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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 24, 2019**

Baxter International Inc.

(Exact name of registrant as specified in its charter)

Delaware	**1-4448**	**36-0781620**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

One Baxter Parkway, Deerfield, Illinois	**60015**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (224) 948-2000

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $1.00 par value	**BAX (NYSE)**	**New York Stock Exchange**
		Chicago Stock Exchange
1.3% Global Notes due 2025	**BAX 25**	**New York Stock Exchange**
1.3% Global Notes due 2029	**BAX 29**	**New York Stock Exchange**
0.4% Global Notes due 2024	**BAX 24**	**New York Stock Exchange**

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On October 24, 2019, Baxter International Inc. (the "Company") issued a press release reporting certain preliminary operating results for the quarter ended September 30, 2019, and announcing that the Company began an internal investigation of misstatements in previously reported non-operating income related to foreign exchange gains and losses. The press release, including attachments, is furnished as Exhibit 99.1 to this report.

Item 8.01 Other Events.

Investigation

As announced in the press release dated October 24, 2019, the Company recently began an investigation into certain intra-Company transactions undertaken for the purpose of generating foreign exchange gains or losses. These transactions used a foreign exchange rate convention historically applied by the Company that was not in accordance with generally accepted accounting principles and enabled intra-Company transactions to be undertaken after the related exchange rates were already known. The Company is being assisted in the investigation by experienced external counsel and consultants.

These intra-Company transactions resulted in certain misstatements in the Company's previously reported non-operating income related to net foreign exchange gains. Within "Other (income) expense, net," the Company previously reported net foreign exchange gains of $8 million, $113 million, $28 million, $50 million, $73 million, and $22 million, for the years 2014, 2015, 2016, 2017, 2018, and the first half of 2019, respectively. The investigation is not limited to these periods and any subsequent adjustments to previously reported foreign exchange gains and losses may alter those non-operating income results.

The Audit Committee of the Company's Board of Directors is overseeing the investigation with the assistance of independent, experienced external advisors. The Company voluntarily advised the staff of the Securities and Exchange Commission ("SEC") that the internal investigation is underway and intends to provide additional information to the SEC as the investigation progresses. The Company does not expect to file its Quarterly Report on Form 10-Q for the period ended September 30, 2019 on a timely basis. The investigation is in its early stages and the Company cannot predict its duration or outcome.

FDA Warning Letter

As previously disclosed, the U.S. Food and Drug Administration ("FDA") commenced an inspection of Claris Injectables Limited's ("Claris") facilities in Ahmedabad, India in July 2017, immediately prior to the closing of the Company's acquisition of Claris. FDA completed the inspection and subsequently issued a related Warning Letter (the "Claris Warning Letter"). While FDA has not yet re-inspected the facilities, the Company is continuing to implement corrective and preventive actions to address FDA's prior observations and other items identified in connection with integrating Claris into our quality systems.

While management cannot speculate on when the Claris Warning Letter will be lifted, management continues to pursue and implement other manufacturing locations, including contract manufacturing organizations, to support the production of new products for distribution in the U.S. in the meantime. As of September 30, 2019, the Company has secured alternative locations to produce a majority of the planned new products for distribution into the U.S.

The Company's Pharmaceuticals global business unit remains committed to pursuing its $550 million goal in 2023 new product revenue, inclusive of Ahmedabad, through accelerated internal programs, external Business Development and Licensing, and alternative manufacturing locations.

Litigation

In August 2019, the Company was served with an amended complaint filed by Fayette County, Georgia in the MDL In re: National Prescription Opiate Litigation pending in the U.S. District Court, Northern District of Ohio (the "Complaint"). The Complaint alleges that multiple manufacturers and distributors of opiate products improperly marketed and diverted these products, which caused harm to Fayette County. The Complaint is limited in its allegations as to Baxter and does not distinguish between injectable opiate products and orally administered opiates. The Company manufactured generic injectable opiate products in its facility in Cherry Hill, NJ. The Company divested this facility in 2011.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Dated October 24, 2019.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

October 24, 2019

BAXTER INTERNATIONAL INC.

By: /s/ JAMES K. SACCARO
Name: James K. Saccaro
Title: Executive Vice President and Chief Financial Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

Media Contact
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BAXTER REPORTS PRELIMINARY THIRD QUARTER 2019 OPERATING RESULTS

- *Third quarter net revenue of $2.85 billion increased 3% on a reported basis and 5% on both a constant currency and operational basis*[1]
- *Third quarter GAAP operating income totaled $503 million or 17.6% of sales; adjusted operating income totaled $555 million or 19.5% of sales*
- *Performance driven by strong top-line results across all global businesses and regions as well as continued execution on business transformation initiatives*
- *Baxter expects fourth quarter 2019 sales growth of 3-4% on a reported basis and approximately 5% on both a constant currency and operational basis*
- *The Company announces internal investigation of misstatements in previously reported non-operating income related to foreign exchange gains and losses*

DEERFIELD, Ill., October 24, 2019 — Baxter International Inc. (NYSE:BAX), a leading global medical products company, today announced certain preliminary operating results for the quarter ended September 30, 2019. Baxter further indicated that the Company is investigating misstatements in previously reported non-operating income. The internal investigation is described in further detail below.

"Our strong preliminary operating results reflect the positive impact of Baxter's ongoing transformation, commitment to innovation and continued operational excellence," said José (Joe) E. Almeida, chairman and chief executive officer. "While the Company is working diligently and expeditiously to address the non-operating related accounting issue, Baxter's 50,000 employees remain intently focused on our Mission to Save and Sustain lives as well as executing on our strategy to deliver top quartile performance for all stakeholders."

Preliminary Third Quarter Operating Results

Worldwide sales in the third quarter totaled approximately $2.85 billion, an increase of 3% on a reported basis, and 5% on both a constant currency and operational basis. Operational sales exclude the impact of foreign exchange and generic competition for U.S. cyclophosphamide.

[1] See the "Non-GAAP Financial Measures" section and the tables attached to this press release for further information and reconciliations of non-GAAP financial measures used in this press release.

Sales in the U.S. totaled $1.2 billion and International sales totaled $1.6 billion. All Baxter geographic regions contributed to positive sales performance in the quarter. Sales in the Americas were $1.5 billion, sales in Europe, Middle East and Africa (EMEA) were $730 million, and sales in Asia Pacific (APAC) were $587 million.

Key performance drivers in the third quarter included strong sales of Baxter's peritoneal dialysis (PD) and continuous renal replacement therapies (CRRT), intravenous (IV) infusion systems and solutions, hemostats and sealants, and certain generic injectable pharmaceuticals. In addition, increased international demand for Baxter's hospital pharmacy compounding services contributed to the strong performance in the quarter. As expected, revenues were partially offset by lower U.S. sales of **Brevibloc** and in-center hemodialysis (ICHD) products.

Please see the attached schedules accompanying this press release for additional details on performance in the quarter, including sales by Baxter's six global business units.

Baxter reported operating income of $503 million for the third quarter. This includes special items totaling $52 million, primarily related to intangible asset amortization and business optimization initiatives, partially offset by insurance recoveries related to the impact of Hurricane Maria. On an adjusted basis, Baxter's third quarter operating income totaled $555 million, or 19.5% of sales, reflecting strong revenues and solid operational performance.

Business Highlights[2]

Baxter continues to achieve significant milestones in pursuit of its Mission for patients and emphasis on accelerating profitable growth. Among recent highlights, the Company:

- Initiated the U.S. and Canadian launches of Baxter's next-generation **PrisMax** system for continuous renal replacement therapy (CRRT) and therapeutic plasma exchange (TPE). Among many advanced features, **PrisMax** incorporates **TrueVue Analytics**, Baxter's proprietary data and analytics platform.
- Announced the agreement to acquire Cheetah Medical, a leading provider of non-invasive hemodynamic monitoring technologies. Once completed, this acquisition will accelerate Baxter's presence in the specialized patient monitoring space, expanding the portfolio with key technology used to guide fluid management based on individual patient needs.
- Announced a partnership with COSMED srl to commercialize **Q-NRG+**, a metabolic monitoring device utilizing indirect calorimetry (IC) technology. IC is used to accurately measure resting energy expenditure (REE) — a patient's caloric needs while at rest — and is recommended in guidelines from nutrition societies around the world.
- Broadened its generic injectable pharmaceuticals portfolio with the U.S. launch of **Myxredlin** (Insulin Human in 0.9% Sodium Chloride Injection), the first and only ready-to-use insulin for IV infusion in the hospital and other acute care settings.

[2] See links to original press releases for additional product information.

- Announced new data associating the use of Baxter's automated peritoneal dialysis (APD) cyclers and the **Sharesource** remote patient management platform with a 39% reduction in hospitalizations for home PD patients receiving care at Baxter Renal Care Services clinics in Colombia. The data also show the use of **Sharesource** is associated with a 54% reduction in the length of hospital stay for home dialysis patients requiring inpatient care. **Sharesource** is the most widely adopted telehealth platform globally for home dialysis and has helped manage approximately 10 million PD treatments in more than 40 countries.

The Company has also received multiple recognitions in recent months. Among them, Baxter was:

- Named to the Dow Jones Sustainability Indices (DJSI) — DJSI World and DJSI North America — recognizing continued leadership in sustainability and corporate responsibility. Baxter has appeared on each of these lists since the introduction of the DJSI in 1999.
- Recognized as a 2019 Top 10 Percent Inclusion Index Company, one of just 14 companies cited for superior achievement in creating an inclusive workplace as part of Diversity Best Practices' annual Inclusion Index.
- Honored by *Working Mother* magazine as one of its 2019 100 Best Companies, and one of its 2019 Best Companies for Dads.

Internal Investigation

Baxter recently began an investigation into certain intra-Company transactions undertaken for the purpose of generating foreign exchange gains or losses. These transactions used a foreign exchange rate convention historically applied by the Company that was not in accordance with generally accepted accounting principles and enabled intra-Company transactions to be undertaken after the related exchange rates were already known. The Company is being assisted in the investigation by experienced external counsel and consultants.

These intra-Company transactions resulted in certain misstatements in the Company's previously reported non-operating income related to net foreign exchange gains. Within "Other (income) expense, net," the Company previously reported net foreign exchange gains of $8 million, $113 million, $28 million, $50 million, $73 million, and $22 million, for the years 2014, 2015, 2016, 2017, 2018, and the first half of 2019, respectively. The investigation is not limited to these periods and any subsequent adjustments to previously reported foreign exchange gains and losses may alter those non-operating income results.

The Audit Committee of the Company's Board of Directors is overseeing this investigation with the assistance of independent, experienced external advisors. Baxter voluntarily advised the staff of the Securities and Exchange Commission (SEC) that the internal investigation is underway and intends to provide additional information to the SEC as the investigation progresses. The Company does not expect to file its quarterly report on Form 10-Q for the period ended September 30, 2019 on a timely basis.

The investigation is in its early stages and the Company cannot predict its duration or outcome. Upon completion of the investigation and the Company's evaluation of the materiality of the misstatements, the Company expects to either amend its periodic reports previously filed with the SEC to include

restated financial statements that correct those misstatements, or include in reports for future periods restated comparative financial statements that correct those misstatements. The Company also will consider the extent to which these matters impact the effectiveness of its internal control over financial reporting.

"Baxter takes this matter very seriously, and the Board along with the Company's leadership team fully supports a comprehensive investigation," Mr. Almeida stated. "The Company is taking steps to strengthen and enhance its internal controls, and we look forward to sharing our full financial results as soon as possible."

As part of any corrections to previously issued financial statements after completion of the non-operating income investigation, Baxter also expects to correct certain items that affect operating income and were immaterial to its previously reported results of operations. These items include the impact of the use of the foreign exchange rate convention to translate the results of the Company's foreign operations into U.S. dollars and the impact of the incorrect accounting for placed equipment that the Company leases to its customers. Correction of these immaterial misstatements would not affect the reported sales growth rate in the third quarter 2019 or the projected reported growth rate or projected operating margin range for the fourth quarter presented herein.

Fourth Quarter 2019 Sales and Operating Margin Outlook[2]

For the fourth quarter of 2019, the Company expects sales growth of 3-4% on a reported basis and approximately 5% on a constant currency and operational basis. Baxter expects operating margin to be between 15.2% and 15.9% on a reported basis and between 18.5% and 19% on an adjusted basis.

Conference Call Information

A webcast of Baxter's third quarter 2019 conference call for investors can be accessed live from a link on the Company's website at www.baxter.com beginning at 7:30 a.m. CDT on October 24, 2019. Please see www.baxter.com for more information regarding this and future investor events and webcasts.

About Baxter

Every day, millions of patients and caregivers rely on Baxter's leading portfolio of critical care, nutrition, renal, hospital and surgical products. For more than 85 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers that make it happen. With products, technologies and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on Twitter, LinkedIn and Facebook.

Non-GAAP Financial Measures

This press release and the accompanying tables contain financial measures that are not calculated in accordance with GAAP. The non-GAAP financial measures include adjusted operating income, adjusted gross margin, adjusted selling, general and administrative expenses, adjusted research and development expenses and adjusted other operating income, net, each excluding special items, and sales growth on a constant currency and operational basis. Special items are excluded because they are highly variable or

unusual, and of a size that may substantially affect the Company's reported operations for a period. These items are excluded from the forecasted ratio of adjusted operating income to net sales for the same reasons and because they are difficult to predict. Certain of those items represent estimates based on information reasonably available at the time of the press release. Future events or new information may result in different actual results.

Net sales growth rates are presented on a constant currency basis. These measures provide information on the percentage change in net sales growth assuming that foreign currency exchange rates have not changed between the prior and current periods. Net sales growth rates are also presented on an operational basis. For the quarter ended September 30, 2019, it excludes the impact of foreign exchange and generic competition for U.S. cyclophosphamide. This measure provides information on the change in net sales growth rates assuming that foreign exchange rates remain constant and excluding the impact of U.S. cyclophosphamide competition.

For the quarter ended September 30, 2019, adjusted operating income and margin exclude the impact of special items including intangible asset amortization, business optimization charges, acquisition and integration expenses, expenses related to European medical devices regulation, and benefits related to insurance recoveries from Hurricane Maria and a legacy product-related matter. These items are excluded because they are highly variable or unusual and of a size that may substantially impact the Company's reported operations for a period. Additionally, intangible asset amortization is excluded as a special item to facilitate an evaluation of current and past operating performance and is consistent with how management and the Company's Board of Directors assess performance.

The fourth quarter outlook for adjusted operating margin reflects the exclusion of special items that are highly variable or unusual, of a size that may substantially affect the Company's forecast for the period, or are difficult to predict. Intangible asset amortization is excluded as a special item to facilitate an evaluation of future and past operating performance and is consistent with how management forecasts future performance. The specific items that have been excluded from the outlook are estimated intangible asset amortization, estimated business optimization charges, estimated acquisition and integration expenses, estimated expenses related to European medical devices regulation, and estimated investigation costs.

Non-GAAP financial measures may provide a more complete understanding of the Company's operations and can facilitate a fuller analysis of those operations, particularly in evaluating performance from one period to another. Management believes that non-GAAP financial measures, when used in conjunction with the results presented in accordance with GAAP and the reconciliations to corresponding GAAP financial measures, may enhance an investor's overall understanding of the Company's past financial performance and prospects for the future. Accordingly, management uses these non-GAAP measures internally in financial planning, to monitor business unit performance, and, in some cases, for purposes of determining incentive compensation. This information should be considered in addition to, and not as substitutes for, information prepared in accordance with GAAP.

Forward Looking Statements

This release includes forward-looking statements concerning the Company's financial results, business development activities, capital structure, cost savings initiatives, and R&D pipeline, including results of clinical trials and planned product launches. These forward-looking statements may include statements with respect to: the outcome of the investigation of misstatements in previously reported non-operating income related to foreign exchange gains and losses; the expectation that the Company will not timely file its Quarterly Report on Form 10-Q for the quarter ended September 30, 2019; the Company's ability to share its full financial results for the quarter ended September 30, 2019 and the timing thereof; the Company's expectation to either amend its periodic reports previously filed with the SEC to include restated financial statements or include in reports for future periods restated comparative financial statements; the Company's expectation to correct certain operational items that were immaterial to its previously reported results of operations; the Company's expected sales growth and operating margin for the fourth quarter of 2019; and the belief that the expected acquisition of Cheetah Medical will accelerate the Company's presence in the specialized patient monitoring space. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: developments in the investigation related to foreign exchange gains and losses, including developments that would expand the scope of the investigation or require the correction of additional misstatements in the previously issued financial statements; demand for and market acceptance of risks for new and existing products; product development risks; product quality or patient safety concerns; continuity, availability and pricing of acceptable raw materials and component supply; inability to create additional production capacity in a timely manner or the occurrence of other manufacturing or supply difficulties (including as a result of a natural disaster or otherwise); breaches or failures of the Company's information technology systems or products, including by cyberattack, unauthorized access or theft; the adequacy of the Company's cash flows from operations and other sources of liquidity to meet its ongoing cash obligations and fund its investment program; loss of key employees or inability to identify and recruit new employees; future actions of regulatory bodies and other governmental authorities, including the FDA, the Department of Justice, the Securities and Exchange Commission, the New York Attorney General and foreign regulatory agencies, including the continued delay in lifting the warning letter at our Ahmedabad facility or proceedings related to the ongoing investigation related to foreign exchange gains and losses; proposed regulatory changes of the U.S. Department of Health and Human Services in kidney health policy and reimbursement, which may substantially change the U.S. end stage renal disease market and demand for our peritoneal dialysis products, necessitating significant multi-year capital expenditures, which are difficult to estimate in advance; failures with respect to compliance programs; accurate identification of and execution on business development and R&D opportunities and realization of anticipated benefits (including the acquisitions of Claris Injectables and two surgical products from Mallinckrodt plc and the expected acquisition of Cheetah Medical); future actions of third parties, including payers; U.S. healthcare reform and other global austerity measures; pricing, reimbursement, taxation and rebate policies of government agencies and private payers; the impact of competitive products and pricing, including generic competition, drug reimportation and disruptive technologies; fluctuations in foreign exchange and interest rates; the ability to enforce owned or in-licensed patents or the prevention or restriction of the manufacture, sale or use of products or technology affected by patents of third parties; the impact of global economic conditions (including potential trade wars); global, trade and tax policies; any change in laws concerning the taxation of

income (including current or future tax reform), including income earned outside the United States and potential taxes associated with the Base Erosion and Anti-Abuse Tax; actions taken by tax authorities in connection with ongoing tax audits; the outcome of pending or future litigation, including with respect to the opioid litigation; and other risks identified in Baxter's most recent filing on Form 10-K and other Securities and Exchange Commission filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements unless otherwise required by the federal securities laws.

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BAXTER INTERNATIONAL INC.
Preliminary Condensed Consolidated Financial Information
For The Three Months Ended September 30, 2019
(unaudited, in millions)

NET SALES	$2,851
GROSS MARGIN	$1,230
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	$ 627
RESEARCH AND DEVELOPMENT EXPENSES	$ 144
OTHER OPERATING INCOME, NET	$ 44
OPERATING INCOME	$ 503

The following preliminary condensed consolidated financial information is prepared on a non-GAAP basis:

ADJUSTED GROSS MARGIN	$1,303 [A]
ADJUSTED SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	$ 614 [A]
ADJUSTED RESEARCH AND DEVELOPMENT EXPENSES	$ 134 [A]
ADJUSTED OTHER OPERATING INCOME, NET	$ — [A]
ADJUSTED OPERATING INCOME	$ 555 [A]

Net sales by operating segment were:

AMERICAS	$1,534
EMEA	730
APAC	587
TOTAL	$2,851

Net sales by GBU for the three months ended September 30, 2019 was:

	U.S.	International	Total
RENAL CARE [1]	$ 199	$ 719	$ 918
MEDICATION DELIVERY [2]	461	240	701
PHARMACEUTICALS [3]	223	304	527
CLINICAL NUTRITION [4]	80	139	219
ADVANCED SURGERY [5]	134	82	216
ACUTE THERAPIES [6]	44	86	130
OTHER [7]	83	57	140
TOTAL	$1,224	$1,627	$2,851
SALES GROWTH — AS REPORTED			3%
SALES GROWTH — CONSTANT CURRENCY			5% [A]
SALES GROWTH — OPERATIONAL			5% [A]

[1] Includes sales of the company's peritoneal dialysis (PD), hemodialysis (HD) and additional dialysis therapies and services.

[2] Includes sales of the company's intravenous (IV) therapies, infusion pumps, administration sets and drug reconstitution devices.

[3] Includes sales of the company's premixed and oncology drug platforms, inhaled anesthesia and critical care products and pharmacy compounding services.

[4] Includes sales of the company's parenteral nutrition (PN) therapies and related products.

[5] Includes sales of the company's biological products and medical devices used in surgical procedures for hemostasis, tissue sealing and adhesion prevention.

[6] Includes sales of the company's continuous renal replacement therapies (CRRT) and other organ support therapies focused in the intensive care unit (ICU).

[7] Includes primarily sales of contract manufacturing services from the company's pharmaceutical partnering business.

For more information on the company's use of non-GAAP financial measures, please see the Non-GAAP Financial Measures section of this press release.

[A] Refer to page 9 for a description of the adjustments and a reconciliation to GAAP measures.

BAXTER INTERNATIONAL INC.
Description of Adjustments and Reconciliation of Preliminary GAAP to Non-GAAP Measures
(unaudited, in millions)

The following is a reconciliation of net sales growth as reported to operational sales growth for the three months ended September 30, 2019:

	Net Sales as Reported	U.S. Cyclophosphamide	FX	**Operational Sales**
Total	**3%**	0%	2%	**5%**

The following is a reconciliation of projected net sales growth as reported to projected operational sales growth for the three months ending December 31, 2019:

	Net Sales as Reported	U.S. Cyclophosphamide	FX	**Operational Sales**
Total	**3% - 4%**	0%	1% - 2%	**5%**

The company's GAAP results for the three months ended September 30, 2019 included special items which impacted the GAAP measures as follows:

	Gross Margin	Selling, General and Administrative Expenses	Research and Development Expenses	Other Operating Income, net	Operating Income
Reported	**$ 1,230**	**$ 627**	**$ 144**	**$ (44)**	**$ 503**
Reported percent of net sales	43.1%	22.0%	5.1%	-1.5%	17.6%
Intangible asset amortization [1]	48	—	—	—	48
Business optimization items [2]	10	(10)	(8)	—	28
Acquisition and integration expenses [3]	8	(3)	(2)	—	13
European medical devices regulation [4]	7	—	—	—	7
Insurance recoveries from a legacy product-related matter [5]	—	—	—	4	(4)
Hurricane Maria insurance recoveries [6]	—	—	—	40	(40)
Adjusted	**$ 1,303**	**$ 614**	**$ 134**	**$ —**	**$ 555**
Adjusted percent of net sales	45.7%	21.5%	4.7%	0.0%	19.5%

[1] The company's results included intangible asset amortization expense of $48 million.
[2] The company's results included charges of $28 million associated with its execution of programs to optimize its global organization and cost structure.
[3] The company's results included $13 million of acquisition and integration expenses. This included integration expenses related to its acquisitions of Claris Injectables Limited and the RECOTHROM and PREVELEAK products in prior periods, as well as the 2019 acquisition of an in-process research and development asset.
[4] The company's results included costs of $7 million related to updating its quality systems and product labeling to comply with the new medical device reporting regulation and other requirements of the European Union's regulations for medical devices that will become effective in 2020.
[5] The company's results included a benefit of $4 million for its allocation of insurance proceeds received pursuant to a settlement and cost-sharing arrangement for a legacy-product related matter.
[6] The company's results included a benefit of $40 million related to insurance recoveries as a result of losses incurred due to Hurricane Maria.

The following is a reconciliation of projected operating margin as reported to projected adjusted operating margin for the three months ending December 31, 2019:

	Operating Margin
Reported	**15.2% - 15.9%**
Estimated intangible asset amortization	1.6%
Estimated business optimization items	0.6% - 0.8%
Estimated acquisition and integration expenses	0.4%
Estimated European medical devices regulation	0.3%
Estimated investigation costs	0.2%
Adjusted	**18.5% - 19.0%**

For more information on the company's use of non-GAAP financial measures, please see the Non-GAAP Financial Measures section of this press release.