



Recommendation Date: April 29th, 2020.

# Regeneron Pharmaceuticals Company Report

In our assessment, Regeneron is under-valued by 8.8%.

Strong current sales growth (18% in 2020) and market control of several products will lead to consistent sales growth.

Pipeline is full of potential with several standout products waiting to explode onto the market (7 Phase II products).

Future performance will not be dependent on one standout product, but rather a combination of several market leaders.

Mixed product launches and several failed trials make this a stock not to take for granted.

# **Key Metrics:**

Ticker: REGN

NAICS: 339950

Market Cap Current: \$59.48B

Implied Equity Value: \$65.22B

P/E: 28.64

EPS: 18.46

Dividend Yield: N/A

Share Price: \$528.60

Target Price: \$579.80

Valuation: -8.8%

#### Contact Details:

Yuting Chen:

Yuting.chen@ucd.ie

Patrick Kyne

Patrick.kyne@ucdconnect.ie

# **Recommendation: HOLD**

Please see the disclaimer at the back of this report for important. information.

## Table of Contents

Company Overview:	3
Key Metrics for Growth:	3
Effect of COVID-19 on Regeneron's Operations	3
Effect of COVID-19 on Regeneron's Revenue	3
Company Commercial Portfolio	4
The Effect of Competition	4
Sales Forecast	5
EYLEA	5
ARCALYST	6
PRALUENT	6
DUPIXENT	7
ZALTRAP	7
KEVZARA	8
LIBTAYO	9
Pipeline	10
FDA and Regeneron Stance on the Approval Process with COVID-19	10
Revenue of the Pipeline	10
Key Performance Indicators (KPIs)	12
Sales	12
COGS	12
SG&A	13
R&D	13
D&A	14
Net Profit & Pre-tax Profit Margin	14
CAPEX	14
Net Working Capital	15
Debt to Equity	15
Valuation	16
Forecast Assumptions	18
Forecasts	21
Sensitivity Analysis	22
Appendix 1: Pipeline	24
Important Disclaimer	28





## Company Overview:

Regeneron Pharmaceutical is a global biotechnology company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious diseases. The key areas for Regeneron are eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, infectious diseases, and rare diseases.

Regeneron's business strategy is to become an integrated, multi-product biotechnology company that provides patients and medical professionals with important options for preventing and treating human diseases.

## Key Metrics for Growth:

The key metrics for revenue growth for Regeneron:

- Approval of new products.
- New competition in the market.
- Continued collaboration with partners.

## Effect of COVID-19 on Regeneron's Operations

Regeneron develops and produces drugs that treat serious and life-threatening diseases. As per the company 10-K report, Regeneron has 3 manufacturing facilities. These facilities are located in New York, US and Limerick, Ireland. Regeneron owns 2 of these facilities and they lease the third. We believe the manufacturing facilities are to remain open and there will be a continuous supply of raw materials to these facilities. The CEO of Regeneron stated that the company is currently looking for a cure for COVID-19 and they would use their current facilities to produce a potential vaccine.

There is a manufacturing agreement with Sanofi that ensures that if either party is not able to meet the demand for one of their collaborative products, the other party is to step in to fulfil the demand.

Using other pharmaceutical companies as a reference, Johnson & Johnson (JNJ), Merck (MRK), and Pfizer (PFE) have all stated that reported that COVID-19 did not affect their manufacturing performance or the sourcing of raw materials. We believe that this will also be the case for Regeneron.

As per an announcement from the CEO of Regeneron, if there is a need for large-scale manufacturing of a vaccine for COVID-19, Regeneron would 'do its' part'. This may have a knock-on impact on the financial performance and future revenue of Regeneron.

## Effect of COVID-19 on Regeneron's Revenue

The current sales of Regeneron are going to be slightly impacted by COVID-19. This is largely based on the social distancing measures that are in place and the slight reduction in demand for physician-administered products. The continued supply of these drugs to these patients is of paramount importance. Therefore, the lower growth rate in 2020 in comparison to both 2019 and 2021 is reasonable.

COVID-19 will have an impact on the pipeline and any clinical trials that are currently ongoing. This will be discussed more in the pipeline section.





## Company Commercial Portfolio

The current product line can be seen in the table below.

Major Commercial Products	Indication	Initial Year of Approval	United States Patent Expiration	European Union Patent Expiration
EYLEA	Wet AMD	2011	2023	2025
DUPIXENT	Asthma	2017	2031	2029
	Interleukin 1	2008		
ARCALYST	inhibitor		2027	2028
	Rheumatoid	2017		
KEVZARA	Arthritis		2028	2027
LIBTAYO	Various Cancers	2018	2035	N/A
PRALUENT	HoFH	2015	2029	2029

Source. Company 10-K and Author's work.

The current commercial portfolio is made up of collaborations with Sanofi and Bayer.

## The Effect of Competition

Regeneron faces strong significant potential and actual competition for all its current products. The effect of competition on Regeneron's sales forecast will be done in line with the findings of Grabowski (2013), where generic competition contributed to a sales decrease in the first year of 11%. Subsequent years saw sales decrease exponentially before steadying off after 5 years at about 10% of the peak sales. Analyzing historical trends of competition in recent years, this trend was followed. Not all competitors will result in a negative impact on the sales forecast. If the drug that comes to market is inferior to the current drug, then there will be no impact on the sales of the product.

Biosimilars have a massive impact on the pharmaceutical industry. Several companies are set to lose billions in annual revenue when their current patents expire. AbbVie (54% of current revenue) and Amgen (\$10 B annually) are set to lose out the most. Pfizer and several other companies have recently introduced biosimilars to the market. Johnson and Johnson reported a 10-15% effect on its sales in the first year of a biosimilar in the market. With this in mind, we project that the effect of a biosimilar will be somewhat consistent with that of a generic drug.





#### Sales Forecast

The sales forecast will be done in two parts, this is due to the collaboration Regeneron has with Sanofi and Bayer. We will firstly forecast the revenue for all the current products. Then we will factor in the agreements with both Bayer and Sanofi to determine the revenue that Regeneron will realize.

The total sales forecast will be done in two parts. The first will calculate the sales forecast for the current portfolio. The second part will forecast the individual drugs in the pipeline. The combination of these will result in the total sales forecast for Regeneron.

To forecast the sales figures, we used the historical growth figures of biological drugs, EYLEA, or a current drug that Regeneron has that is like the new product.

We forecasted each product separately. We projected sales based on the performance of the drug relative to other drugs historically, the effect of potential competition, and the expiration of the patent and potential generic competition.

#### **EYLEA**

Eylea faces significant competition from both products on the market and in development. EYLEA currently is the main driver of sales for Regeneron and currently accounts for 60% of annual sales. Bayer has co-developed EYLEA with Regeneron and so have entered into a collaborative agreement where Bayer distribute and manufacture for all foreign markets.

The list of current competition on the market can be seen in the table below.

<b>Competitor Product</b>	Competitor	Indication	Territory
Lucentis	Novartis and Genentech/Roche	Wet AMD	Worldwide
Avastin	Genentech/Roche	Wet AMD	Worldwide
			United
Beovu	Novartis	Wet AMD	States
Ozurdex	Allergen	DME,RVO	Worldwide
Illuvien	Alimera Sciences	DME	Worldwide
Conbercept	Chengdu Kanghong Pharmaceutical Group	Wet AMD	China

Source. Company 10-K and Author's Work.

The most recent competitor to enter the market was Beovu in Q3 2019. There was no impact on EYLEA's stranglehold of the market. EYLEA posted a 12% growth to \$2Bn in Q4 2019 and an 11% growth for the year. EYLEA is the preferred treatment due to its lower cost and fewer invasive injections being required.

We project that EYLEA will continue its current strong performance from 2019, where it experienced an 11% increase in sales growth rate. This is after a 13% growth rate in 2018. We believe that this downward decline in the sales growth rate will continue until the patent expires in FY 2023. We project that there will be a 9.5% growth in sales for 2020, 7.3% in 2021, and 5% in 2022. This is expected for a drug that has been on the market for 9 years.

The main reason for EYLEA's market dominance is that the price of the drug is less than that of competitors and fewer injections are required than its competitors. This is preferred by



physicians. Due to this trend, we do not believe that any of the current competitors will impact the sales forecast of EYLEA.

In 2023 we expect a biosimilar to enter the market and this will impact the sales going forward for EYLEA. This will result in an 11% decline in sales growth in the first year. We project that this trend will continue and by 2028, EYLEA sales will be 10% of peak sales. This is in line with the historical impact of a biosimilar coming into the market. We do not expect the sales to decrease past this point and the sales will level out.

#### **ARCALYST**

After the FDA approval in 2008, the Net Product Sales of ARCALYST increased to its peak in 2010 and gradually decreased to a stable level of around 15 million.

There are no direct competitors in the market or in development for ARCALYST. The turnover of ARCALYST is insignificant for a biosimilar. There is limited upside potential for this drug, and we do not project to see a competitor in this market. Therefore, we believe that the current sales are going to continues at the same level to perpetuity.

#### **PRALUENT**

PRALUENT is a collaboration between Regeneron and Sanofi. An announcement was made in December 2019 stating that Regeneron had sole rights to PRALUENT in the US. PRALUENT is currently the second drug in its market behind Repatha (Amgen). Repatha currently holds an 80% market share. There are no other competitors currently in this market. We do not expect to see any other competitors or generic drugs to come into the market until at least 2029 at the earliest. We see modest upside potential due to the changes in the agreement between Sanofi and Regeneron.

In 2019, Regeneron posted a loss for PRALUENT. This was after successive strong performances in 2017 and 2018, where sales growth rates of 57% and 67% were obtained. Sanofi and Regeneron renegotiated the arrangement for PARLUENT in December of 2019.

From the earnings call, management does not appear to be confident about the future potential of this product as they are looking for increased efficiency and enhance the focus on DUPIXENT. We have predicted that the results for PRALUENT will continue similarly to ARCALYST, with minimal sales growth year on year.





#### **DUPIXENT**

DUPIXENT is a monoclonal antibody used for allergic diseases, such as eczema and asthma. It is a collaborative project with Sanofi and has had strong results since entering the market in FY 2017. There are currently several competitors on the market. These can be seen in the table below.

<b>Competitor Product</b>	Competitor	Indication	Territory
Eucrisa	Pfizer	Atopic Dermatitis	United States
Xolair	Roche/Novartis	Asthma	Worldwide
Nucala	GSK	Asthma	Worldwide
Cinqair	Teva	Asthma	United States
Fasenra	AstraZeneca	Asthma	Worldwide

Source. Company 10-K and Author's Work.

DUPIXENT is a strong competitor in this market and we believe that this will continue until its patent expiration in 2029. As per the company earning's call, there are still numerous launches left for this product and new location opportunities. We expect that its recent performance and its future revenue potential will lead to a continued strong market performance. We expect that DUPIXENT will continue as a market leader until its patent expires.

Management has highlighted that they want to put a focus on DUPIXENT to generate greater profitability from their partnership with SANOFI. DUPIXENT has reported strong sales growth so far (151% in 2019 and 259% in 2018) and we expect this trend to continue. To simulate future sales growth, we used the growth rate of EYLEA as a proxy as to future sales growth. Using this, we predict that there will be a 60% sales growth rate in 2020 and this will continue to decrease as the drug ages.

DUPIXENT treats Asthma and other allergic diseases and so we do not expect that COVID-19 will affect the sales of this product. We expect sales growth to continue until the patent for this drug expires in 2029. DUPIXENT has been acknowledged as a key driver for future sales growth for Regeneron and we have forecasted for this.

#### **ZALTRAP**

ZALTRAP is a collaboration product with Sanofi. In 2019, ZALTRAP had a sales growth of 0.5%, which for a biologic is extremely low. This was after positive sales growths in 2017 and 2018, but negative growth rates in 2015 and 2016. ZALTRAP is behind market leader Avastin in terms of sales volume, and there is no indication as to whether ZALTRAP can outperform Avastin in testing. Based on this, there is a limited potential upside for ZALTRAP, and we have projected that the sales growth rate will be relatively flat in line with the 2019 figures going forward.





#### **KEVZARA**

This is a treatment for Rheumatoid Arthritis that came to the market in 2017. Several drugs are currently on the market and are outperforming KEVZARA. These can be seen in the table below.

<b>Competitor Product</b>	Competitor	Indication	Territory	
	Genentech/Roche/Chugai			
Actemra	Pharmaceutical	Rheumatoid Arthritis	Worldwide	
Orencia	BMS	Rheumatoid Arthritis	Worldwide	
Xeljianz	Pfizer	Rheumatoid Arthritis	Worldwide	
Olumiant	Eli Lilly/Incyte	Rheumatoid Arthritis	Worldwide	
Rinvoq	AbbVie	Rheumatoid Arthritis	Worldwide	

Source. Company 10-K and Author's Work.

We do not believe that KEVZARA in its current capacity will be able to make significant inroads into the other competitors in this market. In the restructuring in December, Sanofi has obtained global rights to the distribution of KEVZARA. They have recently submitted the drug for potential approval to treat patients with severe cases of COVID-19. The results have not met the desired conditions and there are currently no more patients being enrolled on this test. We do not see many other potential windfalls for this drug and there are limited opportunities for this drug to perform well going forward.

KEVZARA came to market in 2017 and has posted strong sales growth figures for both 2018 and 2019, but the total sales volume figures are significantly lower than what both Sanofi and Regeneron were expecting for this product. In the earnings call, management stated that they wanted to improve the efficiency and to enhance focus on DUPIXENT. In December of last year, Sanofi announced that they would have the global rights to KEVZARA. This involved KEVZARA being tested as a potential COVID-19 drug. It subsequently failed in initial phase III testing.

With this in mind, we do not believe that there is significant upside potential for KEVZARA going forward. We have projected the sales forecast of KEVZARA using EYLEA historical patterns, however, due to the additional focus being put on DUPIXENT by management, we believe that sales growth will be 22% in 2020 and this will scale down to 6% in 2022. The sales growth rate at this point will be relatively flat until the product comes off patent.





LIBTAYO is Regeneron's oncology drug that is being tested on several different forms of cancer. The full list of competitors for this market can be seen in the table below.

Competitor Product	Competitor	Indication	Territory
Keytruda	Merck	Various Cancers	Worldwide
Opdivo	BMS	Various Cancers	Worldwide
Tecentriq	Roche	Various Cancers	Worldwide
Imfinzi	AstraZeneca	Various Cancers	Worldwide
Bavencio	Pfizer/Merck	Various Cancers	Worldwide

Source. Company 10-K and Author's Work.

Oncology is currently the largest market in the pharmaceutical industry, and it is experiencing rapid growth. This market has been largely dominated by both Keytruda and Opdivo. In 2019, Keytruda had 9 different approvals for different forms of cancer. As per the Merck pipeline, there are 14 different phase III trials ongoing for Keytruda for different forms of cancers. LIBTAYO will struggle to gain significant traction in each of these markets.

LIBTAYO was the sixth to market drug in the oncology sector. The impact of being late to market impacts the future potential revenue for the product. In a report by McKinsey (2014), the 6<sup>th</sup> to market drug had on average a 2% market share 10 years after the launch of the first product. This is in comparison to 40% for the first to market product. We believe that this will hamper its future sales growth. Keytruda (Merck) and Opdivo (BMS) have already gained significant market presence and it is hard to see LIBTAYO catching up. LIBTAYO has performed similarly well to Keytruda in similar tests. We believe that this will not be enough for LIBTAYO to generate significant market share.

However, there is still an upside potential for this drug. The promising performances in testing so far are indicative of it generating a significant market share in comparison to its current position.

LIBTAYO launched in 2018 and has experienced significant sales growth. To model the sales growth going forward, we used EYLEA as a proxy, but we have factored in that LIBTAYO is a 6<sup>th</sup> to market drug to accurately determine the sales growth rates going forward. For 2020, sales growth is expected to be 43%. This is also in line with the sales growth Merck expects for Keytruda this year. Going forward from there, we expect a 17% growth rate in 2021 and this will reduce to 5% by 2025. These are in line with the growth rates for EYLEA. We expect minimal growth from 2025 to 2029. This is in line with a mature product on the market.





## Pipeline

Regeneron is actively trying to expand its current portfolio. This includes additional patents on current products, new products, and more collaborations with other manufacturers. Regeneron is also developing products that can be used free of charge during outbreaks. One of these is REGN-EB3, which is an Ebola Virus Antibody. Regeneron believes that they have a social responsibility to use their R&D framework to develop these drugs. We will not forecast sales for these products but are including them as they will impact R&D and the ROI of the pipeline.

The historic probabilities are based on the type of drug being manufactured (biologics) and were obtained from the American Society of Clinical Pharmacology and Therapeutics. The time to market data was obtained from the expected time to completion of the study which is available for each drug from the US National Library of Medicine and Van Norman (2016). Relevant adjustments were made to account for COVID-19.

Table 2. The current pipeline of new products for Regeneron.

	it pipeline of new produc		B 1 100	
Major	Target Indication	Stage	Probability	Time to
Commercial				market
Products				
REGN-EB3	Ebola Virus Antibody	Clinical Phase 3	50.6%	
EVINACUMAB	ANGPTL-3-Antibody	Clinical Phase 3	50.6%	1 Year
FASINUMAB**	NGF Antibody	Clinical Phase 3	50.6%	3 Years
REGN1979	CD20XCD3 Antibody	Clinical Phase 2	17.4%	6 Years
REGN1908-1909	Fel d 1 Antibody	Clinical Phase 2	17.4%	6 Years
REGN3500*	IL-33-Antibody	Clinical Phase 2	17.4%	6 Years
REGN5069	GFRa3 Antibody	Clinical Phase 2	17.4%	7 Years
REGN4461	1 LEPR Antibody Clinical Phase 2		17.4%	8 Years
GARETOSMAB	Activin A Antibody	Clinical Phase 2	17.4%	6 Years
POZELIMAB	C5 Antibody	Clinical Phase 2	17.4%	9 Years
REGN3767	LAG-3 Antibody	Clinical Phase 1	11.5%	10 Years
REGN4018*	MUC16Xcd3 Antibody	Clinical Phase 1	11.5%	11 Years
REGN5093	METxMET Antibody	Clinical Phase 1	11.5%	12 Years
REGN5458*	BCMAxCD3 Antibody	Clinical Phase 1	11.5%	10 Years
REGN5459*	BCMAxCD3 Antibody	Clinical Phase 1	11.5%	12 Years
REGN5678	EGN5678 PSMAxCD28		11.5%	13 Years
	Antibody			
REGN5713/4/5	Betv 1 Antibody	Clinical Phase 1	11.5%	10 Years

<sup>\*</sup>Collaboration with Sanofi. \*\*Collaboration with Teva and Mitsubishi Tanabe.

#### FDA and Regeneron Stance on the Approval Process with COVID-19

The current stance of the FDA is that all clinical trials that are currently in process are to continue until completion if possible. There is a suspension on trials starting until further notice and the addition of patients onto an existing trial. This will not affect drugs seeking marketing approval or the rollout of drugs that have already gained marketing approval.

#### Revenue of the Pipeline

To forecast the revenue of the pipeline we used the following:

• Timeframe to market-based on current ongoing testing. Using the US National Library of Medicine, the end date of current ongoing trials can be determined. We then used





Van Norman (2016) to determine the average time for the remainder of the clinical phases.

- The cost of drugs using the price of similar drugs on the market of the same type (small molecule, gene therapy, cell therapy, Etc.)
- A factor will be applied to the number of people suffering from the target disease and it will be divided by the population of patients of the reference drug.
- We will forecast all current pipeline products for 10 years. We project that this will be the lifespan of the products. This will enable us to determine the Return on Investment of the pipeline.
- The projected sales for phase I and II products can be seen below. The sales for Phase I were accounted for in the Return on Investment for the pipeline. Since these products are oncology drugs LIBTAYO was used as a guide for the sales forecast.

The forecast of the different phase III and phase II products can be seen in Appendix I.





## Key Performance Indicators (KPIs)

Metric	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Sales Growth Rate	59%	21%	-3%	209%	53%	34%	46%	18%	21%	14%	17%
COGS to Sales	0%	0%	1%	6%	7%	7%	10%	6%	7%	6%	10%
Gross Margin	100%	100%	99%	94%	93%	93%	90%	94%	93%	94%	90%
SG&A to Sales	14%	14%	26%	15%	16%	18%	20%	24%	22%	23%	23%
R&D to Sales	105%	107%	119%	45%	41%	45%	39%	42%	35%	33%	39%
Operating Margin	-20%	-21%	-46%	33%	36%	29%	31%	27%	35%	38%	28%
EBITDA Margin	-16%	-17%	-39%	36%	38%	31%	32%	30%	38%	40%	31%
D&A to Sales	4%	4%	7%	3%	2%	2%	2%	2%	2%	2%	3%
EBIT Margin	-20%	-21%	-46%	33%	36%	29%	31%	27%	35%	38%	28%
Net Profit Margin	-18%	-23%	-50%	54%	20%	12%	15%	18%	20%	36%	27%
Pre-tax Profit Margin	-19%	-23%	-50%	30%	34%	27%	30%	27%	35%	38%	31%
CAPEX	97	100	57	49	156	333	678	512	273	383	430
Net Working Capital	332	249	518	1,042	1,498	1,430	2,104	1,939	3,200	5,005	5,593
Current Ratio	5	3	4	7	6	3	4	3	4	4	4
Debt to Equity	0%	0%	57%	24%	26%	18%	10%	11%	11%	8%	7%

Source: Company financial statements and author's work.

#### Sales

The only year Regeneron had Sales decreased was 2011 (-3%), which was followed by an abnormally high increase-year (209%). The Sales decrease was attributable to a decrease (-4.4%) in the Collaboration revenue (mainly caused by the decrease of Substantive milestone payments with Bayer HealthCare), which was 83% of the total revenue that year. The surge of sales was largely driven by the successful commercialization and market penetration of EYLEA (approved by the FDA in November 2011). From 2014 to 2018, EYLEA took more than 99% of Regeneron's net product sales. The ratio dropped to 95% after the launch of Libtayo.

#### **COGS**

Cost of Goods Sold to Sales was very low (almost zero) before 2012. The reason is that before 2012, only a small portion of total revenue was from net product sales. The major part (more than 80%) of total revenue was from reimbursement of R&D (such as Antibody with Sanofi) in Collaboration Revenue. Since the launch of EYLEA in November 2011, COGS increased significantly along with the net product sales. Since 2012, the ratio was stable at around 6-7% except 2015 and 2019 (both were 10%). The first spike was principally due to the increase in U.S. EYLEA net sales, as well as an increase in Limerick start-up costs. The second spike was mainly caused by the newly launched product (Libtayo) sold in the US by Regeneron itself¹ and inventory write-downs and reserves (totaling 73.8 million and 12.5 million, respectively). With the information, we believe the COGS will be normally stable relative to Sales (6.5%) in our forecast window.

<sup>&</sup>lt;sup>1</sup> Including (i) the obligation to pay Sanofi its share of Libtayo's U.S. gross profits and (ii) third-party royalties.





#### SG&A

SG&A to Sales increased from 14% in 2009 to around 23% since 2016 and was stable afterward. The main driver of the increasing trend from 2009 to 2016 was the increasing headcount (as seen in the figure below). The only abnormal value in 2011 (26%) was due to the preparation (including recruitment and marketing) and commercialization for the newly launched product (EYLEA). We expect SG&A will be stable relative to Sales in our forecast window.

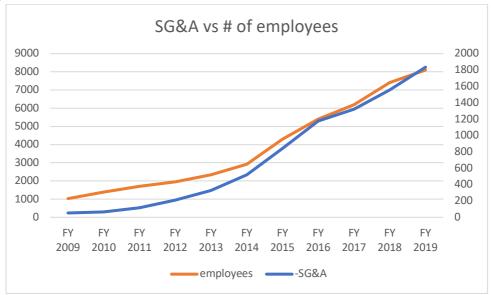


Figure 1. Source: Company financial statements and author's work.

#### R&D

As we see from the table of KPIs, the R&D to Sales was decreasing. The reason is that Sales increase at a higher speed. We found that R&D expenses kept increasing in the last ten years with a linear trend (as shown in the figure below). We used the Hodrick Prescott filter (lambda  $= 10,000)^2$  to find the trend of R&D. The actual R&D expense fluctuates around the trend with a minimum Sum of Squared Residuals. According to Regeneron's announcement related to COVID-19, their R&D is not impacted<sup>3</sup>. Our best guess is that Regeneron follows an R&D strategy that increases expenses following the linear trend.

<sup>&</sup>lt;sup>2</sup> When putting a large lambda, the fitted curve will be very close to a fitted curve using linear regression model on time.

<sup>&</sup>lt;sup>3</sup> DEF 14A 2020





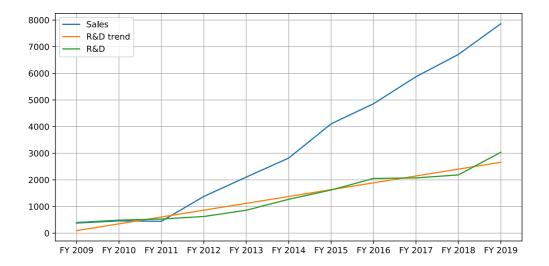


Figure 2. Source: Company financial statements and author's work.

#### D&A

Depreciation and Amortization have accounted for 2-3 % of total sales since 2012 (after the launch of EYLEA) since net product sales accounted for more than 60% of the total revenue. We forecast the ratio will keep stable in our forecast window.

#### Net Profit & Pre-tax Profit Margin

Regeneron started generating positive net income since 2012 and started paying tax since 2013.

#### **CAPEX**

Capital Expenditure highly depends on the business strategies to invest in PP&E. From 2013 to 2015 Regeneron increased its CAPEX mainly to support its facility in Limerick, Ireland. In July 2013, they reached a preliminary agreement to acquire a 400,000 square foot facility in Limerick, Ireland, causing the actual CAPEX 174% of their expected CAPEX. Except for 2013, Regeneron has actual CAPEX smaller than the mid-value of their expected range, reflecting a conservative estimation style. Regeneron owns two facilities in Rensselaer, New York, and Limerick, Ireland and leases one facility in Tarrytown, New York to conduct research, development, manufacturing, and administrative activities. Although Regeneron stated they tend to further develop the current facilities, there is no evidence of any intention to acquire a fourth facility. We then expect the CAPEX in 2020 will be 85% (the average ratio between 2011 to 2019 except 2013) of the mid-value of their expected range (570 million), which equals 485 million.

	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	E 2020
Expected C.	APEX range		50 to 75	50 to 70	80 to 100	350 to 425	650 to 800	580 to 680	375 to 450	420 to 500	410 to 490	520 to 620
Expected C	CAPED mid		62.5	60	90	387.5	725	630	412.5	460	450	570
Actual CAPEX	97	100	57	49	156	333	678	512	273	383	430	
Actual	Actual to Mid		92%	82%	174%	86%	94%	81%	66%	83%	95%	

Source. Company 10-ks and author's work.





As Regeneron only stated their willingness to further develop the current facilities and only have a forecast of CAPEX for 2020 and the CAPEX in the last ten years were volatile, we can only forecast the future CAPEX in our forecast window based on historical trends in similar situations. To investigate the historical situations, we extracted the explanatory statements related to CAPEX from the 10-K documents and found the significant hump between 2013 to 2016 was due to the expenditure on their new facility in Limerick, Ireland. We calculate the CAPEX to Sales ratio and found it stable after 2016 (5.3%). Although we don't expect Regeneron to acquire a new facility in near future, it is likely for it to invest in a new one when the current facilities reach their capacity. We account for that upward pressure by forecasting the CAPEX to be stable relative to Sales (grow with Sales) after 2020.

#### **Net Working Capital**

Regeneron has a current ratio around 4, thus the change of NWC depends more on current assets (as seen in the figure below), of which about 90% are Cash and Cash Equivalents, Marketable Securities, Accounts Receivable and Inventories. With that, in the long term, the NWC should be highly correlated with product sales. We forecast NWC to be 63% of Sales (the average of historical ratios except for the abnormal value in 2011).

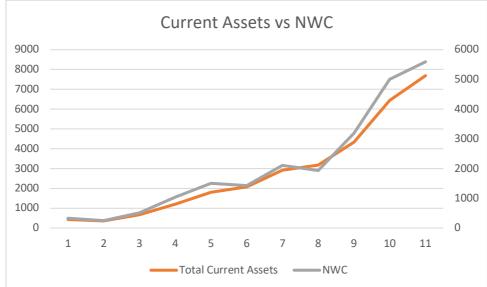


Figure 3. Source: Company financial statements and author's work.

#### Debt to Equity

Regeneron started financing via debt since 2011 (\$400 million) to support its launch of EYLEA and mainly rely on long term debt (Convertible Senior Notes and Credit Agreement). The debt to equity ratio kept decreasing since 2011 and is now 7%. However, all of the current debt are revolving credit<sup>4</sup>. As stated in the 2019 Q4 earnings call, they have the necessary capital to advance and expand their wholly-owned R&D pipeline, there is no urgent need to issue more debt. As described in the CAPEX, Regeneron has no intention to acquire and develop a new facility for the foreseeable future so that there is no need to increase a large amount of debt. The low leverage level in comparison to the industry also minimizes the effects of a financial crisis. We believe the future debt to equity ratio will be back to zero soon and keep zero in the future.

<sup>&</sup>lt;sup>4</sup> 10-k, 2019





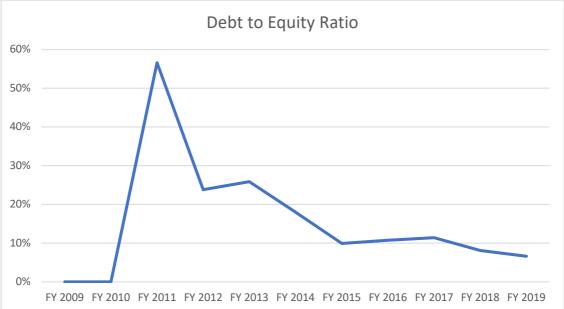


Figure 4. Source: Company financial statements and author's work.

#### Valuation

Given the assumption that the debt to equity ratio is approaching a target level, we decide to use WACC in the DCF valuation.

#### WACC

We estimate WACC at 4.7%. To calculate WACC using equation (1), we first estimate the value of each element according to our analysis.

$$WACC = d_e/(d_e + 1) * (1 - tax) * r_d + 1/(d_e + 1) \cdot r_e$$
 (1)

 $d_e$  refers to the debt to equity ratio, which was estimated as 7%. tax refers to the tax rate for Regeneron, we use the US corporate tax rate (21%).  $r_d$  refers to the cost of debt, which was estimated as the historical average of 6.4%.

 $r_e$  stands for cost of equity estimated using CAPM as in equation (2), where *leveraged*  $\beta$  was estimated from regression (3) on a rolling basis (60-month window).  $r_m$  was the return of Russell 3000 Index<sup>5</sup> and  $r_f$  was the risk-free rate proxied by the 13-week treasury bill rate (0.3% as the average between Sep 2008 and Sep 2018, 10 years after the big crash). The series of beta is plotted in the figure below. Regeneron's performance is in general positively related to the market. There are clear structural breaks in the time series of beta. After the burst of the Internet Bubble, the beta increased to around 2, one possible explanation is that Regeneron was small at that time and was more sensitive to the recession. After the market crash in 2008, Regeneron's beta soared up but reversed soon and kept about 1 for 7 years. We also observed that the beta decreased during the outbreak of COVID-19 because Regeneron's price kept increasing during the outbreak when the market was decreasing. It seems that along with time, Regeneron tends to be less sensitive during bad periods. Between 2017 and 2019 the beta was

\_

<sup>&</sup>lt;sup>5</sup> We believe Russell 3000 is a better proxy of the market as it includes more alternatives.





higher than 1, the reason is that Regeneron's price has increased around 32 times to a very high level since 2009 and became more volatile to investor sentiment. The beta then decreased to around 1 after 2019 and decreased to lower than 1 during the outbreak of COVID-19. We believe the long-term beta should be around 1 in normal periods, however, due to the impact of coronavirus and the recession, the beta level will be lower than 1 for two reasons. 1) in the short-term, the price of Regeneron has a solid upward pressure, and 2) in the long-term, Regeneron has a smaller potential of increasing than the currently more undervalued market. As the firm size increases, beta is naturally approaching 1, we believe the current beta (0.57) is too low to represent the future volatility. We choose the smallest beta before 2020 (0.76 in February 2014) as our best guess of the future beta level. We then estimate  $r_e$  as 4.7% given the market risk premium 5.75% as recommended by KPMG<sup>6</sup>.

$$r_e = \beta \cdot mrp \tag{2}$$

$$r_i - r_f = \alpha_i + \beta_i (r_m - r_f) + \varepsilon \tag{3}$$

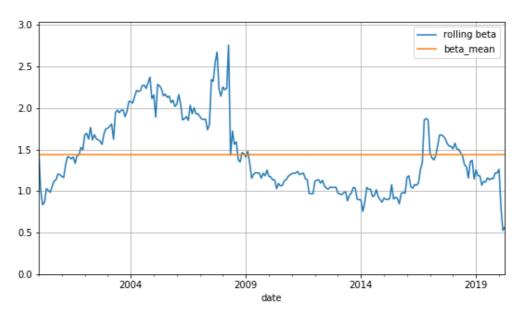


Figure 5. Source: Author's work.

-

<sup>&</sup>lt;sup>6</sup> https://assets.kpmg/content/dam/kpmg/nl/pdf/2019/advisory/equity-market-research-summary-300619.pdf





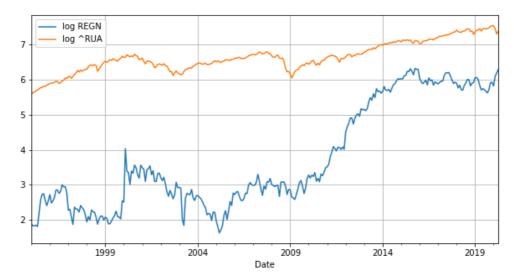


Figure 6. Source: Yahoo Finance and the author's work.

#### **Forecast Assumptions**

#### (1) Sales Growth Rates

As described earlier, the Total Revenue forecast is based on the forecast of the Total Net Product Sales for both Regeneron and its collaborators. We estimate the ratio of Total Revenue to Total Net Product Sales based on the historical data (as seen in the figure below). We observed that after the launch of EYLEA (the major product generates more than 95% of Regeneron's Net Product Sales), the ratio kept decreasing with a linear trend. The reason is the faster increase of Net Product Sales by Regeneron's collaborators (including the EYLEA sales outside of the United States, the Dupixent sales, the ZALTRAP sales, the Praluent sales, and the Kevzara sales).

In our forecast window the growth rate of Net Product Sales keeps increasing with a high speed till 2022 (as seen in the table below), we then estimate the ratio will decrease further with the recent linear trend. We fit the simple regression model with an independent variable of time and predict the values for 2020, 2021, and 2022. As the Net Product Sales growth rate doesn't fluctuate drastically, we are confident the structure will keep stable for the next few years. The forecasted Total Revenue is plotted below.





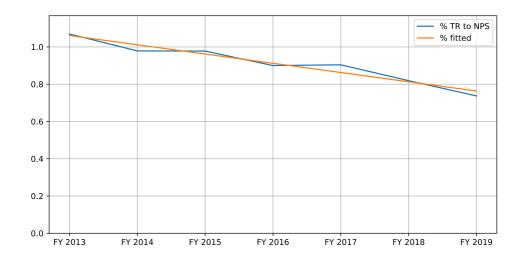


Figure 7. Source: Yahoo Finance and author's work.

million \$	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
NPS	10,669	12,951	15,892	18,474	18,958	19,586	20,086	20,207	19,761	18,858	19,724
NPS growth rate	30%	21%	23%	16%	3%	3%	3%	1%	-2%	-5%	5%
TR/NPS	74%	71%	66%	61%	61%	61%	61%	61%	61%	61%	61%
Total Revenue	7,863	9,243	10,553	11,350	11,648	12,033	12,340	12,415	12,141	11,586	12,118
TR growth rate	17%	18%	14%	8%	3%	3%	3%	1%	-2%	-5%	5%

Source. Author's work.

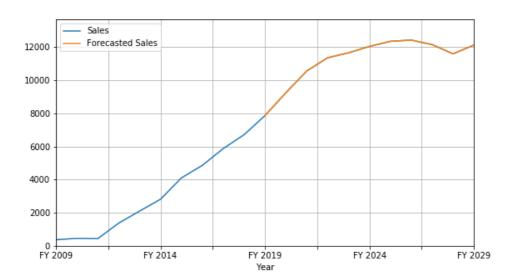


Figure 8: Source: Author's work.

## (2) COGS to Sales

We expect the COGS will continue increasing along with Sales, thus we expect the COGS will be flat around 6.5% of Sales.





- (3) SG&A growth rate
  - We estimate the SG&A will be 23% of the Sales in the forecast window.
- (4) R&D
  - We forecast R&D will continue increasing with a linear trend.
- (5) CapEx to Sales
  - We estimate CapEx to Sales to be flat around 5.3% with an only exception in 2020. We forecast the value in 2020 based on Regeneron's estimation and their average accuracy.
- (6) NWC to Sales
  - We forecast NWC to be 63% of Sales in the forecast window.
- (7) D&A to Sales
  - We forecast the ratio (2.5%) will keep stable in our forecast window.
- (8) Tax Rate
  - As describe in the WACC calculation, we use the U.S. corporate tax rate of 21%.
- (9) Terminal Growth Rate
  - We use a long-term estimation of the GDP growth rate which is  $2\%^7$ .

\_

<sup>&</sup>lt;sup>7</sup> https://data.oecd.org/gdp/real-gdp-long-term-forecast.htm



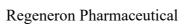


## Forecasts

	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Sales	379	459	446	1,378	2,105	2,820	4,104	4,860	5,872	6,711	7,863
g		21%	-3%	209%	53%	34%	46%	18%	21%	14%	17%
COGS/Sale s	0%	0%	1%	6%	7%	7%	10%	6%	7%	6%	10%
-cogs	2	2	4	84	155	205	393	300	397	434	782
SG&A/Sales	14%	14%	26%	15%	16%	18%	20%	24%	22%	23%	23%
-SG&A	53	65	117	211	329	519	839	1,178	1,320	1,556	1,835
-R&D	399	489	530	626	860	1,271	1,621	2,052	2,075	2,186	3,037
R&D/Sales	105%	107%	119%	45%	41%	45%	39%	42%	35%	33%	39%
EBIT	(74)	(97)	(205)	458	760	824	1,252	1,331	2,080	2,534	2,210
D&A	14	20	31	37	41	53	75	105	146	148	210
EBITDA	(60)	(78)	(174)	495	801	877	1,327	1,435	2,225	2,683	2,420
Capex	97	100	57	49	156	333	678	512	273	383	430
Tax	(4)	-	(1)	(336)	289	423	589	434	880	109	313
NWC	332	249	518	1,042	1,498	1,430	2,104	1,939	3,200	5,005	5,593
NWC_diff		(83)	269	525	456	(68)	674	(165)	1,261	1,805	588
FCFF		(94)	(499)	256	(100)	188	(614)	654	(188)	385	1,090

	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Sales	9,243	10,553	11,350	11,648	12,033	12,340	12,415	12,141	11,586	12,118
g	18%	14%	8%	3%	3%	3%	1%	-2%	-5%	5%
COGS/Sales	7%	7%	7%	7%	7%	7%	7%	7%	7%	7%
-COGS	601	686	738	757	782	802	807	789	753	788
SG&A/Sales	23%	23%	23%	23%	23%	23%	23%	23%	23%	23%
-SG&A	2,126	2,427	2,611	2,679	2,768	2,838	2,855	2,792	2,665	2,787
-R&D	3,293	3,550	3,806	4,063	4,320	4,576	4,833	5,089	5,346	5,603
R&D/Sales	36%	34%	34%	35%	36%	37%	39%	42%	46%	46%
EBIT	3,223	3,890	4,195	4,149	4,164	4,124	3,919	3,470	2,822	2,940
D&A	231	264	284	291	301	309	310	304	290	303
EBITDA	3,454	4,154	4,479	4,440	4,465	4,432	4,230	3,773	3,112	3,243
Capex	485	559	602	617	638	654	658	643	614	642
Tax	634	765	825	815	818	811	770	682	555	578
NWC	5,823	6,648	7,151	7,338	7,581	7,774	7,821	7,649	7,299	7,634
NWC_diff	231	825	502	187	243	193	47	(172)	(350)	335
FCFF	2,105	2,005	2,551	2,820	2,765	2,774	2,755	2,620	2,293	1,688







Items	value
PV of FCF	19,111
terminal value	63,889
PV of terminal value	40379
Intrinsic Enterprise Value	59,491
-Net Debt	-5,734
Intrinsic Equity Value	65,224
Current Equity Value	59,480
% of overvaluation	-8.8%

As seen from tables above, our valuation generates an intrinsic equity value as 65.2 billion dollars, comparing with the current market cap 59.5 billion, we conclude that the equity of Regeneron is 8.8 % under-valued.

#### Sensitivity Analysis

We then conduct sensitivity analysis to see the sensitivity of our valuation to different setting of WACC and terminal growth rates. From the values we used for the base cases, we add five values greater and smaller than the base values respectively. We run the valuation model using different pairs of WACC and terminal growth rates and export both the intrinsic values and corresponding percentage of over/undervaluation ratio in tables below.

	Terminal Growth Rate												
	Mn \$	0.5%	0.8%	1.1%	1.4%	1.7%	2.0%	2.3%	2.6%	2.9%	3.2%	3.5%	
	2.2%	107,965	125,576	152,835	200,659	306,424	737,199	(1,299,526)	(316,999)	(170,965)	(112,137)	(80,362)	
	2.7%	86,103	95,685	108,870	128,164	159,089	216,702	361,772	1,420,651	(623,447)	(237,699)	(139,556)	
	3.2%	72,293	78,204	85,808	95,953	110,169	131,521	167,183	238,791	455,920	(26,767,253)	(392,299)	
	3.7%	62,758	66,707	71,570	77,703	85,681	96,483	111,929	135,838	177,785	270,551	648,381	
WACC	4.2%	55,764	58,553	61,882	65,926	70,943	77,330	85,739	97,312	114,245	141,386	191,950	
WACC	4.7%	50,405	52,456	54,849	57,678	61,073	65,224	70,415	77,093	86,002	98,487	117,238	
	5.2%	46,160	47,716	49,500	51,565	53,986	56,860	60,331	64,604	69,994	77,004	86,496	
	5.7%	42,709	43,918	45,286	46,845	48,637	50,721	53,173	56,101	59,656	64,067	69,684	
	6.2%	39,843	40,802	41,875	43,082	44,449	46,013	47,817	49,923	52,411	55,399	59,051	
	6.7%	37,421	38,195	39,052	40,006	41,075	42,280	43,649	45,220	47,038	49,169	51,700	
	7.2%	35,346	35,979	36,674	37,441	38,292	39,242	40,307	41,512	42,885	44,464	46,300	

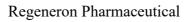




	Terminal Growth Rate											
		0.5%	0.8%	1.1%	1.4%	1.7%	2.0%	2.3%	2.6%	2.9%	3.2%	3.5%
	2.2%	-45%	-53%	-61%	-70%	-81%	-92%	-105%	-119%	-135%	-153%	-174%
	2.7%	-31%	-38%	-45%	-54%	-63%	-73%	-84%	-96%	-110%	-125%	-143%
	3.2%	-18%	-24%	-31%	-38%	-46%	-55%	-64%	-75%	-87%	-100%	-115%
	3.7%	-5%	-11%	-17%	-23%	-31%	-38%	-47%	-56%	-67%	-78%	-91%
WACC	4.2%	7%	2%	-4%	-10%	-16%	-23%	-31%	-39%	-48%	-58%	-69%
WACC	4.7%	18%	13%	8%	3%	-3%	-9%	-16%	-23%	-31%	-40%	-49%
	5.2%	29%	25%	20%	15%	10%	5%	-1%	-8%	-15%	-23%	-31%
	5.7%	39%	35%	31%	27%	22%	17%	12%	6%	0%	-7%	-15%
	6.2%	49%	46%	42%	38%	34%	29%	24%	19%	13%	7%	1%
	6.7%	59%	56%	52%	49%	45%	41%	36%	32%	26%	21%	15%
	7.2%	68%	65%	62%	59%	55%	52%	48%	43%	39%	34%	28%

With the results of the sensitivity analysis, we are more confident to recommend a "hold" to Regeneron as the valuation is sensitive to both WACC and terminal growth rates. Given that the price increased recently to its historical high minimizing the space for future return and the valuation is centered around a small percentage of undervaluation, along with the fact that Regeneron has recently failed its trail on KEVZARA for the COVID-19 treatment, we recommend a "hold" position.







# Appendix 1: Pipeline

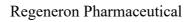
EVINACUMAB	
<b>Current Clinical Phase</b>	3
Type of Drug	Biologic
<b>Expected Year on Market</b>	2021
<b>Probability of Getting to Market</b>	51%
Drug	Praluent
Reference	
Indicator	PCSK9

Year	2021 E	2022 E	2023 E	2024 E	2025 E	2026 E	2027 E	2028 E	2029 E	2030 E
Revenue (\$ mn)	5.31	58.85	98.52	155.24	146.08	166.21	185.82	203.54	218.33	229.24
Growth Rate (%)		1,007.62	67.41	57.58	30.00	13.78	11.80	9.53	7.27	5.00

FASINUMAB		
<b>Current Clinical Phase</b>		3
Type of Drug	Biologic	
Expected Year on Market		2023
Probability of Getting to Market		51%
Drug Reference	KEVZARA/EYLEA	
Reference Sample Size	23,000,000	
Drug Sample Size	30,000,000	

Year	2023 E	2024 E	2025 E	2026 E	2027 E	2028 E	2029 E	2030 E	2031 E	2032 E
Revenue (\$mn)	4.39	31.88	68.21	100.52	127.71	145.74	165.82	185.38	203.06	217.81
Growth Rate (%)		626.315	113.975	47.36747	27.04864	14.11633	13.77682	11.80028	9.533618	7.266951







REGN1979	
<b>Current Clinical Phase</b>	2
Type of Drug	Biologic
<b>Expected Year on Market</b>	2026
Probability of Getting to	17%
Market	
Drug Reference	Libtayo
Indicator	CD20XCD3
	Antibody

Year	2026 E	2027 E	2028 E	2029 E	2030 E	2031 E	2032 E	2033 E	2034 E	2035 E
Revenue	2.58	33.72	48.25	56.51	66.16	72.61	76.31	80.10	83.50	86.37
Growth Rate (%)		1,209.46	43.07	17.14	17.07	9.75	5.09	4.97	4.25	3.44

REGN1908-1909		
<b>Current Clinical Phase</b>		2
Type of Drug		Biologic
Expected Year on Market	2026	
Probability of Getting to Market	17%	
Drug Reference		Dupixent
Indicator		Fel d 1
		Antibody
Reference Drug Sample		300,000
Drug Reference		320,000

Year	2026 E	2027 E	2028 E	2029 E	2030 E	2031 E	2032 E	2033 E	2034 E	2035 E
Revenue	47.61	171.12	429.78	688.22	1,100.5 9	1,477.1 6	1,740.9 3	2,044.3	2,349.4 9	2,632.83
Growth Rate (%)		60.13	59.92	34.22	17.86	17.43	14.93	12.06	9.19	6.32





REGN4461	
<b>Current Clinical Phase</b>	2
Type of Drug	Biologic
<b>Expected Year on Market</b>	2028
Probability of Getting to	17%
Market	
Drug Reference	EYLEA
Indicator	LEPR
	Antibody
Reference Sample	250,000
Drug Sample	
	6,000

Year	2028 E	2029 E	2030 E	2031 E	2032 E	2033 E	2034 E	2035 E	2036 E	2037 E
Revenue	0.10	3.58	7.85	11.59	17.08	21.70	24.76	28.17	31.49	34.50
Growth Rate (%)		3,355.24	119.49	47.54	47.37	27.05	14.12	13.78	11.80	9.53

REGN3500	
<b>Current Clinical Phase</b>	2
Type of Drug	Biologic
<b>Expected Year on Market</b>	2026
Probability of Getting to	17%
Market	
Drug Reference	Dupixent
Indicator	IL-33-
	Antibody

Year	2026 E	2027 E	2028 E	2029 E	2030 E	2031 E	2032 E	2033 E	2034 E	2035 E
Revenue	22.32	80.21	201.46	322.60	515.90	692.42	816.06	958.28	1,101.32	1,234.14
Growth Rate (%)		59.92	34.22	17.86	17.43	14.93	12.06	9.19	6.32	5.06





REGN5069	
<b>Current Clinical Phase</b>	2
Type of Drug	Biologic
<b>Expected Year on Market</b>	2027
Probability of Getting to	17%
Market	
Drug Reference	KEVZARA/EYLEA
Indicator	GFRa3 Antibody

Year	2027 E	2028 E	2029 E	2030 E	2031 E	2032 E	2033 E	2034 E	2035 E	2036 E
Revenue	2.31	16.81	35.97	53.00	67.34	76.84	87.43	97.75	107.07	114.85
Growth Rate (%)		626.32	113.98	47.37	27.05	14.12	13.78	11.80	9.53	7.27

GARETOSUMAB				
<b>Current Clinical Phase</b>	2			
Type of Drug	Biologic			
Expected Year on Market	2026			
Probability of Getting to Market	17%			
Drug Reference	KEVZARA/EYLEA			
Indicator	Activin A Antibody			
Reference Sample	250,000			
Drug Sample	15,000			

Year	2026 E	2027 E	2028 E	2029 E	2030 E	2031 E	2032 E	2033 E	2034 E	2035 E
Revenue	0.14	1.01	2.16	3.18	4.04	4.61	5.25	5.86	6.42	6.89
Growth Rate (%)		626.32	113.98	47.37	27.05	14.12	13.78	11.80	9.53	7.27





POZELIMAB	
<b>Current Clinical Phase</b>	2
Type of Drug	Biologic
<b>Expected Year on Market</b>	2029
Probability of Getting to	17%
Market	
Drug Reference	Libtayo
Indicator	C5
	Antibody
Reference Sample	20,000
Drug Sample	25,000

Year	2029 E	2030 E	2031 E	2032 E	2033 E	2034 E	2035 E	2036 E	2037 E	2038 E
Revenue	3.22	42.15	60.31	70.64	82.70	90.77	95.39	100.12	104.38	107.97
Growth Rate (%)		1,209.46	43.07	17.14	17.07	9.75	5.09	4.97	4.25	3.44

## Important Disclaimer

Please read this document before reading this report. This report has been written by MBA students at Yale's School of Management in partial fulfilment of their course requirements. The report is a student and not a professional report. It is intended solely to serve as an example of student work at Yale's School of Management. It is not intended as investment advice. It is based on publicly available information and may not be complete analyses of all relevant data. If you use this report for any purpose, you do so at your own risk.

YALE UNIVERSITY, YALE SCHOOL OF MANAGEMENT, AND YALE UNIVERSITY'S OFFICERS, FELLOWS, FACULTY, STAFF, AND STUDENTS MAKE NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, ABOUT THE ACCURACY OR SUITABILITY FOR ANY USE OF THESE REPORTS, AND EXPRESSLY DISCLAIM RESPONSIBILITY FOR ANY LOSS OR DAMAGE, DIRECT OR INDIRECT, CAUSED BY USE OF OR RELIANCE ON THESE REPORTS.