

# EQUITY RESEARCH

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Americas/United States  
Industry: Biomedical & Genetics  
Sector: Healthcare

## Celgene Corporation (NASDAQ: CELG)

ACCUMMULATE RECOMMENDATION / COMPANY UPDATE

<b>Rating:</b>	<b>Buy (Undervalued)</b>
<b>Consensus Recommendations:</b>	
Buy	17
Outperform	6
Hold	5
Underperform	1
Sell	0
<b>Price (Current)</b>	<b>112.45</b>
<b>Price Target</b>	<b>129.83</b>

\*Target Price is for 12 months.



Figure 1 - CELG Stock Price Performance

### Q3 FY16 & FY '17 Guidance

- Q3 Result and FY 16 revision:** Celgene Pharmaceutical reported strong beat-and-rise Q3 results with total revenue of \$2,982.8 million vs. \$2,334.1 million in Q3 of FY 15, representing 28.4% YoY growth driven by Revlimid, Pomalyst/Imnovid and Otezla. The GAAP Net Income was \$171 million vs. GAAP Net loss of \$34.1 million in Q3 of FY 15. And the Adjusted net income for Q3 was \$1,263million v \$1,011million for Q3 FY15. Celgene revised the financial guidance for FY16 from ~\$11.0B to ~\$11.2B (22% yoy) with upgrade in sales of Revlimid (~6.8B to ~\$7.0B) due to label expansion growth
- FY 17 Guidance:** The Company reaffirmed its FY 17 guidance across the board, with revenue of \$13.0B - \$13.4B (+18%), EPS: \$5.85- \$6.21; non-GAAP EPS: \$7.10-\$7.25 (+21%). Boosted by sales of Revlimid: \$8.0B-\$8.3B, Pomalyst/Imnovid: ~\$1.6B; Otezla: \$1.5B - 1.7B, Araxane: \$1.0B - ~ \$1.2B. Non-GAAP EPS > \$13.0 on revenues greater than \$21B by 2020 and adjusted diluted EPS is expected to be float between ranges of \$6.75 - \$7.00. According to Morningstar Consensus Estimate date, Annual Earnings Estimates with median of 6.93 will provide 18.7% growth in 2017 along with 5Y growth forecast of 22.1% with forward P/E of 17.4% v S&P 500 18.5%.

Year	12/14A	12/15A	12/16E	12/17E
GAAP EPS	2.39	1.94	3.29	5.48
P / E ratio	46.8	61.7	37.8	21
Revenue (US \$m)	7670	9256	11200	13200
<u>EV / Revenue (x)</u>	12.98x	9.34x	8.60x	6.98x
EBITDA (US \$m)	3986	4942	6650	7910
EV / EBITDA (x)	24.62x	17.31x	14.58x	11.7x
Number of shares (m)	775.2	Enterprise Value (US\$ m)		93,572.00
		Market Cap (US\$ m)		8,196.00

Source: Company datas and Ycharts.com

#### About Celgene Corp.

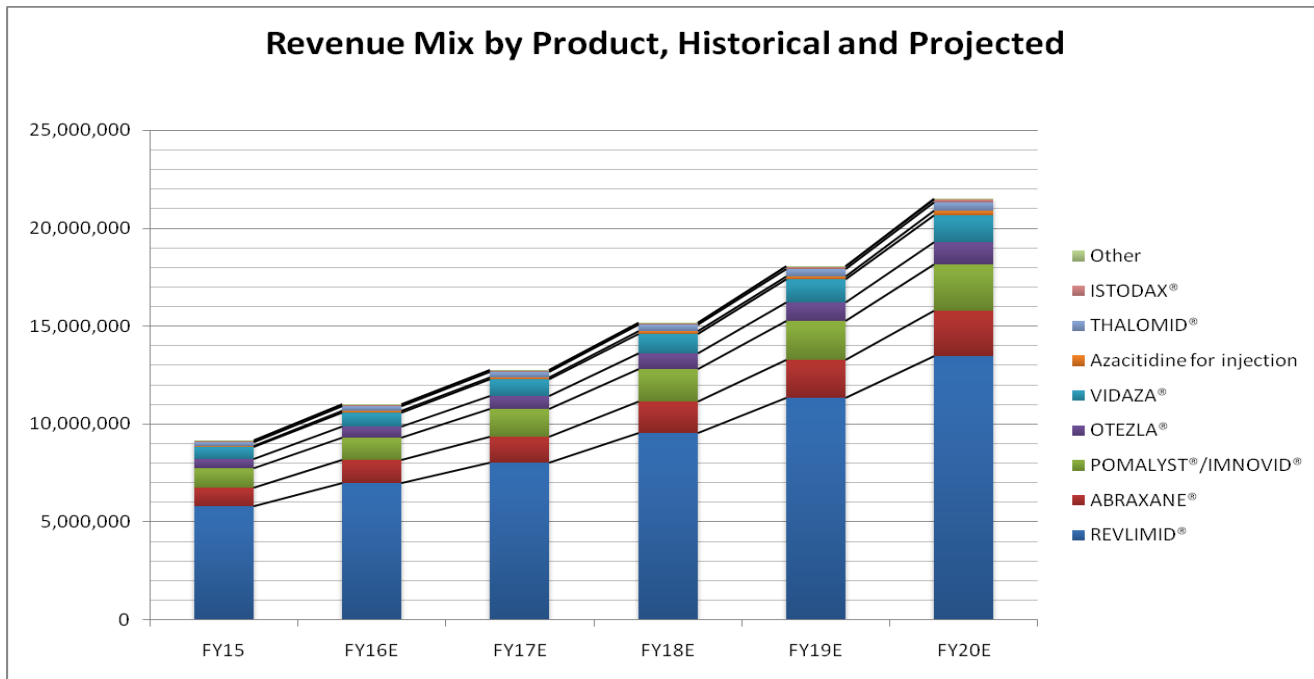
Celgene Corporation, headquartered in Summit, NJ and was founded by David Stirling & Sol Barer in 1986, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions and Protein regulation.

Its targeting areas include intracellular signaling pathways, protein homeostasis and epigenetics in cancer and immune cells, immunomodulation in cancer and autoimmune diseases and therapeutic application of cell therapies.

The company's products include Revlimid, Vidaza, Thalomid, Pomalyst/Imnovid, Abraxane, and Istodax.

# Operations

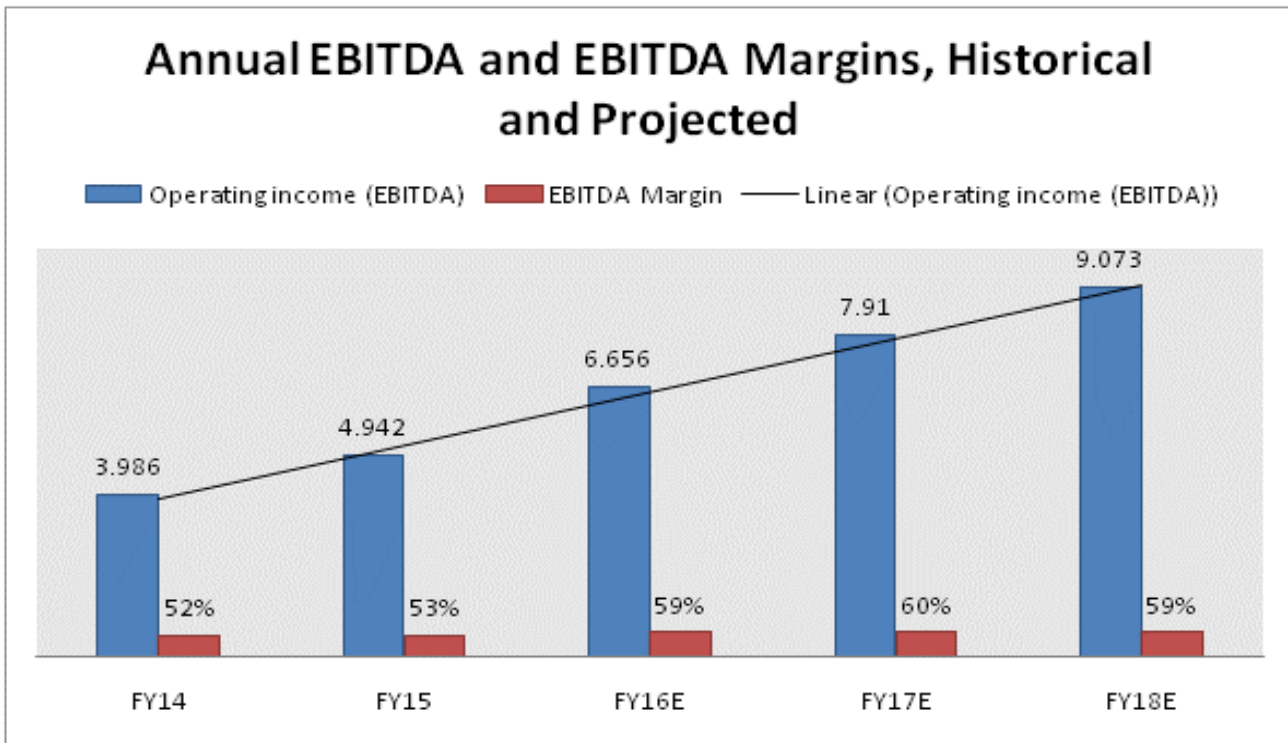
Figure 2 – CELGENE Historical and Projected Revenue Mix by Product (\$'000)



Source: Company data and Individual estimates on basis of Oppenheimer consensus

- Q3 Results:** For the quarter, **revenue came in at \$2.98B**, beating market consensus **estimate of 2.83B (4.7% Revenue surprise)** with 27.79% YoY Growth.
- R&D treatment:** Since Q3, CELG has acquired/collaborated with Anokion, Evotex and Acetylon Pharmaceuticals- which is seen as a complicate deal as Acetylon plans to spin off some of its pipeline into a new company, Regeanancy Pharmaceuticals. However, failure of Bird Bio deal, which revealed not to be successful regarding CAR-T and triggered CELG for taking over JUNO with \$1B investment (paid at premium and loss of this deal continue to effect GAAP EPS). Therefore, analysts need to see more success in such strategic deals CELG is adopting, despite positive deals of Agios pharma's (NASDAQ:AGIO) AG 221 and early 2016 Acquisition of Receptos. Not to mention, according to the data, Celgene investment on R&D is double than other large biotech (\$2B additional R&D expense than average competitor)
- Generics:** Generics competition entering the market as early as FY 18, based on data, several companies have filled for Abbreviated New Drug Application (ANDA) to FDA for approval of generic version of Abraxane or even Revlimid. Celgene has followed it with an infringement lawsuits- decision pending.
- Outlook:** Company projecting total revenue of \$21B by FY20, with more than 18 late stage trials due by 2018 which have potential to add more than \$10B in sales if FDA approvals are within projected timeline. These projected targets represent a 17% average annual rate of revenue through 2020 and 22% for earnings over next 4 years. Accordance with Oppenheimer consensus, Celgene expects to grow at 19% CARG per year for next five years, with product growth of 19.2% per year.

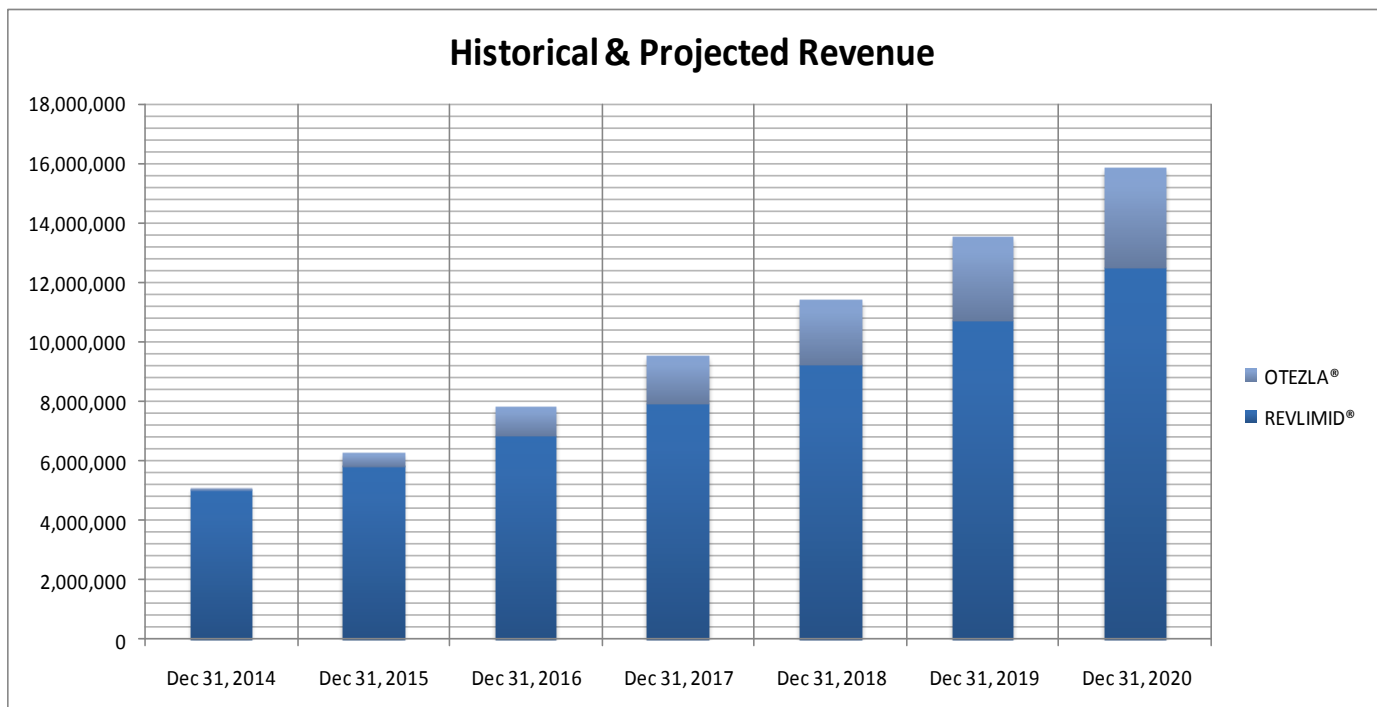
Figure 3 – Celgene Historical and Projected EBITDA and EBITDA Margins



Source: Company data, Goldman Stanley estimates.

- **Q3 Results:** Celgene’s EBITDA for the Q3:16 ending on September 2016 was \$501M with EBITDA for the TTM ending on September was \$3,661M. Celgene’s EBITDA margin sequentially deteriorated when comparing EBITDA to previous month (Q2 \$993M v \$501M Q3), highlighting the pull of 13.94% due to increase in costs and despite Revenue increase to 8.3% to \$2.983M for Q3. Moreover, it is essential to highlight that EDBITDA margin for Q3 was the lower than company average. Observing Q3:2016 results within Major Pharmaceutical Preparation Industry, 39 other companies have achieved higher EBITDA Margin.
- **Outlook:** While Celgene has higher margins than almost any other biotech/pharmaceutical company of its size- there will be limited potential for margin expansion going forward, mostly caused by greater R&D spending as the company develops Revlimid replacements along with various new candidates for trial tests, and ever-increasing sales along with marketing expenses as the company hires more sales reps and raises average compensation.

Figure 4 – Revlimid and Otezla drug Historical & Projected Revenues



Source: Company data, Goldman Stanley estimates.

- Q1 Results:** Q3 starts with the same story regarding the monster performance of Revlimid, the sales for the drug increased 30% YoY (11% Q/Q) to \$1,891M, and were driven by rapidly increased duration of therapy and label expansion (*one-off Russian tender taken into account*) in Multiple Myeloma (MM); pushing the FY16 sales expectations to ~\$7B. The biggest surprise was the gradual rise of Otezla drug, which brought in sales of \$275M **(+98% y/y, +14% Q/Q growths)**, and was primarily driven by market share growth in *psoriasis indication*; this is advantageous in coming year as leading drug like Humira, Stelara and Enbrel are losing market share, while Otezla and Novartis’s Cosentyx are growing market share rapidly. Hence, for the FY16, current trajectory suggests Otezla is anticipated to cross the \$1B mark **(up a whopping 116%)**. It is essential to highlight that despite steady increase in prices for these drugs, the company will out-perform the consensus expectations in FY16 based on this.
- Outlook:** Revlimid growth is expected to grow in Q4 and keeping that pace in FY17 with many drivers pushing the revenue stream upward, such as a response from FDA on 24th February 2017 for approving Revlimid for use as a maintenance treatment in NMDD patient after they receive an autologous stem-cell transplant (ASCT); adding \$1B in annualize sales. Positive trail results from Myeloma XI trail, staMINA trail & CONTINUMM trial will strengthen the drug’s label- further boosting physician and patient confidence. Celgene expects to attain revenues worth of \$1B to \$1.5B from Lymphoma segment by 2020, mostly contributed from Revlimid. While physician and consumer campaigns continue to propel demand for Otezla in the U.S., the company is working on securing reimbursement in several key EU markets. Otezla with aggressive pricing, relatively mild side effect profile, moderate efficacy and needy patients is expected to bring in ~\$1.5B to \$1.7B in FY17.
- Pricing:** Price pushback might happen for Revlimid use in high-cost cancer therapies, which could change given that the cost of these medicines has drawn the ire of cancer-care providers, including the highly regarded Memorial Sloan Kettering Cancer Center, in the past. And Cowen & Co. reported last year that Revlimid’s price was increased 3% in June FY15, 4% FY14 and 6.8% FY16. Henceforth, the gradual multiple increase could raise eyebrows in coming year. However, such price increase is lower than the double-digit price surge that has captured significant media attention; but, it’s still more than double the rate of inflation for analysts and management to take into consideration.

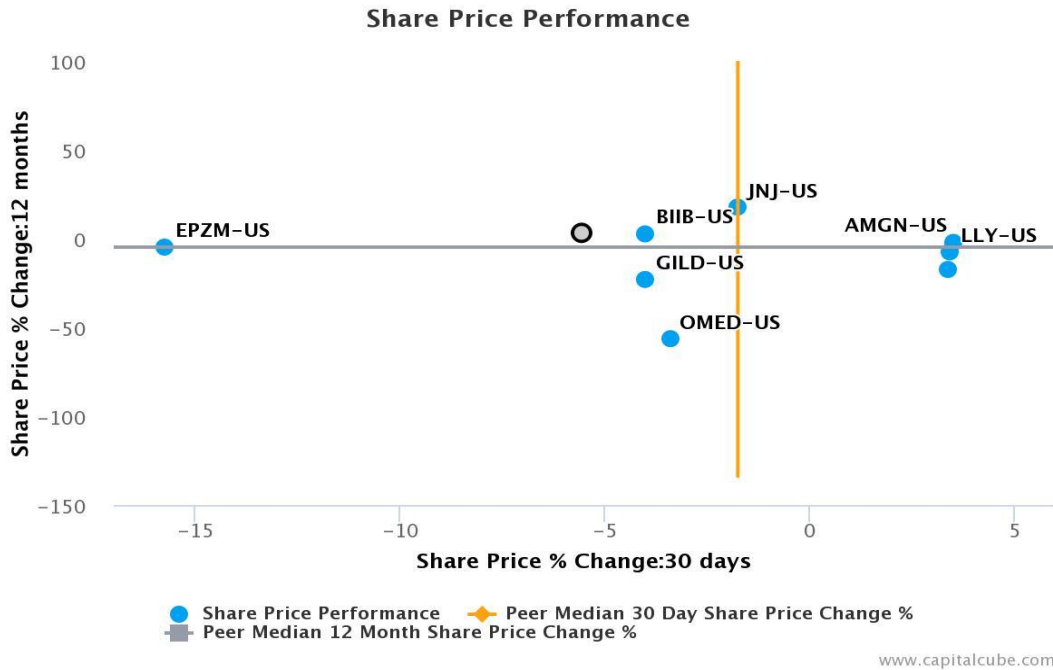
# Reports

## Fundamental Analysis

### Share Price Performance:

CELG change in share price of 5.39% for the last 12 months is better than its peer median\* according to the Historical price data. However, the 30-day trajectory shows that CELG share price performance has struggled to keep the momentum with 4.59% changes that is below the peer median; suggesting that company's recent performance has faded significantly relative to competitors.

Figure 5: Celgene Median Share Price Performance



Source: Stock-analysis & historical data from Yahoo Finance (Graph made from Estimote)

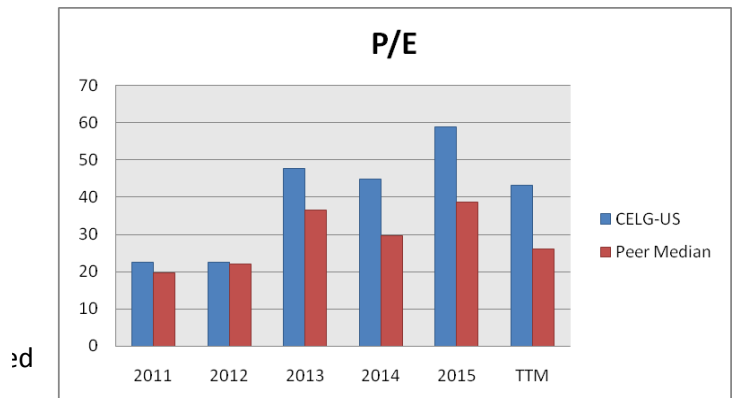
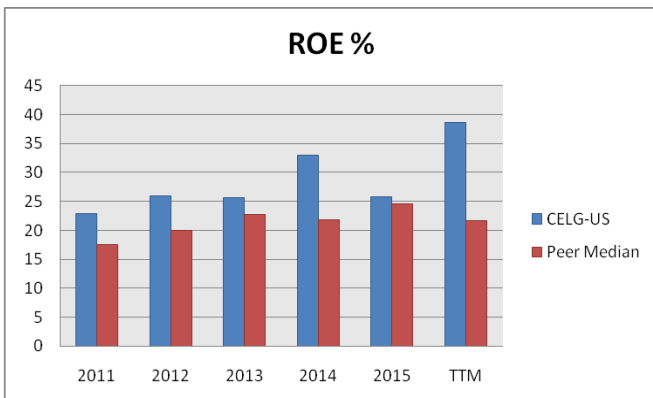
### CELG Outperforming profile relative to peers:

#### Return on Equity

CELG achieved a better operating performance than the median of its selected peers with **ROE TTM** of 38.65% v Peer median of 12.6%, this classifies CELG's ROE being ranked higher than 96% of 862 Companies in the Global Biotechnology industry. And while ROE has increased to 38.65% from FY 15 25.75%, its peer median decreased during this period to 21.60% from 24.50%.

#### Price to Earnings

**P/E** is trading lower than FY15 from 58.80 to 43.30 and industry average also fell to 26.19 from 38.67. However, P/E remains above the 2011 lowest level of 22.44. But the market still expects faster growth from it than those peers (P/E 43.30 v peer median of 26.19)



### Earnings Leverage: CELG focusing on Long-term revenue streams

With strong y/y change in revenues, CELG has managed to outperform its peers; however, its earnings growth has suffered: going below the peer median. This highlights that CELG is more focused on attaining top-line revenues, with aim towards long-term goals. CELG is currently converting 1% change in revenue into -1.21% changes in annual earnings reported.

Figure 6: Celgene's ratio comparison with competitors

		Revenue Growth YoY %	Earnings Growth YoY%
CELG-US	✓	16.47 ⚠	-19.9
AMGN-US	✓	6.49 ✓	34.53
GILD-US	✓	28.71 ✓	49.64
BIIB-US	✓	8.6 ✓	20.86
OMED-US	⚠	-34.53 ⚠	-70.78
LLY-US	✓	1.75 ✓	0.75
JNJ-US	✓	2.41 ✓	7.34
ALXN-US	✓	12.25 ✗	-78.02
ILMN-US	✓	19.25 ✓	30.62
EPZM-US	✗	-93.82 ✗	-140.66
ARIA-US	✓	12.7 ⚠	-42.16

### Gross Margin & Pre-tax margin performance:

- ❖ CELG's gross margin is its highest relative to the preceding years, with lowest being 85.99% in 2011. While Celgene's gross margin remained on the stable phase at 92.55% TTM, its peer median started to decrease to 81.34% from 82.59% during one year period.
- ❖ CELG's pre-tax margin, meanwhile, increased by 200bps from prior year's low- however, it is still below its 5-year average pre-tax margin of 27.84%. While CELG's pre-tax margin went to 24.73% compare to 2015, the peer median also rose during this period to 23.70%

	Gross Margin (%)					
	2011	2012	2013	2014	2015	TTM
CELG-US	85.23	90.9	90.7	91.57	92.15	92.55
Peer Median	82.66	81.32	78.9	81.24	82.59	81.34

	Pre-tax Margin (%)					
	2011	2012	2013	2014	2015	TTM
CELG-US	29.32	30.99	25.69	30.45	22.73	24.73
Peer Median	22.03	23.93	25.69	27.34	22.73	23.7

- ❖ If the gross margin improved without causing significant impact on the deterioration of the working capital days, this will signifies that company's performance is a result of efficient delivery in marketplace

	Working Capital Days				
	30-Sep-15	31-Dec-15	31-Mar-16	30-Jun-16	30-Sep-16
CELG-US	282.85	256.33	262.58	232.07	220.46
Peer Median	231.73	223.15	236.34	224.3	210.97

## Comparable Public Companies

To value Celgene, we use a set of comparable public companies with a focus on **Growth Score & Value Score**

<u>Company</u>	<u>Revenues (mn)</u>	<u>Gross Margin (%)</u>	<u>Pre-Tax Margin (%)</u>	<u>Net Margin (%)</u>
Amgen Inc.	22320	81.3	39.4	34
Gilead Sciences, Inc.	31509	86.7	59.1	47.8
Biogen Inc.	10802.9	92.3	45.7	34.3
OncoMed Pharmaceuticals, Inc.	25.8	N/A	-409.5	-409.5
Eli Lilly and Company	20837.2	73.2	14	11.7
Johnson & Johnson	71919	69.8	27.5	22.8
Alexion Pharmaceuticals, Inc.	2902.9	80.3	18.8	12.7
Illumina, Inc.	2370.6	69.9	23.7	18.8
Epizyme, Inc.	8.1	N/A	-1205.1	-1205.1
ARIAD Pharmaceuticals, Inc.	186.2	91.7	-16.1	-17
Celgene Corporation	11008.2	92.55	24.73	19.71

<u>Company</u>	<u>Market Cap(mn)</u>	<u>Price / Book</u>	<u>Price / Earnings</u>	<u>Dividend Yield (%)</u>
Amgen Inc.	116914.8	3.8	15.4	2.4
Gilead Sciences, Inc.	93881.9	5.5	6.2	2.5
Biogen Inc.	60066.7	5	16.2	-
OncoMed Pharmaceuticals, Inc.	297.5	191.2	-	-
Eli Lilly and Company	83215.6	5.3	34	2.7
Johnson & Johnson	308453.9	-	18.8	-
Alexion Pharmaceuticals, Inc.	28938.6	3.4	78.6	0
Illumina, Inc.	23649.4	10	53.2	0
Epizyme, Inc.	588.3	2.5	-	-
ARIAD Pharmaceuticals, Inc.	4603.2	-	-	-
Celgene Corporation	88068.6	13.9	44.1	-

## CELG: Top Peers Comparison

Figure 7: Celgene share price movement with top 2 rivals





## Precedent Transactions Analysis

We do not view Precedent Transactions as a primary methodology for Celgene, but, nevertheless, the selected set is shown below:

The transactions below were selected based on their participants (i.e. biopharmaceutical companies), size (between \$200 Million and \$10 Billion in LTM Revenue) or other factors.

(\$ in Millions except Per Share and Per Unit Data)

Celgene Corporation- Comparable M&A Transactions					Operating Metrics		Valuation Multiples		
Acquirer Name	Target Name	Date	Transaction Equity Value	Transaction Enterprise Value	LTM	LTM	EV/LTM	EV/LTM	
					Revenue	EBITDA	Revenue	EBITDA	
Johnson & Johnson	Crucell	22-Feb-11	2300	2162	71595	23671	4.3x	13.4x	
Gilead Sciences, Inc.	YM BioSciences Inc	12-Dec-12	510	-	31576	20687	5.3x	5.6x	
Forest Laboratories Inc.	Aptalis Holdings Inc.	8-Jan-14	2,900	2,900	688	315	4.2x	9.2x	
Salix Pharmaceuticals, Inc.	Santarus, Inc.	7-Nov-13	2,600	1,980	338	82	5.9x	24.3x	
Endo Health Solutions Inc.	Paladin Labs Inc.	5-Nov-13	1,600	1,348	264	93	5.1x	14.5x	
Akorn, Inc.	Hi-Tech Pharmacal Co., Inc.	27-Aug-13	640	536	231	48	2.3x	11.3x	
Valeant Pharmaceuticals International, Inc.	Medicis Pharmaceutical Corporation	3-Sep-12	2,600	2,329	764	191	3.1x	12.2x	
TPG Capital, L.P.	Par Pharmaceutical Companies Inc.	16-Jul-12	1,900	1,976	1,035	237	1.9x	8.3x	
Novartis AG	Fougera Pharmaceuticals Inc.	2-May-12	1,525	1,525	429	173	3.6x	8.8x	
Shire Pharmaceutical Holdings Ireland Limited	ViroPharma Inc.	11-Nov-13	4,200	4,097	430	59	9.5x	69.x	
Genomma Lab Internacional SAB de CV	Prestige Brands Holdings, Inc.	21-Feb-12	834	1,263	403	119	3.1x	10.6x	
Takeda Pharmaceuticals U.S.A., Inc.	URL Pharma, Inc.	11-Apr-12	800	800	600	76	1.3x	10.5x	
Pfizer Inc.	King Pharmaceuticals LLC	12-Oct-10	3,600	3,225	1,565	349	2.1x	9.2x	
Endo Pharmaceuticals Holdings Inc.	Qualitest Pharmaceuticals	28-Sep-10	1,200	1,176	309	58	3.8x	20.2x	
Mallinckrodt plc	Questcor Pharmaceuticals, Inc.	7-Apr-14	5,291	4,802	891	517	5.4x	9.3x	
Astellas US Holding, Inc.	OSI Pharmaceuticals Inc.	16-May-10	4,000	3,414	441	176	7.7x	19.4x	
Dainippon Sumitomo Pharma America Holdings, Inc.	Sepracor, Inc.	3-Sep-09	2,600	2,347	1,334	306	1.8x	7.7x	
GlaxoSmithKline plc	Stiefel Laboratories, Inc.	20-Apr-09	3,050	3,450	900	288	3.8x	12.x	
	Maximum				4,802	71,595	23671	9.5x	69.x
	75th Percentile				3,225	1001.25	312.75	5.3x	14.2x
	Median				2,162	644	183.5	3.8x	11.x
	25th Percentile				1,348	409.5	84.75	2.5x	9.2x
	Minimum				536	231	48	1.3x	5.6x

Source: Company data, SEC 14D-9 & 4-trader

## Discounted Cash Flow (DCF) Analysis

Figure 8 – Projected Unlevered Cash Flow

FCF: Projected Unlevered Cash Flow		(\$'Mil)				
	16-Dec	17-Dec	18-Dec	19-Dec	20-Dec	Terminal
EBITDA	6636	7810	8716	10045	11564	11564
D&A	(549)	(642)	(744)	(870)	(1002)	(316)
EBIT	6087	7168	7972	9175	10562	11248
Pro Forma Taxes	(833)	(981)	(1091)	(1255)	(1445)	(1539)
<b>NOPAT</b>	<b>5254</b>	<b>6187</b>	<b>6881</b>	<b>7920</b>	<b>9117</b>	<b>9709</b>
CapEx	(222)	(264)	(275)	(304)	(330)	(330)
NWC Investment	(172)	(202)	(200)	(246)	(257)	(86)
D&A	549	642	744	870	1002	316
<b>Free Cash Flow</b>	<b>5409</b>	<b>6363</b>	<b>7150</b>	<b>8240</b>	<b>9532</b>	<b>9609</b>
% Growth		18%	12%	15%	16%	1%

Source: Company data, Goldman Stanley estimates.

Figure 8.1 – DCF: Revenue Exit Multiple- Calculation of Equity Waterfall

### EQUITY WATERFALL COMPUTATION

	Model			
	Standard	Low	High	Market
Enterprise Value	106,886	97,998	117,660	93,572
(+) Cash & Equivalents	5523	5523	5523	5523
(+) Investments & Other	1346	1346	1346	1346
(-) Debt	(14,304)	(14,304)	(14,304)	(14,304)
(-) Minority Interest & Other	0	0	0	0
(-) Preferred Stock	0	0	0	0
(-) Other	0	0	0	0
<b>Value of Common Equity</b>	<b>99,451</b>	<b>90,563</b>	<b>110,225</b>	<b>86,137</b>
(/) Shares Outstanding	766	766	766	766
<b>Implied Stock Price</b>	<b>129.83</b>	<b>118.23</b>	<b>143.90</b>	<b>112.45</b>
Upside/(Downside)	15.5%	5.1%	28.0%	

Source: Company data, Goldman Stanley estimates.

Figure 8.2 – DCF: Gordon Growth Exit- Calculation of Equity Waterfall

**EQUITY WATERFALL COMPUTATION**

	<i>Model</i>			
	Standard	Low	High	Market
Enterprise Value	105,713	92,608	131,226	93,572
(+) Cash & Equivalents	5523	5523	5523	5523
(+) Investments & Other	1346	1346	1346	1346
(-) Debt	(14,304)	(14,304)	(14,304)	(14,304)
(-) Minority Interest & Other	0	0	0	0
(-) Preferred Stock	0	0	0	0
(-) Other	0	0	0	0
<b>Value of Common Equity</b>	<b>98,278</b>	<b>85,173</b>	<b>123,791</b>	<b>86,137</b>
(/) Shares Outstanding	766	766	766	766
<b>Implied Stock Price</b>	<b>128.30</b>	<b>111.19</b>	<b>161.61</b>	<b>112.45</b>
Upside/(Downside)	14.1%	-1.1%	43.7%	

**Assumptions:**

- **Discount Rate:** 12.20%, Standard WACC is selected along with High (11%) and Low (13%) rates & Beta 1.74
- **Terminal Value:** Long-Term Free Cash Flow Growth Rate of 4.0%, or, alternatively, a Terminal Revenue Exit Multiple of 6.0x.
- **Other:** Mid-Year Convention used, and FCF from Q1 stub period was subtracted from all calculations.

# Investment Analysis

## ETF Alternatives

### ETFs with exposure to Celgene Corporation

Here are the 5 ETFs with the largest exposure to CELG. Comparing the performance and risk of Celgene Corp. with the ETFs that have exposure to it gives similar returns with lower volatility.

Ticker	Fund Name	CELG-US Exposure (%)	1 Year Price Performance (%)	1 Year Volatility (%)	Net Expense Ratio (%)	Number of Holdings
BBH-US	VanEck Vectors Biotech ETF	10.7	14.9	24.7	0.35	26
IBB-US	iShares Nasdaq Biotechnology ETF	7.6	6.9	27.9	0.48	165
PJP-US	Powershares Dynamic Pharmaceuticals Portfolio	4.7	-4.6	20.7	0.58	21
XLV-US	Health Care Select Sector SPDR Fund	3.3	8.7	14	0.14	63
FBT-US	First Trust NYSE Arca Biotechnology Index Fund	3.3	17.6	29.9	0.55	30
CELG-US	Celgene Corp.	100	16.3	7.2	0	1

### ETFs with exposure to stocks in the same focus areas as Celgene Corp.

Here is 5 ETFs with largest exposure to stocks in the same focus area and region as CELG.

Ticker	Fund Name	CELG-US Exposure (%)	Sector Exposure (%)	1 Year Price Performance (%)	1 Year Volatility (%)	Net Expense Ratio (%)	Number of Holdings
BBH-US	VanEck Vectors Biotech ETF	10.7	77.7	14.9	24.7	0.35	26
IBB-US	iShares Nasdaq Biotechnology ETF	7.6	69.6	6.9	27.9	0.48	165
IHE-US	iShares US Pharmaceuticals ETF	minuscule	68.8	4.2	22.5	0.43	42
FTXH-US	First Trust Nasdaq Pharmaceuticals ETF	minuscule	67.9	N/A	N/A	0.6	27
XLV-US	Health Care Select Sector SPDR Fund	3.3	60.4	8.7	14	0.14	63
CELG-US	Celgene Corp.	100	100	16.3	7.2	0	1

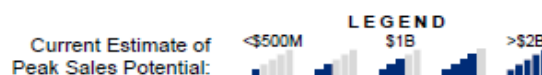
# Investment Thesis and Risks

## Potential Signals to Buy:

- **Revlimid Continues to Deliver:** Celgene is working on expanding Revlimid’s label, with upcoming approvals in NDMM indication and Phase III evaluation program in non-hodgkin lymphoma (NHL) which includes RELEVANCE and AUGMENT trials, with data to be released in 1H of 2017.
- **2020 Outlook Maintained:** Celgene has maintained its outlook for 2020. It continues to project net product sales above \$20bn along with adjusted earnings are expected to go beyond \$13 per share. With 2017 through 2018 to be dominated by news related to its pipeline and label expansion efforts.
- **Label Expansion & Pipeline Development Efforts Encouraging:** Celgene is currently working on label expansion of drugs like
  - I. Pomalyst/Imnovid, which is being evaluated in multiple combination studies in relapsed/refractory MM and MOR-22 in multiple clinical trials.
  - II. Abraxane, currently in various stages of evaluation for breast, pancreatic and non-small cell lung cancers (NSCLC) (in 2016, about half of the total newly diagnosed pancreatic cancer patients in USA were put on Abraxane-gemcitabine combination therapy) and Trial data due in 2017 for the studies in first-line therapy for stage IBB/IV Squamous NSCLC patients. Important to mention that CEO confirmed that CELG will explore opportunities for ABRAXANE to be used in combination with checkpoint inhibitors-this move could trigger sales growth in the coming years.
  - III. Future blockbuster drug, Otelza is being evaluated in phase III studies for Behçet’s disease, atopic dermatitis and expanded indications in psoriatic arthritis and plaque psoriasis.
  - IV. Robust Pipeline: Potential future revenue drivers: Ozanimod & GED-0301 (Phase III-Chrohn’s disease, phase II-UC), CC-486 (phase III- high-risk MDS, Phase II-NSCLC), Enasidenib (phase III- relapsed/refractory AML- regulatory application filed in the U.S.) and Luspatercept (phase III-lower-risk MDS and beta-thalassemia), CELMoDs (Cereblon E3 Ligase Modulation Drugs)- seen as a drug to maintain market share for CELG in blood cancer and autoimmune therapies.
    - (a) Filed at least 8 Investigational New Drug (IND) or Clinical Trial Applications (CTA)
    - (b) Submission of an IND for a new CELMoD® compound in patients with multiple myeloma
    - (c) Submission of an IND for EM901, a T-cell bi-specific antibody targeting BCMA in patients with multiple myeloma
- **Pursuing Deals & Acquisitions to Boost Pipeline:** Celgene has been focused towards striking strategic deals to bolster its pipeline and takeovers in the Q4 ensure investors regarding their long-term targets beyond 2020. The notable takeover includes:
  - I. Triphase Accelerator Corporate; acquired all assets to a brain-penetrant proteasome inhibitor
  - II. EngMab: added EM901, as T-cell bi-specific antibody targeting B-cell maturation antigen to Celgene pipeline
  - III. Quantical: acquired full access to proprietary platform for the single-cell genomic analysis of human cancer

## Pipeline Targets High Unmet Medical Need and Provides Significant, Long-term Commercial Opportunities

Drug	Potential Approval	Current Peak Potential	Drug	Potential Approval	Current Peak Potential
Enasidenib	2017		bb2121	2020	
Ozanimod	2018		Marizomib	2021	
GED-0301	2019		Demcizumab	2021	
JCAR017	2019		CC-122	2021	
Luspatercept	2019		ACY-241	2021	
Durvalumab	2020		RPC-4046	2021	
CC-486	2020		CC-220	2022	



Note: First Durvalumab approval for a hematologic malignancy

## Investment Risks

The following represent the greatest risks to our investment thesis:

- **Over-Dependence on Revlimid:** Depending on the Revlimid, despite its impressive sales number is a concern for Celgene with lower-than expected sales of the drug will have an adverse impact on the growth prospects. The major caution for Revlimid is patent war, as it is known that CELG settled Revlimid patent challenge with Allergan (NYSE:AGN) representing the Indian company Natco. And it's been known that Mylan (NASDAQ:MYL) has been in litigation with CELG to simply obtain the raw material for Revlimid, lenalidomide, trial expected this year. Lastly, another Indian generic company, Dr. Reddy's (NYSE:RDY), recently made filing with FDA for making generic version of Revlimid. While Vidaza sales had been losing momentum by the 2013 entry of a generic competitor, along with struggling performances of Thalomid and Istodax. And Abraxane sales are under-pressure due to a highly competitive US market for lung and breast cancer therapy. Henceforth, such dependence on the Revlimid has its inherent risks.
- **High Competition in Target Markets:** Despite placing its products in the highly lucrative markets, Celgene's products face intense competition in the market from both pharma and biotech companies along with specialty pharmaceutical firms. For instance, hematology, oncology, inflammation and immunology markets are dominated by several household players like Johnson & Johnson, Biogen, Bristol-Myers & Gilead.
- **Pipeline and Regulatory Setbacks:** While the high risk is associated with clinical development, tougher regulations also make it difficult to gain approvals for pipeline candidates. Thus, development and pipeline setbacks for late-stage pipeline candidates would be a major disappointment for the company and have adverse impact on the shares. Below are the 5 notable setbacks Celgene has suffered in its pipeline:
  1. June 2016: Celgene decided not to seek for a marketing approval for an expanded label of Revlimid as maintenance treatment for a certain type of DLBCL patients. This was based on the data from a phase III study, as no benefit was seen in the Revlimid arm where overall survival is concerned
  2. July 2014: The phase III POSTURE study on Otezla in the ankylosing spondylitis indication failed to meet the primary endpoint of the study.
  3. Q1 2013: the RESUME study, comparing Pomalyst to placebo in patients with myeloproliferative neoplasm-associated myelofibrosis and severe anemia with RBC-transfusion dependence, failed to meet its primary endpoint.
  4. June 2013: CELG suffered setback when it discontinued a phase II study evaluating the use of Revlimid as a first-line therapy in elderly patients suffering from B-cell chronic myeloid leukemia.
  5. November 2011: the MAINSAIL study was discontinued, as it was evaluating the use of Revlimid in patients with castrate-resistant prostate-cancer.Hence, with CELG currently having 17 studies in late-stage clinical trials, with most crucial for Ozanimod, which, if clinical setbacks occur, it could damage CELG's revenue as drug could reach peak sales from \$4B to \$6B (if approved).
- **Extremely Active Partnering Program:** It is still somewhat unclear as how wisely it has been investing its funds. For instance, the prominent bluebird bio deal few years ago was revealed to be rather unsuccessful regarding CAR-T, pushing CELG to acquire Juno (NASDAQ: JUNO) for \$1B investment mid-year 2016. Important to mention that CELG paid \$93 per share for JUNO, which closed at \$19.78 (24/01/2017). Thus, analysts need to see enough success along the way to accept Celgene's strategy.

# Catalyst

- 1) Possible Revlimid Label Expansion:** Soon The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) will release its opinion on approval of Revlimid as monotherapy for the maintenance treatment of adult patients with newly diagnosed MM who have undergone ASCT. Once approved, Revlimid will be the first and only maintenance treatment available for these groups of patients. This will indeed contribute towards share price growth following Q4:16 earnings call.
- 2) Ozanimod's Phase 3 clinical trials:** The phase 3 trial SUNBEAM, which is evaluating CELG's Ozanimod in patients with relapsing multiple sclerosis (RMS) is expected in February along with data from the confirmatory Phase 3 RADIANCE trial expected next quarter.
- 3) Donald Trump & Drug prices:** As Donald Trump said during his Time magazine interview "I'm going to bring down drug prices. I don't like what has happened with drug prices". However, it is important to highlight that price floor is an important foundation of a bullish outlook for the biotechnology and pharmaceutical sectors. And according to the consensus in the wallstreet- Republican-controlled Congress will remain highly skeptical of pushing towards any bill that can settle or manage biotech prices. But for next couple of months, Biotech firms will keep an eye on Trump because any news of a sharp price increase can lead to a Twitter rant from the President that can be vicious for any biotech firm also for overall sector. Hence increasing Celgene's risk profile near-term, this can create disturbance in the stock price movement.