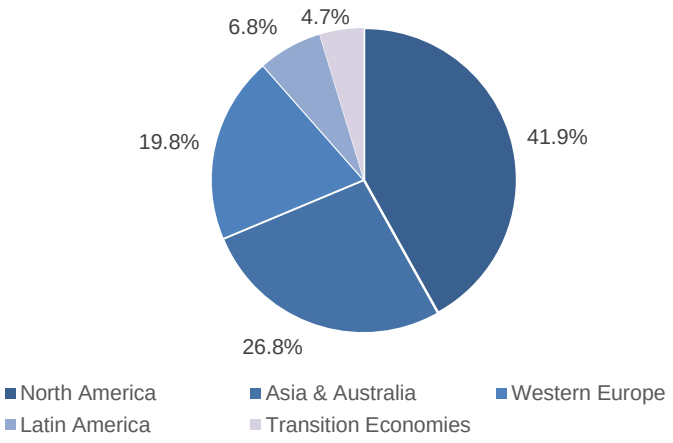
Bio-Tech and Pharmaceuticals

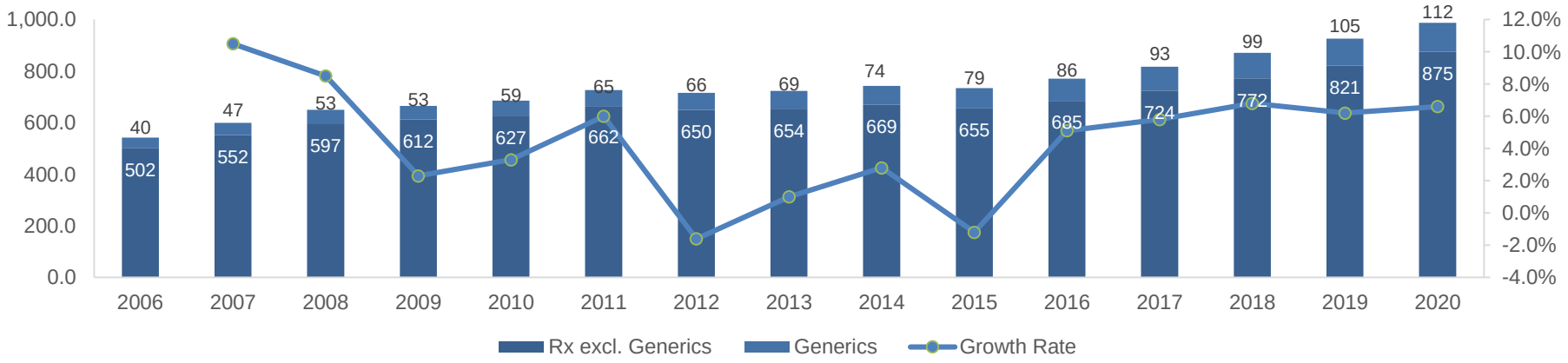
Overview

- Global pharmaceutical sales crossed $1tn in 2014 and are forecasted to reach $1.3tn by 2018
  - Global prescription drugs sales were $743bn in 2014 and are expected to grow at a CAGR of 4.8% to reach $987bn by 2020(1)
- In 2015, pharmaceutical and biotech companies set a new record for the value of deals made in a single calendar year at $462.2bn
  - Seeking out new deals could increasingly generate revenues for these companies in the future
- Between 2015 and 2020, a total of $215bn in sales are at risk from patent expiries
- The pharmaceutical industry generates ~44.5% of its revenue each year from North America
  - The US pharmaceutical market is expected to grow from an estimated $395.2bn in 2014 to $548.4bn by 2020, at a CAGR of 5.6%

Pharmaceutical Sales by Region (2014)



Worldwide Total Prescription Drugs Sales



(1) EvaluatePharma – World Preview 2015 Outlook to 2020

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Industry Overview & Trends

- **New Drug Approvals and Smaller and Frequent Product Launches**
  - Total US sales five-years post launch increased by 43% to $26.1bn, or an average of $522mn per approval
  - The number of FDA approvals has gone up significantly and is reaching record highs
    - For 2014 the FDA approved 50 new drugs (highest in 16 years) and in 2015 the FDA approved 51 drugs (highest in 66 years)
      - 16 of the drugs approved in 2015 are for the treatment of Cancer
      - 5 Hematology drugs were also approved, boosting the number of new therapies to 13 for treating blood disorders
  - Nearly 200 new drugs are forecasted to be launched in the next 5 years, with a number of new molecular entities (NMEs) expected to be launched annually
  - There are currently over 2000 products in late stage clinical development, of which a quarter are oncology therapies
- **Widespread rise of Chronic Diseases and increasing Average Global Age**
  - Rapid urbanization, increasingly sedentary lifestyles, changing diets, and rising obesity, is creating a huge need for innovative treatments across the value chain. Even in emerging markets, cancer and heart disease are becoming the main causes of death
    - 415mn adults had diabetes 2015 worldwide, expected to rise to 642mn by 2040
    - 45% of adults with diabetes are undiagnosed
    - 12% of global healthcare costs ($673bn) are linked to diabetes
  - Life expectancy is expected to increase from ~72.7 years in 2013 to 73.7 years by 2018(1) (in part due to dropping infant mortality rates and the fight against communicable diseases) bringing the number of people globally over age 65 to around 580mn, or over 10% of the total global population
  - Coupled with lengthening life expectancies globally, there is increasing demand for life sciences products to treat age-related diseases such as Alzheimer's, diabetes, and arthritis
- **Growth in Oncology and Anti-diabetics**
  - Oncology and Anti-diabetics are expected to contribute to ~21% of total worldwide prescription drug sales in 2020, up from ~14% in 2014
  - Oncology will remain the largest segment in 2020 with an expected annual growth of 11.6% per year and reaching $153.1bn in 2020
  - Anti-diabetics is forecast to be the second biggest therapy area with sales of $60.5bn in 2020, less than half that of oncology
- **Shift to Personalized Medicines**
  - Personalized medicine (or precision medicine) is about providing "the right patient with the right drug, at the right dose at the right time"
  - With advances in Genomics and Big Data, companies are striving to provide targeted therapies to patients by analyzing their characteristics, needs, preferences and genetic makeup
  - Industry experts state that ~94% of the pharma players such as AstraZeneca, Pfizer, and Roche Holding have invested in personalized medicine research

(1) Source: Economic Intelligence Unit (EIU) – 2015 Global Life sciences Outlook, Deloitte

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Industry Overview & Trends

- **Collaborate to Innovate**
  - Global pharmaceutical giants are projected to lose ~$17bn from expired patents in 2016
  - Companies are likely to adopt in-licensing of mid-to-late stage lucrative drug pipelines, instead of developing a product from scratch, thereby saving a significant amount of funds and time
  - As a result, the giants are expected to focus on acquiring/collaborating with fast-growing businesses; such as innovative biotech companies, to maintain their pace of growth
  - Innovation will be also be driven by an increase in collaboration across the pharmaceutical sector
  - Since the pharmaceutical industry has particularly long product lifecycles, firms can often give off an air of inactivity yet there is an increasing awareness of the sector's need to generate momentum
  - Considering how small biotech players find it challenging to raise funds to continue the development of promising drug pipelines, the potential for deals between biotech and large pharma players seems to have great potential in 2016
  - Other possible trends include a shift from animal testing toward alternative testing technologies that are more cost efficient, as well as a movement away from the traditional batch process toward continuous manufacturing of pharmaceuticals, thereby resulting in an increase in quality, cost efficiency and waste reduction
- **Rising importance of Pharmerging Markets**
  - Pharmerging markets have become the fastest area of growth with Russia and China outpacing the rest of Europe and North America
  - Increasingly higher spending of pharmerging markets implies a growing need for new pharmaceutical products need to be launched on a more global scale for enhanced growth & profitability
  - 6 Middle Eastern countries are among the top 10 globally in terms of type 2 diabetes prevalence: Kuwait (24% of their population), Qatar (23%), Saudi Arabia (23%), Bahrain (22%), UAE (19%) and Lebanon (17%)
- **Advent of Biosimilars in the US**
  - Biosimilars are likely to enter the US in 2016, offering a discount from biologic specialty drug costs
  - 4 biosimilars are poised for approval, with another 50 currently under FDA review
  - It is estimated that these substitutes to branded biologic drugs are likely to offer some counterweight to rising drug prices
  - According to Express Scripts, between 2014–2024, the US pharma market can generate cost savings of $250bn if biosimilars for 11 popular existing biologic drugs including Apotex's version of Amgen's Neupogen, Hospira's versions of Amgen's Epogen and Janssen's Procrit, and Celltrion's version of J&J's Remicade are approved

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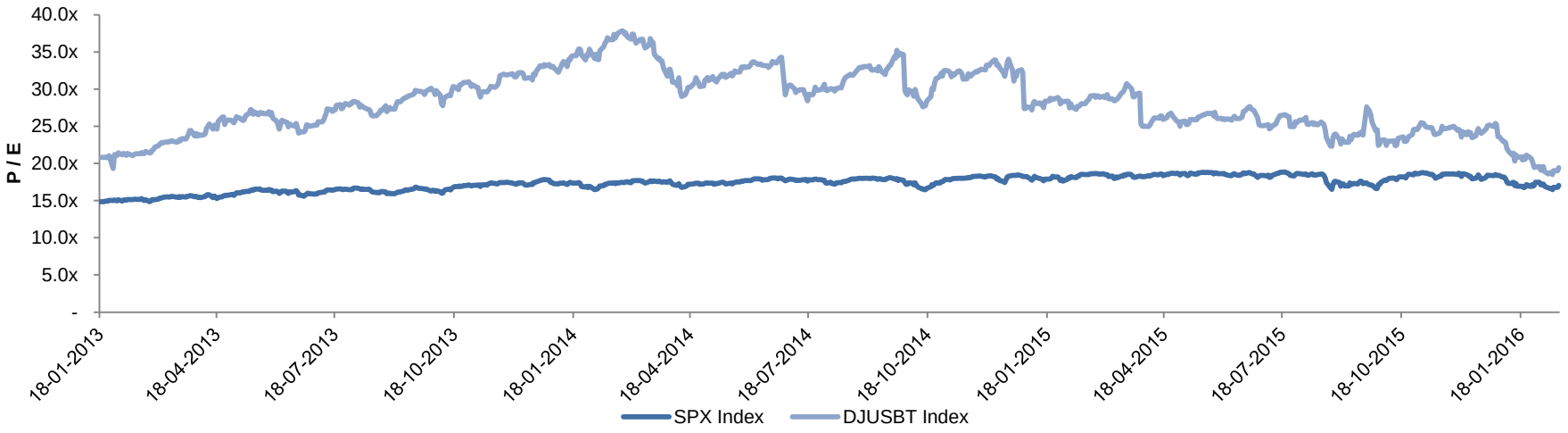
Current Situation

- Biotech stocks have dropped down in the recent months and are trading at the lowest collective valuation in almost a decade
- Fundamental investors agree that long-term business hasn't materially changed and biotech growth remains better than a lot of other global businesses considering biotech has no particular exposure to oil and China
- The unfortunate issue for why the sector is underperforming simply has to do with risk-off, unwinding of investor sentiment and money flow right now
- Growing concerns over high drug prices and rocketing existing prices have spurred public outcry and regulatory investigations globally. This is likely to result in the launch of alternative financing models aimed at reducing payment pressure on end consumers
- Large-cap biotech stocks have a lower price-to-earnings ratio, based on estimates for the next 12 months, than the S&P 500, which has never happened since 2006
- Overall biotech stocks have been trading close to the price-to-earnings ratio of the S&P 500 and could also go below the price-to-earnings ratio of the S&P 500
- The price-to-earnings ratio for the Dow Jones US Biotech index has dropped nearly 30% since January 2015



(1) SPX – S&P 500

(2) DJUSBT – Dow Jones US Biotechnology Index

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Key Issues / Risks

- **Reduction in R&D Productivity**
  - 12 large global life sciences companies found that their expected return on late-stage pipeline projects has declined across four years, to 4.8% in 2013 from 10.5% in 2010. Along with that, the cost to develop and launch a new medicine has increased 18%, to $1.3bn
  - To combat declining R&D productivity, life sciences companies will need to increase efficiency, reduce costs, and maximize the commercial value of their investments
- **Increased Regulation**
  - Among important developments are calls for greater transparency in life sciences companies' business and clinical operations
    - In 2016 patient safety and data transparency will continue as focus areas for regulatory scrutiny and enforcement
    - The FDA recently instituted the Global Unique Device Identification Database (GUDID) to collect substantial volumes of manufacturing and registration information
    - Regulatory processes may prove to be a roadblock for biosimilars due to skepticism from the medical community, and complications in naming and licensing guidelines
    - Lengthy product approvals also remain an issue
- **Global Pricing Pressures**
  - Over the past few months, concerns over drug prices have witnessed a dramatic boost, as companies come under intense scrutiny for sky-high drug prices and sharp price rises for existing drugs
  - There is a growing reluctance of both government and private healthcare providers to fund very expensive drug treatment regimes
  - This has led to a growing apprehension among pharma companies that the rise in pricing pressure may adversely impact their R&D funding
    - Americans pay more for prescription drugs than consumers from any other country
    - The Accountable Care Act (ACA) reforms include a shortened pathway for regulatory approval of biosimilars, generic versions of off-patent biotech drugs
    - The ACA also includes a 2.3% medical device excise tax, which is likely to put pressure on medical device prices
- **Patent Expiries**
  - Between 2015 and 2020, a total of $215bn sales are at risk from patent expiries
    - In contrast, between 2009 and 2014, $120bn of sales were lost
  - The reduction in expected sales lost over the next six years is largely due to softer post-patent sales erosion of biological products

Appendix

ABC Company

Public Comps and Margins

Company	Share Price	Market Cap	Enterprise Value	Enterprise Value / Sales			Enterprise Value / EBITDA			Price / EPS		
				LTM	2016E	2017E	LTM	2016E	2017E	LTM	2016E	2017E
Medtronic PLC	$74.74	105,096.1	123,715.1	4.46x	4.22x	4.02x	14.4x	12.5x	11.1x	17.6x	15.7x	14.3x
Abbott Laboratories	$37.99	56,670.4	58,994.4	2.89x	2.88x	2.70x	13.5x	11.4x	10.4x	20.7x	17.6x	15.6x
Becton Dickinson and Co	$142.12	30,103.4	41,319.4	3.68x	3.21x	3.06x	13.3x	10.9x	9.5x	22.0x	15.2x	13.6x
Boston Scientific Corp	$17.16	23,083.5	28,441.5	3.80x	3.55x	3.39x	NA	12.7x	11.5x	28.3x	16.4x	14.5x
St Jude Medical Inc	$51.94	14,681.4	23,184.9	4.18x	3.88x	3.70x	15.2x	13.3x	12.3x	14.2x	13.0x	11.9x
CR Bard Inc	$187.44	13,820.9	14,268.4	4.18x	3.96x	3.76x	13.6x	12.4x	11.5x	23.0x	18.8x	16.9x
			Low	2.89x	2.88x	2.70x	13.3x	10.9x	9.5x	14.2x	13.0x	11.9x
			Mean	3.87x	3.62x	3.44x	14.0x	12.2x	11.1x	21.0x	16.1x	14.5x
			Median	3.99x	3.72x	3.54x	13.6x	12.4x	11.3x	21.3x	16.0x	14.4x
			High	4.46x	4.22x	4.02x	15.2x	13.3x	12.3x	28.3x	18.8x	16.9x

Company	EBITDA Margin					EBIT Margin					Rev. CAGR	EPS CAGR
	2013	2014	2015	2016E	2017E	2013	2014	2015	2016E	2017E	(2013 - 2017E)	(2013 - 2017E)
Medtronic PLC	34.6%	35.4%	30.9%	33.9%	36.1%	31.4%	31.9%	28.4%	30.4%	31.0%	16.2%	8.2%
Abbott Laboratories	22.4%	23.5%	21.5%	25.3%	25.9%	10.9%	12.8%	14.1%	20.2%	20.7%	2.7%	16.1%
Becton Dickinson and Co	26.5%	26.6%	27.6%	29.3%	32.2%	19.6%	20.0%	18.4%	20.6%	21.3%	13.4%	15.8%
Boston Scientific Corp	22.4%	23.9%	NA	28.0%	29.3%	1.7%	NM	NM	23.5%	24.5%	4.1%	27.3%
St Jude Medical Inc	32.3%	31.3%	27.5%	29.1%	30.2%	19.1%	20.5%	18.6%	24.9%	25.6%	3.3%	3.3%
CR Bard Inc	27.2%	29.8%	30.7%	32.0%	32.6%	21.0%	23.5%	24.7%	26.5%	28.2%	5.6%	17.8%
Low	22.4%	23.5%	21.5%	25.3%	25.9%	1.7%	12.8%	14.1%	20.2%	20.7%	2.7%	3.3%
Mean	27.6%	28.4%	27.6%	29.6%	31.1%	17.3%	21.7%	20.8%	24.4%	25.2%	7.5%	14.7%
Median	26.9%	28.2%	27.6%	29.2%	31.2%	19.4%	20.5%	18.6%	24.2%	25.1%	4.9%	15.9%
High	34.6%	35.4%	30.9%	33.9%	36.1%	31.4%	31.9%	28.4%	30.4%	31.0%	16.2%	27.3%

Source: Bloomberg as of 2/17/2016
All figures in USD mn, except per share data