

Sanofi Announces Strong Q3 2016 Results

	Q3 2016	Change	Change (CER)	9M 2016	Change	Change (CER)
IFRS net sales reported	€9,028m	+2.0%	+3.0%	€24,954m	-2.1%	+0.5%
IFRS net income reported	€1,674m	+2.8%		€3,919m	-0.9%	
IFRS EPS reported	€1.30	+4.0%		€3.04	+0.3%	
Aggregate Company sales ⁽¹⁾	€9,652m	+2.1%	+3.0%	€27,063m	-1.3%	+1.2%
Business net income ⁽²⁾	€2,300m	+9.7%	+11.1%	€5,702m	+0.7%	+4.1%
Business EPS ⁽²⁾	€1.79	+11.2%	+12.4%	€4.43	+2.3%	+5.8%

Following the announcement of exclusive negotiations with Boehringer Ingelheim and as per the IFRS 5 presentation requirement for discontinued operations, net income for Sanofi's Animal Health business (Merial) will be reported on a separate line ("Net income from the held for exchange Animal Health Business") in the Consolidated Income Statement for Q3 2016 and for 9M 2016, and the prior year. As of September 30 2016, Sanofi continues to report the performance of the Animal Health business, which remained an operating segment consistent with IFRS 8 and was included in the key performance indicators of the Company.

2016 guidance raised on strong third-quarter financial results

- Aggregate Company sales⁽¹⁾ increased 3.0%⁽³⁾ (up 2.1% at 2016 exchange rates) to €9,652 million.
- IFRS EPS reported was up 4.0% to €1.30.
- Business EPS⁽²⁾ was up 12.4% at CER to €1.79 and up 11.2% on a reported basis.
- Given the performance in the first nine months, Sanofi now expects 2016 Business EPS⁽²⁾ to grow between 3% and 5%⁽⁴⁾ at CER, barring unforeseen major adverse events.

Continuing to execute the simplification of the portfolio consistent with our 2020 Roadmap

- Decision to initiate a carve-out process in order to divest the EU Generics business within 12-24 months.
- CHC asset swap with Boehringer Ingelheim on track to close around year-end.
- Cost savings now expected to be at least €1.5 billion by 2018.

Initiating a €3.5 billion share repurchase program to be completed by the end of 2017

Solid sales performance despite continuing headwinds in diabetes and the Plavix LOE in Japan

- Sanofi Genzyme (Specialty Care) GBU continues to deliver double-digit growth (+16.9%).
- Sanofi Pasteur grew 14.4% supported by early flu vaccines shipment in the U.S.
- Diabetes and Cardiovascular GBU sales decreased 2.5%. Global diabetes franchise sales declined 1.5%.
- Aggregate sales in Emerging Markets⁽⁵⁾ grew 5.6% driven by Diabetes and Rare Disease portfolios.

Major launches and regulatory updates

- Toujeo[®] generated worldwide sales of €167 million. LixiLan PDUFA date extended to November 2016.
- Praluent[®] now approved in 41 countries.
- Dengvaxia[®] generated sales of €30 million and is now approved in 13 countries.
- Sarilumab: CGMP⁽⁶⁾ observations during an FDA inspection of a Sanofi "fill-finish" facility could impact approval timing.
- Dupixent[®] (dupilumab) BLA accepted for priority review by U.S. FDA with March 29, 2017 PDUFA date.

Sanofi Chief Executive Officer, Olivier Brandicourt, commented:

"We have generated solid sales momentum in the third quarter and seen a strong contribution to our financial performance from savings and efficiencies arising from our more focused organization. As a result, we are able to increase our FY 2016 Business EPS guidance. In addition, we have continued to work diligently to progress our major launches and the pipeline. With the filing of Dupixent[®], we now have another important product under FDA review which we believe will enhance Sanofi's growth profile in the coming years."

(1) Including Merial (see Appendix 8 for definition of Aggregate Company sales) which is reported on a single line in the consolidated income statements in accordance with IFRS 5 (Non-current assets held for sale and discontinued operations). Additionally, Sanofi comments include Merial for every income statement line using the term "Aggregate"; (2) In order to facilitate an understanding of operational performance, Sanofi comments on the business net income statement. Business net income is a non-GAAP financial measure (see Appendix 8 for definitions). The consolidated income statement for Q3 2016 and 9M 2016 is provided in Appendix 4 and a reconciliation of business net income to IFRS net income reported is set forth in Appendix 3; (3) Percentage changes in net sales and Aggregate sales are expressed at constant exchange rates (CER) unless otherwise indicated (see Appendix 8); (4) 2015 Business EPS was €5.64; (5) See page 8; (6) Current Good Manufacturing Practice

2016 third-quarter and nine-month Aggregate Sanofi sales

Unless otherwise indicated, all percentage changes in sales in this press release are stated at CER⁽⁷⁾.

In the third quarter of 2016, Aggregate Company sales were €9,652 million, up 2.1% at 2016 exchange rates. Exchange rate movements had a negative effect of 0.9 percentage points, primarily reflecting the adverse evolution of the Argentine Peso, Chinese Yuan, and British Pound, which more than offset the positive effects from the Japanese Yen and Brazilian Real. At CER, Aggregate Company sales increased 3.0%. Year-to-date Aggregate Company sales reached €27,063 million, down 1.3% at 2016 exchange rates. Exchange rate movements had an unfavorable effect of 2.5 percentage points.

The first nine months performance included a negative currency impact related to the change of exchange rate applied for the translation of Venezuela operations, resulting from the evolution of the exchange system in February 2016 as well as from the persistent inability to exchange Venezuelan bolivars for U.S. dollars at the privileged official rate. In addition, in the first half of 2015, Sanofi benefited from a significant increase in product demand in Venezuela, due to buying patterns associated with local market conditions. As a consequence, sales in Venezuela were €9 million in the first nine months of 2016 compared to €423 million in the first nine months of 2015 (no sales were recorded in the third quarter of 2016 compared to €24 million in the third quarter of 2015). Excluding Venezuela, Aggregate Company sales increased 3.3% and 2.8% in the third quarter and first nine months of 2016, respectively.

Global Business Units

The table below presents sales by Global Business Units (GBU) and reflects the organization of Sanofi which became effective as of January 1, 2016. In this organizational structure, all Pharmaceutical sales in Emerging Markets are now included in the General Medicines and Emerging Markets GBU. This new reporting structure simplifies Sanofi, deepens specialization and allows clear focus on growth drivers.

Net Sales by GBU (€ million)	Q3 2016	Change (CER)	9M 2016	Change (CER)
Sanofi Genzyme (Specialty Care) ^(a)	1,270	+16.9%	3,684	+19.1%
Diabetes and Cardiovascular ^(a)	1,585	-2.5%	4,687	-3.9%
General Medicines & Emerging Markets ^(b)	4,370	-2.4% ^(c)	13,358	-4.1% ^(e)
Sanofi Pasteur (Vaccines)	1,803	+14.4%	3,225	+11.0% ^(f)
Merial (Animal Health)	624	+4.0%	2,109	+10.3%
Total Aggregate Company sales	9,652	+3.0%^(d)	27,063	+1.2%^(g)

(a) Does not include Emerging Markets sales- see definition page 8; (b) Includes Emerging Markets sales for Diabetes & Cardiovascular and Specialty Care; (c) Excluding Venezuela: -1.9%; (d) Excluding Venezuela: +3.3%; (e) Excluding Venezuela: -1.4%; (f) Excluding Venezuela: +11.3%; (g) Excluding Venezuela: +2.8%;

Global Franchises

The table below presents sales by global franchise, which facilitates straightforward peer comparisons. Appendix 1 provides a reconciliation of sales by GBU and franchise.

Net sales by Franchise (€ million)	Q3 2016	Change (CER)	Developed Markets	Change (CER)	Emerging Markets	Change (CER)
Specialty Care	1,517	+18.5%	1,270	+16.9%	247	+26.5% ^(a)
Diabetes and Cardiovascular	1,929	+0.3% ^(b)	1,585	-2.5%	344	+14.2% ^(c)
Established Products	2,535	-7.4% ^(d)	1,587	-12.5%	948	+1.7% ^(e)
Consumer Healthcare (CHC)	791	-1.2% ^(f)	479	+1.3%	312	-4.7% ^(g)
Generics	453	+1.3% ^(h)	257	+2.8%	196	-0.5% ⁽ⁱ⁾
Vaccines	1,803	+14.4%	1,458	+16.4%	345	+6.6%
Animal Health	624	+4.0%	468	+1.1%	156	+13.3%
Total Aggregate net sales	9,652	+3.0%^(j)	7,104	+2.1%	2,548	+5.6%^(k)

(a) Excluding Venezuela: +25.9%; (b) Excluding Venezuela: +0.4%; (c) Excluding Venezuela: +15.2%; (d) Excluding Venezuela: -6.9%; (e) Excluding Venezuela: +3.4%; (f) Excluding Venezuela: -1.0%; (g) Excluding Venezuela: -4.1%; (h) Excluding Venezuela: +2.2%; (i) Excluding Venezuela: +1.5%; (j) Excluding Venezuela: +3.3%; (k) Excluding Venezuela: +6.6%.

(7) See Appendix 8 for definitions of financial indicators.

The table below presents sales by global franchise for the first nine months of 2016.

Net sales by Franchise (€ million)	9M 2016	Change (CER)	Developed Markets	Change (CER)	Emerging Markets	Change (CER)
Specialty Care	4,381	+18.8% ^(a)	3,684	+19.1%	697	+17.5% ^(b)
Diabetes and Cardiovascular	5,723	-1.8%	4,687	-3.9%	1,036	+8.2% ^(c)
Established Products	7,743	-8.5% ^(d)	4,930	-11.6%	2,813	-2.9% ^(e)
Consumer Healthcare (CHC)	2,496	-2.9% ^(f)	1,584	+1.7%	912	-9.3% ^(g)
Generics	1,386	+0.8% ^(h)	810	+0.9%	576	+0.8% ⁽ⁱ⁾
Vaccines	3,225	+11.0% ^(j)	2,268	+9.2%	957	+15.3% ^(k)
Animal Health	2,109	+10.3%	1,645	+7.4%	464	+21.1%
Total Aggregate net sales	27,063	+1.2%^(l)	19,608	+0.5%	7,455	+3.0%^(m)

(a) Excluding Venezuela : +19.3%; (b) Excluding Venezuela : +20.1%; (c) Excluding Venezuela : +12.9%; (d) Excluding Venezuela : -6.1%; (e) Excluding Venezuela : +4.4%; (f) Excluding Venezuela: +0.7%; (g) Excluding Venezuela: -0.7%; (h) Excluding Venezuela: +3.0%; (i) Excluding Venezuela: +5.7%; (j) Excluding Venezuela: +11.3%; (k) Excluding Venezuela: +16.5%; (l) Excluding Venezuela: +2.8%; (m) Excluding Venezuela: +8.7%.

Pharmaceuticals

Third-quarter sales for Pharmaceuticals increased 0.5% to €7,225 million. Growth in the Multiple Sclerosis, Rare Disease and Cardiovascular franchises offset a decrease in Diabetes, CHC and Established Rx Products. Year-to-date sales for Pharmaceuticals decreased 0.9% to €21,729 million. Excluding Venezuela, year-to-date sales for Pharmaceuticals increased 0.9%.

Rare Disease franchise

Net sales (€ million)	Q3 2016	Change (CER)	9M 2016	Change (CER)
Cerezyme®	183	+1.6%	564	+4.5%
Myozyme® / Lumizyme®	185	+16.0%	533	+12.8%
Fabrazyme®	176	+20.4%	492	+15.0%
Aldurazyme®	53	+12.5%	151	+7.5%
Cerdelga®	28	+55.6%	77	+75.0%
Total Rare Diseases	708	+14.3%	2,061	+12.4%

In the third quarter, **Gaucher** (Cerezyme® and Cerdelga®) sales grew 6.3% to €211 million, reflecting Cerezyme® growth in Emerging Markets (up 26.9% to €56 million) and the increasing contribution of Cerdelga® (€28 million versus €18 million in the third quarter of 2015). Year-to-date Gaucher sales increased 9.5% to €641 million.

Third-quarter sales of **Fabrazyme®** increased 20.4% to €176 million. The strong global momentum of Fabrazyme® is a result of continued accrual of new patients as a result of patients switching from competing products and earlier stage patient identification and treatment. Year-to-date sales of Fabrazyme® were up 15.0% to €492 million.

Sales of **Myozyme®/Lumizyme®** increased 16.0% to €185 million in the third quarter, mainly due to new patient accruals as a consequence of increased patient identification. Year-to-date sales of Myozyme®/Lumizyme® increased 12.8% to €533 million.

Multiple Sclerosis franchise

Net sales (€ million)	Q3 2016	Change (CER)	9M 2016	Change (CER)
Aubagio®	334	+49.8%	928	+56.8%
Lemtrada®	112	+69.1%	308	+95.1%
Total Multiple Sclerosis	446	+54.3%	1,236	+64.9%

Third-quarter sales of **Aubagio®** were up 49.8% to €334 million driven by the U.S. (up 50.9% to €239 million) and Europe (up 41.5% to €75 million). Aubagio® is currently the fastest growing oral disease modifying therapy in the Multiple Sclerosis market with patient market share of 9.8% in the U.S. (IMS MIDAS, second week of October). Year-to-date

In the third quarter, sales of **Lemtrada**[®] increased 69.1% to €112 million, including €64 million in the U.S. (up 66.7%) and €37 million in Europe (up 81.8%), mainly generated in the UK. Year-to-date sales of Lemtrada[®] were up 95.1% to €308 million.

Oncology franchise

Net sales (€ million)	Q3 2016	Change (CER)	9M 2016	Change (CER)
Jevtana [®]	88	+12.8%	266	+12.7%
Thymoglobulin [®]	70	+12.7%	204	+11.2%
Taxotere [®]	45	-22.4%	137	-18.5%
Eloxatin [®]	43	-24.1%	129	-19.5%
Mozobil [®]	39	+8.3%	111	+7.6%
Zaltrap [®]	16	-10.5%	50	-13.6%
Total Oncology	363	-2.4%	1,084	-1.6%

In the Third quarter, **Oncology** sales decreased 2.4% to €363 million, reflecting lower sales of Taxotere[®] and Eloxatin[®]. Year-to-date sales of Oncology were €1,084 million, down 1.6%.

Sales of **Jevtana**[®] increased 12.8% to €88 million in the third quarter led by the U.S. (up 21.9% to €38 million) and Japan. Year-to-date sales of Jevtana[®] were up 12.7% to €266 million.

Third-quarter **Thymoglobulin**[®] sales increased 12.7% to €70 million supported by sales in China. Year-to-date sales of Thymoglobulin[®] were up 11.2% to €204 million.

Third-quarter sales of **Eloxatin**[®] were down 24.1% to €43 million reflecting generic competition in Canada. Over the same period, sales of **Taxotere**[®] (docetaxel) decreased 22.4% (to €45 million) due to generic competition in Japan. Year-to-date sales of Taxotere[®] and Eloxatin[®] were down 18.5% (€137 million) and down 19.5% (€129 million), respectively.

Diabetes franchise

Net sales (€ million)	Q3 2016	Change (CER)	9M 2016	Change (CER)
Lantus [®]	1,391	-9.8%	4,251	-10.7%
Toujeo [®]	167	265.2%	411	ns
Total glargine	1,558	-1.9%	4,662	-3.5%
Amaryl [®]	92	+1.1%	273	-4.7%
Apidra [®]	94	+6.8%	272	+2.2%
Insuman [®]	32	-8.3%	98	0.0%
BGM (Blood Glucose Monitoring)	16	+6.7%	50	+6.4%
Lyxumia [®]	9	-11.1%	26	-3.7%
Total Diabetes	1,805	-1.5%	5,396	-3.0%^(a)

(a) Excluding Venezuela: -2.3%;

In the third quarter, **Diabetes franchise** sales were down 1.5% to €1,805 million, reflecting lower sales of Lantus[®] in the U.S. Third-quarter U.S. Diabetes sales were down 5.4% to €1,013 million. Outside the U.S., sales were €792 million, an increase of 3.9% driven by Emerging Markets (up 13.6% to €341 million). Sales in Europe were €325 million, a decrease of 0.6%. In Europe, sales of Toujeo[®] offset lower sales of Lantus[®]. Year-to-date sales for the Diabetes franchise were €5,396 million, down 3.0%.

Third-quarter sales of Sanofi's **glargine** (Lantus[®] and Toujeo[®]) were €1,558 million, down 1.9%. In the U.S., Sanofi's glargine sales of €980 million were down 5.1%. In Europe, sales of Sanofi's glargine increased 0.4% to €248 million despite the launch of a biosimilar glargine in several European markets. Year-to-date sales of Sanofi's glargine were €4,662 million, down 3.5%.

Over the quarter, sales of **Lantus**[®] were €1,391 million down 9.8%. In the U.S., as anticipated, sales of Lantus[®] decreased 13.5% to €858 million mainly reflecting lower average net price and patients switching to Toujeo[®]. In Europe, third-quarter Lantus[®] sales were €215 million (down 11.0%) while in Emerging Markets, sales were €232 million (up

Third-quarter sales of **Toujeo**® were €167 million were recorded in the U.S. and €33 million were from Europe. The global roll-out of this product continues and Sanofi expects Toujeo® to be available in over 40 countries by the end of 2016. In Japan, the two-week prescription limit was lifted in September 2016, resulting in a significant increase in market share (9.2% the second week of October- IMS Market Share of the Basal insulin market in International Units). Year-to-date sales of Toujeo® were €411 million.

Sales of **Amaryl**® were €92 million, up 1.1% in the third quarter, of which €74 million were generated in Emerging Markets (up 6.8%). Year-to-date sales of Amaryl® were €273 million, down 4.7%.

Third-quarter sales of **Apidra**® were up 6.8% to €94 million, reflecting lower sales in the U.S. (down 8.8% to €31 million), which were more than offset by the performance in Emerging Markets (up 33.3% to €19 million) and Europe (up 10.0% to €32 million). Year-to-date sales of Apidra® increased 2.2% to €272 million.

Sanofi has recently been informed by U.S. payers of the 2017 formulary status for its products. Despite the anticipated introduction of biosimilar glargine, Lantus® and Toujeo® remain competitively positioned on the vast majority of formularies in the U.S. Given the recent performance of our diabetes franchise in the EU and Emerging Markets, as well as the aforementioned coverage in the U.S., Sanofi continues to expect global diabetes sales over the period from 2015 to 2018 to decline at an average annualized rate of between 4% and 8% at CER.

Cardiovascular franchise

Praluent® (alirocumab, collaboration with Regeneron) was launched in the U.S. and in a number of European markets in 2015 and 2016. Third-quarter sales of Praluent® were €35 million of which €28 million were in the U.S. and €6 million in Europe. Praluent® was launched in Japan in July. Year-to-date sales of Praluent® were €68 million reflecting significant payer utilization management restrictions in the U.S. and limited market access in Europe.

Third-quarter sales and first nine-month sales of **Multaq**® were €89 million (up 3.5%) and €259 million (up 1.6%), respectively. In August 2016, the District Court of Delaware ruled in favor of Sanofi in the Multaq® patent litigation holding that the defendants infringe both of the patents at suit; the '800 Formulation patent and the 167 Method of Use patent, expiring in 2018 and 2029, respectively. Both defendants appealed that ruling in September.

Established Rx Products

Net sales (€ million)	Q3 2016	Change (CER)	9M 2016	Change (CER)
Plavix®	401	-9.9%	1,181	-18.5% ^(b)
Lovenox®	404	-4.0%	1,222	-2.5% ^(c)
Renvela®/Renagel®	245	+2.9%	687	-0.6%
Aprove®/Avapro®	174	+7.2%	518	-8.4% ^(d)
Synvisc®/Synvisc-One®	100	+4.2%	297	+1.3%
Myslee®/Ambien®/Stilnox®	77	+1.4%	225	+0.5%
Allegra®	31	-18.2%	145	-10.0%
Other	1,103	-12.7%	3,468	-9.3% ^(e)
Total Established Rx Products	2,535	-7.4%^(a)	7,743	-8.5%^(f)

(a) Excluding Venezuela: -6.9%; (b) Excluding Venezuela: -16.3%; (c) Excluding Venezuela: -1.7%; (d) Excluding Venezuela: -0.4%; (e) Excluding Venezuela: -6.5%; (f) Excluding Venezuela: -6.1%;

Third-quarter sales of **Established Rx Products** decreased 7.4% to €2,535 million, reflecting generic competition to Plavix® in Japan, the impact of the termination of Auvi-Q® commercialization in the U.S. and lower sales in Venezuela. Excluding Venezuela and Auvi-Q®, sales of Established Rx Products were down 4.8%. In Emerging Markets, sales of Established Rx Products were €948 million, up 1.7% (up 3.4% excluding Venezuela). In the U.S., sales of Established Rx Products were down 13.2% (to €375 million). Excluding Auvi-Q®, sales of Established Rx Products were down 0.5% in the U.S. In Europe, sales of Established Rx Products decreased 7.6% to €856 million. Year-to-date sales of Established Rx Products decreased 8.5% to €7,743 million and 6.1% excluding Venezuela.

In the third quarter, sales of **Lovenox**® decreased 4.0% to €404 million reflecting generic competition in the U.S. (down 25.0% to € 12 million) and lower sales in Europe (down 2.3% to €248 million) and in Emerging Markets (down 3.1% to €120 million). In September, two enoxaparin biosimilars were approved in the European Union. Year-to-date sales of Lovenox® were €1,222 million down 2.5%.

Third-quarter sales of **Plavix**® decreased 9.9% to €401 million due to generic competition in Japan that started in June 2015 (sales in Japan were down 48.3% to €88 million), which was partially offset by the growth in China (up 18.1% to €122 million).

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