

SUPPLEMENT TO “FINANCIAL HEALTH ECONOMICS”: APPENDIX
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BY RALPH S. J. KOIJEN, TOMAS J. PHILIPSON, AND HARALD UHLIG

IN SECTION A.1., WE DISCUSS possible specifications of the preferences of the entrepreneurs. In Section A.2., we compute the medical innovation premium for different data frequencies (monthly and annually) and different sample periods. In Section A.3., we report the section “Risk Factors” from the 10-K filings of Apple and Pfizer.

A.1. REVERSE-ENGINEERING THE PREFERENCES OF
THE ENTREPRENEUR

Given the numerical solution to the model, it may be instructive to “reverse-engineer” the preferences, that is, to find a value function $V(\{c_{e,t}\}_t)$ in terms of the stochastic stream of entrepreneurial consumptions so that the assumed stochastic discount factors result from the appropriate first-order conditions. It should be clear that there is considerable freedom in doing so.

Consider the decomposition of the stochastic discount factor as $M_{t+1} = R^{-1}X_{t+1}$, where X_{t+1} is the stochastic component that reflects government intervention risk, with $E[X_{t+1}] = 1$. Suppose now, that the preferences of the entrepreneur are time separable,

$$V(\{c_{e,t}\}_t) = E \left[\sum_{t=0}^{\infty} \tilde{\beta}^t u(c_{e,t}) \right].$$

The consumption of the entrepreneur $c_{e,t}$ in the absence of government intervention is proportional to profits minus outlays for R&D. The consumption of the entrepreneur with government intervention could either be read as zero, or, in a slight extension of the model, assumed to be some fraction $0 \leq \xi_t < 1$ of the nonintervention consumption $c_{e,t}$ at the time of the intervention.

The standard relationships between preferences and stochastic discount factors deliver

$$(A.1) \quad R^{-1} \underline{X} = \tilde{\beta} \frac{u'(c_{e,t+1})}{u'(c_{e,t})},$$

$$(A.2) \quad R^{-1} \overline{X} = \tilde{\beta} \frac{u'(\xi_t c_{e,t+1})}{u'(c_{e,t})}.$$

From the numerical calculation done for $t = 1, \dots, 6$, one finds that entrepreneurial consumption is growing over time, though not exactly at a constant rate.

The easiest solution to the equations (A.1) and (A.2) above is to assume that the utility function is piecewise linear, with a concave kink at some positive level of consumption below $c_{e,1}$ and with imposing that ξ_t takes post-intervention consumption to a level below $c_{e,1}$: $\xi_t = 0$ will be one possibility that does the trick. This is the assumption we have used in the main text. With the piecewise linear utility function, one needs to solve for β per

$$(A.3) \quad R^{-1} \underline{X} = \tilde{\beta}$$

and find the slope below the kink (at $c = 0$, say) relative to the slope above the kink (at $c_{e,t}$, say) per

$$\frac{\overline{X}}{\underline{X}} = \frac{u'(0)}{u'(c_{e,t})}.$$

Such preferences are a simple version of loss-aversion preferences that have been proposed for a variety of phenomena, including asset pricing; see [Kahneman and Tversky \(1979\)](#).

If $\tilde{\beta}$ does not satisfy (A.3), but instead is some other value between that value and, say, $\beta = 1$, one can solve the integration problem as follows. For a given value of $\tilde{\beta}$ strictly in this range and with some normalization for $u'(c_{e,1}) > 0$, calculate recursively

$$u'(c_{e,t+1}) = \frac{\underline{X}}{\tilde{\beta}R} u'(c_{e,t}).$$

Note that $0 < u'(c_{e,t+1}) < u'(c_{e,t})$. Find a continuous decreasing nonnegative function $u'(c_e)$ connecting these points: this is feasible, since $c_{e,t}$ is an increasing sequence. Integrate to find the utility function $u(c_e)$.

While there are many solutions, it may be instructive to see whether one can bound this exercise, using the constant relative risk aversion (CRRA) specification. While the CRRA specification will not work exactly, one can calculate $\overline{\eta}$ as the minimal η so that

$$(A.4) \quad R^{-1} \underline{X} \geq \tilde{\beta} \left(\frac{c_{e,t+1}}{c_{e,t}} \right)^{-\eta} \quad \text{for all } t = 1, \dots, 6,$$

and calculate $\underline{\eta}$ as the maximal η , so that

$$(A.5) \quad R^{-1} \underline{X} \leq \tilde{\beta} \left(\frac{c_{e,t+1}}{c_{e,t}} \right)^{-\eta} \quad \text{for all } t = 1, \dots, 6.$$

Imposing CRRA preferences with these η , one can furthermore ask what consumption reduction fraction ξ_t will be necessary to reach the marginal utilities

TABLE A.1
CALCULATING η BOUNDS AND THE CORRESPONDING CONSUMPTION REDUCTION FRACTION
AS A FUNCTION OF β

$\tilde{\beta}$ (p.a.):	0.92	0.94	0.97	0.98	1.00
$\bar{\eta}$:	0.0	0.6	1.1	1.5	1.8
cons.reduct.fract.:	arb.	0.04	0.16	0.26	0.33
$\underline{\eta}$:	0.0	0.5	1.0	1.3	1.6
cons.reduct.fract.:	arb.	0.03	0.13	0.22	0.29

required for the intervention case. The results are given in Table A.1. It turns out that the η bounds are fairly close to each other, indicating that CRRA is a pretty good fit even for $\tilde{\beta}$ values different from that in equation (A.3) for any of the values of β . Furthermore, the values for η are within the entirely reasonable range of $[0, 2]$.

The consumption reduction fraction is arbitrary for $\eta = 0$ and otherwise ranges from 0.04 to 0.33. A slightly different utility specification uses a (close to) CRRA utility function above these consumption levels and a linear level below, splicing it together smoothly at that point: then one may use any post-intervention consumption level below that consumption reduction level. In that case, one needs a different felicity function for every period.

It should finally be noted that one needs

$$R^{-1} = \tilde{\beta} \frac{u'(\tilde{c}_{e,t+1})}{u'(\tilde{c}_{e,t})}$$

for the post-intervention consumption levels $\tilde{c}_{e,t}$. This will automatically be satisfied for $\tilde{c}_{e,t} \equiv 0$ and the kinked utility specification detailed above. For the CRRA specification, one will need a constant growth rate of $\tilde{c}_{e,t}$. Since the required preferences are not exactly CRRA, one needs slightly uneven growth for $\tilde{c}_{e,t}$ so as to compensate.

A.2. ROBUSTNESS OF THE MEDICAL INNOVATION PREMIUM

In the main text, we document the medical innovation premium for annual returns for our main sample from 1961 to 2012 using both the CAPM and the three-factor Fama and French model.

For robustness, we estimate the model at both a monthly frequency and an annual frequency. If we estimate the model at a monthly frequency, we multiply the alphas by 12 to annualize them. We also consider three different sample periods: 1927.1–2013.7, 1946.1–2013.7, and 1961.1–2013.7. The first sample period is the longest sample available. The second sample focuses on the post-war period. The third sample coincides with the period for which we have data on

aggregate health care spending. The returns on services start only in the late sixties and we, therefore, exclude them from the table. However, their returns are well explained by standard models and the alphas are close to zero.

The annual results are shown in panel A and the monthly results are shown in panel B of Table A.2. The first number corresponds to the alpha; the second number is the t -statistics using ordinary least squares (OLS) standard errors. We find that the health care industry tends to produce economically and statistically significant alphas between 3–5% per annum, depending on the benchmark model and the sample period. If we remove health services and focus on pharmaceutical products and medical equipment, the alphas are even higher, at 4–7% per annum. This is because the alphas on medical services are close to zero.

We also report the alphas on the other industries, which do not have large alphas relative to the standard models. We typically find that the results are somewhat stronger using the Fama–French model. We conclude that there is a risk premium for holding health care stocks that cannot be explained by standard asset pricing factors.

A.3. ITEM 1.A OF THE 10-K FILINGS OF APPLE AND PFIZER

The complete 10-K Filings may be found at <http://www.sec.gov/Archives/edgar/data/320193/000119312513416534/d590790d10k.htm> and <http://www.sec.gov/Archives/edgar/data/78003/000007800313000006/pfe-12312012x10k.htm>.

Item 1A. Risk Factors

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding any statement in this Form 10-K or elsewhere. The following information should be read in conjunction with Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the consolidated financial statements and related notes in Part II, Item 8, “Financial Statements and Supplementary Data” of this Form 10-K.

Because of the following factors, as well as other factors affecting the Company’s financial condition and operating results, past financial performance should not be considered to be a reliable indicator of future performance, and investors should not use historical trends to anticipate results or trends in future periods.

Global and regional economic conditions could materially adversely affect the Company.

The Company’s operations and performance depend significantly on global and regional economic conditions. Uncertainty about global and regional economic conditions poses a risk as consumers and businesses postpone spending in response to tighter credit, higher unemployment, financial market volatility,

TABLE A.2
INDUSTRY ALPHAS

	Consumer Goods	Manufacturing	HiTec	Health	Other	Medical Equipment	Drugs
Panel A: Annual returns							
1927–2012							
CAPM	1.25	1.12	0.68	3.98	−0.96	4.33	4.35
	1.22	1.49	0.57	2.35	−1.01	2.11	2.48
Fama and French	0.78	0.53	2.11	5.56	−2.60	5.80	5.96
	0.74	0.74	1.73	3.37	−3.54	2.83	3.42
1946–2012							
CAPM	1.19	1.66	−0.29	4.29	−0.86	4.07	4.68
	1.07	1.81	−0.21	2.10	−0.77	1.70	2.25
Fama and French	−0.06	0.92	1.91	5.72	−3.10	6.27	6.06
	−0.05	0.96	1.25	2.77	−3.82	2.36	2.87
1961–2012							
CAPM	1.81	1.66	−0.83	3.31	0.22	3.71	3.70
	1.40	1.54	−0.54	1.61	0.17	1.40	1.78
Fama and French	−0.13	1.04	1.67	5.01	−2.66	6.44	5.37
	−0.09	0.84	0.86	2.44	−2.75	2.05	2.63
Panel B: Monthly returns							
1927.1–2013.7							
CAPM	1.46	0.74	0.46	3.07	−1.24	3.27	3.47
	2.12	1.24	0.52	2.43	−1.50	2.03	2.54
Fama and French	1.45	0.26	1.60	3.89	−2.72	3.53	4.34
	2.12	0.48	2.06	3.16	−3.91	2.22	3.27
1946.1–2013.7							
CAPM	1.25	1.34	−0.59	3.18	−0.92	2.85	3.67
	1.61	1.91	−0.58	2.40	−1.12	1.71	2.54
Fama and French	0.58	0.25	1.57	4.85	−3.02	3.81	5.50
	0.75	0.39	1.75	3.78	−4.13	2.25	3.98
1961.1–2013.7							
CAPM	1.76	1.33	−1.01	2.64	−0.10	2.82	3.11
	1.92	1.55	−0.84	1.76	−0.10	1.65	1.89
Fama and French	0.79	0.17	1.24	4.78	−2.46	4.10	5.54
	0.85	0.21	1.14	3.29	−2.82	2.33	3.52

government austerity programs, negative financial news, declines in income or asset values and/or other factors. These worldwide and regional economic conditions could have a material adverse effect on demand for the Company's products and services. Demand also could differ materially from the Company's expectations because the Company generally raises prices on goods and services sold outside the U.S. to correspond with the effect of a strengthening of the U.S. dollar. Other factors that could influence worldwide or regional demand include increases in fuel and other energy costs, conditions in the real estate and mortgage markets, unemployment, labor and healthcare costs, access to credit, consumer confidence, and other macroeconomic factors af-

fecting consumer spending behavior. These and other economic factors could materially adversely affect demand for the Company's products and services.

In the event of further financial turmoil affecting the banking system and financial markets, additional consolidation of the financial services industry, or significant financial service institution failures, there could be a new or incremental tightening in the credit markets, low liquidity, and extreme volatility in fixed income, credit, currency, and equity markets. This could have a number of effects on the Company's business, including the insolvency or financial instability of outsourcing partners or suppliers or their inability to obtain credit to finance development and/or manufacture products resulting in product delays; inability of customers, including channel partners, to obtain credit to finance purchases of the Company's products; failure of derivative counterparties and other financial institutions; and restricting the Company's ability to issue new debt. Other income and expense also could vary materially from expectations depending on gains or losses realized on the sale or exchange of financial instruments; impairment charges resulting from revaluations of debt and equity securities and other investments; interest rates; cash balances; volatility in foreign exchange rates; and changes in fair value of derivative instruments. Increased volatility in the financial markets and overall economic uncertainty would increase the risk of the actual amounts realized in the future on the Company's financial instruments differing significantly from the fair values currently assigned to them.

Global markets for the Company's products and services are highly competitive and subject to rapid technological change, and the Company may be unable to compete effectively in these markets.

The Company's products and services compete in highly competitive global markets characterized by aggressive price cutting and resulting downward pressure on gross margins, frequent introduction of new products, short product life cycles, evolving industry standards, continual improvement in product price/performance characteristics, rapid adoption of technological and product advancements by competitors, and price sensitivity on the part of consumers.

The Company's ability to compete successfully depends heavily on its ability to ensure a continuing and timely introduction of innovative new products and technologies to the marketplace. The Company believes it is unique in that it designs and develops nearly the entire solution for its products, including the hardware, operating system, numerous software applications, and related services. As a result, the Company must make significant investments in research and development. The Company currently holds a significant number of patents and copyrights and has registered and/or has applied to register numerous patents, trademarks and service marks. In contrast, many of the Company's competitors seek to compete primarily through aggressive pricing and very low cost structures, and emulating the Company's products and infringing on its intellectual property. If the Company is unable to continue to develop and sell

innovative new products with attractive margins or if competitors infringe on the Company's intellectual property, the Company's ability to maintain a competitive advantage could be adversely affected.

The Company markets certain mobile communication and media devices based on the iOS mobile operating system and also markets related third-party digital content and applications. The Company faces substantial competition in these markets from companies that have significant technical, marketing, distribution and other resources, as well as established hardware, software and digital content supplier relationships; and the Company has a minority market share in the smartphone market. Additionally, the Company faces significant price competition as competitors reduce their selling prices and attempt to imitate the Company's product features and applications within their own products or, alternatively, collaborate with each other to offer solutions that are more competitive than those they currently offer. The Company also competes with illegitimate ways to obtain third-party digital content and applications. Some of the Company's competitors have greater experience, product breadth and distribution channels than the Company. Because some current and potential competitors have substantial resources and/or experience and a lower cost structure, they may be able to provide products and services at little or no profit or even at a loss. The Company also expects competition to intensify as competitors attempt to imitate the Company's approach to providing components seamlessly within their individual offerings or work collaboratively to offer integrated solutions. The Company's financial condition and operating results depend substantially on the Company's ability to continually improve iOS and iOS devices in order to maintain their functional and design advantages.

The Company is the only authorized maker of hardware using OS X, which has a minority market share in the personal computer market. This market is dominated by computer makers using competing operating systems, most notably Windows. In the market for personal computers and peripherals, the Company faces a significant number of competitors, many of which have broader product lines, lower priced products, and a larger installed customer base. Historically, consolidation in this market has resulted in larger competitors. Price competition has been particularly intense as competitors selling Windows-based personal computers have aggressively cut prices and lowered product margins. An increasing number of Internet-enabled devices that include software applications and are smaller and simpler than traditional personal computers compete for market share with the Company's existing products. The Company's financial condition and operating results also depend on its ability to continually improve the Mac platform to maintain its functional and design advantages.

There can be no assurance the Company will be able to continue to provide products and services that compete effectively.

To remain competitive and stimulate customer demand, the Company must successfully manage frequent product introductions and transitions.

Due to the highly volatile and competitive nature of the industries in which the Company competes, the Company must continually introduce new products, services and technologies, enhance existing products and services, and effectively stimulate customer demand for new and upgraded products. The success of new product introductions depends on a number of factors including, but not limited to, timely and successful product development, market acceptance, the Company's ability to manage the risks associated with new product production ramp-up issues, the availability of application software for new products, the effective management of purchase commitments and inventory levels in line with anticipated product demand, the availability of products in appropriate quantities and costs to meet anticipated demand, and the risk that new products may have quality or other defects or deficiencies in the early stages of introduction. Accordingly, the Company cannot determine in advance the ultimate effect of new product introductions and transitions.

The Company depends on the performance of distributors, carriers and other resellers.

The Company distributes its products through cellular network carriers, wholesalers, national and regional retailers, and value-added resellers, many of whom distribute products from competing manufacturers. The Company also sells its products and third-party products in most of its major markets directly to education, enterprise and government customers, and consumers and small and mid-sized businesses through its online and retail stores.

Carriers providing cellular network service for iPhone typically subsidize users' purchases of the device. There is no assurance that such subsidies will be continued at all or in the same amounts upon renewal of the Company's agreements with these carriers or in agreements the Company enters into with new carriers.

Many resellers have narrow operating margins and have been adversely affected in the past by weak economic conditions. Some resellers have perceived the expansion of the Company's direct sales as conflicting with their business interests as distributors and resellers of the Company's products. Such a perception could discourage resellers from investing resources in the distribution and sale of the Company's products or lead them to limit or cease distribution of those products. The Company has invested and will continue to invest in programs to enhance reseller sales, including staffing selected resellers' stores with Company employees and contractors and improving product placement displays. These programs could require a substantial investment while providing no assurance of return or incremental revenue. The financial condition of these resellers could weaken, these resellers could stop distributing the Company's products, or uncertainty regarding demand for the Company's products could cause resellers to reduce their ordering and marketing of the Company's products.

The Company faces substantial inventory and other asset risk in addition to purchase commitment cancellation risk.

The Company records a write-down for product and component inventories that have become obsolete or exceed anticipated demand or net realizable value and accrues necessary cancellation fee reserves for orders of excess products and components. The Company also reviews its long-lived assets, including capital assets held at its suppliers' facilities and inventory prepayments, for impairment whenever events or circumstances indicate the carrying amount of an asset may not be recoverable. If the Company determines that impairment has occurred, it records a write-down equal to the amount by which the carrying value of the assets exceeds its fair value. Although the Company believes its provisions related to inventory, capital assets, inventory prepayments and other assets and purchase commitments are currently adequate, no assurance can be given that the Company will not incur additional related charges given the rapid and unpredictable pace of product obsolescence in the industries in which the Company competes.

The Company must order components for its products and build inventory in advance of product announcements and shipments. Consistent with industry practice, components are normally acquired through a combination of purchase orders, supplier contracts, and open orders, in each case based on projected demand. Where appropriate, the purchases are applied to inventory component prepayments that are outstanding with the respective supplier. Purchase commitments typically cover forecasted component and manufacturing requirements for periods up to 150 days. Because the Company's markets are volatile, competitive and subject to rapid technology and price changes, there is a risk the Company will forecast incorrectly and order or produce excess or insufficient amounts of components or products, or not fully utilize firm purchase commitments.

Future operating results depend upon the Company's ability to obtain components in sufficient quantities.

Because the Company currently obtains components from single or limited sources, the Company is subject to significant supply and pricing risks. Many components, including those that are available from multiple sources, are at times subject to industry-wide shortages and significant commodity pricing fluctuations. While the Company has entered into various agreements for the supply of components, there can be no assurance that the Company will be able to extend or renew these agreements on similar terms, or at all. The follow-on effects from global economic conditions on the Company's suppliers, described in "*Global economic conditions could materially adversely affect the Company*" above, also could affect the Company's ability to obtain components. Therefore, the Company remains subject to significant risks of supply shortages and price increases.

The Company and other participants in the markets for mobile communication and media devices and personal computers also compete for various

components with other industries that have experienced increased demand for their products. The Company uses some custom components that are not common to the rest of these industries. The Company's new products often utilize custom components available from only one source. When a component or product uses new technologies, initial capacity constraints may exist until the suppliers' yields have matured or manufacturing capacity has increased. Continued availability of these components at acceptable prices, or at all, may be affected if those suppliers decided to concentrate on the production of common components instead of components customized to meet the Company's requirements. The supply of components for a new or existing product could be delayed or constrained, or a key manufacturing vendor could delay shipments of completed products to the Company.

The Company depends on component and product manufacturing and logistical services provided by outsourcing partners, many of whom are located outside of the U.S.

Substantially all of the Company's manufacturing is performed in whole or in part by a few outsourcing partners located primarily in Asia. The Company has also outsourced much of its transportation and logistics management. While these arrangements may lower operating costs, they also reduce the Company's direct control over production and distribution. It is uncertain what effect such diminished control will have on the quality or quantity of products or services, or the Company's flexibility to respond to changing conditions. Although arrangements with these partners may contain provisions for warranty expense reimbursement, the Company may remain responsible to the consumer for warranty service in the event of product defects and could experience an unanticipated product defect or warranty liability. While the Company relies on its partners to adhere to its supplier code of conduct, material violations of the supplier code of conduct could occur.

The Company relies on sole-sourced outsourcing partners in the U.S., Asia and Europe to supply and manufacture many critical components, and on outsourcing partners in Asia for final assembly of substantially all of the Company's hardware products. Any failure of these partners to perform may have a negative impact on the Company's cost or supply of components or finished goods. In addition, manufacturing or logistics in these locations or transit to final destinations may be disrupted for a variety of reasons including, but not limited to, natural and man-made disasters, information technology system failures, commercial disputes, military actions or economic, business, labor, environmental, public health, or political issues.

The Company has invested in manufacturing process equipment, much of which is held at certain of its outsourcing partners, and has made prepayments to certain of its suppliers associated with long-term supply agreements. While these arrangements help ensure the supply of components and finished goods, if these outsourcing partners or suppliers experience severe financial problems

or other disruptions in their business, the net realizable value of these assets could be negatively impacted.

The Company's products and services may experience quality problems from time to time that can result in decreased sales and operating margin and harm to the Company's reputation.

The Company sells complex hardware and software products and services that can contain design and manufacturing defects. Sophisticated operating system software and applications, such as those sold by the Company, often contain "bugs" that can unexpectedly interfere with the software's intended operation. The Company's online services may from time to time experience outages, service slowdowns, or errors. Defects may also occur in components and products the Company purchases from third parties. There can be no assurance the Company will be able to detect and fix all defects in the hardware, software and services it sells. Failure to do so could result in lost revenue, significant warranty and other expenses, and harm to the Company's reputation.

The Company relies on access to third-party digital content, which may not be available to the Company on commercially reasonable terms or at all.

The Company contracts with numerous third parties to offer their digital content through the iTunes Store. This includes the right to make available music, movies, TV shows and books currently available through the iTunes Store. The licensing arrangements with these third parties are short-term and do not guarantee the continuation or renewal of these arrangements on reasonable terms, if at all. Some third-party content providers and distributors currently or in the future may offer competing products and services, and could take action to make it more difficult or impossible for the Company to license their content in the future. Other content owners, providers or distributors may seek to limit the Company's access to, or increase the cost of, such content. The Company may be unable to continue to offer a wide variety of content at reasonable prices with acceptable usage rules, or continue to expand its geographic reach. Failure to obtain the right to make available third-party digital content, or to make available such content on commercially reasonable terms, could have a material adverse impact on the Company's financial condition and operating results.

Some third-party digital content providers require the Company to provide digital rights management and other security solutions. If requirements change, the Company may have to develop or license new technology to provide these solutions. There is no assurance the Company will be able to develop or license such solutions at a reasonable cost and in a timely manner. In addition, certain countries have passed or may propose and adopt legislation that would force the Company to license its digital rights management, which could lessen the protection of content and subject it to piracy and also could negatively affect arrangements with the Company's content providers.

The Company's future performance depends in part on support from third-party software developers.

The Company believes decisions by customers to purchase its hardware products depend in part on the availability of third-party software applications and services. There is no assurance that third-party developers will continue to develop and maintain software applications and services for the Company's products. If third-party software applications and services cease to be developed and maintained for the Company's products, customers may choose not to buy the Company's products.

With respect to its Mac products, the Company believes the availability of third-party software applications and services depends in part on the developers' perception and analysis of the relative benefits of developing, maintaining, and upgrading such software for the Company's products compared to Windows-based products. This analysis may be based on factors such as the market position of the Company and its products, the anticipated revenue that may be generated, continued growth of Mac sales, and the costs of developing such applications and services. If the Company's minority share of the global personal computer market causes developers to question the Company's prospects, developers could be less inclined to develop or upgrade software for the Company's products and more inclined to devote their resources to developing and upgrading software for the larger Windows market.

With respect to iOS devices, the Company relies on the continued availability and development of compelling and innovative software applications, which are distributed through a single distribution channel, the App Store. The absence of multiple distribution channels, which are available for competing platforms, may limit the availability and acceptance of third-party applications by the Company's customers, thereby causing developers to reduce or curtail development for the iOS platform. In addition, iOS devices are subject to rapid technological change, and, if third-party developers are unable to or choose not to keep up with this pace of change, third-party applications might not successfully operate and may result in dissatisfied customers. As with applications for the Company's Mac products, the availability and development of these applications also depend on developers' perceptions and analysis of the relative benefits of developing software for the Company's products rather than its competitors' platforms, such as Android. If developers focus their efforts on these competing platforms, the availability and quality of applications for the Company's iOS devices may suffer.

The Company relies on access to third-party intellectual property, which may not be available to the Company on commercially reasonable terms or at all.

Many of the Company's products include third-party intellectual property, which requires licenses from those third parties. Based on past experience and industry practice, the Company believes such licenses generally can be

obtained on reasonable terms. There is, however, no assurance that the necessary licenses can be obtained on acceptable terms or at all. Failure to obtain the right to use third-party intellectual property, or to use such intellectual property on commercially reasonable terms, could preclude the Company from selling certain products or otherwise have a material adverse impact on the Company's financial condition and operating results.

The Company could be impacted by unfavorable results of legal proceedings, such as being found to have infringed on intellectual property rights.

The Company is subject to various legal proceedings and claims that have not yet been fully resolved and that have arisen in the ordinary course of business, and additional claims may arise in the future.

For example, technology companies, including many of the Company's competitors, frequently enter into litigation based on allegations of patent infringement or other violations of intellectual property rights. In addition, patent holding companies seek to monetize patents they have purchased or otherwise obtained. As the Company has grown, the intellectual property rights claims against it have increased and may continue to increase. In particular, the Company's cellular enabled products compete with mobile communication and media device companies that hold significant patent portfolios, and the number of patent claims against the Company has significantly increased. The Company is vigorously defending infringement actions in courts in a number of U.S. jurisdictions and before the U.S. International Trade Commission, as well as internationally in Europe and Asia. The plaintiffs in these actions frequently seek injunctions and substantial damages.

Regardless of the scope or validity of such patents or other intellectual property rights, or the merits of any claims by potential or actual litigants, the Company may have to engage in protracted litigation. If the Company is found to infringe one or more patents or other intellectual property rights, regardless of whether it can develop non-infringing technology, it may be required to pay substantial damages or royalties to a third-party, or it may be subject to a temporary or permanent injunction prohibiting the Company from marketing or selling certain products.

In certain cases, the Company may consider the desirability of entering into licensing agreements, although no assurance can be given that such licenses can be obtained on acceptable terms or that litigation will not occur. These licenses may also significantly increase the Company's operating expenses.

Regardless of the merit of particular claims, litigation may be expensive, time-consuming, disruptive to the Company's operations, and distracting to management. In recognition of these considerations, the Company may enter into arrangements to settle litigation.

In management's opinion, there is not at least a reasonable possibility the Company may have incurred a material loss, or a material loss in excess of a recorded accrual, with respect to loss contingencies, including matters related

to infringement of intellectual property rights. However, the outcome of litigation is inherently uncertain.

Although management considers the likelihood of such an outcome to be remote, if one or more legal matters were resolved against the Company in a reporting period for amounts in excess of management's expectations, the Company's consolidated financial statements for that reporting period could be materially adversely affected. Further, such an outcome could result in significant compensatory, punitive or trebled monetary damages, disgorgement of revenue or profits, remedial corporate measures or injunctive relief against the Company that could materially adversely affect its financial condition and operating results.

The Company is subject to laws and regulations worldwide, changes to which could increase the Company's costs and individually or in the aggregate adversely affect the Company's business.

The Company is subject to laws and regulations affecting its domestic and international operations in a number of areas. These U.S. and foreign laws and regulations affect the Company's activities including, but not limited to, areas of labor, advertising, digital content, consumer protection, real estate, billing, e-commerce, promotions, quality of services, telecommunications, mobile communications and media, television, intellectual property ownership and infringement, tax, import and export requirements, anti-corruption, foreign exchange controls and cash repatriation restrictions, data privacy requirements, anti-competition, environmental, health, and safety.

By way of example, laws and regulations related to mobile communications and media devices in the many jurisdictions in which the Company operates are extensive and subject to change. Such changes could include, among others, restrictions on the production, manufacture, distribution, and use of devices, locking devices to a carrier's network, or mandating the use of devices on more than one carrier's network. These devices are also subject to certification and regulation by governmental and standardization bodies, as well as by cellular network carriers for use on their networks. These certification processes are extensive and time consuming, and could result in additional testing requirements, product modifications, delays in product shipment dates, or preclude the Company from selling certain products.

Compliance with these laws, regulations and similar requirements may be onerous and expensive, and they may be inconsistent from jurisdiction to jurisdiction, further increasing the cost of compliance and doing business. Any such costs, which may rise in the future as a result of changes in these laws and regulations or in their interpretation could individually or in the aggregate make the Company's products and services less attractive to the Company's customers, delay the introduction of new products in one or more regions, or cause the Company to change or limit its business practices. The Company has implemented policies and procedures designed to ensure compliance with

applicable laws and regulations, but there can be no assurance that the Company's employees, contractors, or agents will not violate such laws and regulations or the Company's policies and procedures.

The Company's business is subject to the risks of international operations.

The Company derives a significant portion of its revenue and earnings from its international operations. Compliance with applicable U.S. and foreign laws and regulations, such as import and export requirements, anti-corruption laws, tax laws, foreign exchange controls and cash repatriation restrictions, data privacy requirements, environmental laws, labor laws, and anti-competition regulations, increases the costs of doing business in foreign jurisdictions. Although the Company has implemented policies and procedures to comply with these laws and regulations, a violation by the Company's employees, contractors, or agents could nevertheless occur.

The Company also could be significantly affected by other risks associated with international activities including, but not limited to, economic and labor conditions, increased duties, taxes and other costs, and political instability. Margins on sales of the Company's products in foreign countries, and on sales of products that include components obtained from foreign suppliers, could be materially adversely affected by international trade regulations, including duties, tariffs and antidumping penalties. The Company is also exposed to credit and collectability risk on its trade receivables with customers in certain international markets. There can be no assurance the Company can effectively limit its credit risk and avoid losses.

The Company's Retail segment has required and will continue to require a substantial investment and commitment of resources and is subject to numerous risks and uncertainties.

The Company's retail stores have required substantial investment in equipment and leasehold improvements, information systems, inventory and personnel. The Company also has entered into substantial operating lease commitments for retail space. Certain stores have been designed and built to serve as high-profile venues to promote brand awareness and serve as vehicles for corporate sales and marketing activities. Because of their unique design elements, locations and size, these stores require substantially more investment than the Company's more typical retail stores. Due to the high cost structure associated with the Retail segment, a decline in sales or the closure or poor performance of individual or multiple stores could result in significant lease termination costs, write-offs of equipment and leasehold improvements, and severance costs.

Many factors unique to retail operations, some of which are beyond the Company's control, pose risks and uncertainties. These risks and uncertainties include, but are not limited to, macro-economic factors that could have an adverse effect on general retail activity, as well as the Company's inability to

manage costs associated with store construction and operation, the Company's failure to manage relationships with its existing retail channel partners, more challenging environments in managing retail operations outside the U.S., costs associated with unanticipated fluctuations in the value of retail inventory, and the Company's inability to obtain and renew leases in quality retail locations at a reasonable cost.

Investment in new business strategies and acquisitions could disrupt the Company's ongoing business and present risks not originally contemplated.

The Company has invested, and in the future may invest, in new business strategies or acquisitions. Such endeavors may involve significant risks and uncertainties, including distraction of management from current operations, greater than expected liabilities and expenses, inadequate return of capital, and unidentified issues not discovered in the Company's due diligence. These new ventures are inherently risky and may not be successful.

The Company's business and reputation may be impacted by information technology system failures or network disruptions.

The Company may be subject to information technology system failures and network disruptions. These may be caused by natural disasters, accidents, power disruptions, telecommunications failures, acts of terrorism or war, computer viruses, physical or electronic break-ins, or other events or disruptions. System redundancy may be ineffective or inadequate, and the Company's disaster recovery planning may not be sufficient for all eventualities. Such failures or disruptions could prevent access to the Company's online stores and services, preclude retail store transactions, compromise Company or customer data, and result in delayed or cancelled orders. System failures and disruptions could also impede the manufacturing and shipping of products, delivery of online services, transactions processing and financial reporting.

There may be breaches of the Company's information technology systems that materially damage business partner and customer relationships, curtail or otherwise adversely impact access to online stores and services, or subject the Company to significant reputational, financial, legal, and operational consequences.

The Company's business requires it to use and store customer, employee, and business partner personally identifiable information ("PII"). This may include, among other information, names, addresses, phone numbers, email addresses, contact preferences, tax identification numbers, and payment account information. Although malicious attacks to gain access to PII affect many companies across various industries, the Company is at a relatively greater risk of being targeted because of its high profile and the amount of PII it manages.

The Company requires user names and passwords in order to access its information technology systems. The Company also uses encryption and authentication technologies to secure the transmission and storage of data and prevent

access to Company data or accounts. As with all companies, these security measures are subject to third-party security breaches, employee error, malfeasance, faulty password management, or other irregularities. For example, third parties may attempt to fraudulently induce employees or customers into disclosing user names, passwords or other sensitive information, which may in turn be used to access the Company's information technology systems. To help protect customers and the Company, the Company monitors accounts and systems for unusual activity and may freeze accounts under suspicious circumstances, which may result in the delay or loss of customer orders.

The Company devotes significant resources to network security, data encryption, and other security measures to protect its systems and data, but these security measures cannot provide absolute security. To the extent the Company was to experience a breach of its systems and was unable to protect sensitive data, such a breach could materially damage business partner and customer relationships, and curtail or otherwise adversely impact access to online stores and services. Moreover, if a computer security breach affects the Company's systems or results in the unauthorized release of PII, the Company's reputation and brand could be materially damaged, use of the Company's products and services could decrease, and the Company could be exposed to a risk of loss or litigation and possible liability.

The Company's business is subject to a variety of U.S. and international laws, rules, policies and other obligations regarding data protection.

The Company is subject to federal, state and international laws relating to the collection, use, retention, security and transfer of PII. In many cases, these laws apply not only to third-party transactions, but also to transfers of information between the Company and its subsidiaries, and among the Company, its subsidiaries and other parties with which the Company has commercial relations. Several jurisdictions have passed laws in this area, and other jurisdictions are considering imposing additional restrictions. These laws continue to develop and may be inconsistent from jurisdiction to jurisdiction. Complying with emerging and changing international requirements may cause the Company to incur substantial costs or require the Company to change its business practices. Noncompliance could result in penalties or significant legal liability.

The Company's privacy policy and related practices concerning the use and disclosure of data are posted on its website. Any failure by the Company, its suppliers or other parties with whom the Company does business to comply with its posted privacy policy or with other federal, state or international privacy-related or data protection laws and regulations could result in proceedings against the Company by governmental entities or others.

The Company is also subject to payment card association rules and obligations under its contracts with payment card processors. Under these rules and obligations, if information is compromised, the Company could be liable to payment card issuers for associated expenses and penalties. In addition, if the

Company fails to follow payment card industry security standards, even if no customer information is compromised, the Company could incur significant fines or experience a significant increase in payment card transaction costs.

The Company's success depends largely on the continued service and availability of key personnel.

Much of the Company's future success depends on the continued availability and service of key personnel, including its Chief Executive Officer, executive team and other highly skilled employees. Experienced personnel in the technology industry are in high demand and competition for their talents is intense, especially in Silicon Valley, where most of the Company's key personnel are located.

The Company's business may be impacted by political events, war, terrorism, public health issues, natural disasters and other circumstances.

War, terrorism, geopolitical uncertainties, public health issues, and other business interruptions have caused and could cause damage or disruption to international commerce and the global economy, and thus could have a material adverse effect on the Company, its suppliers, logistics providers, manufacturing vendors and customers, including channel partners. The Company's business operations are subject to interruption by, among others, natural disasters, fire, power shortages, nuclear power plant accidents, terrorist attacks and other hostile acts, labor disputes, public health issues, and other events beyond its control. Such events could decrease demand for the Company's products, make it difficult or impossible for the Company to make and deliver products to its customers, including channel partners, or to receive components from its suppliers, and create delays and inefficiencies in the Company's supply chain. Should major public health issues, including pandemics, arise, the Company could be adversely affected by more stringent employee travel restrictions, additional limitations in freight services, governmental actions limiting the movement of products between regions, delays in production ramps of new products, and disruptions in the operations of the Company's manufacturing vendors and component suppliers. The majority of the Company's research and development activities, its corporate headquarters, information technology systems, and other critical business operations, including certain component suppliers and manufacturing vendors, are in locations that could be affected by natural disasters. In the event of a natural disaster, the Company could incur significant losses, require substantial recovery time and experience significant expenditures in order to resume operations.

The Company expects its quarterly revenue and operating results to fluctuate.

The Company's profit margins vary across its products and distribution channels. The Company's software, accessories, and service and support contracts generally have higher gross margins than certain of the Company's other products. Gross margins on the Company's hardware products vary across product

lines and can change over time as a result of product transitions, pricing and configuration changes, and component, warranty, and other cost fluctuations. The Company's direct sales generally have higher associated gross margins than its indirect sales through its channel partners. In addition, the Company's gross margin and operating margin percentages, as well as overall profitability, may be materially adversely impacted as a result of a shift in product, geographic or channel mix, component cost increases, the strengthening U.S. dollar, price competition, or the introduction of new products, including those that have higher cost structures with flat or reduced pricing.

The Company has typically experienced higher net sales in its first quarter compared to other quarters due in part to seasonal holiday demand. Additionally, new product introductions can significantly impact net sales, product costs and operating expenses. The Company could be subject to unexpected developments late in a quarter, such as lower-than-anticipated demand for the Company's products, issues with new product introductions, an internal systems failure, or failure of one of the Company's logistics, components supply, or manufacturing partners.

The Company's stock price is subject to volatility.

The Company's stock continues to experience substantial price volatility. Additionally, the Company, the technology industry, and the stock market as a whole have experienced extreme stock price and volume fluctuations that have affected stock prices in ways that may have been unrelated to these companies' operating performance. Price volatility over a given period may cause the average price at which the Company repurchases its own stock to exceed the stock's price at a given point in time. The Company believes its stock price reflects expectations of future growth and profitability. The Company also believes its stock price reflects expectations that its cash dividend will continue at current levels or grow and that its current share repurchase program will be fully consummated. Future dividends are subject to declaration by the Company's Board of Directors, and the Company's share repurchase program does not obligate it to acquire any specific number of shares. If the Company fails to meet any of these expectations related to future growth, profitability, dividends, share repurchases or other market expectations its stock price may decline significantly, which could have a material adverse impact on investor confidence and employee retention.

The Company's financial performance is subject to risks associated with changes in the value of the U.S. dollar versus local currencies.

The Company's primary exposure to movements in foreign currency exchange rates relates to non-U.S. dollar denominated sales and operating expenses worldwide. Weakening of foreign currencies relative to the U.S. dollar adversely affects the U.S. dollar value of the Company's foreign currency-denominated sales and earnings, and generally leads the Company to raise

international pricing, potentially reducing demand for the Company's products. Margins on sales of the Company's products in foreign countries, and on sales of products that include components obtained from foreign suppliers, could be materially adversely affected by foreign currency exchange rate fluctuations. In some circumstances, for competitive or other reasons, the Company may decide not to raise local prices to fully offset the dollar's strengthening, or at all, which would adversely affect the U.S. dollar value of the Company's foreign currency denominated sales and earnings. Conversely, a strengthening of foreign currencies relative to the U.S. dollar, while generally beneficial to the Company's foreign currency-denominated sales and earnings, could cause the Company to reduce international pricing and incur losses on its foreign currency derivative instruments, thereby limiting the benefit. Additionally, strengthening of foreign currencies may also increase the Company's cost of product components denominated in those currencies, thus adversely affecting gross margins.

The Company uses derivative instruments, such as foreign currency forward and option contracts, to hedge certain exposures to fluctuations in foreign currency exchange rates. The use of such hedging activities may not offset any or more than a portion of the adverse financial effects of unfavorable movements in foreign exchange rates over the limited time the hedges are in place.

The Company is exposed to credit risk and fluctuations in the market values of its investment portfolio.

Given the global nature of its business, the Company has both domestic and international investments. Credit ratings and pricing of the Company's investments can be negatively affected by liquidity, credit deterioration, financial results, economic risk, political risk, sovereign risk or other factors. As a result, the value and liquidity of the Company's cash, cash equivalents and marketable securities may fluctuate substantially. Therefore, although the Company has not realized any significant losses on its cash, cash equivalents and marketable securities, future fluctuations in their value could result in a significant realized loss.

The Company is exposed to credit risk on its trade accounts receivable, vendor non-trade receivables and prepayments related to long-term supply agreements, and this risk is heightened during periods when economic conditions worsen.

The Company distributes its products through third-party cellular network carriers, wholesalers, retailers and value-added resellers. A substantial majority of the Company's outstanding trade receivables are not covered by collateral or credit insurance. The Company's exposure to credit and collectability risk on its trade receivables is higher in certain international markets and its ability to mitigate such risks may be limited. The Company also has unsecured vendor non-trade receivables resulting from purchases of components by outsourcing partners and other vendors that manufacture sub-assemblies or assemble final products for the Company. In addition, the Company has made

prepayments associated with long-term supply agreements to secure supply of inventory components. As of September 28, 2013, a significant portion of the Company's trade receivables was concentrated within cellular network carriers, and its non-trade receivables and prepayments related to long-term supply agreements were concentrated among a few individual vendors located primarily in Asia. While the Company has procedures to monitor and limit exposure to credit risk on its trade and vendor non-trade receivables as well as long-term prepayments, there can be no assurance such procedures will effectively limit its credit risk and avoid losses.

The Company could be subject to changes in its tax rates, the adoption of new U.S. or international tax legislation or exposure to additional tax liabilities.

The Company is subject to taxes in the U.S. and numerous foreign jurisdictions, including Ireland, where a number of the Company's subsidiaries are organized. Due to economic and political conditions, tax rates in various jurisdictions may be subject to significant change. The Company's future effective tax rates could be affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, or changes in tax laws or their interpretation, including in the U.S. and Ireland. The Company is also subject to the examination of its tax returns and other tax matters by the Internal Revenue Service and other tax authorities and governmental bodies. The Company regularly assesses the likelihood of an adverse outcome resulting from these examinations to determine the adequacy of its provision for taxes. There can be no assurance as to the outcome of these examinations. If the Company's effective tax rates were to increase, particularly in the U.S. or Ireland, or if the ultimate determination of the Company's taxes owed is for an amount in excess of amounts previously accrued, the Company's operating results, cash flows, and financial condition could be adversely affected.

Item 1A. Risk Factors

The statements in this section describe the major risks to our business and should be considered carefully. In addition, these statements constitute our cautionary statements under the Private Securities Litigation Reform Act of 1995.

Our disclosure and analysis in this 2012 Form 10-K and in our 2012 Annual Report to Shareholders contain forward-looking statements that set forth anticipated results based on management's plans and assumptions. From time to time, we also provide forward-looking statements in other materials we release to the public, as well as oral forward-looking statements. Such forward-looking statements involve substantial risks and uncertainties. We have tried, wherever possible, to identify such statements by using words such as "will," "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "target," "forecast", "goal", "objective" and other words and terms of similar meaning, or by using future dates in connection with any discussion of, among other things, our anticipated future operating or financial performance, business plans and prospects, in-line products and product candidates, strategic reviews, capital allocation, business-development plans and plans relating to share repurchases and dividends. In particular, these include statements relating to future actions, business plans and prospects, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, interest rates, foreign exchange rates, the outcome of contingencies, such as legal proceedings, plans relating to share repurchases and dividends, government regulation and financial results, including, in particular, the financial guidance set forth in the Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Financial Guidance for 2013 section of the MD&A in our 2012 Financial Report and the anticipated costs and cost reductions set forth in the Analysis of the Consolidated Statements of Income—Restructuring Charges and Other Costs Associated with Acquisitions and Cost-Reduction/Productivity Initiatives section of the MD&A in our 2012 Financial Report.

We cannot guarantee that any forward-looking statement will be realized, although we believe we have been prudent in our plans and assumptions. Achievement of anticipated results is subject to substantial risks, uncertainties and inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. You should bear this in mind as you consider forward-looking statements, and you are cautioned not to put undue reliance on forward-looking statements.

We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our Form 10-Q and 8-K reports and our other filings with the SEC. Also note that we provide the following cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our businesses. These are factors that, individually or in the aggregate, may cause our actual results to differ materially from

expected and historical results. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.

U.S. Healthcare Reform/Healthcare Legislation

As mentioned above under *Government Regulation and Price Constraints*, the ACA was enacted by Congress in March 2010 and its provisions become effective on various dates. We expect that the rebates, discounts, taxes and other costs resulting from the ACA over time will have a significant effect on our expenses and profitability in the future. See the discussion under the *Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Operating Environment—U.S. Healthcare Legislation* section of the MD&A in our 2012 Financial Report and in *Item 1. Business* under the caption *Government Regulation and Price Constraints*. Furthermore, the IPAB created by the ACA to reduce the per capita rate of growth in Medicare spending, could potentially limit access to certain treatments or mandate price controls for our products. Moreover, expanded government investigative authority may increase the costs of compliance with new regulations and programs. We also face the uncertainties that might result from any modification, repeal or invalidation of any of the provisions of the ACA.

U.S. Deficit Reduction and Debt Ceiling Actions

As discussed above under *Government Regulation and Price Constraints—Budget Control Act of 2011*, while we do not know the specific nature of the spending reductions under the Budget Control Act that will affect Medicare, we do not expect that those reductions will have a material adverse impact on our results of operations. However, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, and/or any significant additional taxes or fees that may be imposed on us, as part of any broader deficit-reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our results of operations.

Similarly, as discussed above under *Government Regulation and Price Constraints—Federal Debt Ceiling*, the possible failure of the U.S. federal government to suspend enforcement of the federal debt ceiling beyond May 18, 2013 or to increase the federal debt ceiling, and any resulting inability of the federal government to satisfy its financial obligations, including making payments under Medicare, Medicaid and other publicly funded or subsidized health programs could have an adverse impact on our results of operations.

Pricing Pressures and Government Regulation

U.S. and foreign governmental regulations mandating price controls and limitations on patient access to our products impact our business, and our

future results could be adversely affected by changes in such regulations or policies. In the U.S., many of our biopharmaceutical products are subject to increasing pricing pressures. Such pressures have increased as a result of the 2003 Medicare Modernization Act (2003 MMA) due to the enhanced purchasing power of the private sector plans that negotiate on behalf of Medicare beneficiaries. In addition, if the 2003 MMA or the ACA were amended to impose direct governmental price controls and access restrictions, it would have a significant adverse impact on our business. Furthermore, MCOs, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. Other matters also could be the subject of U.S. federal or state legislative or regulatory action that could adversely affect our business, including, among others, changes in patent laws, restrictions on U.S. direct-to-consumer advertising, limitations on interactions with healthcare professionals, or the use of comparative effectiveness methodologies that could be implemented in a manner that focuses primarily on cost differences and minimizes the therapeutic differences among pharmaceutical products and restricts access to innovative medicines. Further, there continue to be legislative proposals to amend U.S. laws to allow the importation into the U.S. of prescription drugs, which can be sold at prices that are regulated by the governments of various foreign countries. In addition to well-documented safety concerns, such as the increased risk of counterfeit products entering the supply chain, such importation could impact pharmaceutical prices in the U.S.

The prohibition against the use of federal funds for reimbursement of erectile dysfunction medications by the Medicaid program, which became effective January 1, 2006, and the similar federal funding prohibition for the Medicare Part D program, which became effective January 1, 2007, has had an adverse effect on our business. Any prohibitions on the use of federal funds for reimbursement of other classes of drugs in the future may also have an adverse effect.

We encounter similar regulatory and legislative issues in most other countries. In Europe, Canada, China, South Korea and some other international markets, governments provide healthcare at low direct cost to consumers and regulate pharmaceutical prices or patient reimbursement levels to control costs for government-sponsored healthcare systems. In particular, there were government-mandated price reductions for certain biopharmaceutical products in Japan and certain European and emerging market countries in 2012, and we anticipate continuing pricing pressures in Japan, Europe and emerging markets in 2013. This international patchwork of price regulation has led to different prices and some third-party trade in our products between countries. As a result, it is expected that pressures on the pricing component of operating results will continue. The adoption of restrictive price controls in new jurisdictions or more restrictive ones in existing jurisdictions, failure to obtain timely

or adequate government-approved pricing or formulary placement where required for our products or obtaining such pricing or placement at unfavorable pricing could also adversely impact revenue. In our vaccines business, we participate in a tender process in many countries for participation in national immunization programs. Failure to secure participation in national immunization programs or to obtain acceptable pricing in the tender process could adversely affect our business.

Managed Care Trends

MCOs and other private insurers frequently adopt their own payment or reimbursement reductions. Consolidation among MCOs has increased the negotiating power of these entities. Private third-party payers, as well as governments, increasingly employ formularies to control costs by negotiating discounted prices in exchange for formulary inclusion. Failure to obtain timely or adequate pricing or formulary placement for our products or obtaining such pricing or placement at unfavorable pricing could adversely impact revenue. In addition to formulary tier co-pay differentials, private health insurance companies and self-insured employers have been raising co-payments required from beneficiaries, particularly for branded pharmaceuticals and biotechnology products. Private health insurance companies also are increasingly imposing utilization management tools, such as requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine. As the U.S. payer market concentrates further and as more drugs become available in generic form, biopharmaceutical companies may face greater pricing pressure from private third-party payers, who will continue to drive more of their patients to use lower cost generic alternatives.

Generic Competition

Competition from manufacturers of generic drugs is a major challenge for us around the world, and the loss or expiration of intellectual property rights can have a significant adverse effect on our revenues. Upon the expiration or loss of patent protection for one of our products, or upon the “at-risk” launch (despite pending patent infringement litigation against the generic product) by a generic manufacturer of a generic version of one of our patented products, we can lose the major portion of revenues for that product in a very short period of time, which can adversely affect our business. As discussed above, a number of our current products are expected to face significantly increased generic competition over the next few years.

Also, the patents covering several of our medicines, including *Viagra*, *Lyricea*, *Sutent*, *Rapamune*, *EpiPen*, *Torisel*, *Pristiq* and *Embeda* extended-release capsules are being challenged by generic manufacturers. In addition, our patent-protected products may face competition in the form of generic versions of competitors’ branded products that lose their market exclusivity.

Competitive Products

We cannot predict with accuracy the timing or impact of the introduction of competitive products or their possible effect on our sales. Products that compete with ours, including some of our best-selling medicines, are launched from time to time. Competitive product launches have occurred in recent years, and certain potentially competitive products are in various stages of development, some of which have been filed for approval with the FDA and with regulatory authorities in other countries.

Dependence on Key In-Line Products

We recorded direct product revenues of more than \$1 billion for each of 10 biopharmaceutical products in 2012: *Lyrica*, *Lipitor*, *Enbrel*, *Prevnar 13/Prevenar 13*, *Celebrex*, *Viagra*, *Norvasc*, *Zyvox*, *Sutent*, and the *Premarin* family. Those products accounted for 49% of our total biopharmaceutical revenues in 2012. If these products or any of our other major products were to become subject to problems such as loss of patent protection, changes in prescription growth rates, material product liability litigation, unexpected side effects, regulatory proceedings, publicity affecting doctor or patient confidence, pressure from existing competitive products, changes in labeling or, if a new, more effective treatment should be introduced, the adverse impact on our revenues could be significant. As noted, patents covering several of our best-selling medicines have recently expired or will expire in the next few years (including some of our billion-dollar and previously billion-dollar products such as *Lipitor* and *Xalatan/Xalacom*), and patents covering a number of our best-selling medicines are the subject of pending legal challenges. In addition, our revenues could be significantly impacted by the timing and rate of commercial acceptance of key new products.

Further, our Alliance revenues will be adversely affected by the termination or expiration of collaboration agreements that we have entered into and that we may enter into from time to time. For example, our rights to *Aricept* in Japan returned to Eisai in December 2012; our collaboration with Boehringer Ingelheim for *Spiriva* expires on a country-by-country basis between 2012 and 2016, including the expiration in certain EU markets, Canada and Australia in 2012; our U.S. and Canada collaboration agreement with Amgen Inc. (Amgen) for *Enbrel* will expire in October 2013 (our exclusive rights to *Enbrel* outside the U.S. and Canada will not be affected by the expiration of the co-promotion agreement with Amgen); and our collaboration agreement with EMD Serono Inc. (Serono) to co-promote *Rebif* in the U.S. will expire either at the end of 2013 or the end of 2015, depending on the outcome of pending litigation between us and Serono concerning the interpretation of the agreement. See the *Analysis of the Consolidated Statements of Income—Biopharmaceutical—Selected Product Descriptions and Overview of Our Performance, Operating Environment, Strategy and Outlook—The Loss or Expiration of Intellectual Property Rights* sections of the MD&A in our 2012 Financial Report for additional information on the expirations of these agreements.

Research and Development Investment

The discovery and development of safe, effective new products, and the development of additional uses for existing products, are necessary for the continued strength of our business. Our product lines must be replenished over time in order to offset revenue losses when products lose their exclusivity, as well as to provide for revenue and earnings growth. Our growth potential depends in large part on our ability to identify and develop new products or new indications for existing products that address unmet medical needs and receive reimbursement from payers, either through internal research and development or through collaborations, acquisitions, joint ventures or licensing or other arrangements with third parties. However, balancing current growth and investment for the future remains a major challenge. Our ongoing investments in new product introductions and in research and development for new products and existing product extensions could exceed corresponding sales growth. This could produce higher costs without a proportional increase in revenues.

Additionally, our research and development investment plans and resources may not be correctly matched between science and markets, and failure to invest in the right technology platforms, therapeutic segments, product classes, geographic markets and/or in-licensing and out-licensing opportunities in order to deliver a robust pipeline could adversely impact the productivity of our pipeline. Further, even if the areas with the greatest market attractiveness are identified, the science may not work for any given program despite the significant investment required for research and development.

In 2011, we announced a focus on fewer disease areas where we believe we can deliver the greatest medical and commercial success, as well as the implementation of our R&D footprint reduction by moving forward on our productivity initiatives. There can be no assurance that this strategy will deliver the desired result in the targeted timeframe or at all, which could affect profitability in the future.

Development, Regulatory Approval and Marketing of Products

The outcome of the lengthy and complex process of identifying new compounds and developing new products is inherently uncertain and involves a high degree of risk. Drug discovery and development is time-consuming, expensive and unpredictable. The process from early discovery or design to development to regulatory approval can take many years. Drug candidates can fail at any stage of the process. There can be no assurance as to whether or when we will receive regulatory approval for new products or for new indications or dosage forms for existing products. Decisions by regulatory authorities regarding labeling, ingredients and other matters could adversely affect the availability or commercial potential of our products, and there is no assurance that any of our late stage pipeline products will receive regulatory approval and/or be commercially successful or that recently approved products will be approved in other markets and/or be commercially successful. There is also a risk that we

may not adequately address existing regulatory agency findings concerning the adequacy of our regulatory compliance processes and systems or implement sustainable processes and procedures to maintain regulatory compliance and to address future regulatory agency findings, should they occur.

There are many considerations that can affect the marketing of our products around the world. Regulatory delays, the inability to successfully complete or adequately design and implement clinical trials within the anticipated quality, time and cost guidelines or in compliance with applicable regulatory expectations, claims and concerns about safety and efficacy, new discoveries, patent disputes and claims about adverse side effects are a few of the factors that can adversely affect the realization of research and development and product-related, forward-looking statements. Further, claims and concerns about safety and efficacy can result in a negative impact on product sales, product recalls or withdrawals, and/or consumer fraud, product liability and other litigation and claims. Also, increasing regulatory scrutiny of drug safety and efficacy, with regulatory authorities increasingly focused on product safety and the risk/benefit profile of products as they relate to already-approved products, has resulted in a more challenging, expensive and lengthy regulatory approval process due to requests for, among other things, additional clinical trials prior to granting approval or increased post-approval requirements, such as risk evaluation and mitigation strategies (see *Post-Approval Data* below).

In addition, failure to put in place adequate controls and/or resources for effective collection, reporting and management of adverse events from clinical trials and post-marketing surveillance (see *Post-Approval Data* below), in compliance with current and evolving regulatory requirements could result in risks to patient safety, regulatory actions and risks to product sales.

Post-Approval Data

As a condition to granting marketing approval of a product, the FDA may require a company to conduct additional clinical trials. The results generated in these Phase IV trials could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. The Food and Drug Administration Amendments Act of 2007 (the FDAAA) gave the FDA enhanced post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of its authority under the FDAAA has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products. Non-U.S. regulatory agencies often have similar authority and may impose comparable costs. For example, a post-marketing study as part of a post-approval commitment to marketing authorization is becoming

more common in China, where the SFDA requires additional clinical data in the Chinese population in order to further assess the safety and efficacy of a product, sometimes independent of the level of global clinical data available. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of the affected products. Accordingly, new data about our products, or products similar to our products, could negatively impact demand for our products due to real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in updated labeling, restrictions on use, product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

Patent Protection

Our long-term success largely depends on our ability to market technologically competitive products. We rely and expect to continue to rely on a combination of intellectual property, including patent, trademark, trade dress, copyright, trade secret and domain name protection laws, as well as confidentiality and license agreements with our employees and others, to protect our intellectual property and proprietary rights. If we fail to obtain and maintain adequate intellectual property protection, we may not be able to prevent third parties from launching generic versions of our products, using our proprietary technologies or from marketing products that are very similar or identical to ours. Our currently pending or future patent applications may not result in issued patents, or be granted on a timely basis. Similarly, any term extensions that we seek may not be granted on a timely basis, if at all. In addition, our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage, including exclusivity in a particular product area. The scope of our patent claims also may vary between countries, as individual countries have distinctive patent laws. We may be subject to challenges by third parties regarding our intellectual property, including, among others, claims regarding validity, enforceability, scope and effective term.

Our ability to enforce our patents also depends on the laws of individual countries and each country's practice with respect to enforcement of intellectual property rights, and the extent to which certain sovereigns may seek to engage in a policy of routine compulsory licensing of pharmaceutical intellectual

property as a result of local political pressure or in the case of national emergencies. In addition, mechanisms exist in much of the world permitting some form of challenge by competitors or generic drug marketers to our patents prior to, or immediately following, the expiration of any regulatory exclusivity, and generic companies are increasingly employing aggressive strategies, such as “at risk” launches to challenge our patent rights. Further, if we are unable to maintain our existing license agreements or other agreements pursuant to which third parties grant us rights to intellectual property, including because such agreements expire or are terminated, our operating results and financial condition could be materially adversely affected.

Likewise, in the U.S. and other countries, we currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third party objection, which could prevent the maintenance or issuance of the same. As our products mature, our reliance on our trademarks to differentiate us from our competitors increases and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected. We actively seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants, other advisors and other third parties to execute proprietary information and confidentiality agreements upon the commencement of their employment, engagement or other relationship. Despite these efforts and precautions, we may be unable to prevent a third party from copying or otherwise obtaining and using our trade secrets or our other intellectual property without authorization, and legal remedies in some countries may not adequately compensate us for the damages caused by such unauthorized use. Further, others may independently and lawfully develop substantially similar or identical products that circumvent our intellectual property by means of alternative designs or processes or otherwise.

Biotechnology Products

As discussed above in *Patents and Intellectual Property and Government Regulation and Price Constraints—Biosimilars*, abbreviated legal pathways for the approval of biosimilars exist in certain international markets and, since the passage of the ACA, a framework for such approval exists in the U.S. If competitors are able to obtain marketing approval for biosimilars referencing our biotechnology products, our biotechnology products may become subject to competition from biosimilars, with attendant competitive pressure. The expiration or successful challenge of applicable patent rights could trigger this competition, assuming any relevant exclusivity period has expired. We may face more litigation with respect to the validity and/or scope of patents relating to our biotechnology products with substantial revenue.

We are developing biosimilar medicines. The developing pathway for registration and approval of biosimilar products in the U.S. could diminish the

value of our past and future investments in biosimilars. Other risks related to our development of biosimilars include the potential for steeper than anticipated price erosion due to increased competitive intensity, coupled with high costs associated with clinical development or intellectual property challenges that may preclude timely commercialization of our potential biosimilar products. There is also a risk of lower prescriptions of biosimilars due to potential concerns over comparability with innovator medicines.

Research Studies

Decisions about research studies made early in the development process of a drug candidate can have a substantial impact on the marketing strategy and payer reimbursement possibilities once the drug receives approval. For example, more detailed studies can lead to approval for a broader set of indications that may impact the marketing and payer reimbursement process, but each additional indication must be balanced against the time and resources required to demonstrate benefit and the potential delays to approval of the primary indication. We try to plan clinical trials prudently and to reasonably foresee challenges, but there is no guarantee that an optimal balance between speed, trial conduct and desired outcome will be achieved each time. The quality of our decisions in this area could affect our future results.

Foreign Exchange and Interest Rate Risk

Significant portions of our revenues and earnings, as well as our substantial international net assets, are exposed to changes in foreign exchange rates. 61% of our total 2012 revenues were derived from international operations, including 26% from the Europe region and 21% from the Japan and the rest of Asia region. As we operate in multiple foreign currencies, including the euro, the Japanese yen, the U.K. pound, the Chinese renminbi, the Canadian dollar and approximately 100 other currencies, changes in those currencies relative to the U.S. dollar will impact our revenues and expenses. If the U.S. dollar weakens against a specific foreign currency, our revenues will increase, having a positive impact, and our overall expenses will increase, having a negative impact, on net income. Likewise, if the U.S. dollar strengthens against a specific foreign currency, our revenues will decrease, having a negative impact, and our overall expenses will decrease, having a positive impact, on net income. Therefore, significant changes in foreign exchange rates, including the impact of possible currency devaluations in countries experiencing high inflation rates, can impact our results and our financial guidance.

In addition, our interest-bearing investments and borrowings are subject to risk from changes in interest rates and foreign exchange rates. These risks and the measures we have taken to help contain them are discussed in the *Forward-Looking Information and Factors That May Affect Future Results—Financial Risk Management* section of the MD&A in our 2012 Financial Report. For additional details, see the Notes to Consolidated Financial Statements—*Note*

7E. Financial Instruments: Derivative Financial Instruments and Hedging Activities in our 2012 Financial Report. Those sections of our 2012 Financial Report are incorporated by reference.

Notwithstanding our efforts to foresee and mitigate the effects of changes in fiscal circumstances, we cannot predict with certainty changes in currency and interest rates, inflation or other related factors affecting our businesses.

Risks Affecting International Operations

Our international operations also could be affected by currency fluctuations, capital and exchange controls, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, trade regulations and procedures and actions affecting approval, production, pricing, and marketing of, reimbursement for and access to our products, as well as by political unrest, unstable governments and legal systems and inter-governmental disputes. Any of these changes could adversely affect our business.

Many emerging markets have experienced growth rates in excess of the world's largest markets, leading to an increased contribution to the industry's global performance. As a result, we have been employing strategies to grow in emerging markets. However, there is no assurance that our strategies in emerging markets will be successful or that these countries will continue to sustain these growth rates. In addition, some emerging market countries may be particularly vulnerable to periods of financial instability or significant currency fluctuations or may have limited resources for healthcare spending, which, as discussed above, can adversely affect our results.

Specialty Pharmaceuticals

Specialty pharmaceuticals are medicines that treat rare or life-threatening conditions that typically have smaller patient populations. The growing availability and use of innovative specialty pharmaceuticals, combined with their relative higher cost as compared to other types of pharmaceutical products, has generated payer interest in developing cost-containment strategies targeted to this sector. While the impact on us of payers' efforts to control access to and pricing of specialty pharmaceuticals has been limited to date, our growing portfolio of specialty products, combined with the increasing use of health technology assessment in markets around the world, and the deteriorating finances of certain governments, may lead to a more significant adverse business impact in the future.

Animal Health

The Animal Health operating segment may be impacted by, among other things, emerging restrictions and bans on the use of antibacterials in food-producing animals; perceived adverse effects on human health linked to the consumption of food derived from animals that utilize our products; increased

regulation or decreased governmental support relating to the raising, processing or consumption of food-producing animals; an outbreak of infectious disease carried by animals; adverse weather conditions and the availability of natural resources; adverse global economic conditions; and failure of the R&D, acquisition and licensing efforts to generate new products. See *Global Economic Conditions* below.

Consumer Healthcare

The Consumer Healthcare operating segment may be impacted by economic volatility, the timing and severity of the cough, cold and flu season, generic or store brand competition affecting consumer spending patterns and market share gains of competitors' branded products or generic store brands. In addition, regulatory and legislative outcomes regarding the safety, efficacy or unintended uses of specific ingredients in our Consumer Healthcare products may require withdrawal and/or reformulation of certain products (e.g., cough/cold products). See *Global Economic Conditions* below.

Global Economic Conditions

In addition to industry-specific factors, we, like other businesses, continue to face the effects of the challenging economic environment, which have impacted our biopharmaceutical operations in the U.S. and Europe, including the countries that use the euro, affecting the performance of products such as *Lyrica*, *Enbrel*, *Prevnar 13/Prevenar 13* and *Celebrex*, and in a number of emerging markets. We believe that patients, experiencing the effects of the challenging economic environment, including high unemployment levels, and increases in co-pays, sometimes switch to generic products, delay treatments, skip doses or use less effective treatments to reduce their costs. Challenging economic conditions in the U.S. also have increased the number of patients in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many states, to formulary restrictions limiting access to brand-name drugs, including ours. In addition, we continue to experience pricing pressure in various markets around the world, including in developed European markets, Japan and in a number of emerging markets, with government-mandated reductions in prices for certain biopharmaceutical products and government-imposed access restrictions in certain countries.

The challenging global economic environment has not had, nor do we anticipate it will have, a material impact on our liquidity or capital resources. Due to our significant operating cash flows, financial assets, access to capital markets and available lines of credit and revolving credit agreements, we continue to believe that we have the ability to meet our liquidity needs for the foreseeable future. As market conditions change, we continue to monitor our liquidity position. However, there can be no assurance that our liquidity or capital resources will not be affected by possible future changes in global financial markets and global economic conditions.

Other potential impacts of these challenging economic conditions include declining sales; increased costs; changes in foreign exchange rates; a decline in the value of, or a lower rate of return on, our financial assets and pension plan investments, which may require us to increase our pension funding obligations; adverse government actions; delays or failures in the performance of customers, suppliers, and other third parties on whom we may depend for the performance of our business; and the risk that our allowance for doubtful accounts may not be adequate.

Outsourcing

We outsource certain services to third parties in areas including transaction processing, accounting, information technology, manufacturing, clinical trial execution, non-clinical research, safety services and other areas. For example, during 2012, we implemented the transfer of approximately 200 on-going clinical trials to two strategic partners (clinical research organizations or CROs), and any issues with either or both of these CROs may adversely impact the progression of our clinical trial programs. Outsourcing of services to third parties could also expose us to sub-optimal quality of service delivery, which may result in missed deadlines, supply disruptions, non-compliance or reputational harm, all with potential negative implications for our results.

We continue to pursue a multi-year initiative to outsource some transaction-processing activities within certain accounting processes and are migrating to a consistent enterprise resource planning system across the organization. These are enhancements of ongoing activities to support the growth of our financial shared service capabilities and standardize our financial systems. If any difficulties in the migration to or in the operation of the new system were to occur, they could adversely affect our operations, including, among other ways, through a failure to meet demand for our products, or adversely affect our ability to meet our financial reporting obligations.

Interactions with Healthcare Professionals and Government Officials

Risks and uncertainties apply where we provide something of value to a healthcare professional and/or government official, which, if found to be improper, could potentially result in government enforcement actions and penalties. These risks may increase as non-U.S. jurisdictions adopt new anti-bribery laws and regulations.

Difficulties of Our Wholesale Distributors

In 2012, our largest wholesale distributor accounted for approximately 12% of our total revenue (and 28% of our total U.S. revenue), and our top three wholesale distributors accounted for approximately 28% of our total revenue (and 68% of our total U.S. revenue). If one of our significant wholesale distributors should encounter financial or other difficulties, such distributor might decrease the amount of business that it does with us, and we might be unable

to collect all the amounts that the distributor owes us on a timely basis or at all, which could negatively impact our results of operations.

Product Manufacturing and Marketing Risks

Difficulties or delays in product manufacturing or marketing could affect future results through regulatory actions, shut-downs, approval delays, withdrawals, recalls, penalties, supply disruptions or shortages, reputational harm, product liability, unanticipated costs or otherwise. Examples of such difficulties or delays include, but are not limited to, the inability to increase production capacity commensurate with demand; the failure to predict market demand for, or to gain market acceptance of, approved products; the possibility that the supply of incoming materials may be delayed or become unavailable and that the quality of incoming materials may be substandard and not detected; the possibility that we may fail to maintain appropriate quality standards throughout the internal and external supply network and/or comply with current Good Manufacturing Practices and other applicable regulations; or risk to supply chain continuity as a result of natural or man-made disasters at our facilities or at a supplier or vendor.

Counterfeit Products

A counterfeit medicine is one that has been deliberately and fraudulently mislabeled as to its identity and source. A counterfeit Pfizer medicine, therefore, is one manufactured by someone other than Pfizer, but which appears to be the same as an authentic Pfizer medicine. Counterfeit medicines pose a risk to patient health and safety because of the conditions under which they are manufactured—in unregulated, unlicensed, uninspected and often unsanitary sites—as well as the lack of regulation of their contents. Failure to mitigate the threat of counterfeit medicines, which is exacerbated by the complexity of our supply chain, could adversely impact our business, by, among other things, causing the loss of patient confidence in the Pfizer name and in the integrity of our medicines.

Cost and Expense Control/Unusual Events/Intangible Assets and Goodwill

Growth in costs and expenses, changes in product, segment and geographic mix and the impact of acquisitions, divestitures, restructurings, product withdrawals, recalls and other unusual events that could result from evolving business strategies, evaluation of asset realization and organizational restructuring could adversely affect future results. Such risks and uncertainties include, in particular, our ability to realize the projected benefits of our cost-reduction and productivity initiatives, including those related to our research and development function.

In addition, our consolidated balance sheet contains significant amounts of intangible assets, including goodwill. For IPR&D assets, the risk of failure is significant, and there can be no certainty that these assets will ultimately yield

successful products. The nature of the biopharmaceutical business is high-risk and requires that we invest in a large number of projects in an effort to achieve a successful portfolio of approved products. Our ability to realize value on these significant investments is often contingent upon, among other things, regulatory approvals and market acceptance. As such, we expect that many of these IPR&D assets will become impaired and be written off at some time in the future. For goodwill, we have seven reporting units with associated goodwill balances and, while we do not believe that the risk of goodwill impairment for any of our reporting units is significant at this time, all reporting units can confront events and circumstances that can lead to a goodwill impairment charge (such as, among other things, unanticipated competition, an adverse action or assessment by a regulator, a significant adverse change in legal matters or in the business climate and/or a failure to replace the contributions of products that lose exclusivity).

Changes in Laws and Accounting Standards

Our future results could be adversely affected by changes in laws and regulations, including, among others, changes in accounting standards, taxation requirements (including tax rate changes, new tax laws and revised tax law and regulatory interpretations, including changes affecting the taxation by the U.S. of income earned outside the U.S. that may result from pending and possible future proposals), competition laws, privacy laws and environmental laws in the U.S. and other countries.

Terrorist Activity

Our future results could be adversely affected by changes in business, political and economic conditions, including the cost and availability of insurance, due to the threat of terrorist activity in the U.S. and other parts of the world and related U.S. military action overseas.

Legal Proceedings

We and certain of our subsidiaries are involved in various patent, product liability, consumer, commercial, securities, antitrust, environmental, employment and tax litigations and claims, government investigations and other legal proceedings that arise from time to time in the ordinary course of our business. Litigation is inherently unpredictable, and excessive verdicts do occur. Although we believe we have substantial defenses in these matters, we could in the future incur judgments, enter into settlements of claims or revise our expectations regarding the outcomes of certain matters, and such developments could have a material adverse effect on our results of operations in the period in which the amounts are accrued and/or our cash flows in the period in which the amounts are paid.

Our activities relating to the sale and marketing and the pricing of our products are subject to extensive regulation under the U.S. Federal Food, Drug,

and Cosmetic Act, the Medicaid Drug Rebate Program, the U.S. Foreign Corrupt Practices Act (FCPA) and other federal and state statutes, including those discussed elsewhere in this 2012 Form 10-K, as well as anti-kickback and false claims laws, and similar laws in foreign jurisdictions. Like many companies in our industry, we have from time to time received inquiries and subpoenas and other types of information demands from government authorities, and been subject to claims and other actions related to our business activities brought by governmental authorities, as well as by consumers and private payers. In some instances, we have incurred significant expense, civil payments, fines and other adverse consequences as a result of these claims, actions and inquiries. For example, these claims, actions and inquiries may relate to alleged failures to accurately interpret or identify or prevent non-compliance with the laws and regulations associated with the dissemination of product information (approved and unapproved), potentially resulting in government enforcement and damage to our reputation. This risk may be heightened by digital marketing, including social media, mobile applications and blogger outreach.

In connection with the resolution of certain U.S. government investigations concerning various products in September 2009, we entered into a Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the U.S. Department of Health and Human Services, which is effective through December 31, 2014. In connection with the resolution of our FCPA matters in August 2012, one of our subsidiaries entered into a Deferred Prosecution Agreement (DPA) with the U.S. Department of Justice, which has a term of approximately two years. In the CIA and DPA, we agreed to implement and/or maintain certain compliance program elements to promote compliance with federal healthcare program and FDA requirements, and anti-bribery and anti-corruption and other applicable laws. A material failure to comply with the CIA or DPA could result in severe sanctions against us.

Patent claims include challenges to the coverage and/or validity of our patents on various products or processes. Although we believe we have substantial defenses to these challenges with respect to all our material patents, there can be no assurance as to the outcome of these matters, and a loss in any of these cases could result in a loss of patent protection for the drug at issue, which could lead to a significant loss of sales of that drug and could materially affect future results of operations.

Business Development Activities

We expect to continue to enhance our in-line products and product pipeline through acquisitions, licensing and alliances. See the *Overview of Our Performance, Operating Environment, Strategy and Outlook—Our Business Development Initiatives* section of the MD&A in our 2012 Financial Report, which is incorporated by reference. However, these enhancement plans are subject to the availability and cost of appropriate opportunities and competition from other pharmaceutical companies that are seeking similar opportunities and our ability to successfully identify, structure and execute transactions.

Information Technology and Security

Significant disruptions of information technology systems or breaches of information security could adversely affect our business. We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure, and as a result we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third party vendors with whom we contract, make such systems potentially vulnerable to service interruptions. The size and complexity of our and our vendors' systems and the large amounts of confidential information that is present on them also makes them potentially vulnerable to security breaches from inadvertent or intentional actions by our employees or vendors, or from attacks by malicious third parties. We and our vendors could be susceptible to third party attacks on our information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups, "hactivists," and others. While we have invested heavily in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems that could adversely affect our business operations and/or result in the loss of critical or sensitive information, and any such interruption or breach could result in financial, legal, business and reputational harm to us.

Failure to Realize the Anticipated Benefits of Strategic Initiatives and Acquisitions

Our future results may be affected by (i) the impact of, and our ability to successfully execute, any strategic alternative we may decide to pursue with regard to our remaining ownership stake in Zoetis, as well as any other corporate strategic initiatives we may pursue in the future, and (ii) our ability to realize the projected benefits of any acquisitions, divestitures or other initiatives we may pursue in the future.

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London Business School, Regent's Park, London, NW1 4SA, U.K.; rkoijen@london.edu,

Irving B. Harris Graduate School of Public Policy, University of Chicago, Suite 112, 1155 E. 60th Street, Chicago, IL 60637, U.S.A.; t-philipson@uchicago.edu,
and

Dept. of Economics, University of Chicago, RO 325A, 1126 East 59th Street, Chicago, IL 60637, U.S.A.; huhlig@uchicago.edu.

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