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Shares at December 31, 2017

20,161

2,625

Granted

6,074

1,142

Issued

(6,684  
)

(1,151  
)

Canceled/forfeited/adjusted

(1,091  
)

(122  
)

Shares at December 30, 2018

18,460

2,494

The average fair value of the restricted share units granted was \$119.67, \$107.69 and \$92.45 in 2018, 2017 and 2016, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was \$613.7 million, \$596.5 million and \$587.7 million in 2018, 2017 and 2016, respectively.

The weighted average fair value of the performance share units granted was \$120.64, \$114.13 and \$105.30 in 2018, 2017 and 2016, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value

of performance share units issued was \$128.8 million, \$132.5 million and \$127.7 million in 2018, 2017 and 2016, respectively.

## 18. Segments of Business and Geographic Areas

| (Dollars in Millions)   | Sales to Customers |        |        | % Change       |                |
|-------------------------|--------------------|--------|--------|----------------|----------------|
|                         | 2018               | 2017   | 2016   | '18 vs.<br>'17 | '17 vs.<br>'16 |
| <b>CONSUMER</b>         |                    |        |        |                |                |
| <b>Baby Care</b>        |                    |        |        |                |                |
| U.S.                    | \$422              | 449    | 488    | (6.0 )%        | (8.0 )         |
| International           | 1,436              | 1,467  | 1,513  | (2.1 )         | (3.0 )         |
| Worldwide               | 1,858              | 1,916  | 2,001  | (3.0 )         | (4.2 )         |
| <b>Beauty</b>           |                    |        |        |                |                |
| U.S.                    | 2,403              | 2,335  | 2,135  | 2.9            | 9.4            |
| International           | 1,979              | 1,865  | 1,762  | 6.1            | 5.8            |
| Worldwide               | 4,382              | 4,200  | 3,897  | 4.3            | 7.8            |
| <b>Oral Care</b>        |                    |        |        |                |                |
| U.S.                    | 637                | 616    | 648    | 3.4            | (4.9 )         |
| International           | 918                | 915    | 920    | 0.3            | (0.5 )         |
| Worldwide               | 1,555              | 1,531  | 1,568  | 1.6            | (2.4 )         |
| <b>OTC</b>              |                    |        |        |                |                |
| U.S.                    | 1,850              | 1,716  | 1,675  | 7.8            | 2.4            |
| International           | 2,484              | 2,410  | 2,302  | 3.1            | 4.7            |
| Worldwide               | 4,334              | 4,126  | 3,977  | 5.0            | 3.7            |
| <b>Women's Health</b>   |                    |        |        |                |                |
| U.S.                    | 13                 | 12     | 19     | 8.3            | (36.8)         |
| International           | 1,036              | 1,038  | 1,048  | (0.2 )         | (1.0 )         |
| Worldwide               | 1,049              | 1,050  | 1,067  | (0.1 )         | (1.6 )         |
| <b>Wound Care/Other</b> |                    |        |        |                |                |
| U.S.                    | 436                | 437    | 455    | (0.2 )         | (4.0 )         |
| International           | 239                | 342    | 342    | (30.1)         | 0.0            |
| Worldwide               | 675                | 779    | 797    | (13.4)         | (2.3 )         |
| <b>TOTAL CONSUMER</b>   |                    |        |        |                |                |
| U.S.                    | 5,761              | 5,565  | 5,420  | 3.5            | 2.7            |
| International           | 8,092              | 8,037  | 7,887  | 0.7            | 1.9            |
| Worldwide               | 13,853             | 13,602 | 13,307 | 1.8            | 2.2            |
| <b>PHARMACEUTICAL</b>   |                    |        |        |                |                |
| <b>Immunology</b>       |                    |        |        |                |                |
| U.S.                    | 9,073              | 8,871  | 8,846  | 2.3            | 0.3            |
| International           | 4,047              | 3,373  | 3,122  | 20.0           | 8.0            |
| Worldwide               | 13,120             | 12,244 | 11,968 | 7.2            | 2.3            |
| <b>REMICADE®</b>        |                    |        |        |                |                |
| U.S.                    | 3,664              | 4,525  | 4,842  | (19.0)         | (6.5 )         |
| U.S. Exports            | 436                | 563    | 782    | (22.6)         | (28.0)         |
| International           | 1,226              | 1,227  | 1,342  | (0.1 )         | (8.6 )         |
| Worldwide               | 5,326              | 6,315  | 6,966  | (15.7)         | (9.3 )         |



|  |       |       |       |        |        |
|--|-------|-------|-------|--------|--------|
| SIMPONI / SIMPONI ARIA®                                  |       |       |       |        |        |
| U.S.   | 1,051 | 954   | 959   | 10.2   | (0.5 ) |
| International  | 1,033 | 879   | 786   | 17.5   | 11.8   |
| Worldwide  | 2,084 | 1,833 | 1,745 | 13.7   | 5.0    |
| STELARA®   |       |       |       |        |        |
| U.S.   | 3,469 | 2,767 | 2,263 | 25.4   | 22.3   |
| International  | 1,687 | 1,244 | 969   | 35.6   | 28.4   |
| Worldwide  | 5,156 | 4,011 | 3,232 | 28.5   | 24.1   |
| TREMFAVA®  |       |       |       |        |        |
| U.S.   | 453   | 62    | —     | *      | *      |
| International  | 91    | 1     | —     | *      | *      |
| Worldwide  | 544   | 63    | —     | *      | *      |
| OTHER IMMUNOLOGY   |       |       |       |        |        |
| U.S.   | —     | —     | —     | —      | —      |
| International  | 10    | 22    | 25    | (54.5) | (12.0) |
| Worldwide  | 10    | 22    | 25    | (54.5) | (12.0) |
| Infectious Diseases                                      |       |       |       |        |        |
| U.S.   | 1,378 | 1,358 | 1,461 | 1.5    | (7.0 ) |
| International  | 1,926 | 1,796 | 1,747 | 7.2    | 2.8    |
| Worldwide  | 3,304 | 3,154 | 3,208 | 4.8    | (1.7 ) |
| EDURANT® / rilpivirine                                   |       |       |       |        |        |
| U.S.   | 58    | 58    | 52    | 0.0    | 11.5   |
| International  | 758   | 656   | 521   | 15.5   | 25.9   |
| Worldwide  | 816   | 714   | 573   | 14.3   | 24.6   |
| PREZISTA® / PREZCOBIX® / REZOLSTA® / SYMTUZA®            |       |       |       |        |        |
| U.S.   | 1,169 | 1,109 | 1,143 | 5.4    | (3.0 ) |
| International  | 786   | 712   | 708   | 10.4   | 0.6    |
| Worldwide  | 1,955 | 1,821 | 1,851 | 7.4    | (1.6 ) |
| OTHER INFECTIOUS DISEASES                                |       |       |       |        |        |
| U.S.   | 151   | 191   | 266   | (20.9) | (28.2) |
| International  | 382   | 428   | 518   | (10.7) | (17.4) |
| Worldwide  | 533   | 619   | 784   | (13.9) | (21.0) |
| Neuroscience   |       |       |       |        |        |
| U.S.   | 2,574 | 2,630 | 2,628 | (2.1 ) | 0.1    |
| International  | 3,503 | 3,356 | 3,457 | 4.4    | (2.9 ) |
| Worldwide  | 6,077 | 5,986 | 6,085 | 1.5    | (1.6 ) |
| CONCERTA® / Methylphenidate                              |       |       |       |        |        |
| U.S.   | 229   | 384   | 468   | (40.4) | (17.9) |
| International  | 434   | 407   | 395   | 6.6    | 3.0    |
| Worldwide  | 663   | 791   | 863   | (16.2) | (8.3 ) |
| INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA® |       |       |       |        |        |
| U.S.   | 1,791 | 1,590 | 1,343 | 12.6   | 18.4   |
| International  | 1,137 | 979   | 871   | 16.1   | 12.4   |
| Worldwide  | 2,928 | 2,569 | 2,214 | 14.0   | 16.0   |



|                              |       |       |       |        |        |
|------------------------------|-------|-------|-------|--------|--------|
| RISPERDAL CONSTA®            |       |       |       |        |        |
| U.S.                         | 315   | 360   | 381   | (12.5) | (5.5 ) |
| International                | 422   | 445   | 512   | (5.2 ) | (13.1) |
| Worldwide                    | 737   | 805   | 893   | (8.4 ) | (9.9 ) |
| OTHER NEUROSCIENCE           |       |       |       |        |        |
| U.S.                         | 239   | 296   | 436   | (19.3) | (32.1) |
| International                | 1,510 | 1,525 | 1,679 | (1.0 ) | (9.2 ) |
| Worldwide                    | 1,749 | 1,821 | 2,115 | (4.0 ) | (13.9) |
| Oncology                     |       |       |       |        |        |
| U.S.                         | 4,331 | 3,098 | 2,335 | 39.8   | 32.7   |
| International                | 5,513 | 4,160 | 3,472 | 32.5   | 19.8   |
| Worldwide                    | 9,844 | 7,258 | 5,807 | 35.6   | 25.0   |
| DARZALEX®                    |       |       |       |        |        |
| U.S.                         | 1,203 | 884   | 471   | 36.1   | 87.7   |
| International                | 822   | 358   | 101   | *      | *      |
| Worldwide                    | 2,025 | 1,242 | 572   | 63.0   | *      |
| IMBRUVICA®                   |       |       |       |        |        |
| U.S.                         | 1,129 | 841   | 613   | 34.2   | 37.2   |
| International                | 1,486 | 1,052 | 638   | 41.3   | 64.9   |
| Worldwide                    | 2,615 | 1,893 | 1,251 | 38.1   | 51.3   |
| VELCADE®                     |       |       |       |        |        |
| U.S.                         | —     | —     | —     | —      | —      |
| International                | 1,116 | 1,114 | 1,224 | 0.2    | (9.0 ) |
| Worldwide                    | 1,116 | 1,114 | 1,224 | 0.2    | (9.0 ) |
| ZYTIGA® /abiraterone acetate |       |       |       |        |        |
| U.S.                         | 1,771 | 1,228 | 1,089 | 44.2   | 12.8   |
| International                | 1,727 | 1,277 | 1,171 | 35.2   | 9.1    |
| Worldwide                    | 3,498 | 2,505 | 2,260 | 39.6   | 10.8   |
| OTHER ONCOLOGY               |       |       |       |        |        |
| U.S.                         | 228   | 145   | 162   | 57.2   | (10.5) |
| International                | 362   | 359   | 338   | 0.8    | 6.2    |
| Worldwide                    | 590   | 504   | 500   | 17.1   | 0.8    |
| Pulmonary Hypertension       |       |       |       |        |        |
| U.S.                         | 1,651 | 773   | —     | *      | *      |
| International                | 922   | 554   | —     | 66.4   | *      |
| Worldwide                    | 2,573 | 1,327 | —     | 93.9   | *      |
| OPSUMIT®                     |       |       |       |        |        |
| U.S.                         | 700   | 320   | —     | *      | *      |
| International                | 515   | 253   | —     | *      | *      |
| Worldwide                    | 1,215 | 573   | —     | *      | *      |
| TRACLEER®                    |       |       |       |        |        |
| U.S.                         | 268   | 161   | —     | 66.5   | *      |
| International                | 278   | 242   | —     | 14.9   | *      |
| Worldwide                    | 546   | 403   | —     | 35.5   | *      |





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|                                     |        |        |        |        |        |
|-------------------------------------|--------|--------|--------|--------|--------|
| UPTRAVI®                            |        |        |        |        |        |
| U.S.                                | 598    | 238    | —      | *      | *      |
| International                       | 65     | 25     | —      | *      | *      |
| Worldwide                           | 663    | 263    | —      | *      | *      |
| OTHER                               |        |        |        |        |        |
| U.S.                                | 85     | 54     | —      | 57.4   | *      |
| International                       | 64     | 34     | —      | 88.2   | *      |
| Worldwide                           | 149    | 88     | —      | 69.3   | *      |
| Cardiovascular / Metabolism / Other |        |        |        |        |        |
| U.S.                                | 4,279  | 4,744  | 4,855  | (9.8 ) | (2.3 ) |
| International                       | 1,537  | 1,543  | 1,541  | (0.4 ) | 0.1    |
| Worldwide                           | 5,816  | 6,287  | 6,396  | (7.5 ) | (1.7 ) |
| XARELTO®                            |        |        |        |        |        |
| U.S.                                | 2,477  | 2,500  | 2,288  | (0.9 ) | 9.3    |
| International                       | —      | —      | —      | —      | —      |
| Worldwide                           | 2,477  | 2,500  | 2,288  | (0.9 ) | 9.3    |
| INVOKANA® / INVOKAMET®              |        |        |        |        |        |
| U.S.                                | 711    | 944    | 1,273  | (24.7) | (25.8) |
| International                       | 170    | 167    | 134    | 1.8    | 24.6   |
| Worldwide                           | 881    | 1,111  | 1,407  | (20.7) | (21.0) |
| PROCRIT® / EPREX®                   |        |        |        |        |        |
| U.S.                                | 674    | 675    | 767    | (0.1 ) | (12.0) |
| International                       | 314    | 297    | 338    | 5.7    | (12.1) |
| Worldwide                           | 988    | 972    | 1,105  | 1.6    | (12.0) |
| OTHER                               |        |        |        |        |        |
| U.S.                                | 417    | 625    | 527    | (33.3) | 18.6   |
| International                       | 1,053  | 1,079  | 1,069  | (2.4 ) | 0.9    |
| Worldwide                           | 1,470  | 1,704  | 1,596  | (13.7) | 6.8    |
| TOTAL PHARMACEUTICAL                |        |        |        |        |        |
| U.S.                                | 23,286 | 21,474 | 20,125 | 8.4    | 6.7    |
| International                       | 17,448 | 14,782 | 13,339 | 18.0   | 10.8   |
| Worldwide                           | 40,734 | 36,256 | 33,464 | 12.4   | 8.3    |
| MEDICAL DEVICES                     |        |        |        |        |        |
| Diabetes Care                       |        |        |        |        |        |
| U.S.                                | 371    | 612    | 739    | (39.4) | (17.2) |
| International                       | 638    | 1,003  | 1,050  | (36.4) | (4.5 ) |
| Worldwide                           | 1,009  | 1,615  | 1,789  | (37.5) | (9.7 ) |
| Diagnostics                         |        |        |        |        |        |
| U.S.                                | —      | —      | —      | —      | —      |
| International                       | —      | 1      | 66     | *      | *      |
| Worldwide                           | —      | 1      | 66     | *      | *      |
| Interventional Solutions            |        |        |        |        |        |
| U.S.                                | 1,283  | 1,148  | 1,031  | 11.8   | 11.3   |
| International                       | 1,363  | 1,148  | 1,024  | 18.7   | 12.1   |
| Worldwide                           | 2,646  | 2,296  | 2,055  | 15.2   | 11.7   |



|                        |       |       |       |        |        |
|------------------------|-------|-------|-------|--------|--------|
| Orthopaedics           |       |       |       |        |        |
| U.S.                   | 5,281 | 5,404 | 5,438 | (2.3 ) | (0.6 ) |
| International          | 3,604 | 3,654 | 3,690 | (1.4 ) | (1.0 ) |
| Worldwide              | 8,885 | 9,058 | 9,128 | (1.9 ) | (0.8 ) |
| HIPS                   |       |       |       |        |        |
| U.S.                   | 841   | 827   | 798   | 1.7    | 3.6    |
| International          | 577   | 567   | 563   | 1.8    | 0.7    |
| Worldwide              | 1,418 | 1,394 | 1,361 | 1.7    | 2.4    |
| KNEES                  |       |       |       |        |        |
| U.S.                   | 911   | 948   | 943   | (3.9 ) | 0.5    |
| International          | 591   | 575   | 581   | 2.8    | (1.0 ) |
| Worldwide              | 1,502 | 1,523 | 1,524 | (1.4 ) | (0.1 ) |
| TRAUMA                 |       |       |       |        |        |
| U.S.                   | 1,599 | 1,576 | 1,545 | 1.5    | 2.0    |
| International          | 1,100 | 1,040 | 1,024 | 5.8    | 1.6    |
| Worldwide              | 2,699 | 2,616 | 2,569 | 3.2    | 1.8    |
| SPINE & OTHER          |       |       |       |        |        |
| U.S.                   | 1,930 | 2,053 | 2,152 | (6.0 ) | (4.6 ) |
| International          | 1,336 | 1,472 | 1,522 | (9.2 ) | (3.3 ) |
| Worldwide              | 3,266 | 3,525 | 3,674 | (7.3 ) | (4.1 ) |
| Surgery                |       |       |       |        |        |
| U.S.                   | 4,125 | 4,085 | 4,026 | 1.0    | 1.5    |
| International          | 5,776 | 5,474 | 5,270 | 5.5    | 3.9    |
| Worldwide              | 9,901 | 9,559 | 9,296 | 3.6    | 2.8    |
| ADVANCED               |       |       |       |        |        |
| U.S.                   | 1,657 | 1,620 | 1,524 | 2.3    | 6.3    |
| International          | 2,345 | 2,136 | 1,993 | 9.8    | 7.2    |
| Worldwide              | 4,002 | 3,756 | 3,517 | 6.5    | 6.8    |
| GENERAL                |       |       |       |        |        |
| U.S.                   | 1,751 | 1,728 | 1,669 | 1.3    | 3.5    |
| International          | 2,806 | 2,735 | 2,693 | 2.6    | 1.6    |
| Worldwide              | 4,557 | 4,463 | 4,362 | 2.1    | 2.3    |
| SPECIALTY              |       |       |       |        |        |
| U.S.                   | 717   | 737   | 833   | (2.7 ) | (11.5) |
| International          | 625   | 603   | 584   | 3.6    | 3.3    |
| Worldwide              | 1,342 | 1,340 | 1,417 | 0.1    | (5.4 ) |
| Vision                 |       |       |       |        |        |
| U.S.                   | 1,777 | 1,575 | 1,032 | 12.8   | 52.6   |
| International          | 2,776 | 2,488 | 1,753 | 11.6   | 41.9   |
| Worldwide              | 4,553 | 4,063 | 2,785 | 12.1   | 45.9   |
| CONTACT LENSES / OTHER |       |       |       |        |        |
| U.S.                   | 1,237 | 1,122 | 1,032 | 10.2   | 8.7    |
| International          | 2,065 | 1,914 | 1,753 | 7.9    | 9.2    |
| Worldwide              | 3,302 | 3,036 | 2,785 | 8.8    | 9.0    |



## SURGICAL

|               |       |       |   |      |   |
|---------------|-------|-------|---|------|---|
| U.S.          | 540   | 453   | — | 19.2 | * |
| International | 711   | 574   | — | 23.9 | * |
| Worldwide     | 1,251 | 1,027 | — | 21.8 | * |

## TOTAL MEDICAL DEVICES

|               |        |        |        |     |     |
|---------------|--------|--------|--------|-----|-----|
| U.S.          | 12,837 | 12,824 | 12,266 | 0.1 | 4.5 |
| International | 14,157 | 13,768 | 12,853 | 2.8 | 7.1 |
| Worldwide     | 26,994 | 26,592 | 25,119 | 1.5 | 5.9 |

## WORLDWIDE

|               |          |        |        |     |       |
|---------------|----------|--------|--------|-----|-------|
| U.S.          | 41,884   | 39,863 | 37,811 | 5.1 | 5.4   |
| International | 39,697   | 36,587 | 34,079 | 8.5 | 7.4   |
| Worldwide     | \$81,581 | 76,450 | 71,890 | 6.7 | % 6.3 |

\*Percentage greater than 100% or not meaningful

| (Dollars in Millions)                                  | Income Before Tax   |                     |                     | Identifiable Assets |         |
|--|---------------------|---------------------|---------------------|---------------------|---------|
|  | 2018 <sup>(3)</sup> | 2017 <sup>(4)</sup> | 2016 <sup>(5)</sup> | 2018                | 2017    |
| Consumer   | \$2,320             | 2,524               | 2,441               | \$25,877            | 25,030  |
| Pharmaceutical   | 12,568              | 11,083              | 12,827              | 56,636              | 59,450  |
| Medical Devices  | 4,397               | 5,392               | 5,578               | 46,254              | 45,413  |
| Total  | 19,285              | 18,999              | 20,846              | 128,767             | 129,893 |
| Less: Expense not allocated to segments <sup>(1)</sup> | 1,286               | 1,326               | 1,043               |                     |         |
| General corporate <sup>(2)</sup>                       |                     |                     |                     | 24,187              | 27,410  |
| Worldwide total  | \$17,999            | 17,673              | 19,803              | \$152,954           | 157,303 |

| (Dollars in Millions) | Additions to Property, Plant & Equipment |       |       | Depreciation and Amortization |       |       |
|-----------------------|--|-------|-------|-------------------------------|-------|-------|
|                       | 2018                                     | 2017  | 2016  | 2018                          | 2017  | 2016  |
| Consumer              | \$438                                    | 485   | 486   | \$688                         | 674   | 608   |
| Pharmaceutical        | 1,012                                    | 936   | 927   | 3,802                         | 2,416 | 886   |
| Medical Devices       | 1,843                                    | 1,566 | 1,472 | 2,103                         | 2,216 | 1,928 |
| Segments total        | 3,293                                    | 2,987 | 2,885 | 6,593                         | 5,306 | 3,422 |
| General corporate     | 377                                      | 292   | 341   | 336                           | 336   | 332   |
| Worldwide total       | \$3,670                                  | 3,279 | 3,226 | \$6,929                       | 5,642 | 3,754 |

| (Dollars in Millions)             | Sales to Customers |        |        | Long-Lived Assets <sup>(6)</sup> |         |
|-----------------------------------|--------------------|--------|--------|----------------------------------|---------|
|                                   | 2018               | 2017   | 2016   | 2018                             | 2017    |
| United States                     | \$41,884           | 39,863 | 37,811 | \$37,117                         | 38,556  |
| Europe                            | 18,753             | 17,126 | 15,770 | 51,433                           | 56,677  |
| Western Hemisphere excluding U.S. | 6,113              | 6,041  | 5,734  | 2,752                            | 2,990   |
| Asia-Pacific, Africa              | 14,831             | 13,420 | 12,575 | 2,733                            | 2,773   |
| Segments total                    | 81,581             | 76,450 | 71,890 | 94,035                           | 100,996 |
| General corporate                 |                    |        |        | 1,064                            | 1,143   |
| Other non long-lived assets       |                    |        |        | 57,855                           | 55,164  |
| Worldwide total                   | \$81,581           | 76,450 | 71,890 | \$152,954                        | 157,303 |

—

See Note 1 for a description of the segments in which the Company operates.

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Export sales are not significant. In 2018, the Company had three wholesalers distributing products for all three segments that represented approximately 14.0%, 11.0% and 11.0% of the total consolidated revenues. In 2017, the Company had two wholesalers distributing products for all three segments that represented approximately 14.0% and 10.0% of the total consolidated revenues. In 2016, the Company had two wholesalers distributing products for all three segments that represented approximately 13.5% and 10.7% of the total consolidated revenues.

- (1) Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.
- (2) General corporate includes cash, cash equivalents and marketable securities.  
The Consumer segment includes a gain of \$0.3 billion from the divestiture of NIZORAL<sup>®</sup> and litigation expense of \$0.3 billion. The Pharmaceutical segment includes an in-process research and development charge of \$1.1 billion related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of \$0.2 billion,
- (3) Actelion acquisition related costs of \$0.2 billion, unrealized loss on securities of \$0.2 billion and a gain of \$0.2 billion from the divestiture of certain non-strategic Pharmaceutical products. The Medical Devices segment includes net litigation expense of \$1.7 billion, a restructuring related charge of \$0.6 billion, AMO acquisition related costs of \$0.1 billion and a gain of \$0.5 billion from the divestiture of the LifeScan business in the fiscal fourth quarter.  
The Pharmaceutical segment includes \$0.8 billion for Actelion acquisition related costs, an in-process research and development expense of \$0.4 billion and litigation expense of \$0.1 billion. The Medical Devices segment includes
- (4) litigation expense of \$1.1 billion, a restructuring related charge of \$0.8 billion, an asset impairment of \$0.2 billion primarily related to the insulin pump business and \$0.1 billion for AMO acquisition related costs. The Medical Devices segment includes a gain of \$0.7 billion from the divestiture of Codman Neurosurgery. The Consumer segment includes a gain of \$0.5 billion from the divestiture of COMPEED<sup>®</sup>.  
Includes net litigation expense of \$0.8 billion and a restructuring related charge of \$0.7 billion in the Medical
- (5) Devices segment. The Pharmaceutical segment includes a positive adjustment of \$0.5 billion to previous reserve estimates and gains from the divestitures of the controlled substance raw material and active pharmaceutical ingredient (API) business and certain anesthetic products in Europe.
- (6) Long-lived assets include property, plant and equipment, net for 2018, and 2017 of \$17,035 and \$17,005, respectively, and intangible assets and goodwill, net for 2018 and 2017 of \$78,064 and \$85,134, respectively.

## 19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2018 and 2017 are summarized below:

| (Dollars in Millions Except Per Share Data)   | 2018    |         |         |         | 2017    |         |         |          |
|---|---------|---------|---------|---------|---------|---------|---------|----------|
|   | First   | Second  | Third   | Fourth  | First   | Second  | Third   | Fourth   |
|   | Quarter | Quarter | Quarter | Quarter | Quarter | Quarter | Quarter | Quarter  |
|   | (1)     | (2)     | (3)     | (4)     | (5)     | (6)     | (7)     | (8)      |
| Segment sales to customers                    |         |         |         |         |         |         |         |          |
| Consumer                                      | \$3,398 | 3,504   | 3,415   | 3,536   | 3,228   | 3,478   | 3,356   | 3,540    |
| Pharmaceutical                                | 9,844   | 10,354  | 10,346  | 10,190  | 8,245   | 8,635   | 9,695   | 9,681    |
| Medical Devices                               | 6,767   | 6,972   | 6,587   | 6,668   | 6,293   | 6,726   | 6,599   | 6,974    |
| Total sales                                   | 20,009  | 20,830  | 20,348  | 20,394  | 17,766  | 18,839  | 19,650  | 20,195   |
| Gross profit                                  | 13,395  | 13,903  | 13,759  | 13,433  | 12,357  | 12,993  | 12,725  | 12,936   |
| Earnings before provision for taxes on income | 5,481   | 4,973   | 4,423   | 3,122   | 5,575   | 4,748   | 4,790   | 2,560    |
| Net earnings (loss)                           | 4,367   | 3,954   | 3,934   | 3,042   | 4,422   | 3,827   | 3,764   | (10,713) |
| Basic net earnings (loss) per share           | \$1.63  | 1.47    | 1.47    | 1.14    | 1.63    | 1.42    | 1.40    | (3.99)   |
| Diluted net earnings (loss) per share         | \$1.60  | 1.45    | 1.44    | 1.12    | 1.61    | 1.40    | 1.37    | (3.99)   |

(1) The first quarter of 2018 includes an Actelion acquisition related cost of \$92 million after-tax (\$96 million before-tax) and a restructuring related charge of \$81 million after-tax (\$107 million before-tax).

(2) The second quarter of 2018 includes a litigation expense of \$609 million after-tax (\$703 million before-tax) and a restructuring related charge of \$152 million after-tax (\$176 million before-tax).

(3) The third quarter of 2018 includes an in-process research and development expense of \$859 million after-tax (\$1,126 million before-tax) related to the Alios and XO1 assets and the corresponding XO1 contingent liability reversal of \$184 million after and before tax, a restructuring related charge of \$162 million after-tax (\$190 million before-tax) and a \$265 million benefit after-tax from the impact of tax legislation.

(4) The fourth quarter of 2018 includes a litigation expense of \$1,113 million after-tax (\$1,288 million before-tax), a restructuring related charge of \$190 million after-tax (\$227 million before-tax) and a \$137 million benefit after-tax from the impact of tax legislation.

(5) The first quarter of 2017 includes a restructuring charge of \$121 million after-tax (\$161 million before-tax) and an AMO acquisition related cost of \$251 million after-tax (\$38 million before-tax).

(6) The second quarter of 2017 includes a litigation expense of \$352 million after-tax (\$493 million before-tax), Actelion acquisition related costs of \$199 million after-tax (\$213 million before-tax) a restructuring charge of \$101 million after-tax (\$128 million before-tax) and an asset impairment charge of \$125 million after-tax (\$182 million before-tax).

(7) The third quarter of 2017 includes a litigation expense of \$97 million after-tax (\$118 million before-tax), Actelion acquisition related costs of \$255 million after-tax (\$367 million before-tax) and a restructuring charge of \$136 million after-tax (\$187 million before-tax).

(8) The fourth quarter of 2017 includes a litigation expense of \$506 million after-tax (\$645 million before-tax), Actelion acquisition related costs of \$313 million after-tax (\$217 million before-tax), a restructuring charge of \$237 million after-tax (\$284 million before-tax), an in-process research and development expense of \$266 million after-tax (\$408 million before-tax) and an after-tax benefit of \$116 million related to the insulin pump business.

Additionally, the fourth quarter of 2017 includes a provisional charge of \$13.6 billion for recently enacted tax legislation.



## 20. Business Combinations and Divestitures

Certain businesses were acquired for \$0.9 billion in cash and \$0.1 billion of liabilities assumed during 2018. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2018 acquisitions primarily included: Zarbee's, Inc., a privately held company that is a leader in naturally-based consumer healthcare products; Medical Enterprises Distribution LLC, a privately held healthcare technology firm focused on surgical procedure innovation; BeneVir Biopharm, Inc. (BeneVir), a privately-held, biopharmaceutical company specializing in the development of oncolytic immunotherapies and Orthotaxy, a privately-held developer of software-enabled surgery technologies, including a differentiated robotic-assisted surgery solution.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to \$1.0 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

On October 23, 2018, the Company entered into an agreement to acquire Ci:z Holdings Co., Ltd., a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products for a total purchase price of approximately ¥230 billion, which equates to approximately \$2.1 billion, using the exchange rate of 109.06 Japanese Yen to each U.S. Dollar on January 16, 2019. The acquisition was completed on January 17, 2019, through a series of transactions that included an all-cash tender offer to acquire the publicly held shares not already held by the Company for ¥5,900 per share. Upon completion of the tender offer and the related transactions, the Company acquired 89% of the outstanding shares. The Company plans to acquire the remaining shares that were not tendered in the tender offer through a share consolidation under Japanese law during the first half of 2019 and take appropriate actions to delist from the Tokyo Stock Exchange. The acquisition will include the range of brands comprising DR.CI:LABO, LABO LABO and GENOMER line of skincare products. The Company expects to treat this transaction as a business combination and will include it in the Consumer segment.

On February 13, 2019, the Company entered into a definitive agreement to acquire Auris Health, Inc. for approximately \$3.4 billion in cash. Additional contingent payments of up to \$2.35 billion, in the aggregate, may be payable upon reaching certain predetermined milestones. Auris Health is a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures. The closing is subject to antitrust clearance and other customary closing conditions. The transaction is expected to close by the end of the second quarter of 2019. The Company expects to treat this transaction as a business combination and will include it in the Medical Devices segment.

During 2017 certain businesses were acquired for \$35.2 billion in cash and \$1.8 billion of liabilities assumed. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2017 acquisitions primarily included: Actelion Ltd, an established leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH); Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, which included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health; Neuravi Limited, a privately-held medical device company that develops and markets medical devices for neurointerventional therapy; TearScience Inc., a manufacturer of products dedicated to treating meibomian gland dysfunction; Sightbox, Inc., a privately-held company that developed a subscription vision care service that connects consumers with eye care professionals and a supply of contact lenses; Torax Medical, Inc., a privately-held medical device company that manufactures and markets the LINX™ Reflux Management System for the surgical treatment of gastroesophageal reflux disease and Megadyne Medical Products, Inc., a privately-held medical device company that develops, manufactures and markets electrosurgical tools.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to \$34.4 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately \$1.1 billion has been identified as the value of IPR&D, primarily associated with the acquisition of Actelion Ltd. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

During 2017, the Company completed the acquisition of Actelion Ltd through an all cash tender offer in Switzerland for \$280 per share, amounting to \$29.6 billion, net of cash acquired. As part of the transaction, immediately prior to

the completion of the acquisition, Actelion spun out its drug discovery operations and early-stage clinical development assets into a newly created Swiss biopharmaceutical company, Idorsia Ltd. The shares of Idorsia are listed on the SIX Swiss Exchange (SIX). In 2017 the Company held 9.9% of the shares of Idorsia and had rights to an additional 22.1% of Idorsia equity through a convertible loan with a principal amount of approximately \$0.5 billion. As a result of Idorsia raising additional capital in July 2018, the Company currently holds 9.0% of the shares of Idorsia and has rights to an additional 20.8% of Idorsia equity through a convertible loan with a principal amount of approximately \$0.5 billion. The convertible loan may be converted into Idorsia shares as follows: (i) up to an aggregate shareholding of 16% of Idorsia shares as a result of certain shareholders holding more than 20% of the issued Idorsia shares, and (ii) up to the balance of the remaining amount within 20 business days of the maturity date of the convertible loan, which has a 10 year term, or if Idorsia undergoes a change of control transaction. The investment in Idorsia was recorded as a cost method investment in Other assets in the Company's consolidated Balance Sheet. The Company also exercised the option acquired on ACT-132577, a product within Idorsia being developed for resistant hypertension currently in phase 2 of clinical development. The Company has also entered into an agreement to provide Idorsia

with a Swiss franc denominated credit facility of approximately \$250 million. As of December 30, 2018, Idorsia has not made any draw-downs under the credit facility. Actelion has entered into a transitional services agreement with Idorsia. Actelion has established a leading franchise of differentiated, innovative products for pulmonary arterial hypertension (PAH) that are highly complementary to the existing portfolio of the Company. The addition of Actelion's specialty in-market medicines and late-stage products is consistent with the Company's efforts to grow in attractive and complementary therapeutic areas and serve patients with serious illnesses and significant unmet medical need.

During the fiscal second quarter of 2018, the Company finalized the purchase price allocation to the individual assets acquired and liabilities assumed using the acquisition method. The following table presents the amounts recognized for assets acquired and liabilities assumed as of the acquisition date with adjustments made through the second quarter of 2018:

(Dollars in Millions)

|                               |        |
|-------------------------------|--------|
| Cash & Cash equivalents       | 469    |
| Inventory <sup>(1)</sup>      | 759    |
| Accounts Receivable           | 485    |
| Other current assets          | 93     |
| Property, plant and equipment | 104    |
| Goodwill                      | 6,161  |
| Intangible assets             | 25,010 |
| Deferred Taxes                | 99     |
| Other non-current assets      | 19     |
| Total Assets Acquired         | 33,199 |

|                               |       |
|-------------------------------|-------|
| Current liabilities           | 956   |
| Deferred Taxes                | 1,776 |
| Other non-current liabilities | 413   |
| Total Liabilities Assumed     | 3,145 |

Net Assets Acquired 30,054

<sup>(1)</sup> Includes adjustment of \$642 million to write-up the acquired inventory to its estimated fair value.

The adjustments made since the date of acquisition were \$0.2 billion to the deferred taxes and \$0.4 billion to the current liabilities with the offset to goodwill. The assets acquired are recorded in the Pharmaceutical segment. The acquisition of Actelion resulted in approximately \$6.2 billion of goodwill. The goodwill is primarily attributable to synergies expected to arise from the acquisition. The goodwill is not expected to be deductible for tax purposes.

The purchase price allocation to the identifiable intangible assets is as follows:

(Dollars in Millions)

Intangible assets with definite lives:

|                               |          |
|-------------------------------|----------|
| Patents and trademarks*       | \$24,230 |
| Total amortizable intangibles | 24,230   |

In-process research and development 780

Total intangible assets \$25,010

\*Includes \$0.4 billion related to VALCHLOR<sup>®</sup>, one of the acquired products, which was divested in the fiscal second quarter of 2018.

The patents and trademarks acquired are comprised of developed technology with a weighted average life of 9 years and was primarily based on the patent life of the marketed products. The intangible assets with definite lives were

assigned asset lives ranging from 4 to 10 years. The in-process research and development intangible assets were valued for technology programs for unapproved products. The value of the IPR&D was calculated using probability adjusted cash flow projections discounted for the risk inherent in such projects. The discount rate applied was 9%.

The acquisition was accounted for using the acquisition method and, accordingly, the results of operations of Actelion were reported in the Company's financial statements beginning on June 16, 2017, the date of acquisition. For the year ended December 31, 2017, total sales and a net loss for Actelion from the date of acquisition were \$1.4 billion and \$1.4 billion, respectively.

The following table provides pro forma results of operations for the fiscal year ended December 31, 2017 and January 1, 2017, as if Actelion had been acquired as of January 4, 2016. The pro forma results include the effect of certain purchase accounting adjustments such as the estimated changes in depreciation and amortization expense on the acquired tangible and intangible assets. However, pro forma results do not include any anticipated cost savings or other effects of the planned integration of Actelion. Accordingly, such amounts are not necessarily indicative of the results if the acquisition had occurred on the dates indicated or which may occur in the future.

Unaudited  
Pro forma  
Consolidated  
Results

| (Dollars in Millions Except Per Share Data) | 2017   | 2016   |
|---|--------|--------|
| Net Sales                                   | 77,681 | 74,339 |
| Net Earnings                                | 1,509  | 13,916 |
| Diluted Net Earnings per Common Share       | 0.55   | 4.99   |

The Company recorded Actelion acquisition related costs before tax of approximately \$0.2 billion and \$0.8 billion in 2018 and 2017, respectively, which was recorded in Other (income)/expense and Cost of products sold.

During 2017, the Company acquired Abbott Medical Optics (AMO), a wholly-owned subsidiary of Abbott Laboratories, for \$4.3 billion, net of cash acquired. The acquisition included ophthalmic products related to: cataract surgery, laser refractive surgery and consumer eye health. The net purchase price was primarily recorded as amortizable intangible assets for \$2.3 billion and goodwill for \$1.7 billion. The weighted average life of total amortizable intangibles, the majority being customer relationships, is approximately 14.4 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not deductible for tax purposes. The intangible assets and goodwill amounts are based on the final purchase price allocation. The assets acquired were recorded in the Medical Devices segment.

Certain businesses were acquired for \$4.5 billion in cash and \$0.1 billion of liabilities assumed during 2016. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2016 acquisitions primarily included: Vogue International LLC, a privately-held company focused on the marketing, development and distribution of salon-influenced and nature inspired hair care and other personal products; NeuWave Medical, Inc., a privately-held medical device company that manufactures and markets minimally invasive soft tissue microwave ablation systems; NeoStrata Company, Inc., a global leader in dermocosmetics; and the global rights for the commercialization of RHINOCORT® allergy spray outside the United States.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to \$4.1 billion and has been assigned to identifiable intangible assets, with any residual recorded to goodwill.

The net purchase price for Vogue International LLC of \$3.3 billion was primarily recorded as amortizable intangible assets for \$2.3 billion and goodwill for \$1.1 billion. The weighted average life for the \$2.3 billion of total amortizable intangibles is approximately 22 years. The trademark asset values were determined to have definite lives ranging from 10 to 22 years, with the majority being 22 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is expected to be deductible for tax purposes. The assets acquired were recorded in the Consumer segment.

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of \$20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the

Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

With the exception of the Actelion Ltd acquisition, supplemental pro forma information for 2018, 2017 and 2016 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

During 2018, the Company divested the LifeScan Inc business for approximately \$2.1 billion and retained certain net liabilities. Other divestitures in 2018 included: NIZORAL<sup>®</sup>, RoC<sup>®</sup> and certain non-strategic Pharmaceutical products. In 2018, the pre-tax gains on the divestitures were approximately \$1.2 billion. Additionally, in 2018, the Company accepted the binding

offer from Fortive Corporation to acquire its Advanced Sterilization Products (ASP) business for approximately \$2.7 billion, subject to customary adjustments. The transaction is expected to close in 2019. As of December 30, 2018, the assets held for sale on the Consolidated Balance Sheet were \$0.2 billion of inventory, \$0.1 billion of property, plant and equipment and \$0.3 billion of goodwill. The Company will retain certain net receivables of approximately \$0.1 billion associated with the ASP business.

In 2018, the Company accepted a binding offer to form a strategic collaboration with Jabil Inc., one of the world's leading manufacturing services providers for health care products and technology products. The Company is expanding a 12-year relationship with Jabil to produce a range of products within the Ethicon Endo-Surgery and DePuy Synthes businesses. This transaction includes the transfer of employees and manufacturing sites. As of December 30, 2018, the assets held for sale on the Consolidated Balance Sheet were \$0.3 billion of inventory and \$0.1 billion of property, plant and equipment, net. For additional details on the global supply chain restructuring see Note 22 to the Consolidated Financial Statements.

During 2017, the Company divestitures primarily included: the Codman Neurosurgery business, to Integra LifeSciences Holdings Corporation and the divestiture of COMPEED® to HRA Pharma. In 2017, the pre-tax gains on the divestitures were approximately \$1.3 billion.

During 2016, the Company divestitures included: the controlled substance raw material and active pharmaceutical ingredient (API) business; certain anesthetic products in Europe; and certain non-strategic Consumer brands. In 2016, the pre-tax gains on the divestitures were approximately \$0.6 billion.

#### 21. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial, supplier indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of December 30, 2018, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

#### PRODUCT LIABILITY

Johnson & Johnson and certain of its subsidiaries are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of

litigation. The Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages and other losses. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include: the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; the PINNACLE® Acetabular Cup System; pelvic meshes; RISPERDAL®; XARELTO®; body powders containing talc, primarily JOHNSONS® Baby Powder; INVOKANA®; and ETHICON PHYSIOMESH® Flexible Composite Mesh. As of December 30, 2018, in the United States there were approximately 1,800 plaintiffs with direct claims in pending lawsuits



regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 10,500 with respect to the PINNACLE® Acetabular Cup System; 34,800 with respect to pelvic meshes; 13,400 with respect to RISPERDAL®; 25,600 with respect to XARELTO®; 13,000 with respect to body powders containing talc; 1,050 with respect to INVOKANA®; and 2,100 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle two pending class actions which have been approved by the Québec Superior Court and the Supreme Court of British Columbia. The British Columbia order is currently the subject of an appeal. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and DePuy ASR™ Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and Johnson & Johnson (collectively, DePuy) relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in some state courts and in countries outside of the United States. Several adverse verdicts have been rendered against DePuy, one of which was reversed on appeal and remanded for retrial, the second remains under appeal and the third is pending decision on post-trial motions in the district court. The Company has established an accrual for product liability litigation associated with the PINNACLE® Acetabular Cup System. The Company is negotiating settlements of these cases and the related costs are reflected in the Company's accruals.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. The Company has settled or otherwise resolved a majority of the United States cases and the costs associated with these settlements are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands and Belgium, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. In Australia, a trial of class action issues has been completed and the parties are awaiting a decision. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH® Flexible Composite Mesh, claims for personal injury have been made against Ethicon, Inc. and Johnson & Johnson alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi county litigation (MCL) has also been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals with respect to product liability litigation associated with ETHICON PHYSIOMESH® Flexible Composite Mesh.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I

disorder and irritability associated with autism, and related compounds. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the United States cases and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO<sup>®</sup>, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson; and JPI's collaboration partner for XARELTO<sup>®</sup> Bayer AG and certain of its affiliates. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States. Many of these cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania; and there are coordinated proceedings in Delaware, California and Missouri. Class action lawsuits also have been filed in Canada. The Company has established an accrual for defense costs only in connection with product liability litigation associated with XARELTO<sup>®</sup>.

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSONS<sup>®</sup> Baby Powder. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in July 2018 of \$4.7 billion. The Company believes that it has strong grounds on appeal to overturn these verdicts. The Company has established an accrual for defense costs only in connection with product liability litigation associated with body powders containing talc.

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson and certain named officers in the United States District Court for the District of New Jersey, alleging that Johnson & Johnson violated the federal securities laws by failing to adequately disclose the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S<sup>®</sup> Baby Powder, and that purchasers of Johnson & Johnson's shares suffered losses as a result. Plaintiffs are seeking damages. In October 2018, a shareholder derivative lawsuit was filed against Johnson & Johnson as the nominal defendant and its current directors as defendants in the United States District Court for the District of New Jersey, alleging a breach of fiduciary duties related to the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S<sup>®</sup> Baby Powder, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. Plaintiff is seeking damages and an order for the Company to reform its internal policies and procedures. In January 2019, two ERISA class action lawsuits were filed by participants in the Johnson & Johnson Savings Plan against Johnson & Johnson, its Pension and Benefits Committee, and certain named officers in the United States District Court for the District of New Jersey, alleging that the defendants breached their fiduciary duties by offering Johnson & Johnson stock as a Johnson & Johnson Savings Plan investment option when it was imprudent to do so because of failures to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S<sup>®</sup> Baby Powder. Plaintiffs are seeking damages and injunctive relief. Each of these matters will be adjudicated in conjunction with the multi-district litigation referenced in the prior paragraph. In addition, the Company has received preliminary inquiries and subpoenas to produce documents regarding these matters from Senator Murray, a member of the Senate Committee on Health, Education, Labor and Pensions, the Department of Justice and the Securities and Exchange Commission. The Company is cooperating with these government inquiries and will be producing documents in response.

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Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA<sup>®</sup>, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. Lawsuits filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts in Pennsylvania, California and New Jersey. Class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the cases and claims in the United States and the costs associated with these settlements are reflected in the Company's accruals.

## INTELLECTUAL PROPERTY

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company's products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, require the payment of past damages and future royalties, and may result in a non-cash impairment charge for any associated intangible asset. The most significant of these matters are described below.

### Medical Devices

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court for the Eastern District of Texas alleging that JJVCI's manufacture and sale of its ACUVUE® ADVANCE and ACUVUE OASYS® Hydrogel Contact Lenses infringed Rembrandt's United States Patent No. 5,712,327 and seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida, where a trial in May 2012 resulted in a verdict of non-infringement that was subsequently upheld on appeal. In July 2014, Rembrandt sought a new trial based on alleged new evidence, which the district court denied. In April 2016, the Court of Appeals overturned that ruling and remanded the case to the district court for a new trial. A new trial was held in August 2017, and the jury returned a verdict of non-infringement in favor of JJVCI. Rembrandt has appealed the verdict to the United States Court of Appeals for the Federal Circuit (CAFC). In February 2019, the CAFC affirmed the judgment in favor of JJVCI.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that Cordis's sales of the CYPHER™ and CYPHER SELECT™ stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorneys' fees. Although Johnson & Johnson has since sold Cordis, it has retained liability for this case. After trial in January 2014, the district court dismissed the case, finding Medinol unreasonably delayed bringing its claims (the laches defense). In September 2014, the district court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol appealed the decision to the United States Court of Appeals for the Federal Circuit. In March 2017, the United States Supreme Court held that the laches defense is not available in patent cases. In April 2018, the United States Court of Appeals for the Federal Circuit remanded the case back to the district court to reconsider Medinol's motion for a new trial, and briefing in the district court was completed in June 2018.

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. In April 2017, MedIdea filed an amended complaint adding DePuy Synthes Products, Inc. and DePuy Synthes Sales, Inc. as named defendants. MedIdea alleges infringement of United States Patent Nos. 6,558,426 ('426); 8,273,132 ('132); 8,721,730 ('730) and 9,492,280 ('280) relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts. A claim construction hearing was held in October 2018, and a claim construction order was issued in November 2018. In December 2018, MedIdea stipulated to non-infringement of the '132, '730 and '280 patents, based on the district court's claim construction and reserving its right to appeal that construction, leaving only the '426 patent at issue before the district court. In January 2019, the district court stayed the case pending a decision in the Inter Partes Review proceeding on the '426 patent (see below). In December 2017, DePuy Synthes Products, Inc. filed a Petition for Inter Partes Review with the United States Patent and Trademark Office (USPTO), seeking to invalidate the two claims of the '426 patent asserted in the district court

litigation, and in June 2018, the USPTO instituted review of those claims. A hearing trial is scheduled for March 2019, and a decision in the proceeding is due by June 2019.

In December 2016, Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (now known as Ethicon LLC) sued Covidien, Inc. in the United States District Court for the District of Massachusetts seeking a declaration that United States Patent Nos. 6,585,735 (the '735 patent); 7,118,587; 7,473,253; 8,070,748 and 8,241,284 (the '284 patent), are either invalid or not infringed by Ethicon's ENSEAL® X1 Large Jaw Tissue Sealer product. In April 2017, Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, Covidien) answered and counterclaimed, denying the allegations, asserting willful infringement of the '735 patent, the '284 patent and United States Patent Nos. 8,323,310 (the '310 patent); 9,084,608; 9,241,759 (the '759 patent) and 9,113,882, and seeking damages and an injunction. Covidien filed a motion for preliminary injunction, which was denied in

October 2017. The parties have entered joint stipulations such that only the '735 patent, the '310 patent and the '759 patent remain in dispute. Trial is scheduled to begin in September 2019.

In November 2017, Board of Regents, The University of Texas System and Tissugen, Inc. (collectively, UT) filed a lawsuit in the United States District Court for the Western District of Texas against Ethicon, Inc. and Ethicon US, LLC alleging the manufacture and sale of VICRYL® Plus Antibacterial Sutures, MONOCRYL® Plus Antibacterial Sutures, PDS® Plus Antibacterial Sutures, STRATAFIX® POS® Antibacterial Sutures and STRATAFIX® MONOCRYL® Plus Antibacterial Sutures infringe plaintiffs' United States Patent Nos. 6,596,296 and 7,033,603 directed to implantable polymer drug releasing biodegradable fibers containing a therapeutic agent. UT is seeking damages and an injunction. In December 2018, Ethicon filed petitions with the USPTO, seeking Inter Partes Review (IPR) of both asserted patents. Those petitions have been stayed by the USPTO pending a decision by the U.S. Court of Appeals for the Federal Circuit in an unrelated case.

#### Pharmaceutical

In April 2016, MorphoSys AG, a German biotech company, filed a patent infringement lawsuit against Janssen Biotech, Inc. (JBI), Genmab U.S. Inc. and Genmab A/S (collectively, Genmab) in the United States District Court for the District of Delaware. MorphoSys alleged that JBI's manufacture and sale of DARZALEX® (daratumumab) willfully infringed MorphoSys' United States Patent Nos. 8,263,746, 9,200,061 and 9,785,590. MorphoSys sought money damages. JBI licenses patents and the commercial rights to DARZALEX® from Genmab. In January 2019, the district court granted summary judgment in JBI and Genmab's favor, invalidating the asserted claims of the patents-in-suit, and the parties filed a joint stipulation of dismissal of the action.

In August 2016, Sandoz Ltd and Hexal AG (collectively, Sandoz) filed a lawsuit in the English High Court against G.D. Searle LLC, a Pfizer company (Searle) and Janssen Sciences Ireland UC (JSI) alleging that Searle's supplementary protection certificate SPC/GB07/038 (SPC), which is exclusively licensed to JSI, is invalid and should be revoked. Janssen-Cilag Limited sells PREZISTA® (darunavir) in the United Kingdom pursuant to this license. In October 2016, Searle and JSI counterclaimed against Sandoz for threatened infringement of the SPC based on statements of its plans to launch generic darunavir in the United Kingdom. Sandoz admitted that its generic darunavir product would infringe the SPC if it is found valid. Searle and JSI are seeking an order enjoining Sandoz from marketing its generic darunavir before the expiration of the SPC. Following a trial in April 2017, the court entered a decision holding that the SPC is valid and granting a final injunction. Sandoz has appealed the court's decision and the injunction is stayed pending the appeal. In January 2018, the court referred the issue on appeal to the Court of Justice for the European Union (CJEU) and stayed the proceedings pending the CJEU's ruling on the issue.

In April 2018, Acerta Pharma B.V., AstraZeneca UK Ltd and AstraZeneca Pharmaceuticals LP filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Pharmacylics LLC and Abbvie Inc. (collectively, Abbvie), alleging that the manufacture and sale of IMBRUVICA® infringes U.S. Patent No. 7,459,554. Janssen Biotech, Inc., which commercializes IMBRUVICA® jointly with Abbvie, intervened in the action in November 2018. A trial is scheduled to begin in January 2021.

#### REMICADE® Related Cases

In August 2014, Celltrion Healthcare Co. Ltd. and Celltrion Inc. (collectively, Celltrion) filed an application with the United States Food and Drug Administration (FDA) for approval to make and sell its own infliximab biosimilar. In March 2015, Janssen Biotech, Inc. (JBI) filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira Healthcare Corporation (Hospira), which has exclusive marketing rights for Celltrion's infliximab biosimilar in the United States, seeking, among other things, a declaratory judgment that their biosimilar product infringes or potentially infringes several JBI patents, including United States Patent No. 6,284,471 relating to REMICADE® (infliximab) (the '471 patent) and United States Patent No. 7,598,083 (the '083 patent)

directed to the cell culture media used to make Celltrion's biosimilar. In August 2016, the district court granted both Celltrion's and Hospira's motions for summary judgment of invalidity of the '471 patent. JBI appealed those decisions to the United States Court of Appeals for the Federal Circuit. In January 2018, the Federal Circuit dismissed the appeal as moot based on its affirmance of a decision by the USPTO's Patent Trial and Appeal Board affirming invalidity of the '471 patent.

In June 2016, JBI filed two additional patent infringement lawsuits asserting the '083 patent, one against Celltrion and Hospira in the United States District Court for the District of Massachusetts and the other against HyClone Laboratories, Inc., the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product, in the United States District Court for the District of Utah. On July 30, 2018 the district court granted Celltrion's motion for summary judgment of non-infringement and entered an order dismissing the '083 lawsuit against Celltrion and Hospira. JBI appealed to the United States Court of



Appeals for the Federal Circuit. The litigation against HyClone in Utah is stayed pending the outcome of the Massachusetts actions.

The FDA approved the first infliximab biosimilar for sale in the United States in 2016, and a number of such products have been launched.

#### Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement and invalidity of the applicable patents. In the event the subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the third-party companies involved would have the ability, upon approval of the FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The Inter Partes Review (IPR) process with the United States Patent and Trademark Office (USPTO), created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits, to challenge the applicable patents.

#### ZYTIGA®

In July 2015, Janssen Biotech, Inc., Janssen Oncology, Inc. and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against a number of generic companies (and certain of their affiliates and/or suppliers) who filed ANDAs seeking approval to market a generic version of ZYTIGA® 250mg before the expiration of United States Patent No. 8,822,438 (the '438 patent). The generic companies include Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, Dr. Reddy's); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (collectively, Sun); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward) and Hikma Pharmaceuticals, LLC (Hikma).

Janssen and BTG also initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Amerigen Pharmaceuticals Limited (Amerigen) in May 2016, and Glenmark Pharmaceuticals, Inc. (Glenmark) in June 2016, each of whom filed an ANDA seeking approval to market its generic version of ZYTIGA® before the expiration of the '438 patent. These lawsuits have been consolidated with the lawsuit filed in July 2015.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia, which has been stayed.

In August 2017, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of ZYTIGA® 500mg before the expiration of the '438 patent. This lawsuit has been consolidated with the lawsuit filed in July 2015.

In February 2018, Janssen and BTG filed a patent infringement lawsuit against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (collectively, MSN) in United States District Court for the District of New Jersey based

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on its ANDA seeking approval for a generic version of ZYTIGA® prior to the expiration of the '438 patent.

In November 2018, Janssen and BTG initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. (collectively, Qilu), who filed an ANDA seeking approval to market a generic version of ZYTIGA® before the expiration of the '438 patent.

In December 2017, Janssen and BTG entered into a settlement agreement with Glenmark. In January 2018, Janssen dismissed its lawsuit against Sun after it withdrew its ANDA. In April 2018, Janssen and BTG entered into a settlement agreement with Apotex.

In October 2018, the United States District Court for the District of New Jersey issued a ruling invalidating all asserted claims of the '438 patent. The court held that the patent claims would be infringed if the patent were valid. Janssen appealed the court's decision.

In November 2018, the United States Court of Appeals for the Federal Circuit denied Janssen's request for an injunction pending appeal. As a result, several generic versions of ZYTIGA<sup>®</sup> have entered the market. Janssen has appealed the decision of the United States District Court for the District of New Jersey, and the oral argument on the appeal is scheduled for March 2019.

The lawsuits against MSN and Qilu remain pending in the district courts. In each of these lawsuits, Janssen is seeking an order enjoining the defendants from marketing their generic versions of ZYTIGA<sup>®</sup> before the expiration of the '438 patent.

Several generic companies including Amerigen, Argentum Pharmaceuticals LLC (Argentum), Mylan, Wockhardt, Actavis, Amneal, Dr. Reddy's, Sun, Teva, West-Ward and Hikma filed Petitions for Inter Partes Review (IPR) with the USPTO, seeking to invalidate the '438 patent. In January 2018, the USPTO issued decisions finding the '438 patent claims unpatentable, and Janssen requested rehearing. In December 2018, the USPTO denied Janssen's request for rehearing of the IPR decisions. Janssen filed an appeal, which was consolidated with the above-mentioned appeal of the decision of the United States District Court for the District of New Jersey.

In October 2017, Janssen Inc. and Janssen Oncology, Inc. (collectively, Janssen) initiated two Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) and the Minister of Health in Canada in response to Teva's filing Abbreviated New Drug Submissions (ANDS) and seeking approval to market generic versions of ZYTIGA<sup>®</sup> 250mg and ZYTIGA<sup>®</sup> 500mg before the expiration of Canadian Patent No. 2,661,422. In June 2018, the parties entered into a settlement agreement.

In November 2017, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA<sup>®</sup> before the expiration of Canadian Patent No. 2,661,422. The federal court of Canada scheduled the Final Hearing for April 2019. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Apotex's ANDS before the expiration of Janssen's patent.

In January 2019, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex and the Minister of Health in Canada in response to Apotex's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a film-coated generic version of ZYTIGA<sup>®</sup> before the expiration of Canadian Patent No. 2,661,422. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Apotex's ANDS before the expiration of Janssen's patent.

#### XARELTO<sup>®</sup>

Beginning in October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO<sup>®</sup> before expiration of Bayer's United States Patent Nos. 7,157,456, 7,585,860 and 7,592,339 relating to XARELTO<sup>®</sup>. JPI is the exclusive sublicensee of the asserted patents. The following generic companies are named defendants: Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, Aurobindo); Breckenridge Pharmaceutical, Inc. (Breckenridge); InvaGen Pharmaceuticals Inc. (InvaGen); Micro Labs USA Inc. and Micro Labs Ltd (collectively, Micro); Mylan Pharmaceuticals Inc. (Mylan); Princeton Pharmaceuticals, Inc.;

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Sigmapharm Laboratories, LLC (Sigmapharm); Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. (collectively, Torrent). Trial concluded in April 2018. In July 2018 the district court entered judgment against Mylan and Sigmapharm, holding that the asserted compound patent is valid and infringed. In September 2018, the district court entered judgment against the remaining defendants. None of the defendants appealed the judgment.

Beginning in April 2017, JPI and Bayer Intellectual Property GmbH and Bayer AG (collectively, Bayer AG) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer AG's United States Patent No. 9,539,218 ('218) relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patent. The following generic companies are named defendants: Alembic Pharmaceuticals Limited, Alembic Global Holding SA and Alembic Pharmaceuticals, Inc. (Alembic); Aurobindo; Breckenridge; InvaGen; Lupin Limited and Lupin Pharmaceuticals, Inc.

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(collectively, Lupin); Micro; Mylan; Sigmapharm; Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively, Taro) and Torrent. Lupin counterclaimed for declaratory judgment of noninfringement and invalidity of United States Patent No. 9,415,053, but Lupin dismissed its counterclaims after it was provided a covenant not to sue on that patent. Aurobindo, Taro, Torrent, Micro, Breckenridge, InvaGen, Sigmapharm, Lupin and Alembic have agreed to have their cases stayed and to be bound by the outcome of any final judgment rendered against any of the other defendants. The '218 cases have been consolidated for discovery and trial, and are currently set for trial in April 2019.

In December 2018, JPI and Bayer AG filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) who filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of Bayer AG's '218 patent.

In each of these lawsuits, JPI is seeking an order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents.

In May 2018, Mylan filed a Petition for Inter Partes Review with the USPTO, seeking to invalidate the '218 patent. In December 2018, the USPTO issued a decision denying institution of Mylan's Petition for Inter Partes Review.

#### PREZISTA®

In May 2018, Janssen Products, L.P. and Janssen Sciences Ireland UC (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Dr. Reddys Laboratories, Inc., Dr. Reddys Laboratories, Ltd., Laurus Labs, Ltd. and Pharmaq, Inc. (collectively, DRL) who filed an ANDA seeking approval to market generic versions of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,126,015; and 7,595,408. Trial is scheduled to begin in May 2020.

In December 2018, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals Company GmbH, Amneal Pharmaceuticals of New York, LLC, Amneal Pharmaceuticals Pvt Ltd., and Raks Pharma Pvt. Ltd. (collectively, Amneal), who filed an ANDA seeking approval to market generic versions of PREZISTA® before the expiration of United States Patent Nos. 8,518,987; 7,126,015; and 7,595,408.

In each of these lawsuits, Janssen is seeking an order enjoining the defendants from marketing its generic versions of PREZISTA® before the expiration of the relevant patents.

#### INVOKANA®/INVOKAMET®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey, the United States District Court for the District of Colorado and the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of INVOKANA® and/or INVOKAMET® before expiration of MTPC's United States Patent Nos. 7,943,582 and/or 8,513,202 relating to INVOKANA® and INVOKAMET®. Janssen is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Apotex Inc. and Apotex Corp. (Apotex); Aurobindo Pharma USA Inc. (Aurobindo); Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.; InvaGen Pharmaceuticals, Inc. (InvaGen); Princeton Pharmaceuticals Inc.; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd; Hetero

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USA, Inc., Hetero Labs Limited Unit-V and Hetero Labs Limited; MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc.; Laurus Labs Ltd.; Indoco Remedies Ltd.; Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz); Teva Pharmaceuticals USA, Inc.; and Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Beginning in July 2017, Janssen and MTPC filed patent infringement lawsuits in the United States District Court for the District of New Jersey and the United States District Court for the District of Colorado against Sandoz and InvaGen, who filed ANDAs seeking approval to market generic versions of INVOKANA<sup>®</sup> and/or INVOKAMET<sup>®</sup> before expiration of MTPC's United States Patent No. 7,943,788 (the '788 patent) relating to INVOKANA<sup>®</sup> and INVOKAMET<sup>®</sup> and against Zydus, who filed ANDAs seeking approval to market generic versions of INVOKANA<sup>®</sup> and INVOKAMET<sup>®</sup> before expiration of the '788 patent, MTPC's United States Patent No. 8,222,219 relating to INVOKANA<sup>®</sup> and INVOKAMET<sup>®</sup> and MTPC's United States Patent No. 8,785,403 relating to INVOKAMET<sup>®</sup>, and against Aurobindo, who filed an ANDA seeking approval to market a generic version of INVOKANA<sup>®</sup> before expiration of the '788 patent and the '219 patent relating to INVOKANA<sup>®</sup>.

Janssen is the exclusive licensee of the asserted patents. In October 2017, the Colorado lawsuits against Sandoz were dismissed. In December 2017, the Delaware lawsuits against Apotex and Teva were dismissed.

In April 2018, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Princeton, who filed an ANDA seeking approval to market a generic version of INVOKANA<sup>®</sup> before expiration of the '788 patent relating to INVOKANA<sup>®</sup>.

In each of these lawsuits, Janssen and MTPC are seeking an order enjoining the defendants from marketing their generic versions of INVOKANA<sup>®</sup> and/or INVOKAMET<sup>®</sup> before the expiration of the relevant patents.

#### OPSUMIT<sup>®</sup>

In January 2018, Actelion Pharmaceuticals Ltd (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA) Inc. (Zydus) and Amneal Pharmaceuticals LLC (Amneal), each of whom filed an ANDA seeking approval to market a generic version of OPSUMIT<sup>®</sup> before the expiration of United States Patent No. 7,094,781. In the lawsuit, Actelion is seeking an order enjoining Zydus and Amneal from marketing generic versions of OPSUMIT<sup>®</sup> before the expiration of the patent. In December 2018, the district court entered an order wherein one of the defendants, Amneal, stipulated to infringement. Trial is scheduled to commence in October 2020.

#### INVEGA SUSTENNA<sup>®</sup>

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA<sup>®</sup> before the expiration of United States Patent No. 9,439,906. In the lawsuit, Janssen is seeking an order enjoining Teva from marketing a generic version of INVEGA SUSTENNA<sup>®</sup> before the expiration of the patent.

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen) initiated a Notices of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) and the Minister of Health in response to Teva's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of INVEGA SUSTENNA<sup>®</sup> before the expiration of Canadian Patent Nos. 2,309,629 and 2,655,335. Janssen is seeking an order prohibiting the Minister of Health from issuing a Notice of Compliance with respect to Teva's ANDS before the expiration of these patents. The Final Hearing is scheduled to begin in September 2019.

#### IMBRUVICA<sup>®</sup>

Beginning in January 2018, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of IMBRUVICA<sup>®</sup> before expiration of Pharmacyclics' United States Patent Nos. 8,008,309, 7,514,444, 8,697,711, 8,735,403, 8,957,079, 9,181,257, 8,754,091, 8,497,277, 8,925,015, 8,476,284, 8,754,090, 8,999,999, 9,125,889, 9,801,881, 9,801,883, 9,814,721, 9,795,604, 9,296,753, 9,540,382, 9,713,617 and/or 9,725,455 relating to IMBRUVICA<sup>®</sup>. JBI is the exclusive licensee of the asserted patents. The following generic companies are named defendants: Cipla Limited and Cipla USA Inc. (Cipla); Fresenius Kabi USA, LLC, Fresenius Kabi USA, Inc., and Fresenius Kabi Oncology Limited (Fresenius Kabi); Sandoz Inc. and Lek Pharmaceuticals d.d. (Sandoz); Shilpa Medicare Limited (Shilpa); Sun Pharma Global FZE and Sun Pharmaceutical Industries Limited (Sun); Teva Pharmaceuticals USA, Inc. (Teva); and Zydus Worldwide DMCC and Cadila Healthcare Limited (Zydus). Trial is scheduled to begin in October 2020.

In October 2018, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Sun asserting newly issued United States Patent No. 10,004,746.

In each of the lawsuits, Pharmacyclics and JBI are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

In January 2019, Pharmacyclics and JBI amended their complaints against Fresenius Kabi, Zydus, Teva and Sandoz to further allege infringement of U.S. Patent Nos. 10,106,548, and 10,125,140.

In January 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Zydus, who filed an ANDA seeking approval to market a generic version of IMBRUVICA® 70 mg before the



expiration of U.S. Patent Nos. 514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,540,382, 9,713,617, 9,725,455, 10,106,548, and 10,125,140.

## GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

### Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWP's in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. Two cases remain pending. In a case brought by Illinois, trial has been scheduled for March 2019. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation.

### Opioids Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in more than 1,600 lawsuits brought by certain state and local governments related to the marketing of opioids, including DURAGESIC<sup>®</sup>, NUCYNTA<sup>®</sup> and NUCYNTA<sup>®</sup> ER. To date, complaints against pharmaceutical companies, including Johnson & Johnson and JPI, have been filed in state court by the state Attorneys General in Arkansas, Florida, Kentucky, Louisiana, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, Ohio, Oklahoma and South Dakota. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Alabama; Arkansas; California; Connecticut; Florida; Georgia; Illinois; Kentucky; Louisiana; Maine; Maryland; Massachusetts; Mississippi; Missouri; Nevada; New Hampshire; New Jersey; New Mexico; New York; North Carolina; Ohio; Oklahoma; Oregon; Pennsylvania; Rhode Island; South Carolina; South Dakota; Tennessee; Texas; Utah; Virginia; Washington; West Virginia and Wisconsin. The Government of Puerto Rico filed suit in Superior Court of San Juan. In addition, the Province of British Columbia filed suit in Canada. These actions allege a variety of claims related to opioids marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. These cases are in early stages of litigation. In October 2017, Johnson & Johnson and JPI were both served with a motion to consolidate 66 pending matters into a federal Multi District Litigation in the Southern District of Ohio. In December 2017, the MDL was approved in the Northern District of Ohio and there are over 1,400 cases that have been transferred to the MDL.

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Johnson & Johnson, JPI and other pharmaceutical companies have also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, Montana, New Hampshire, South Carolina, Tennessee, Texas and Washington. In September 2017, Johnson & Johnson and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation. The multi-state coalition served Johnson & Johnson and JPI with subpoenas as part of the investigation. Johnson & Johnson and JPI have also received requests for information from the ranking minority member of the United States Senate Committee on Homeland Security and Governmental Affairs regarding the sales, marketing, and educational strategies related to the promotion of opioids use.

Other

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In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now known as DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (collectively DePuy) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the DePuy ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a qui tam case filed pursuant to the False Claims Act against the companies. In February 2016, the district court granted the companies' motion to dismiss with prejudice, unsealed the qui tam complaint, and denied the qui tam relators' request for leave to file a further amended complaint. The qui tam relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the district court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. The relators' remaining claims are now pending before the district court, and fact discovery is currently scheduled to close in September 2019. Additionally, DePuy filed a petition for certiorari with the United States Supreme Court, seeking review of the First Circuit's decision. The Supreme Court denied the petition in April 2018.

Since October 2013, a group of State Attorneys General have issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. In July 2014, the Oregon Department of Justice, which was investigating these matters independently of the other states, announced a settlement of its ASR™ XL Hip device investigation with the State of Oregon. In December 2018, the Company, the remaining states and the District of Columbia agreed to settle all of the investigations, and on January 22, 2019, the states and the Company filed consent judgments resolving the matter.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a series of tolling agreements with the 47 states and the District of Columbia participating in the multi-state investigation and have responded to Civil Investigative Demands served by certain of the participating states. The states are seeking monetary and injunctive relief. In May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon and Ethicon US, LLC alleging violations of their consumer protection statutes. Similar complaints were filed against the companies by Kentucky in August 2016 and by Mississippi in October 2017. Johnson & Johnson and Ethicon have entered into a new tolling agreement with the remaining 43 states and the District of Columbia.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® and Cellex® Systems during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013, and OCD was divested in June 2014. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014 and March 2016, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with those requests. In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants failed to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. Trial is stayed pending interlocutory appeal of a denial of JJCI's motion for summary judgment.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products.

The demand was issued in connection with an investigation under the False Claims Act.

In January 2017, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Department of Justice relating to allegations concerning the sales and marketing practices of OLYSIO®. In December 2017, Johnson & Johnson and JPI were served with a whistleblower lawsuit filed in the United States District Court for the Central District of California alleging the off-label promotion of OLYSIO® and additional products, including NUCYNTA®, XARELTO®, LEVAQUIN® and REMICADE®. At this time, the federal and state governments have declined to intervene and the lawsuit, which is related to the Civil Investigative Demand, is being prosecuted by a former company employee. The United States

District Court for the Central District of California dismissed the claim in April 2018. In May 2018, the relator filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit.

In November 2018, a second whistleblower lawsuit was unsealed in the United States District Court for the Central District of California. The lawsuit is substantially similar to the lawsuit under appeal but is brought in the name of the original relator. The federal and state governments have declined to intervene in the second suit at this time.

In February 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking the production of records pertaining to payments to any 501(c)(3) charitable organization that provides financial assistance to Medicare patients. Multiple pharmaceutical companies have publicly reported receipt of subpoenas and ongoing inquiries similar to this one and the one described below. The government has represented that it will not be pursuing action against the company in this matter.

Actelion Pharmaceuticals US, Inc. (Actelion US), received a subpoena in May 2016, with follow-up requests for documents from the United States Attorney's Office for the District of Massachusetts. The subpoena seeks the production of records pertaining to Actelion US' payments to 501(c)(3) charitable organizations that provide financial assistance to Medicare patients. In December 2018, the Company and the United States Department of Justice agreed to a settlement in this matter.

In March 2017, Janssen Biotech, Inc. received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE® or SIMPONI ARIA®.

In April and September 2017, Johnson & Johnson received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX®, OLYSIO®, REMICADE®, SIMPONI®, STELARA® and ZYTIGA®. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. spinal implants at three hospitals in Boston as well as interactions of employees of Company subsidiaries with physicians at these hospitals. Johnson & Johnson and DePuy Synthes, Inc. have produced documents in response to the subpoena and are fully cooperating with the government's investigation.

In July 2018, Advanced Sterilization Products (ASP) received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning the pricing, quality, marketing and promotion of EvoTech ECR, Tyvek Peel Pouches, or Sterrad Cyclesure 24 biological indicators.

In July 2018 the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. The United States Department of Justice and the United States Securities and Exchange Commission have made additional preliminary inquiries about the inspection in Brazil, and Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. is cooperating with those requests.

From time to time, the Company has received requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate

with these inquiries by producing the requested information.

GENERAL LITIGATION

In April 2016, a putative class action was filed against Johnson & Johnson, Johnson & Johnson Sales and Logistics Company, LLC and McNeil PPC, Inc. (now known as Johnson & Johnson Consumer, Inc.) in New Jersey Superior Court, Camden County on behalf of persons who reside in the state of New Jersey who purchased various McNeil over-the-counter products from December 2008 through the present. The complaint alleges violations of the New Jersey Consumer Fraud Act. Following the grant of a motion to dismiss and the filing of an amended complaint, in May 2017, the court denied a motion to dismiss the amended complaint. In December 2018, a settlement was reached and the matter has been dismissed.

In May 2014, two purported class actions were filed in federal court, one in the United States District Court for the Central District of California and one in the United States District Court for the Southern District of Illinois, against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI) alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI). Both cases seek injunctive relief and monetary damages; neither includes a claim for personal injuries. In October 2016, both cases were transferred to the United States District Court for the District Court of New Jersey as part of a newly created federal multi-district litigation. In July 2017, the district court granted Johnson & Johnson's and JJCI's motion to dismiss one of the cases. In September 2018, the United States Court of Appeals for the Third Circuit affirmed this dismissal. In September 2017, the plaintiff in the second case voluntarily dismissed their complaint. In March 2018, the plaintiff in the second case refiled in Illinois State Court.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed a Petition for Relief in July 2015.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI) and other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints allege that the manufacturers reached agreements with each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. In June 2016, the district court denied motions to dismiss filed by JJVCI and other defendants. Discovery is ongoing. In March 2017, the plaintiffs filed a motion for class certification. The district court held a hearing on the motion for class certification in August 2018. In December 2018, the district court granted the plaintiffs motion for class certification.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages.

In May 2017, Lonza Sales AG (Lonza) filed a Request for Arbitration with the London Court of International Arbitration against Janssen Research & Development, LLC (Janssen R&D). Lonza alleges that Janssen R&D breached a 2005 agreement between the parties by sublicensing certain Lonza technology used in the manufacture of daratumumab without Lonza's consent. Lonza seeks monetary damages. The arbitration hearing was held in September 2018. Post hearing briefing is complete, and the parties are awaiting a decision.

In May 2017, a purported class action was filed in the United States District Court for the Western District of Washington against LifeScan Inc., Johnson & Johnson, other diabetes test strip manufacturers and certain Pharmacy Benefit Managers (PBMs). The complaint alleges that consumers paid inflated prices for glucose monitor test strips as a consequence of undisclosed rebates and other incentives paid by manufacturers to PBMs. The complaint includes RICO, ERISA, and state consumer protection claims. The complaint seeks equitable relief and damages. In November 2017, the case was ordered transferred to United States District Court for the District of New Jersey. The LifeScan business was divested in October 2018 and Johnson & Johnson retained liability that may result from these claims prior to the closing of the divestiture.

In September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that

Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief.

Beginning in September 2017, multiple purported class actions were filed against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) alleging that Janssen's REMICADE® contracting strategies violated federal and state antitrust and consumer laws and seeking damages and injunctive relief. In November 2017, the cases were consolidated for pre-trial purposes in United States District Court for the Eastern District of Pennsylvania as In re Remicade Antitrust Litigation.



In June 2018, Walgreen Co. and Kroger Co. filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in the United States District Court for the Eastern District of Pennsylvania. The complaint alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health.

Andover Healthcare, Inc. (Andover) filed a Lanham act case against Johnson & Johnson Consumer Inc. in April 2017 in the United States District Court for the District of Massachusetts. Andover asserts that the claim “not made with natural rubber latex” on COACH® Sports Wrap, BAND-AID® Brand SECURE-FLEX® Wrap and BAND-AID® Brand HURT-FREE® Wrap is false. Andover seeks actual damages and pre-judgment interest thereon, disgorgement of profits, treble damages, attorney’s fees and injunctive relief. In December 2018, the parties entered into a settlement agreement.

In October 2018, two separate putative class actions were filed against Actelion Pharmaceutical Ltd., Actelion Pharmaceuticals US, Inc., and Actelion Clinical Research, Inc. (collectively “Actelion”) in United States District Court for the District of Maryland and United States District Court for the District of Columbia. The complaints allege that Actelion violated state and federal antitrust and unfair competition laws by allegedly refusing to supply generic pharmaceutical manufacturers with samples of TRACLEER®. TRACLEER® is subject to a Risk Evaluation and Mitigation Strategy, which imposes restrictions on distribution of the product. In January 2019, the plaintiffs dismissed the District of Columbia case and filed a consolidated complaint in federal court in Maryland.

In December 2018, Janssen Biotech, Inc., Janssen Oncology, Inc, Janssen Research & Development, LLC, and Johnson & Johnson (collectively, Janssen) were served with a qui tam complaint filed on behalf of the United States, 28 states, and the District of Columbia. The complaint, which was filed in December 2017 in United States District Court for the Northern District of California, alleges that Janssen violated the federal False Claims Act and state law when providing pricing information for ZYTIGA® to the government in connection with direct government sales and government-funded drug reimbursement programs. At this time, the federal and state governments have declined to intervene.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

## 22. Restructuring

In the first quarter of 2016, the Company announced restructuring actions in its Medical Devices segment to better serve the needs of patients and customers in today’s evolving healthcare marketplace. The Company has undertaken actions to strengthen its go-to-market model, accelerate the pace of innovation, further prioritize key platforms and geographies, and streamline operations while maintaining high quality standards.

In 2018, the Company recorded a pre-tax charge of \$462 million, of which \$46 million was included in cost of products sold and \$227 million was included in other (income) expense. Total project costs of \$2.5 billion have been recorded since the restructuring has been announced. This restructuring program was completed in the fiscal fourth quarter of 2018.

On April 17, 2018, the Company announced plans to implement a series of actions across its Global Supply Chain that are intended to focus resources and increase investments in the critical capabilities, technologies and solutions

necessary to manufacture and supply its product portfolio, enhance agility and drive growth. The Global Supply Chain actions will include expanding the use of strategic collaborations and bolstering initiatives to reduce complexity, improve cost-competitiveness, enhance capabilities and optimize the Supply Chain network. For additional details on the global supply chain restructuring strategic collaborations see Note 20 to the Consolidated Financial Statements. In 2018, the Company recorded a pre-tax charge of \$238 million, of which \$59 million was included in cost of products sold and \$117 million was included in other (income) expense. See the following table for additional details on the restructuring programs.

In total, the Company expects the Global Supply Chain actions to generate approximately \$0.6 billion to \$0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately \$1.9 billion to \$2.3 billion, over the 4 to 5 year period of this activity. These costs are associated with network optimizations, exit costs and accelerated depreciation and amortization.

The following table summarizes the severance charges and the associated spending under these initiatives through the fiscal year ended 2018:

| (Dollars in Millions)               | Severance | Asset<br>Write-offs | Other** | Total |
|-------------------------------------|-----------|---------------------|---------|-------|
| Reserve balance, January 3, 2016    | \$ 484    | —                   | 17      | 501   |
| 2016 activity                       | (104 )    | —                   | (16 )   | (120) |
| Reserve balance, January 1, 2017    | 380       | —                   | 1       | 381   |
| 2017 activity                       | (151 )    | —                   | 37      | (114) |
| Reserve balance, December 31, 2017  | 229       | —                   | 38      | 267   |
| Current year activity:              |           |                     |         |       |
| Charges                             | —         | 132                 | 568     | 700   |
| Cash payments                       | (35 )     | —                   | (558 )  | (593) |
| Settled non cash                    | —         | (132 )              | —       | (132) |
| Reserve balance, December 30, 2018* | \$ 194    | —                   | 48      | 242   |

\*Cash outlays for severance are expected to be substantially paid out over the next 2 years in accordance with the Company's plans and local laws.

\*\*Other includes project expense such as salaries for employees supporting the initiative and consulting expenses.

Although the Medical Devices restructuring program was completed in 2018, the Company expects that severance charges will continue beyond that date. The Company continuously reevaluates its severance reserves related to restructuring and the timing of payments has extended due to the planned release of associates regarding several longer-term projects. The Company believes that the existing severance reserves are sufficient to cover the Global Supply Chain plans given the period over which the actions will take place. The Company will continue to assess and make adjustments as necessary if additional amounts become probable and estimable. Approximately 2,375 individuals received separation payments since these restructuring announcements.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Johnson & Johnson

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Johnson & Johnson and its subsidiaries (the “Company”) as of December 30, 2018 and December 31, 2017, and the related consolidated statements of earnings, of comprehensive income, of equity, and of cash flows for each of the three years in the period ended December 30, 2018 including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company's internal control over financial reporting as of December 30, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 30, 2018 and December 31, 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 30, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 30, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on the Company’s consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/PricewaterhouseCoopers LLP

Florham Park, New Jersey  
February 20, 2019

We have served as the Company's auditor since at least 1920. We have not been able to determine the specific year we began serving as auditor of the Company.

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of December 30, 2018. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company's processes and assessment, as described above, management has concluded that, as of December 30, 2018, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of December 30, 2018 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

/s/ Alex Gorsky

Alex Gorsky

Chairman, Board of Directors

Chief Executive Officer

/s/ Joseph J. Wolk

Joseph J. Wolk

Executive Vice President, Chief Financial Officer

## Shareholder Return Performance Graphs

Set forth below are line graphs comparing the cumulative total shareholder return on the Company's Common Stock for periods of five years and ten years ending December 31, 2018, against the cumulative total return of the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index. The graphs and tables assume that \$100 was invested on December 31, 2013 and December 31, 2008 in each of the Company's Common Stock, the Standard & Poor's 500 Stock Index, the Standard & Poor's Pharmaceutical Index and the Standard & Poor's Health Care Equipment Index and that all dividends were reinvested.

## 5 Year Shareholder Return Performance J&amp;J vs. Indices

|                                | 2013     | 2014     | 2015     | 2016     | 2017     | 2018     |
|--------------------------------|----------|----------|----------|----------|----------|----------|
| Johnson & Johnson              | \$100.00 | \$117.34 | \$118.69 | \$136.88 | \$170.29 | \$161.54 |
| S&P 500 Index                  | \$100.00 | \$113.68 | \$115.24 | \$129.02 | \$157.17 | \$150.27 |
| S&P Pharmaceutical Index       | \$100.00 | \$122.22 | \$129.29 | \$127.27 | \$143.27 | \$154.86 |
| S&P Healthcare Equipment Index | \$100.00 | \$126.28 | \$133.82 | \$142.50 | \$186.53 | \$216.82 |

## 10 Year Shareholder Return Performance J&amp;J vs. Indices

|                                | 2008     | 2009     | 2010     | 2011     | 2012     | 2013     | 2014     | 2015     | 2016     | 2017     | 2018     |
|--------------------------------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| Johnson & Johnson              | \$100.00 | \$111.28 | \$110.63 | \$121.57 | \$134.73 | \$181.37 | \$212.81 | \$215.28 | \$248.26 | \$308.85 | \$292.99 |
| S&P 500 Index                  | \$100.00 | \$126.45 | \$145.49 | \$148.55 | \$172.31 | \$228.09 | \$259.29 | \$262.86 | \$294.28 | \$358.50 | \$342.75 |
| S&P Pharmaceutical Index       | \$100.00 | \$118.62 | \$119.54 | \$140.77 | \$161.07 | \$217.82 | \$266.21 | \$281.62 | \$277.21 | \$312.06 | \$337.32 |
| S&P Healthcare Equipment Index | \$100.00 | \$128.79 | \$125.30 | \$124.30 | \$145.76 | \$186.12 | \$235.04 | \$249.08 | \$265.23 | \$347.17 | \$403.55 |



Item CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL  
9. DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. At the end of the period covered by this Report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Wolk concluded that, as of the end of the period covered by this Report, the Company's disclosure controls and procedures were effective

Reports on Internal Control Over Financial Reporting. The information called for by this item is incorporated herein by reference to "Management's Report on Internal Control Over Financial Reporting", and the attestation regarding internal controls over financial reporting included in the "Report of Independent Registered Public Accounting Firm" included in Item 8 of this Report.

Changes in Internal Control Over Financial Reporting. During the fiscal quarter ended December 30, 2018, there were no changes in the Company's internal control over financial reporting identified in connection with the evaluation required under Rules 13a-15 and 15d-15 under the Exchange Act that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In response to this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item is incorporated herein by reference to the discussion of the Audit Committee under the caption "Item 1. Election of Directors - Board Committees"; and the material under the captions "Item 1. Election of Directors" and "Stock Ownership and Section 16 Compliance – Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement; and the material under the caption "Executive Officers of the Registrant" in Part I of this Report.

The Company's Code of Business Conduct, which covers all employees (including the Chief Executive Officer, Chief Financial Officer and Controller), meets the requirements of the SEC rules promulgated under Section 406 of the Sarbanes-Oxley Act of 2002. The Code of Business Conduct is available on the Company's website at [www.jnj.com/code-of-business-conduct](http://www.jnj.com/code-of-business-conduct), and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code of Business Conduct or any waiver of the Code granted to the Chief Executive Officer, the Chief Financial Officer or the Controller will be posted on the Company's website at [www.investor.jnj.com/gov.cfm](http://www.investor.jnj.com/gov.cfm) within five business days (and retained on the website for at least one year).

In addition, the Company has adopted a Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers. The Code of Business Conduct & Ethics for Members of the Board of Directors and

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Executive Officers is available on the Company's website at [www.investor.jnj.com/gov/boardconduct.cfm](http://www.investor.jnj.com/gov/boardconduct.cfm), and copies are available to shareholders without charge upon written request to the Secretary at the Company's principal executive offices. Any substantive amendment to the Code or any waiver of the Code granted to any member of the Board of Directors or any executive officer will be posted

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on the Company’s website at [www.investor.jnj.com/gov.cfm](http://www.investor.jnj.com/gov.cfm) within five business days (and retained on the website for at least one year).

**Item 11. EXECUTIVE COMPENSATION**

The information called for by this item is incorporated herein by reference to the material under the captions “Item 1. Election of Directors – Director Compensation,” and “Item 2. Compensation Committee Report,” “Compensation Discussion and Analysis” and “Executive Compensation Tables” in the Proxy Statement.

The material incorporated herein by reference to the material under the caption “Compensation Committee Report” in the Proxy Statement shall be deemed furnished, and not filed, in this Report and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, as a result of this furnishing, except to the extent that the Company specifically incorporates it by reference.

**Item SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND 12. RELATED STOCKHOLDER MATTERS**

The information called for by this item is incorporated herein by reference to the material under the caption “Item 1. Stock Ownership and Section 16 Compliance” in the Proxy Statement; and Note 17 “Common Stock, Stock Option Plans and Stock Compensation Agreements” of the Notes to Consolidated Financial Statements in Item 8 of this Report.

**Equity Compensation Plan Information**

The following table provides certain information as of December 30, 2018 concerning the shares of the Company’s Common Stock that may be issued under existing equity compensation plans.

| Plan Category   | Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights | Weighted Average Exercise Price of Outstanding Options and Rights | Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans <sup>(2)(3)</sup> |
|---|---|---|--|
| Equity Compensation Plans Approved by Security Holders <sup>(1)</sup> | 130,605,768   | \$82.52   | 351,079,202  |
| Equity Compensation Plans Not Approved by Security Holders            | -   | -   | -  |
| Total   | 130,605,768   | \$82.52   | 351,079,202  |

(1) Included in this category are the following equity compensation plans which have been approved by the Company’s shareholders: 2005 Long-Term Incentive Plan and 2012 Long-Term Incentive Plan.

(2) This column excludes shares reflected under the column “Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights.”

(3) The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan.

**Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information called for by this item is incorporated herein by reference to the material under the captions “Item 1. Election of Directors - Director Independence” and “Related Person Transactions” in the Proxy Statement.

**Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information called for by this item is incorporated herein by reference to the material under the caption “Item 3. Ratification of Appointment of Independent Registered Public Accounting Firm” in the Proxy Statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this report:

1. Financial Statements

Consolidated Balance Sheets at end of Fiscal Years 2018 and 2017

Consolidated Statements of Earnings for Fiscal Years 2018, 2017 and 2016

Consolidated Statements of Comprehensive Income for Fiscal Years 2018, 2017 and 2016

Consolidated Statements of Equity for Fiscal Years 2018, 2017 and 2016

Consolidated Statements of Cash Flows for Fiscal Years 2018, 2017 and 2016

Notes to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

All schedules are omitted because they are not applicable or the required information is included in the financial statements or notes.

2. Exhibits Required to be Filed by Item 601 of Regulation S-K

The information called for by this item is incorporated herein by reference to the Exhibit Index in this Report.

Item 16. FORM 10-K SUMMARY

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. The Company has elected not to include such summary information.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 20, 2019

JOHNSON & JOHNSON

(Registrant)

By /s/ A. Gorsky

A. Gorsky, Chairman, Board of Directors,  
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature                            | Title  | Date              |
|--------------------------------------|--|-------------------|
| /s/ A. Gorsky<br>A. Gorsky           | Chairman, Board of Directors<br>Chief Executive Officer<br>(Principal Executive Officer) | February 20, 2019 |
| /s/ J. J. Wolk<br>J. J. Wolk         | Chief Financial Officer<br>(Principal Financial Officer)                                 | February 20, 2019 |
| /s/ R. A. Kapusta<br>R. A. Kapusta   | Controller and Chief Accounting Officer<br>(Principal Accounting Officer)                | February 20, 2019 |
| /s/ M. C. Beckerle<br>M. C. Beckerle | Director   | February 20, 2019 |
| /s/ D. S. Davis<br>D. S. Davis       | Director   | February 20, 2019 |
| /s/ I. E. L. Davis<br>I. E. L. Davis | Director   | February 20, 2019 |
| /s/ J. A. Doudna<br>J. A. Doudna     | Director   | February 20, 2019 |

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| Signature                                | Title    | Date              |
|--|----------|-------------------|
| /s/ M. B. McClellan<br>M. B. McClellan   | Director | February 20, 2019 |
| /s/ A. M. Mulcahy<br>A. M. Mulcahy       | Director | February 20, 2019 |
| /s/ W. D. Perez<br>W. D. Perez           | Director | February 20, 2019 |
| /s/ C. Prince<br>C. Prince               | Director | February 20, 2019 |
| /s/ A. E. Washington<br>A. E. Washington | Director | February 20, 2019 |
| /s/ R. A. Williams<br>R. A. Williams     | Director | February 20, 2019 |

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## EXHIBIT INDEX

Reg. S-K

Exhibit  
Table Description

Item No. of Exhibit

- 3(i) Restated Certificate of Incorporation effective February 19, 2016 — Incorporated herein by reference to Exhibit 3(i) of the Registrant’s Form 10-K Annual Report for the fiscal year ended January 3, 2016.
- 3(ii) By-Laws of the Company, as amended effective January 26, 2016 — Incorporated herein by reference to Exhibit 3.1 the Registrant’s Form 8-K Current Report filed January 26, 2016.
- 4(a) Upon the request of the Securities and Exchange Commission, the Registrant will furnish a copy of all instruments defining the rights of holders of long-term debt of the Registrant.
- 10(a) 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 4 of the Registrant’s S-8 Registration Statement filed with the Commission on May 10, 2005 (file no. 333-124785).\*
- 10(b) Form of Stock Option Certificate under the 2005 Long-Term Incentive Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant’s Form 8-K Current Report filed January 13, 2012.\*
- 10(c) 2012 Long-Term Incentive Plan — Incorporated herein by reference to Appendix A of the Registrant’s Proxy Statement filed with the Commission on March 15, 2017.\*
- 10(d) Form of Stock Option Certificate, Restricted Share Unit Certificate and Performance Share Unit Certificate under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.2, 10.3 and 10.4 of the Registrant’s Form 10-Q Quarterly Report filed May 7, 2012.\*
- 10(e) Global NonQualified Stock Option Award Agreement, Global Restricted Share Unit Award Agreement and Global Performance Share Unit Award Agreement under the 2012 Long-Term Incentive Plan — Incorporated herein by reference to Exhibits 10.1, 10.2 and 10.3 of the Registrant’s Form 10-Q Quarterly Report filed May 1, 2018.\*
- 10(f) Johnson & Johnson Executive Incentive Plan (as amended) — Incorporated herein by reference to Exhibit 10(f) of the Registrant’s Form 10-K Annual Report for the fiscal year ended December 31, 2000.\*
- 10(g) Domestic Deferred Compensation (Certificate of Extra Compensation) Plan — Incorporated herein by reference to Exhibit 10(g) of the Registrant’s Form 10-K Annual Report for the year ended December 28, 2003.\*
- 10(h) Amendments to the Certificate of Extra Compensation Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(j) of the Registrant’s Form 10-K Annual Report for the year ended December 28, 2008.\*
- 10(i) 2009 Certificates of Long-Term Performance Plan — Incorporated herein by reference to Exhibit 10.1 of the Registrant’s Form 10-Q Quarterly Report for the quarter ended September 27, 2009.\*
- 10(j) Amended and Restated Deferred Fee Plan for Directors (Amended as of January 17, 2012) — Incorporated herein by reference to Exhibit 10(k) of the Registrant’s Form 10-K Annual Report for the fiscal year ended January 1, 2012.\*
- 10(k) The Johnson & Johnson Executive Income Deferral Plan (Amended and Restated Effective January 1, 2010) — Incorporated herein by reference to Exhibit 10.1 of the Registrant’s Form 10-Q Quarterly Report for the quarter ended September 30, 2012.\*
- 10(l) Excess Savings Plan (Effective as of January 1, 1996) — Incorporated herein by reference to Exhibit 10(j) of the Registrant’s Form 10-K Annual Report for the fiscal year ended December 29, 1996.\*
- 10(m) Amendments to the Johnson & Johnson Excess Savings Plan effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(p) of the Registrant’s Form 10-K Annual Report for the fiscal year ended December 28, 2008.\*
- 10(n)\*\* Excess Benefit Plan (Supplemental Retirement Plan) — Incorporated herein by reference to Exhibit 10(h) of the Registrant’s Form 10-K Annual Report for the fiscal year ended January 3, 1993.\*
- 10(o)

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Amendments to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies effective as of January 1, 2009 — Incorporated herein by reference to Exhibit 10(r) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2008.\*

10(p) Amendment to the Excess Benefit Plan of Johnson & Johnson and Affiliated Companies, effective as of January 1, 2015 — Incorporated herein by reference to Exhibit 10(q) of the Registrant's Form 10-K Annual Report for the fiscal year ended December 28, 2014.\*

10(q)\*\* Executive Life Plan Agreement — Incorporated herein by reference to Exhibit 10(i) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 1993.\*

10(r) Executive Life Plan Agreement Closure Letter — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended March 29, 2015.\*

10(s) Employment Agreement for Dr. Paulus Stoffels - Incorporated herein by reference to Exhibit 10.2 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 30, 2012.\*

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| Reg.<br>S-K<br>Exhibit<br>Table<br>Item<br>No. | Description<br>of Exhibit  |
|--|--|
| <u>10(t)</u>                                   | Summary of Employment Arrangements for Sandra E. Peterson — Incorporated herein by reference to Exhibit 10(t) of the Registrant's Form 10-K Annual Report for the year ended December 30, 2012.*   |
| <u>10(u)</u>                                   | Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies, Amended and Restated as of October 1, 2014 — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended September 28, 2014.*   |
| <u>10(v)</u>                                   | First Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10.1 of the Registrant's Form 10-Q Quarterly Report for the quarter ended June 28, 2015.*   |
| <u>10(w)</u>                                   | Second Amendment to the Severance Pay Plan of Johnson & Johnson and U.S. Affiliated Companies (as amended and restated effective October 1, 2014) — Incorporated herein by reference to Exhibit 10(x) of the Registrant's Form 10-K Annual Report for the fiscal year ended January 3, 2016.*  |
| <u>21</u>                                      | Subsidiaries - Filed with this document.   |
| <u>23</u>                                      | Consent of Independent Registered Public Accounting Firm — Filed with this document.   |
| <u>31.1</u>                                    | Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.   |
| <u>31.2</u>                                    | Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act — Filed with this document.   |
| <u>32.1</u>                                    | Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.   |
| <u>32.2</u>                                    | Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act — Furnished with this document.   |
| 101  | XBRL (Extensible Business Reporting Language) The following materials from this Report for the fiscal year ended December 30, 2018, formatted in Extensive Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Earnings, (iii) Consolidated Statements of Comprehensive Income, (iv) Consolidated Statements of Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements. |

\* Management contract or compensatory plan.

\*\* Paper filing.

A copy of any of the Exhibits listed above will be provided without charge to any shareholder submitting a written request specifying the desired exhibit(s) to the Secretary at the principal executive offices of the Company. Pursuant to Item 601(b)(4)(iii)(A) of Regulation S-K, the Company has not filed as exhibits to this Form 10-K certain long-term debt instruments, including indentures, under which the total amount of securities authorized does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company hereby agrees to furnish a copy of any such instrument to the SEC upon request.