

# Zile's Revenue Diversification STRATEGY

RECOMMENDATION BY:  
**THE SENTINELS**



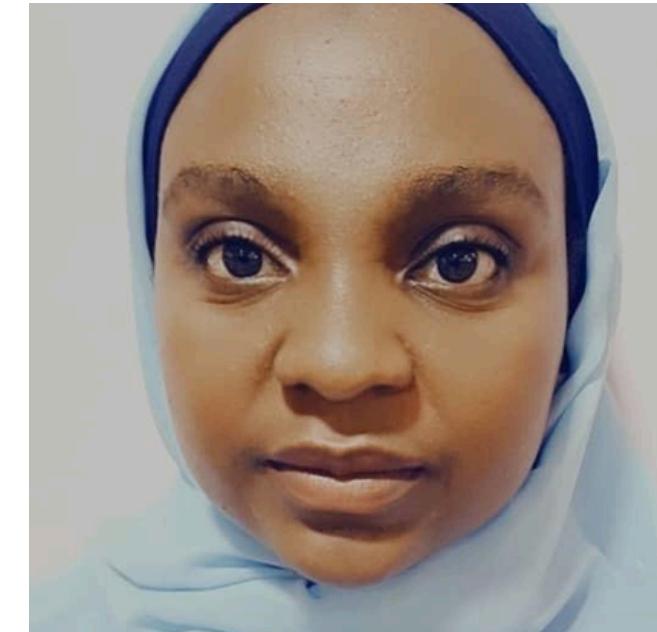
# Meet Our Team



**Ezinne Aso**  
MBA Candidate  
Market Access Expert



**Brad Presson**  
MBA Candidate



**Oluwakemi Balogun**  
MBA Candidate



**Samuel Onwubiko**  
Business Development  
Professional (MD, MPH, MBA)



# Outline



01

**Overview of Zile**

---

02

**Strategic Goals**

---

03

**Overall Portfolio Plan**

---

04

**Kendizo Strategy**

05

**Budget/ Financial Plan**

---

06

**Implementation Roadmap**

---

07

**Key Performance Indicators**

---

08

**Challenges & Mitigation**



# About Zile Pharmaceutical



- Zile Biosciences, based in Boston, is the 12th-largest biopharmaceutical company globally under the leadership of CEO Sloane Grant..
- Grossed \$29.11B in the US market in 2023.
- Established in 1984 with an initial focus on oncology.
- Expanded into immunology and metabolic diseases, though oncology remains the primary revenue driver, led by the blockbuster drug Kendizo.
- Launched its first FDA-approved drug, Loganar, for NSCLC in 1989.
- Strengths: Known for a dynamic corporate culture and strong talent acquisition. Prioritizes substantial investment in research and development (R&D).
- Core Values: Resilience, Innovation, Sustainability, and Collaboration (RISC).

# Our Vision

"To be a global leader in pharmaceutical innovation, providing trusted solutions that empower people to live healthier, longer lives. We envision a world where our breakthroughs in medicine make high-quality healthcare accessible to all."



# Our Mission

We are dedicated to advancing patient care, ensuring accessibility, and supporting healthcare providers in their commitment to transforming lives worldwide."

# Diversifying our brand portfolio

"We are committed to proactively investing in R&D to develop innovative medicines that empower our patients to live healthier, longer lives. Our goal is to be recognized as a company that champions access to groundbreaking therapies.

To sustain this innovation, we recognize the importance of profitability. Our revenue diversification strategy outlines key activities and investments we plan to pursue over the next decade to ensure continued growth and impact.



# Overall Roadmap

**Diversify Revenue Streams for Zile's**  
This is one of our top goals this strategy. With Kendizo accounting for 52% of our Revenue, we desire to expand and diversify our portfolio before LOE and ensure we make the best business case



**Ongoing Investment in Kendizo strategy-**  
Being a market leader, we would invest in efforts to ensure Kendizo remains useful. Including R&D for new indication



**Diversify investment in Immunology-** Expand Zile's Immunology portfolio via Acquisition of blockbuster molecules.



**Enter the Generic market** - To maintain our competitive edge for our blockbuster molecules, we would develop a strategy to enter into the generic market



**Accelerate Development of Metabolic Disease Assets**- Exceed expectations, retain existing clients for GLP- 1 and new indication for Glycadex for CKD (in Phase 4)



**Pricing Strategy** - To retain existing clients on Kendizo, we would enter pricing agreement with Providers for bundled price reduction

# The Importance of Our Diversification Plan

## Realizing Growth Potential

Exploiting opportunities in high-potential marker areas, like in the metabolic diseases space or biosimilars, will place Zile in a lucrative future position.



## Risk Management

Transitioning away from blockbuster drug revenue reliance. A diversification in revenue strategy will help mitigate financial risk.

## Competitive Advantage

The plan allows Zile to invest in opportunities that add value and develop the firm's pipelines. Thus, the strategic plan gives Zile a sustainable and resilient competitive advantage over competitors.

# Strategic Plan Framework by Therapeutic Areas

## Oncology

Problems we are solving or opportunity we are going after

- Treatment option expansion.
- Market leadership
- Cost containment.

Support we need to achieve this goal

- R&D funding for next-generation oncology therapies
- Biosimilar manufacturing
- New Kendizo indications

How will achieving this goal have a great impact?

- Establish resilient market share
- Reduce costs
- Meet more patient needs

Key Metrics. How will we know we have achieved this goal? How do we know if we are successful?

- Oncology drugs in Phase III clinical trial
- 2 biosimilar products by 2032

## Immunology

- Autoimmune disease treatment expansion.
- Blockbuster revenue dependence reduction.
- Strengthen market presence

- Increase R&D for autoimmune therapies.
- Funding for acquisition

- Diversifies revenue beyond oncology.
- Improves outcomes in autoimmune care.

- Increase market share in immunology market
- Immunology revenue at 20% by 2030.

## Metabolic Disease

- Address rising diabetes and obesity rates.
- Market potential capitalization.
- Address unmet needs for CKD

- Increase R&D for CKD clinical trial
- Funding for acquisition

- Taps into high-demand markets.
- Improves public health outcomes.

- 15% annual revenue growth.

# Kendizo Strategy



# Kendizo Strategy



Intensifying  
marketing efforts

- Increase brand awareness and customer loyalty to reduce switching and profit erosion
- Offer patients and payers discounts, coupons and rebates to enhance customer retention



Launching Authorized  
generic

- Launch generic version to capture a share of the market
- Cost savings due to economies of scale -Increased profit



Research and  
development for new  
indication

- New indications will increase therapeutic profile, drug reach and revenue generation
- Skinny labeling will help retain exclusivity on new indication

# Kendizo: Revenue risk assessment

Kendizo Current Price	\$175,000.00
Percentage deduction (Entry of 2 generics)	32.70%
Implied (New) Price	\$117,775

The looming patent expiry makes Zile vulnerable to a marked loss of revenue and a negative impact on its financial stability.

The two approved generics could mean a 32.7% drop in Kendizo's list price to \$117,775. Subsequent total revenue will be ~\$10.19m.

Revenue Implications of Generic Entry					
Payer	Patients served	Gross revenue (\$B)	Rebate %	Net revenue (\$B)	Implied Price
Private plans	67,300	7.93	10%	\$7.13	\$105,997.50
Medicare	32,448	3.82	20%	\$3.06	\$94,220.00
	99,748	\$11.75		\$10.19	

The execution of the Inflation reduction act (IRA) portends a further decrease in the price of Kendizo since it is enroled in Medicare Part D

Zile could lose ~\$50bn in revenue over the next 10 years i.e \$4.95bn annually if strategies are not put in place to prevent this loss

# Investment Strategy



**Given the fund allocation of \$4.5 Billion,  
we would utilize Zile's investment in this  
category:**

- Diversification
- R&D Growth Investing
- Asset Acquisition
- Intensified Marketing Strategy



# RESOURCE ALLOCATION – JUSTIFICATION

01

## Expand Oncology R&D

We would invest in new oncology indication for Kendizo even as we expand our Oncology portfolio

03

## Metabolic Disease - New Indication

Expanding on the success of Glycadex, we would invest in clinical trial success for the indication of CKD, this is a strategic move allowing us to tap into a new market and to meet new customer demands.

02

## Acquisition of Belvedere

Zile should invest in acquiring a new immunology drug - Belvedere. This is a strategic purchase to improving our market share and position in the market.

04

## Kendizo Generic Development Strategy

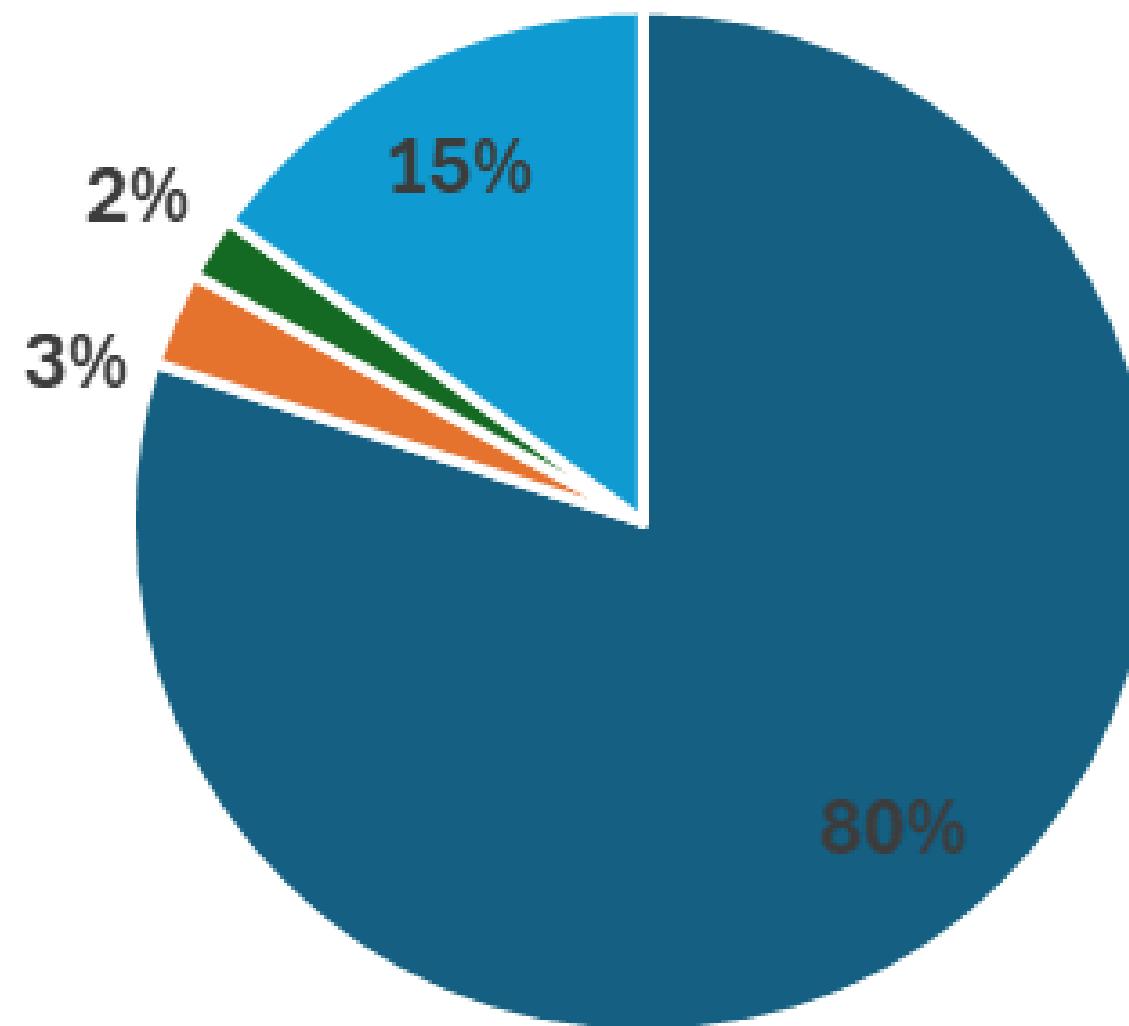
In anticipation of fluctuations and unpredictability in operations, such as possible changing demand or market conditions, requiring agility and responsiveness. We would invest in low cost alternative brand for indications,

05

## Marketing Effort

We would invest in continuous branding and marketing effort to position Zile's new portfolios and offerings

# Resource Allocation

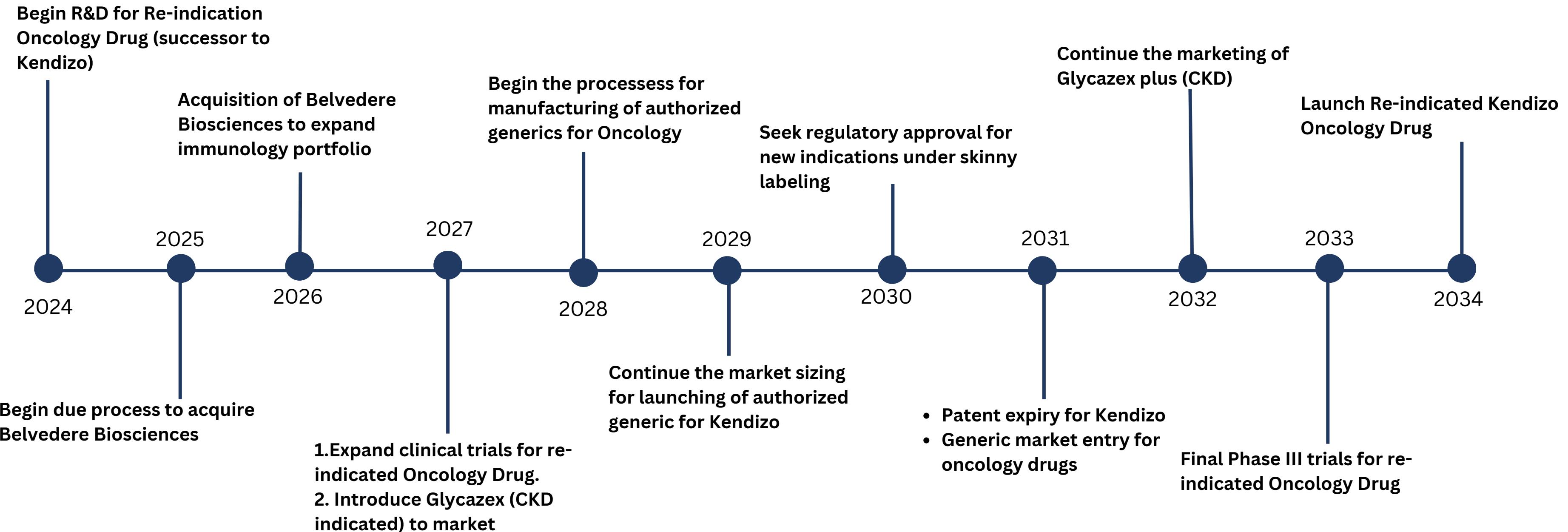


- Belvedere Biosciences Acquisition
- Generic Market Entry
- Metabolic Disease Drug Expansion
- Kendizo Skinny Labeling

# Resource Allocation: Detailed

Area of Fund Allocation	Amount (\$B)	Justification	Expected ROI and Metrics	Supporting Quotes/Exhibits
Acquisition in Immunology (e.g., Belvedere)	\$3.5	Acquiring Belvedere Biosciences to enhance the immunology portfolio, specifically targeting high-growth RA and SLE segments, which align with rising immunology demand.	ROI: 11.33% increase in immunology revenue over 8 years Metrics: Acquisition completion, integration by 2026	"Belvedere... targeting autoimmune diseases including a highly promising biologic"
Expansion in Metabolic Disease (GLP-1)	\$0.144	Fast-tracking the improved version of GLP-1 in Phase III with very high PTRS benchmark	ROI: 21288.9% revenue in metabolic disease over 10years Metrics: Market launch of GLP-1 product after 3 years	"GLP-1 agonists... market size of >\$125B in the country by 2033" Exhibit H: Revenue Strategies
Generic Market Entry	\$0.0076	Entry into generics for high-demand oncology drugs provides Zile access to cost-sensitive markets, counterbalancing revenue loss from Kendizo generics post-2031.	ROI: Capture 20% market share in target generics Metrics: Launch 1 generic by 2031	"Generics reduce... market share and force the originator's price down"
Expand Pipeline via Re-Indications and Skinny Labeling	\$0.680	Utilizing skinny labeling and re-indications for Kendizo will extend its exclusivity in new therapeutic areas, helping sustain revenue even as generics compete for original indications.	ROI: New indications contribute 444.12% of oncology revenue by 2031 Metrics: Two new indications approved by 2030	"Skinny labeling could prevent generics from fully competing in new indications" Exhibit F: Portfolio Review

# Implementation Plan (Timeline)





---

# Revenue Diversification

Business Case Analysis



# Revenue Diversification -Business Case

## STRATEGY 1: Acquisition of Belverdere

### Key Assumptions:

1. Acquisition Cost: \$3.5B
2. Revenue Growth: 12.98% CAGR over 8 years (Derived from 5 year Revenue for Immunology)
3. Operating Margin: 25% (industry average)
4. Cost of Capital: 8% (Industry average)
5. Integration Synergies: 5% cost savings

### Calculations:

Base Year Revenue: \$900M

Yearly Revenue (with 12.98% CAGR):

CAGR = Cumulative Annual Growth Rate

To forecast the revenue from year 1 to 8, using the formula  $R_0 \times (1+CAGR)^t$  where  $R_0$  = base revenue,  $t$  = time in years

Year	Forecasted Revenue (in Millions)
Year 1(2027)	1,016.82
Year 2 (2028)	1,148.67
Year 3 (2029)	1,300.05
Year 4(2030)	1,471.23
Year 5(2031)	1,664.79
Year 6(2032)	1,881.07
Year 7(2033)	2,120.74
Year 8(2034)	2,386.57
Cumulative	12989.94

Operating Income (25% margin): \$3,247.25M

Synergy Savings (5%): \$649.45M

Total 8-year Operating Income: \$3,896.7

Expected ROI:

$(\$3,896.7 - \$3,500M) / \$3,500M = 11.33\%$  over 8 years

# Revenue Diversification (1)

## *Acquisition of Belverdere:*

We recommend making this acquisition in 2026 for the following reasons:

- Kendizo patent expiration: With Kendizo losing exclusivity in 2031, acquiring Belvedere in 2026 gives Zile 5 years to integrate and grow the new products before Kendizo's revenue drop.
  - R&D pipeline maturation: Allowing 2-3 years for Belvedere's pipeline to mature further reduces risk and potentially increases the value of the acquisition.
  - Financial preparation: This timing gives Zile a couple of years to accumulate cash and prepare financially for the large acquisition.
- Market conditions: The case mentions increasing M&A activity in the biopharma space. Waiting until 2026 allows Zile to potentially get a better deal as market conditions evolve.
- Strategic alignment: This timing aligns with Zile's need to diversify its portfolio and reduce reliance on Kendizo before patent expiration.

# Revenue Diversification -Business Case

Strategy 2: Introduction of Authorized Generics for Oncology (Kendizo)

## Key Assumptions:

- R&D cost = Not go through R&D
- Requires: manufacturing costs, legal and regulatory compliance cost, Marketing and distribution costs, FDA User fees (average of 1.7% of development cost)
- Does not require new FDA approval
- Capitalized cost: \$7.06M
- Time: Main factors would be manufacturing adjustments, packaging changes and necessary regulatory notifications approximately 3 years
- Investment time: 2028
- Estimated Revenue: \$4.17B (see derivation below)
- 20% less than the adjusted Kendizo price  $= 117775 * (1-0.20) = 94,220$
- This generic will be divided among the Medicare and Private Plan patients this way

# Revenue Diversification -Business Case

Strategy 2: Introduction of Authorized Generics for Oncology (Kendizo)

Generic Price					
Payer	Patients served	Gross revenue (\$B)	Rebate %	Net revenue (\$B)	Implied Price
Private plans	67,300 /2 = 33650	\$3.17	10%	\$2.85	\$84,798.00
Medicare	32,448 /2 = 16224	\$1.53	20%	\$1.22	\$75376.00
	99,748/2 = 49874	\$4.70		\$4.17	

CAGR for Oncologyg = 2.83%

Estimated Revenues for Year 2032, 2033, 2034 done using the formula R0 x (1+CAGR) t

2031=\$4.17    2032 = \$4.29

2033=\$4.41

2034 = \$4.54

Total Revenue for the 4 years = \$17.41B

Operating Margin (25% margin): \$4.35B

Total 4-year Operating Income: \$4.35B

Expected ROI:

(\$4.35- \$7.06M) / \$3,500M = 61514.7% over 4 years

# Revenue Diversification -Business Case

## Strategy 3: Metabolic Disease Drug Expansion

### Key Assumptions:

- R&D cost (phase III) =  $142 + 2 = 144\text{M}$
- Time: 5.7- 6years
- Investment time: 2024
- Benchmark PTRS: Phase III to Approval: 81% to 98%  
(Low risk)
- Assuming CAGR for Immunology: 18.94%
- Estimated Revenue: Using the metabolic numbers, the growth rate multiplied by the base revenue (\$3.49B)
- Operating margin (25% margin): \$25.67B
- Total 10-year Operating Income: \$25.67B
- Expected ROI:
- $(\$30.8\text{B} - \$0.144\text{B}) / \$0.144\text{B} = 17677.78.9\%$  over 6-10 years

Year	Forecasted Revenue (USD in Billions )
Year 1	4.15
Year 2	4.94
Year 3	5.87
Year 4	6.99
Year 5	8.33
Year 6	9.91
Year 7	11.8
Year 8	14.05
Year 9	16.73
Year 10	19.9
Cumulative	102.67

# Revenue Diversification -Business Case

Strategy 4: . R&D for New Indication Kendizo (advanced melanoma and / or Kidney cancer)

## Key Assumptions:

- Assumptions:
- R&D cost = 680M
- Time: 7.5- 10years
- Investment time: 2024
- Launch time to Market: 2034
- Estimated Revenue: Same as Kendizo – \$15.14B
- Operating margin (25% margin): Apply to the revenue
- Operating Income: \$3.79B
- Expected ROI:
- $(\$3.79B - \$0.680M) / \$0.680M = 444.12\%$  in 2034

## Overall

- \$4.5 billion Allocation
- 1. M&A – \$3.5b
- 2. Metabolic Disease Drug Expansion – 144M = \$0.144B
- 3. Introduction of Authorized Generics for Oncology (Kendizo) = \$0.0076B
- 4. R&D for Extra Indication for Kendizo = \$0.680B

Total spent from \$4.5B = \$4.33B

Balance = \$0.17B



# Revenue Diversification -Business Case

Summary of Investment Allocations over the next 10 years

Zile Revenue Allocation - Summary (\$B)



1. M&A – \$3.5b
2. Metabolic Disease Drug Expansion – 144M = \$0.144B
3. Introduction of Authorized Generics for Oncology (Kendizo) = \$0.0076B
4. R&D for Extra Indication for Kendizo = \$0.680B

Total spent from  
\$4.5B = \$4.33B  
Balance = \$0.17B

# ➤➤➤ Challenges & Mitigation

## Challenges

### New Entrants:

- Risk of loss of market share with introduction of generics
- Innovation-driven production of more efficacious, cost competitive drugs by new entrants
- Acquisition of innovative new entrants by other firms could lead to steeper competition.

### Inflation Reduction Act:

This could impact Medicare pricing of Kendizo leading to even lower margins

### Multi-Assets Management:

Limited revenue potential of other medications in Zile's portfolio due to market saturation

## Mitigation

- Gain patients, physicians and payers trust to prevent switching.
- Develop robust R&D pipeline to launch follow-up drugs/ new therapies that diversify revenue.
- Acquire startups with complementary tech or meds

- Pricing strategies to maintain profits through Private payers

- A futuristic outlook towards digital medicine strategies that align with existing therapies

# Conclusion

In conclusion, we aimed to diversify revenue to reduce reliance on Kendizo. Our strategy focused on expanding into metabolic diseases, acquiring assets like Belvedere to increase market share in immunology, developing authorized oncology generics, and advancing Glycadex for CKD. We allocated \$4.33 billion to execute these initiatives, addressing patent expirations, generic competition, and regulatory risks to ensure sustained growth and reduced financial dependence on a single product.

## Next Steps

- Implement Immunology Expansion
- Advance Metabolic Disease Pipeline
- Develop Oncology Generics: authorized generics of Kendizo to maintain market share post-patent expiry.
- Focus on R&D for New Indications: Invest in developing advanced melanoma and kidney cancer indications
- Enhance Competitive Position: Strengthen pricing strategies, ensure physician and patient loyalty, and explore partnerships for digital medicine strategies.



# Appendix

# ACQUISITION PLAN – BELEVERE

Category	Value	Source
Proposed Acquisition year	2026	Justification provided below
Acquisition Cost	\$3.5B	Given in the case
Year 1 Revenue	\$900M	Given in the case
CAGR	12.98%	Derived CAGR from Zile's 5year Immunology revenue
8-year Cumulative Revenue	\$12989M	Calculated (See appendix)
Operating Income (25% margin)	\$3247.25M	Industry average of 25% from S&P global market intelligence, IBISWorld and Evaluate Pharma
Synergy Savings (5%)	\$649.45M	Industry average of 5% from S&P global market intelligence, IBISWorld and Evaluate Pharma
Total 8-year Operating Income	\$3,896.7M	
ROI (8 years)	11.33%	* = Operating income/Acquisition cost expressed in percentage

Year	Forecasted Revenue (in Millions)
Year 1(2027)	1,016.82
Year 2 (2028)	1,148.67
Year 3 (2029)	1,300.05
Year 4(2030)	1,471.23
Year 5(2031)	1,664.79
Year 6(2032)	1,881.07
Year 7(2033)	2,120.74
Year 8(2034)	2,386.57
Cumulative	12989.94

- Operating Income (25% margin): \$3,247.25M
- Synergy Savings (5%): \$649.45M
- Total 8-year Operating Income: \$3,896.7
- Expected ROI: (\$3,896.7- \$3,500M) / \$3,500M = **11.33% over 8 years**

