

## **Exelixis Inc (NASDAQ: EXEL)**

Current Price: \$36.70 Target Price: \$48.61 Implied Upside: 29.27%

Proprietary Research | Subject to Further Review and Evaluation

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## **Overview**

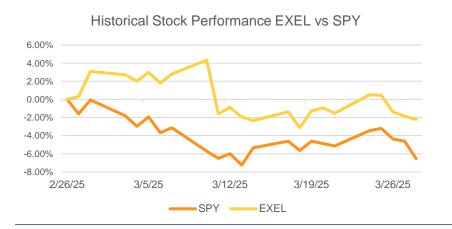
## **Exelixis Inc. Overview**

Clinical stage biopharmaceutical cancer therapeutics company

### **Business Description & Strategy**

Overview: Exelixis Inc. (NASDAQ: EXEL) is a clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing next-generation oncology treatments. Exelixis specializes in combination therapies involving kinase inhibitors and immune checkpoint inhibitors, significantly advancing treatment paradigms in multiple cancer indications. The company's strategic partnerships and pipeline are designed to establish new standards of care, particularly for difficult-to-treat cancers. The company currently has four promising Phase III clinical trials underway, combining its lead compounds, cabozantinib and zanzalintinib (XL092), with immune checkpoint inhibitors atezolizumab (Roche) and nivolumab (BMS), targeting multiple tumor types, including renal cell carcinoma (RCC), colorectal cancer (CRC), and other advanced malignancies.

#### **EXEL Performance vs Benchmark**



### **Current Market Data (Mar 28)**

Mkt Cap (billion)	\$10.31	EV (billion)	\$9.39
Price	\$17.85	2024 Fiscal Revenue	\$2.17B
52 Week High	\$40.02	EV/R&D	10.32x
52 Week Low	\$20.14	Div. Yield % (LTM)	0.00%
50 day moving avg	\$35.75	Beta	0.57
Float	235.9M	P/E (Trailing)	20.93

#### Moat

- Patent Portfolio: Extensive intellectual property around centered around its kinase inhibitors—cabozantinib (Cabometyx®) and the newer candidate zanzalintinib. These patents create substantial barriers to entry for competitors, providing Exelixis with a strong, legally protected position that secures revenue streams and market exclusivity well into the late 2030s
- Clinical Development Leadership: Advanced clinical-stage pipeline in combination therapies positions Exelixis ahead of peers in innovative oncology treatments
- Strategic Partnerships: Long-term collaborations with global pharma companies Roche and BMS provide substantial operational leverage and shared risk, significantly reducing R&D costs

## **Competitive Landscape**

Company Name	Ticker	Price	Market Cap (\$M)	P/E	EV (\$M)	EV/EBIDTA	Price/Book
Eli Lilly and Co	LLY	822.51	780,002.42	70.42	809,160.22	35.56	38.70
Bristol—Myers Squibb Co	ВМҮ	60.02	121,432.54	22.79	159,375.54	51.28	7.48
Pfizer Inc	PFE	25.21	142,977.25	28.33	255,382.18	13.07	2.82
Merck & Co Inc	MRK	89.23	225,398.55	167.86	267,636.46	18.93	6.43
Novartis AG	NOVN	98.62	298,300.00	18.92	205,200.00	10.76	4.39
Exelixis	EXEL	36.65	\$521,324.95	33.50	5,967.55	24.84	3.10

Average	61.66	339,350.90	25.92	11.96
Median	28.33	255,382.20	18.93	6.43

## **Standard of Care**

EXEL beats all industry standards, driven by their flagship product

#### **Prostate Cancer**

- Abiraterone + Prednisone: Shown to improve metastasis-free and overall survival in high-risk non-metastatic prostate cancer when combined with androgen deprivation therapy (ADT). However, toxicity and discontinuation rates are concerns.
- Enzalutamide: Demonstrated significant improvement in metastasis-free survival and secondary endpoints in high-risk biochemically recurrent prostate cancer.

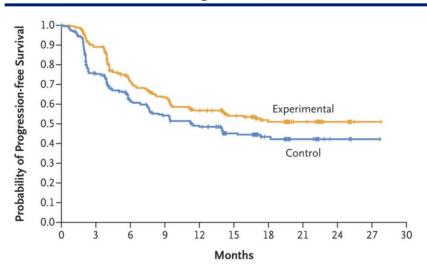
## **Renal Cell Carcinoma (RCC)**

- Nivolumab + Ipilimumab: Dual checkpoint inhibitors approved for first-line treatment of advanced RCC. They improve survival and progression-free survival compared to sunitinib.
- Cabozantinib: Often used as a monotherapy or in combinations for advanced RCC, including triplet regimens with nivolumab and ipilimumab

## **Cabozantinib Advantage**

- Cabozantinib + atezolizumab reduces risk of progression or death vs. hormonal therapies in mCRPC (CONTACT-02)
- Inhibits MET and VEGFR2, showing anti-tumor effects in prostate cancer and bone mets, improving PFS and pain
- Shows synergistic potential with immune checkpoint inhibitors like atezolizumab

## **Cabozantinib Advantage**



## **Standard of Care**

EXEL beats all industry standards, driven by their flagship product

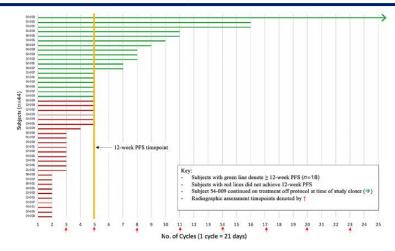
#### **Colorectal Cancer**

- First-line chemo: Fluoropyrimidines, oxaliplatin, and irinotecan (alone or in combos)
- Targeted therapies depend on RAS/BRAF status:
  - EGFR inhibitors: Cetuximab, panitumumab (only if RAS wild-type)
  - Anti-VEGF agents: Bevacizumab, ramucirumab, ziv-aflibercept

### Non-Clear Cell Renal Cell Carcinoma

- Targeted therapies (e.g., sunitinib, cabozantinib) show modest efficacy; cabozantinib had higher ORR (23%) vs. sunitinib (4%) in PAPMET
- VEGF + IO combos (e.g., cabozantinib + nivolumab, lenvatinib + pembrolizumab) show promising activity → emerging standard of care
- MET inhibitors (e.g., savolitinib) may work in MET-driven papillary RCC but require further validation

## **Cabozantinib Advantage**



## **Cabozantinib Advantage**

- Cabozantinib + nivolumab showed promising efficacy in most non-clear-cell RCC variants tested in this trial, particularly those with prominent papillary features
- Treatment effects were limited in chromophobe RCC



# **Catalysts**

## Catalyst 1a: FDA Approval of **Zanzalintinib** + Atezolizumab and Nivolumab

The application of Zanzalintinib as an adjunct treatment with ICIs is in a favorable position to gain FDA approval

## **Addressable Indications & Patient Populations**

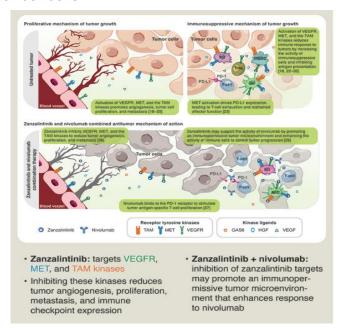
- Metastatic Colorectal Cancer (mCRC): mCRC is the third most common cancer globally and one of the leading causes of cancer death. There 50,000 new colorectal cancer cases in the U.S. annually; around 50,000 are metastatic. A large subset of patients progresses after initial therapy and lacks effective options—especially those without liver metastases, where zanzalintinib + atezolizumab has shown the strongest efficacy.
- Non-Clear Cell Renal Cell Carcinoma (nccRCC): Accounts for 15–20% of RCC cases, a historically underserved segment. STELLAR-304 is the first large Phase III trial tailored to nccRCC using a combination strategy (zanzalintinib + nivolumab). With few effective frontline options, Exelixis could position zanzalintinib as standard of care, and in theory capture significant first-line share

#### **Clinical Trial Statistics**

- The current median Progression Free Survival (PFS) rate of nccRCC is 3.3 months using Sunitinib, data from the STELLAR –001 Trial shows that Zanzalintinib in combination with nivolumab extends median PFS of nonmetastasized nccRCC to 8.8 months
- Zanzalintinib + ICI has shown strong efficacy in mCRC regardless of biomarker status (MSS vs MSI), and the FDA values treatments that benefit broader patient populations without needing complex diagnostics

### **Mechanism of Action**

- Mechanism: Zanzalintinib blocks VEGFR, MET, and TAM kinases—broad coverage compared to older TKIs. This makes it potentially more effective and synergistic with immune checkpoint inhibitors
  - Atezolizumab (anti–PD-L1) and Nivolumab (anti–PD-1) are immune checkpoint inhibitors (ICIs) that restore
    T-cell activity and allow the immune system to attack cancer cells



## Catalyst 1b: FDA Approval of Cabozantinib + Atezolizumab and Nivolumab

Street is drastically underestimating the success and approval conditions for new, innovative ADCs

## **Street Expectations**

- Too focused on the OS (overall survival) miss in clinical trials and underestimating the potential for conditional approval
- Sell-side analysts simply don't understand Street views OS as the gold standard for approvals, not PFS (progression-free survival)
- Pessimism still lingering off of worries that EXEL's pipeline is not compelling enough to offset cabozantinib's eventual decline (postpatent expiration in 2030)

## Trial results point to an FDA approval win

- Street hasn't considered the FDA's history of approving cancer therapies based on surrogate endpoints like PFS especially in cases where treatment options are limited
- Precedent proves: In March 2022, the FDA approved Pluvicto for the treatment of unque mCRPC patients who had undergone prior treatments -- based on demonstrated efficacy in a specific patient population with limited options

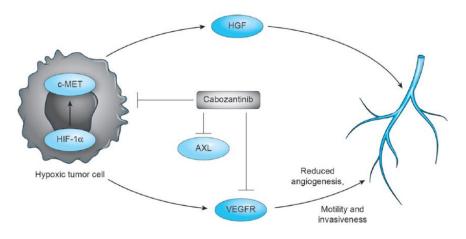
## Improvements in PFS compared to NHT

For Renal Cell Carcinoma (RCC):

The COSMIC-313 trial (Phase 3) showed that cabozantinib + ICIs widely improved PFS versus a standard checkpoint inhibitor + TKI regimen

For Prostate Cancer:

In the CONTACT-02 (Phase 3) trial, patients experienced a median PFS of 6.3 months, compared to 4.2 months for those treated with a second NHT



## Catalyst 1c: Brief Stock Analysis (2024 – 2025)

## **Street Reactions Mirror Clinical Trial Data** Results YTD for Zanzalintinib and Cabozantinib

- December 4, 2023. Event: Phase 2/3 trial launched for head and neck cancer. Stock Impact: Positive; showed pipeline breadth and tumor-type expansion.
- January 25, 2025. Event: Phase 1b/2 data showed meaningful PFS improvement in mCRC patients without liver metastases; Stock Impact: Shares dipped 6% intraday due to mixed readout across full population. Analysts noted cautious optimism.



- March 21, 2024. Event: U.S. District Court upheld critical patents protecting Cabometyx (cabozantinib) through 2031. Stock Impact: EXEL rose 14% as investors gained confidence in sustained revenue from its flagship drug
- November 18, 2024. Event: Exelixis provided an update at the Stifel Healthcare Conference on the submission of a supplemental NDA for Cabo in NETs. **Stock Impact:** Slight bump; regulatory momentum supported bullish sentiment on Cabo's durability.
- October 8, 2024. Event: Trial launched for cabozantinib in advanced neuroendocrine tumors (NETs). Stock Impact: Strong uptick; showed continued R&D investment and lifecycle expansion for Cabo.
- October 14, 2024. Event: Exelixis and Merck partnered to explore zanzalintinib + pembrolizumab for HNSCC and RCC. Stock **Impact:** Positive sentiment due to big pharma validation.

## Catalyst 2: Well Positioned To Capture Market After Patent Expirations

Street has not fully priced in EXEL's patent exclusivity amidst cliffs for industry competitors

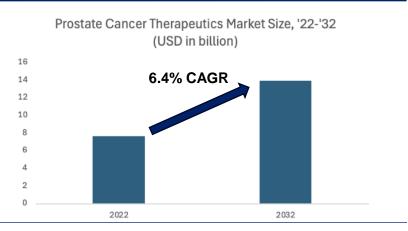
## Expiration of enzalutamide (2027) & abiraterone (2028)

- The primary composition of matter patent for enzalutamide in the United States is set to expire on August 13, 2027, and for abiraterone acetate, the patent is scheduled to expire on August 24, 2027. Still, an earlier version of abiraterone faced generic competition in 2018 due to a court ruling invalidating one of its patents, (though its official patent cliff was set for 2028) -- this early entry of generics caused a sharp drop in revenue for Johnson & Johnson
- **Enzalutamide and abiraterone are dominant first-line options** in metastatic prostate cancer. Their dominance has limited widespread adoption of newer agents like cabozantinib. Once enzalutamide & abiraterone go generic, clinicians may reconsider treatment sequencing and look to newer or more targeted second-line options, like cabozantinib, sooner
- Moreover, as more patients use generics earlier, the pool of patients progressing after AR-targeted therapy will grow, increasing the market size for cabozantinib

#### **Exelixis Patent Extension**

In October 2024, the U.S. District Court upheld the validity of three key patents related to cabozantinib—U.S. Patents No. 11.091.439 (crystalline salt), 11,091,440 (pharmaceutical compositions), and 11,098,015 (methods of treatment). These patents are set to expire on January 15, 2030, effectively preventing MSN Laboratories from introducing a generic version until that date

## **Future Dominance In Growing Market**



## Catalyst 3: EXEL is exempt from bearish sentiment on biotech sector

The healthcare/biotech space has suffered from over-pessimism and overreactions

## **Policy and Regulatory Uncertainties**

- The Inflation Reduction Act (IRA) of 2022 empowered Medicare to begin negotiating prices on certain high-cost drugs. Most significant impacts won't hit until 2026, investors have already priced in future revenue pressures for pharmaceutical companies. People fearing that government price controls will squeeze profit margins have made investors more cautious on pharma/biotech stocks
- Under the Biden Administration, the FTC challenged healthcare deals and created a less predictable environment for M&A activity in the biotech space. However, the new Trump administration is taking a more business-friendly FTC and encouraging healthcare M&As, which is good for the healthcare sector outlook

#### Market Pessimism Is Overdone For EXEL

- Policy risks like Medicare price negotiation will have limited impact on Exelixis' flagship drug, Cabometyx, as it is an oncology drug, which are exempt from Medicare price negotiations
- Another contributor of healthcare pessimism is RFK Jr.'s appointment as HHS secretary and how he is leading 10,000 job cuts and leads to concerns of how terminations will delay drug approval. However, Exelixis prostate cancer drug is in phase 3 clinical trial and the NDA approval rate is a high 56.3% for prostate cancer drugs

## **Election Impact on Healthcare Sector**



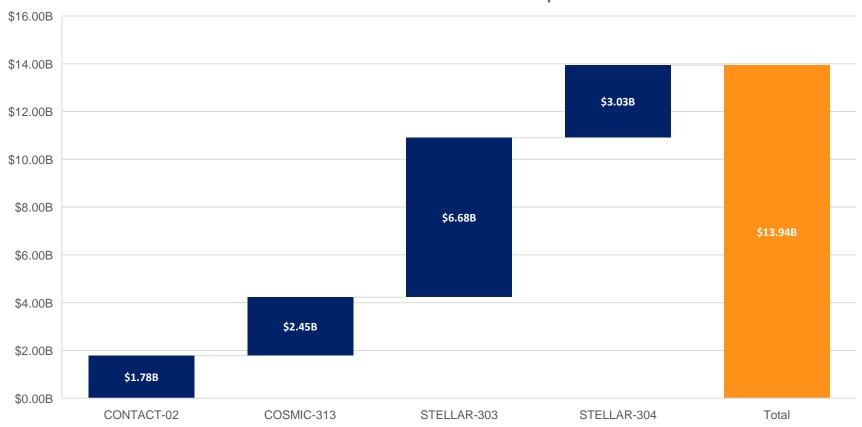


## **Model**

## **Market and Revenue Build**



#### **Estimated Peak Sales for EXEL Phase-3 Pipeline**



## **UFCF**

# Algory Capital

Year			2025	2026		2027		2028		2029
EBIT		\$	749,870,773.00	\$ 874,887,556.40	\$1	1,465,169,733.75	\$2	2,082,092,847.65	\$3	,117,563,515.07
Less: adjusted taxes		\$	134,976,739.14	\$ 157,479,760.15	\$	263,730,552.08	\$	374,776,712.58	\$	561,161,432.71
Less: capex*										
Plus: D&A*										
WC			:	\$ 2,025,271.89	\$	9,562,571.27	\$	9,994,154.45	\$	16,774,624.81
Less: increase in WC**			:	\$ 2,025,271.89	\$	7,537,299.38	\$	431,583.17	\$	6,780,470.37
Unlevered FCF		\$	614,894,033.86	\$ 715,382,524.36	\$1	1,193,901,882.30	\$:	1,706,884,551.90	\$2	,549,621,611.99
Years			1	2		3		4		5
Discount rate			11.80%	11.80%		11.80%		11.80%		11.80%
Discount factor			89.44%	80.00%		71.56%		64.00%		57.25%
PV of Risk-Adjusted Ca	ash Flows	\$	549,982,365.21	\$ 572,315,222.03	\$	854,307,250.70	\$:	1,092,441,244.75	\$1	,459,547,245.05
-	203	0	2031	2032		2033		2034		2035
	\$4,151,316,157.95	5	\$4,228,448,045.68	\$ 4,299,735,932.90	\$4	4,623,940,346.77	\$!	5,045,867,021.71	\$5	,560,713,987.70
	\$ 747,236,908.43	3	\$ 761,120,648.22	\$ 773,952,467.92	\$	832,309,262.42	\$	908,256,063.91	\$1	,000,928,517.79
	\$ 16,746,792.81	l	\$ 1,249,536.58	\$ 1,154,863.77	\$	5,252,111.50	\$	6,835,212.13	\$	8,340,520.85
	\$ (27,832.00	0)	\$ (15,497,256.23)	\$ (94,672.81)	\$	4,097,247.73	\$	1,583,100.63	\$	1,505,308.71
	\$3,404,107,081.52	2	\$3,482,824,653.69	\$ 3,525,878,137.79	\$3	3,787,533,836.62	\$4	4,136,027,857.18	\$4	,558,280,161.20
		6	7	8		9		10		11
	11.809	%	11.80%	11.80%		11.80%		11.80%		11.80%
	51.209	%	45.80%	40.96%		36.64%		32.77%		29.31%
	\$1,742,986,903.46	5	\$1,595,037,896.87	\$ 1,444,292,577.01	\$1	1,387,691,370.72	\$:	1,355,402,575.71	\$1	,336,085,807.85

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## **DCF**



WACC						
In \$M						
Shares Outstanding	281.70					
Equity	10558.12					
Debt	0					
Equity + Debt	10558.12					
% Equity	100%					
RFR	4.25%					
Market rate of return	17.50%					
Beta	0.57					
Cost of Equity	11.80%					
% Debt	0					
Interest expense	0					
Tax rate	18.00%					
Cost of Debt	0					
WACC	11.80%					

DCF						
In \$M						
Sum of CF	13390.09					
Terminal Value	0					
Present Value of TV	0					
EV	13390.09					
Net Cash	707.50					
Market Cap	14097.60					
Shares outstanding	290					
Implied Share Price	\$48.61					
% Upside	29.27%					

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## **Risks**

## **Risks and Mitigations**

The biotechnology sector presents unique challenges and risks, and Exelixis is no exception

#### Risks

## Mitigations

#### Risk 1: Regulatory and political uncertainty

RFK Jr.'s appointment as HHS Secretary may shift pharma regulations and vaccine policy, impacting drug approvals and market dynamics.



Exelixis manages regulatory risk through lobbying, policy engagement, and revenue diversification beyond the U.S.

#### Risk 2: Dependence on a single product

Exelixis's reliance on Cabometyx makes it vulnerable to revenue hits from competition, patent risks, or regulatory shifts.



• Exelixis is broadening its pipeline and partnerships to reduce reliance on Cabometyx, backed by a strong cash position in its balance sheet for strategic flexibility.

#### **Risk 3: Clinical Trial Challenges**

Exelixis's growth hinges on pipeline success, but trial setbacks—like the failed Phase 3 CONTACT-03 highlight risks to product diversification.



Exelixis mitigates trial risk with a diversified R&D strategy, pursuing multiple pathways to cushion against individual setbacks.



## **Risks and Mitigations Impact and Possibility**

