £5,274 million, largely driven by a strong US performance. *Flixotide/Flovent* sales increased 2% to £796 million, and *Ventolin* sales grew 2% to £642 million. *Xyzal* sales, almost exclusively made in Japan, grew 26% to £137 million, reflecting a strong allergy season.

In the US, Respiratory sales grew 7%, with *Advair* up 8% to £2,769 million, compared with 6% estimated underlying growth for the year (5% volume decline more than offset by an 11% positive impact of price and mix). *Flovent* sales were up 6% to £482 million with estimated underlying growth for the year up 6% (4% volume decrease offset by a 10% positive impact of price and mix). *Ventolin* grew 4% to £291 million, with estimated underlying growth of 8% driven mostly by improved price realisation in the first half of the year. The launch of *Breo Ellipta* began in Q4 2013 with £5 million of sales recorded in the quarter.

European Respiratory sales were down 2% reflecting increased competition in many markets. *Seretide* sales were down 2% to £1,458 million, with a 2% volume decrease and no net impact of price and mix.

Respiratory sales in Emerging Markets grew 4%, but 9% excluding China, led by *Seretide*, which grew 4% to £429 million (12% excluding China). *Seretide* continued to deliver strong growth across many Emerging Markets markets. *Veramyst*, grew 16% to £71 million and *Ventolin* increased 2% to £171 million.

In Japan, Respiratory sales grew 10% to £554 million, with strong growth from both *Xyzal* and *Veramyst. Adoair* sales grew 8% to £277 million. *Relvar Ellipta* was launched in December 2013, recording sales of £3 million.

Oncology

Oncology sales grew 22% to £969 million, marking the second consecutive year of double digit percentage growth for the business. US sales were up 17% with strong performances by *Votrient*, *Promacta* and *Arzerra*, but also contributions from the launches of two new metastatic melanoma products *Tafinlar* and *Mekinist*. Sales in Europe grew 28% and Emerging Markets grew 18%. *Votrient* sales grew 80% to £331 million, *Promacta* sales grew 46% to £186 million and *Arzerra* sales grew 23% to £75 million. *Tykerb/Tyverb* sales fell 13% to £207 million due to increased competition. Both *Hycamtin* in Europe and Emerging Markets and Argatroban in the US continued to be adversely affected by generic competition.

In the US, there were continued strong growth contributions from *Votrient*, up 56% to £144 million, and *Promacta*, up 33% to £73 million, which benefited from a new indication for thrombocytopenia associated with Hepatitis C received during Q4 2012. *Arzerra* grew 18% to £46 million. The US performance also reflects contributions totalling £21 million from *Tafinlar* and *Mekinist*, which were both launched in Q2 2013 as monotherapy treatments and achieved strong uptake in the BRAF V600 melanoma market during the first few months on the market. In January 2014, *Tafinlar* and *Mekinist* were approved by the FDA for combination use.

In Europe, sales grew 28% to £339 million, led by sales of *Votrient*, which increased by 91% to £130 million, as it continued to build market share in many markets. *Revolade* received approval in Europe for use in thrombocytopenia associated with Hepatitis C at the end of Q3 2013 and sales in the year increased by 47% to £55 million. *Tafinlar* was launched in Q3 2013 in certain markets and has achieved strong uptake in these early launch markets.

Emerging Markets sales grew 18% to £149 million led by strong growth of *Votrient* (up 77% to £37 million) and *Promacta* (up 92% to £22 million). In the region *Tykerb* was down 9% to £47 million, and *Hycamtin* was down 36% to £7 million.

Cardiovascular, metabolic and urology

Sales in the category fell 5% primarily as a result of the impact of the conclusion of the Vesicare co-promotion agreement in Q1 2012.

The *Avodart* franchise grew 10% to £857 million with 31% growth in sales of *Duodart/Jalyn. Avodart* sales grew 5% to £648 million.

The increase in Metabolic product sales primarily reflected higher sales of *Prolia* in Europe and EMAP.

Other pharmaceuticals

Sales of Anti-virals more than doubled reflecting tender shipments of *Relenza* in Japan.

Augmentin sales grew 5% to £630 million with strong growth in Emerging Markets, reflecting, in part, a comparison with some supply interruptions in 2012. Zinnat sales were flat at £169 million, and Zinacef sales fell 14% to £55 million.

Dermatology sales declined 5% to £631 million, primarily as a result of the decline in the US, down 37% to £115 million, which continued to suffer from the impact of generic competition, particularly to *Bactroban*, *Duac* and *Soriatane*, together with the effect of the disposal of a number of tail brands in Q2 2013. Emerging Markets sales grew 8% to £289 million, reflecting strong growth in *Bactroban*, *Dermovate* and *Duac* particularly in Middle East/Africa and Latin America. European sales grew 6% to £170 million.

Volibris, up 21% to £147 million, and *Mepron*, up 8% to £101 million, were the main drivers of the 7% growth in the Rare diseases category. *Flolan* sales fell 16% to £103 million, primarily as a result of the biennial price reduction in Japan in Q2 2012 and continued generic competition in the US and Europe.

Immuno-inflammation

Benlysta turnover in the year was £146 million, with £134 million in the US. Total in-market sales of *Benlysta* in the US in 2012 were £96 million.

ViiV Healthcare (HIV)

ViiV Healthcare sales of £1,386 million were flat as sales in the US were up 5%, Europe down 3% and Emerging Markets down 12%. *Epzicom/Kivexa* sales increased 14% to £763 million and *Selzentry* was up 10% to £143 million. *Tivicay* recorded sales of £19 million from the early stages of its launch in the US, which started in August 2013. *Tivicay* was approved in Europe in January 2014 and launches are planned in several markets throughout 2014.

Growth contributions within this business were offset by declines in the mature portion of the portfolio, mainly *Combivir*, down 36% to £116 million

Established Products

Established Products declined 8% to £3,874 million as sales of Lovaza fell 5% to £584 million as a result of increased competition and the decline in the non-statin dyslipidemia prescription market. Declines in Zeffix and Hepsera reflected the sales decline in China.

Serevent sales were down 10%. Seroxat/Paxil sales fell 16% to £285 million, primarily due to generic competition in Japan and Europe and Requip sales fell 18% to £125 million reflecting generic competition in the US and Europe. Lamictal sales fell 7% to £557 million, primarily as a result of generic competition to Lamictal XR in the US, which started in Q1 2013. Sales of the Lamictal franchise in the US fell 18% to £276 million.

Vaccines turnover

	2013	2012	Growth	Growth
	£m	£m	CER%	$\mathfrak{£}\%$
Vaccines sales	3,420	3,325	2	3

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Performance of the Vaccines business improved towards the end of the year, with a significant increase in tender sales in the last quarter. The 2% increase in Vaccines sales was principally attributable to the growth of *Infanrix/Pediarix*, *Fluarix/FluLaval* and *Boostrix*, which was largely offset by the decline of *Cervarix* in Japan, reflecting the suspension of the recommendations for the use of HPV vaccines in Japan, together with an adverse comparison with strong *Cervarix* sales in 2012, which benefited from the final stages of the HPV vaccination catch-up programme in Japan. *Cervarix* sales declined 37% to £172 million. Excluding *Cervarix* in Japan, Vaccines sales increased by 5%.

Infanrix/Pediarix sales increased 9% to £862 million, with the growth primarily reflecting stronger tender shipments in Europe and Emerging Markets as well as the benefit in the US of a competitor supply shortage. *Boostrix* sales, which also benefited from a competitor supply issue in the US, grew 19% to £288 million.

Sales of hepatitis vaccines fell 4% to £629 million, primarily reflecting lower sales in the US as a result of the return of competing vaccines to the market during the second half of 2012, together with declines in Europe and China.

Synflorix sales increased 2% to £405 million, helped by strong tender sales in Middle East/Africa and Latin America.

Rotarix sales grew 5% to £375 million, with strong growth in Middle East/Africa and Europe partially offset by the impact of increased competition in Japan.

Fluarix, FluLaval sales increased 25% to £251 million, following the launch of the Quadrivalent formulation in the US.

Consumer Healthcare turnover

		2012		
	2013	(restated)	Growth	Growth
	£m	£m	CER%	$\mathfrak{£}\%$
Wellness	1,865	1,991	(5)	(6)
Oral care	1,884	1,806	6	4
Nutrition	627	590	12	6
Skin health	380	360	6	6
	4,756	4,747	2	

		2012		
	2013	(restated)	Growth	Growth
	£m	£m	CER%	$\mathfrak{t}\%$
USA	951	926	1	3
Europe	1,392	1,386	(2)	
ROW	2,413	2,435	5	(1)
	4,756	4,747	2	

Consumer Healthcare turnover grew 2% in the year.

Wellness

Total wellness sales, excluding the non-core OTC brands that were divested in H1 2012, fell 5%. In both the US and Europe *alli* reported strong growth, in large part due to being out of stock for much of 2012. A severe cold and flu season in early 2013 helped drive growth of several respiratory brands including *Coldrex*, *Beechams* and *Panadol Cold and Flu*. This growth was partly offset by a 57% reduction in sales in China of *Contac*, due to new shelving requirements, and *Fenbid*, down 31%, in advance of mandatory price reductions.

Oral care

Strong growth in Oral care sales was led by growth in Specialist oral health, with *Sensodyne* Sensitivity and Acid erosion up 15% and denture care brands up 9%, but *Aquafresh* was down 12%.

Nutrition

Nutrition sales grew 12% with strong growth in Rest of World markets, led by *Horlicks*, up 14%, and *Boost* in India and key expansion markets in the sub-continent.

Skin health

Skin health sales grew 6%, led by *Abreva* in the US.

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Regional performance

US sales grew 1%, led by strong contributions from Oral care brands, *alli* and *Abreva*. This was partially offset by declines in Gastro-intestinal products, reflecting increased competitor activity, and Smoking control products impacted by supply disruptions. In Europe, sales declined 2% helped by sales of *alli* and strong growth in products for Respiratory health and Pain.

Oral care sales in Europe were flat, as strong growth in *Sensodyne* and denture care brands was offset by a decline in *Aquafresh*, due in part to supply issues in Q4 2013. Rest of World markets grew 5%, reflecting growth across most categories and markets, particularly in India, partially offset by a 23% reduction of sales in China, mainly due to the reduction in sales of *Contac* and *Fenbid*.

Core results

Core results exclude the following items from total results: amortisation and impairment of intangible assets (excluding computer software) and goodwill; major restructuring costs, including those costs following material acquisitions; legal charges (net of insurance recoveries) and expenses on the settlement of litigation and government investigations; other operating income other than royalty income; disposals of associates, products and businesses, and acquisition accounting adjustments for material acquisitions, together with the tax effects of all of these items. The analyses that follow do not exclude divestments completed in 2013.

Major restructuring costs charged in arriving at operating profit include costs arising under the Operational Excellence restructuring programme, initiated in 2007 and expanded in 2009, 2010 and 2011, the Major Change restructuring programme initiated in 2013 and restructuring costs following the acquisitions of Human Genome Sciences, Inc. in August 2012 and Stiefel Laboratories, Inc. in July 2009.

Reconciliations of core results to total results are presented on page 65.

Core results reporting aligns business performance reporting around the underlying trading performance of the Group and its primary growth drivers by removing the volatility inherent in many of the non-core items.

Core results reporting is utilised as the basis for internal performance reporting and the core results are presented and discussed in this Financial review as we believe that this approach provides investors with a clearer view of the underlying trading performance of the Group. We also believe that this approach should make the Group s results more comparable with the majority of our peers, many of which use similar forms of underlying performance reporting to discuss their results, although the precise calculations may differ. The Financial review also presents and discusses the total results of the Group.

Cost of sales

				2012		
		2013 (restated)				
		% of		% of	Growth	l
	£m	turnover	£m	turnover (CER% £%	6
Cost of sales	(7,549)	(28.5)	(7,109)	(26.9)	6 6	6

Core cost of sales was 28.5% of turnover compared with 26.9% in 2012. Net of currency effects of 0.3 percentage points and the impact of a 0.3 percentage point reduction to the 2012 cost of sales percentage due to the settlement in early 2012 of a royalty agreement and the conclusion of the Vesicare agreement, the cost of sales percentage increased 1.0 percentage points. This reflected the expected impact of the unwinding of costs of manufacturing volume shortfalls, adverse mix and the impact of preparing for the launches of new pipeline products, partially offset by ongoing cost management, better price realisation and restructuring benefits.

Selling, general and administration

				2012	
		2013		(restated)	
		% of		% of	Growth
	£m	turnover	£m	turnover	CER% £%
Selling, general and administration	(7,928)	(29.9)	(7,905)	(29.9)	1

Core SG&A costs as a percentage of sales were 29.9%, flat on 2012, as the net favourable year-on-year benefits of the Group s restructuring programmes and ongoing cost management efforts funded investments in growth businesses and preparations for new product launches.

Advertising and promotion expenses decreased 2%, Selling and distribution decreased 1% and general administration increased 6%.

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Research and development

				2012		
		2013		(restated)		
		% of % of		% of	Gro	wth
	£m	turnover	£m	turnover	CER%	$\mathfrak{t}\%$
Research and development	(3,400)	(12.8)	(3,485)	(13.2)	(3)	(2)

Core R&D expenditure declined 3% to £3,400 million (12.8% of turnover) compared with £3,485 million (13.2% of turnover) in 2012. This reflected the completion of a number of large trials, the phasing of ongoing project spending as well as continuing cost management.

We remain focused on delivering an improved return on our investment in R&D. Sales contribution, reduced attrition and cost reduction are all important drivers of an improving internal rate of return. R&D expenditure is not determined as a percentage of sales, but instead capital is allocated using strict returns based criteria.

The operations of Pharmaceuticals R&D are broadly split into Discovery activities (up to the completion of phase IIa trials) and Development work (from phase IIb onwards).

The table below analyses core R&D expenditure by these categories:

		2012
	2013	(restated)
	£m	£m
Discovery	742	800
Development	1,535	1,655
Facilities and central support functions	449	377
Pharmaceuticals R&D	2,726	2,832
Vaccines R&D	496	498
Consumer Healthcare R&D	178	155
Core R&D	3,400	3,485

The proportion of Pharmaceuticals R&D investment made in the late-stage portfolio decreased from 58% of Pharmaceuticals R&D costs in 2012 to 56% in 2013.

Royalty income

Royalty income was £387 million (2012: £306 million) and included a prior year royalty catch-up adjustment recorded early in 2013.

Core operating profit

2013 2012 % of (restated)

	1	turnover		% of	Growth
	£m		£m	turnover (CER% £%
Core operating profit	8,015	30.2	8,238	31.2	(3)

Core operating profit was £8,015 million, flat in CER terms on a turnover increase of 1%. The core operating margin of 30.2% was 1.0 percentage points lower than in 2012. Excluding currency effects, the margin declined 0.5 percentage points. This reflected the negative impact of an expected increase in cost of sales, partially offset by higher royalty income and lower R&D expenditure, as the Group s continuing restructuring programmes contributed incremental year-on-year savings of around £400 million from both ongoing and structural initiatives.

The contribution in 2013 from structural benefits was approximately £115 million lower than in 2012. Total savings realised from changes to post-retirement medical obligations in 2013 were approximately £280 million. In 2012, the Group realised £395 million of savings from the capping of future pensionable salary increases and a change in the basis of future discretionary pension increases from RPI to CPI in certain legacy plans.

Net finance costs

Finance income	2013 £m	2012 £m
Interest and other income	59	77
Fair value movements	2	2
	61	79
Finance expense		
Interest expense	(726)	(745)
Unwinding of discounts on liabilities		(10)
Remeasurements and fair value movements	(5)	(24)
Other finance expense	(22)	(24)
	(753)	(803)

Core net finance expense was £692 million compared with £724 million in 2012, despite higher average net debt levels during the year, largely driven by continuing share repurchases and dividends to shareholders. This reflected our strategy to improve the funding profile of the Group. Net debt at 31 December 2013 was £1.4 billion lower than at 31 December 2012, reflecting receipts of £2.5 billion from the disposals of businesses, intangible assets, Aspen shares and other investments realised largely at the end of the year.

Share of after tax profits of associates and joint ventures

The share of after tax profits of associates of £43 million (2012 £29 million) principally arose from the Group s holding in Aspen Pharmacare.

Core profit before taxation

				2012	
		2013		(restated)	
		% of		% of	Growth
	£m	turnover	£m	turnover	CER% £%
Core profit before tax	7,366	27.8	7,543	28.5	(2)

Taxation

Tax on core profit amounted to £1,695 million and included recognition of US R&D credits reflected in the effective core tax rate of 23.0% (2012: 24.4%).

We continue to believe that we have made adequate provision for the liabilities likely to arise from periods which are open and not yet agreed by tax authorities. The ultimate liability for such matters may vary from the amounts provided and is dependent upon the outcome of agreements with the relevant tax authorities or litigation.

Core earnings per share

Core EPS of 112.2p (2012 111.4p) increased 4% in CER terms and 1% at actual exchange rates.

Dividend

The Board declared four interim dividends resulting in a dividend for the year of 78 pence, a 4 pence increase on the dividend for 2012. See Note 16 to the financial statements, Dividends .

Total results

		2013		2012 (restated)		
		% of		% of	Grov	wth
	£m	turnover	£m	turnover	CER%	$\mathfrak{t}\%$
Turnover	26,505	100	26,431	100	1	
Cost of sales	(8,585)	(32.4)	(7,925)	(30.0)	8	8
Selling, general and administration	(8,480)	(32.0)	(8,789)	(33.3)	(3)	(4)
Research and development	(3,923)	(14.8)	(3,979)	(15.1)	(2)	(1)
Royalty income	387	1.5	306	1.2	25	26
Other operating income	1,124	4.2	1,256	4.8	(10)	(11)
Operating profit	7,028	26.5	7,300	27.6	(1)	(4)
Net finance costs	(706)		(729)			
Profit on disposal of interest in associates	282					
Share of after tax profits of associates and joint ventures	43		29			
Profit before taxation	6,647		6,600		4	1
Taxation	(1,019)		(1,922)			
Total profit after taxation for the year	5,628		4,678		24	20
Total profit attributable to shareholders	5,436		4,499			
Earnings per share (p)	112.5		91.6		27	23
Earnings per ADS (US\$)	3.53		2.91			

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Cost of sales

Total cost of sales was 32.4% of turnover compared with 30.0% in 2012. The increase primarily reflected the expected impact of the unwinding of costs of manufacturing volume shortfalls, adverse mix effects, the impact of preparing for the launches of new pipeline products and higher amortisation and impairments of intangible assets, partially offset by ongoing cost management, better price realisation and restructuring benefits.

Selling, general and administration

Total SG&A costs decreased to 32.0% of turnover compared with 33.3% in 2012, reflecting lower legal and restructuring charges. The net favourable year-on-year benefits of the Group s restructuring programmes and ongoing cost management efforts funded investments in growth businesses and preparations for new product launches.

Advertising and promotion expenses decreased 2%, selling and distribution fell 1% and general and administration decreased 5%, primarily reflecting lower legal charges.

Research and development

Total R&D expenditure declined 2% to £3,923 million (14.8% of turnover) compared with £3,979 million (15.1% of turnover) in 2012. This reflected the completion of a number of large trials, the phasing of ongoing project spending as well as continuing cost management, partially offset by higher restructuring and required regulatory charges.

Other operating income

Other operating income of £1,124 million (2012 £1,256 million) included the profit on the disposal of the *Lucozade* and *Ribena* business and the anti-coagulant products of £1,331 million. The 2012 income included gains on the profit on disposal of the non-core OTC brands of £559 million and the gain of £581 million arising on the revaluation of pre-existing collaborations as part of the HGS and ViiV Healthcare/Shionogi joint venture acquisitions.

Operating profit

Total operating profit was £7,028 million compared with £7,300 million in 2012. The non-core items resulted in total net charges of £987 million in 2013 (2012 £938 million).

The intangible asset amortisation of £547 million (2012 £477 million) included £94 million related to the amortisation of the *Benlysta* intangible asset acquired as part of the HGS acquisition in late 2012. Intangible asset impairments of £739 million (2012 £693 million) included write-offs of several R&D assets, together with the partial impairment of *Lovaza*, reflecting a reassessment of the Group s expectations on the likelihood of potential generic competition.

Major restructuring charges of £517 million (2012 £557 million) comprised £238 million under the Operational Excellence programme, £260 million under the Major Change programme and £19 million related to the acquisition of HGS.

The Operational Excellence programme was initiated in 2007 and after several expansions is expected to cost approximately £4.85 billion. It is expected to deliver annual pre-tax savings of approximately £2.9 billion by the end of 2014.

The Major Change programme focuses on opportunities to simplify our supply chain processes, build the Group's capabilities in manufacturing and R&D, and restructure our European Pharmaceuticals business. The programme is expected to cost £1.5 billion, of which the non-cash charge will be £350 million, and is expected to deliver annual pre-tax savings of at least £1.0 billion by 2016.

Legal charges of £252 million (2012 £436 million) principally related to provisions for existing product liability matters.

Acquisition accounting and other credits of a net £1,068 million (2012 £1,225 million credit) included items related to major acquisitions, business, equity investment and asset disposals, one-off required regulatory charges in R&D and certain other adjusting items. The 2013 net credit included gains on the disposals of the *Lucozade* and *Ribena* business and the anti-coagulant products of £1,331 million. The 2012 net credit included gains on the profit on disposal of the non-core OTC brands of £559 million and the gain of £581 million arising on the revaluation of pre-existing collaborations as part of the HGS and ViiV Healthcare/Shionogi joint venture acquisitions.

Net finance costs

Finance income	2013 £m	2012 £m
Interest and other finance income	59	77
Fair value movements	2	2
	61	79
Finance expense		
Interest expense	(726)	(745)
Unwinding of discounts on liabilities	(14)	(15)
Remeasurements and fair value movements	(5)	(24)
Other finance expense	(22)	(24)
	(767)	(808)

Total net finance expense was £706 million compared with £729 million in 2012, despite higher average net debt levels during the year, reflecting our strategy to improve the funding profile of the Group.

Profit on disposal of interest in associates

The pre-tax profit on disposal of interest in associates was £282 million (2012 £nil) and reflected the disposal of 28.2 million ordinary shares in Aspen Pharmacare for £429 million.

Share of after tax profits of associates and joint ventures

The share of after tax profits of associates of £43 million (2012 £29 million) principally arose from the Group s holdings in Aspen Pharmacare.