ImmuCell Corporation (ICCC)

Date: 09/24/2024 | Ticker: (ICCC) | Price: $3.60

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ImmuCell Corporation

Current Price:

$3.60

We believe ImmuCell is worth:

>$10.00

Company Overview

ImmuCell (ICCC) is an animal health company improving the health and productivity of dairy and beef cattle.

Business Segments

Scours *(100% Revenue)*

- Newborn calf scours (diarrhea) is the second largest economic impact for dairy and cattle farmers.
- ImmuCell's First Defense product helps to prevent scours in newborn calves.
- The only product on the calf-level market with claims against all three newborn calf scours causing pathogens: *E. coli*, coronavirus and rotavirus.

Mastitis

- Mastitis is the largest economic impact for dairy farmers and the most common disease for dairy cows.
- It is an infectious disease resulting in inflammation in the mammary gland (udder) of the cow.
- Re-Tain is a revolutionary treatment option for Mastitis without the use of traditional antibiotics.
- Re-Tain is currently in the final phase of the FDA approval process.

Company Overview

Founded: 1982

IPO: 1987

HQ: Portland, Maine

Insider Ownership: 6.6%

Capital Structure	
Stock Price	$3.60
S/O	7.83M
Market Cap	**$28M**
Cash	$1M
Debt	$12M
Enterprise Value	**$39M**

ImmuCell (ICCC) – Thesis Summary

ImmuCell is significantly undervalued with several upcoming fundamental catalysts that will lead to the stocks rerating:

1. **Obscured Financials**
   - Value of the profitable Scours business is obscured by losses from the Mastitis segment. 2024 is a defining turning point for the Mastitis segment.

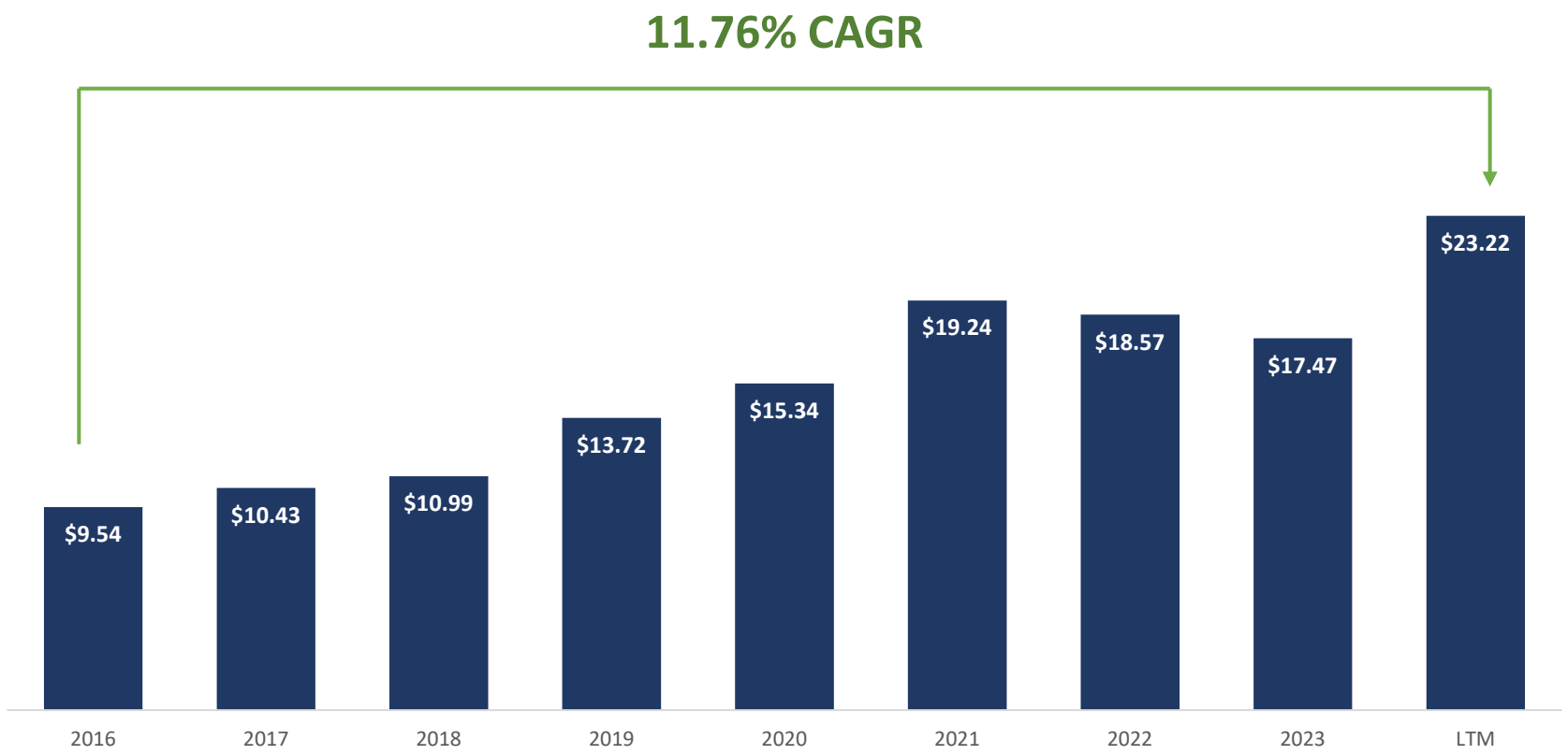
2. **Return to Growth**
   - Production/Supply disruptions in ’22/’23 led to a revenue and earnings decline. Recent quarters show production has normalized.

3. **Margin Improvement**
   - A price increase in the Scours segment combined with normalized production output will lead to improved margins in the second half of FY24.

Financial Performance

($ in millions)

Revenue

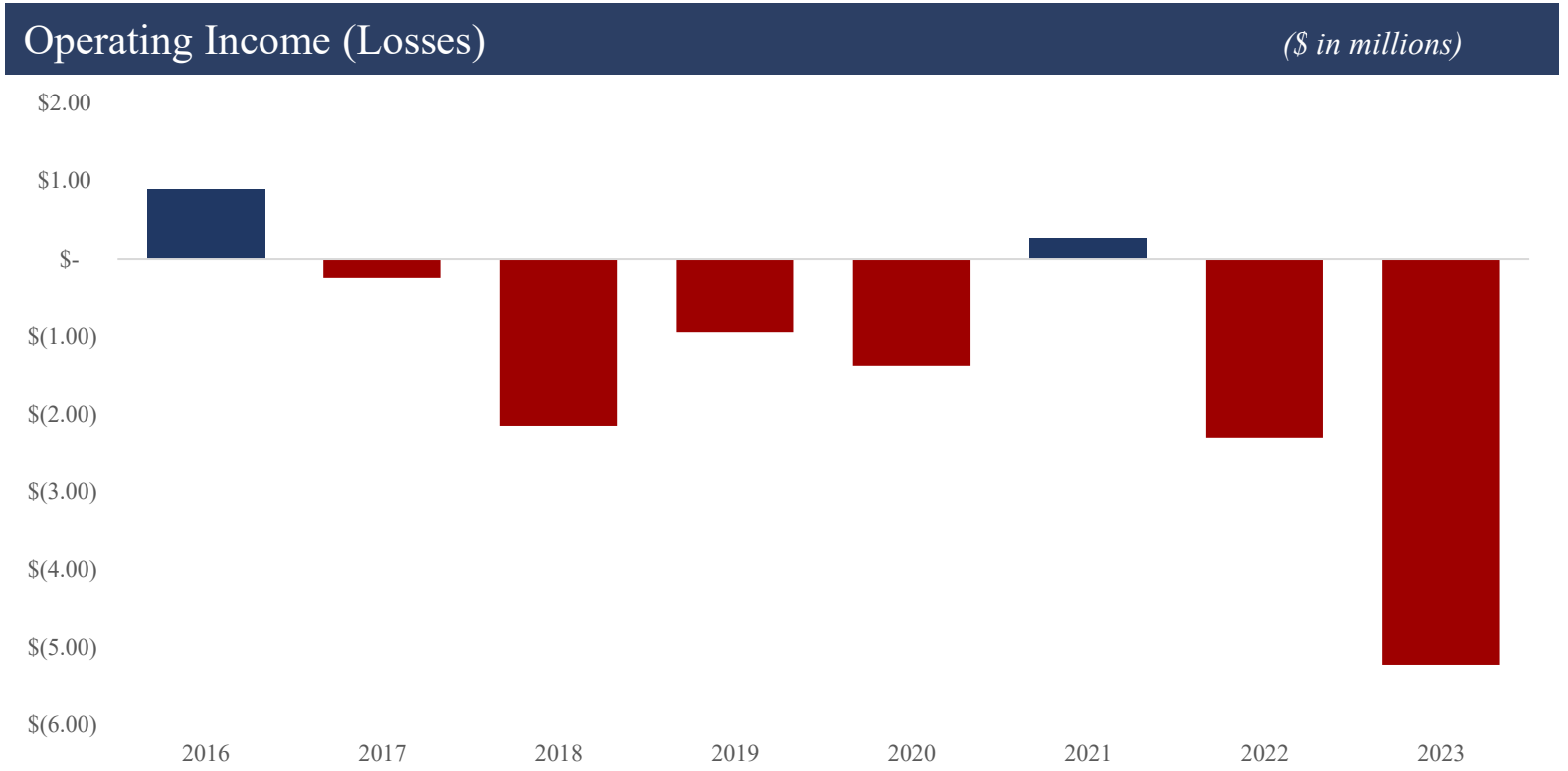


Stock Performance

Despite the growth in revenue, ImmuCell's stock has traded sideways for more than a decade.

Weak Historical Consolidated Operating Performance

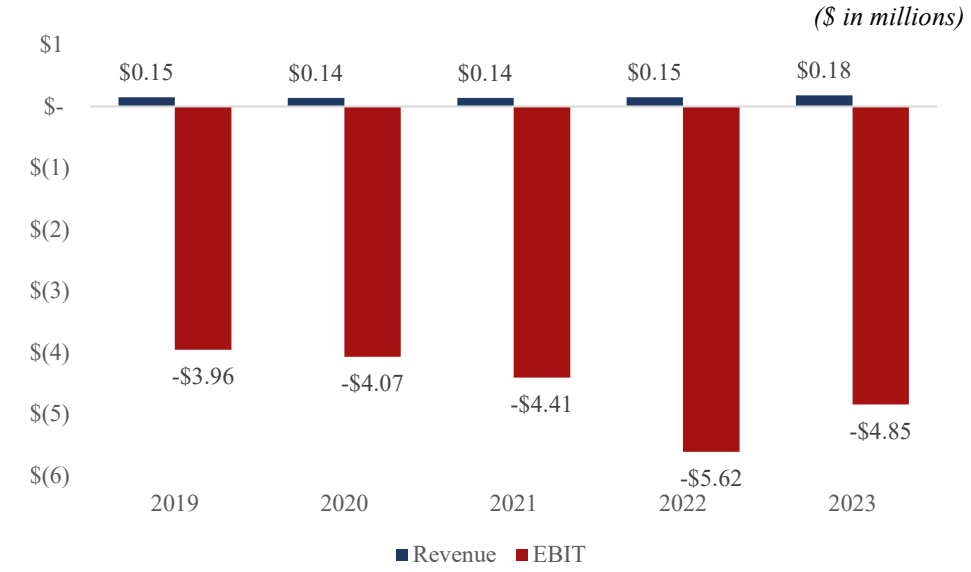
The primary reason for ImmuCell's long-term stock price underperformance has been due to consistent operating losses. From 2016 to 2023, ImmuCell's cumulative operating losses have amounted to -$11.09M.



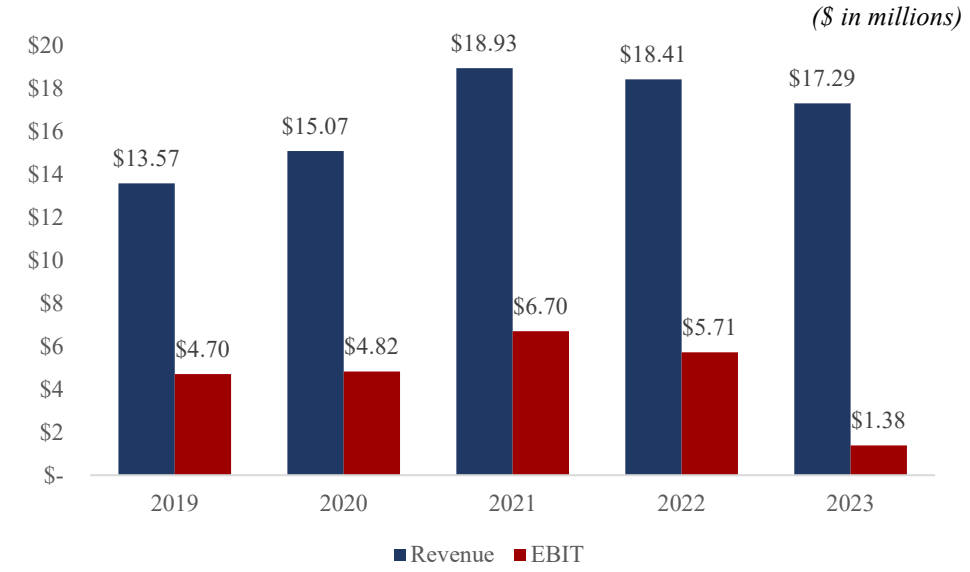
Segment Financial Performance

An analysis of the Company's two business segments, Mastitis and Scours, reveals that Mastitis has been the primary driver of the Company's poor operating performance.

Mastitis



Scours



Source: ImmuCell Form 10-K
1. Excludes corporate overhead.

Losses in the Mastitis Segment Will Not Persist Forever

We believe the market is significantly undervaluing ImmuCell. 2024 is likely a definitive turning point for losses within the Mastitis segment.

- FDA comments for the final section of approval for Re-Tain is expected by the end of FY25Q1.

- We believe there are two probable scenarios depending on the outcome of the FDA review, **both positive for the stock:**
  1. **<u>FDA approval is achieved.</u>** Re-Tain becomes a revenue generating product driving growth for ImmuCell.
     - Segment loss improves to $1-2 million until breakeven.

  2. **<u>FDA approval is NOT achieved.</u>** In this scenario, we believe ImmuCell will not continue to pursue FDA approval for Re-Tain.
     - This assumption is based on conversations with management and their realization of the opportunity the company has with the Scours business and the value that is being neglected by continued losses in the Mastitis segment from attempting to pursue this section of FDA approval for a potential fifth submission.

Scour Segment Return to Growth

ImmuCell is on track to produce record revenue in 2024. Previous contamination events have been rectified and production output is normalizing.

- Revenue declines in 2022 and 2023 were supply driven caused by several factors:
  1. Additional equipment to increase capacity was delayed.
  2. Equipment failure reduced output capacity.
  3. Three separate contamination events caused significant production declines.

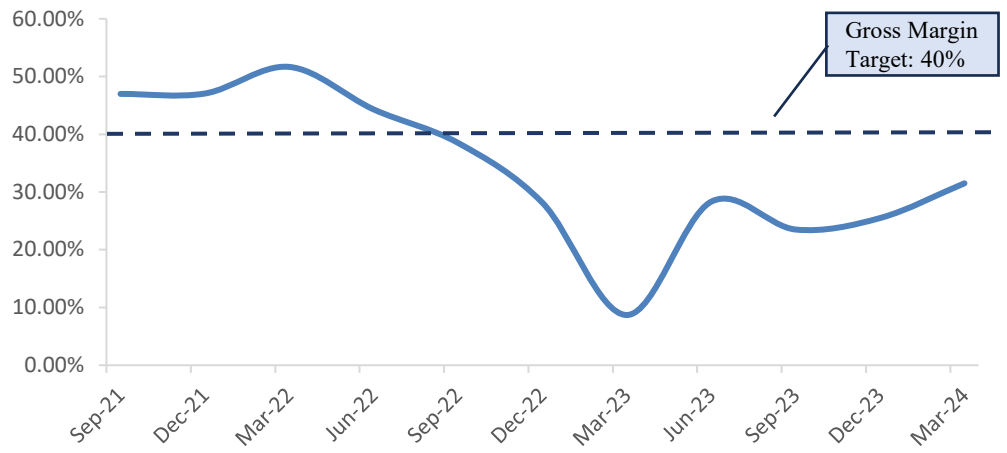
- All three of these issues have been resolved:
  - FY24H1 results show production output has steadily improved to 85% and guidance for the second half of the year is for output to reach 95% of capacity.
  - Revenue for the first six months of FY24 has increased 82% to $12.73M.

Source: Company filings.

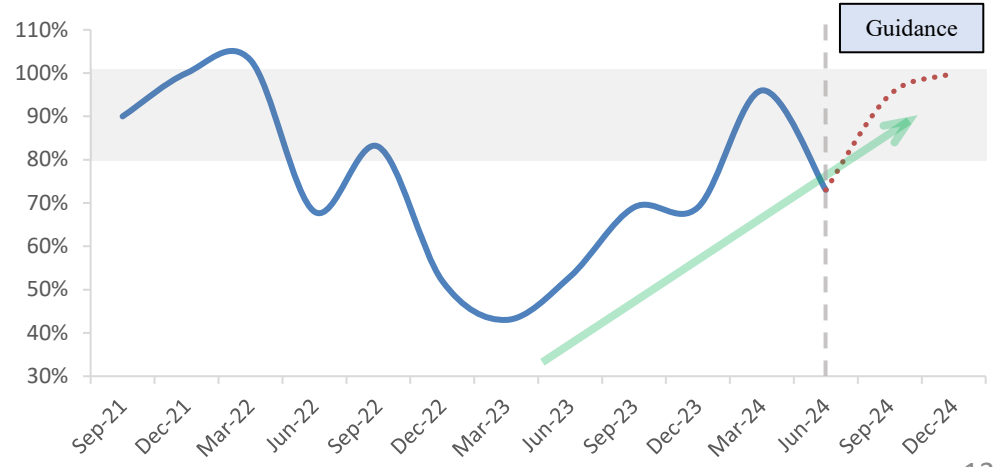
Margin Improvement

- Contamination events throughout the past year have caused production slowdowns and inefficient capacity utilization resulting in significant gross margin deterioration as fixed costs of the operation were spread over lower volumes.
- Gross Margins have not recovered yet due to the 6-month production cycle from raw milk to finished product that is required to produce First Defense. This creates a lag effect to margins as costs of goods sold (COGs) that flow through the quarterly income statement are a result of production conditions over the previous 6-months.
- First six months of FY24 capacity utilization averaged 85%. Management has guided to 95% capacity utilization for the remainder of the year. This increased capacity utilization will likely lead to a significant improvement to Gross Margins over the remainder of FY24.

Gross Margin



Capacity Utilization



Source: ImmuCell public filings, SRK Capital estimates.

Margin Improvement

Gross margins will improve to managements gross margin target of 40% by the end of FY24

- Target of 40% gross margins will be achieved through normalized production, increased capacity utilization, and manufacturing efficiencies.
- +8% price increase was implemented in 4Q23 for the First Defense product line.
- Additional margin improvement will be realized as the biological yield (higher antibodies) from new source cows increases over time.
  - As part of resolving contamination issues, the company has expanded the number of farms they source colostrum (milk) from. This involves the use of ImmuCell's proprietary vaccine to produce antibodies which are used in First Defense products. The initial use of the vaccine produces lower doses of antibodies per cow (lower yield); the yield tends to increase following subsequent doses. Higher yield allows for the use of less milk that needs to be processed to produce a dose of First Defense and higher gross margins.

Source: ImmuCell 10-K.

Scours

Bovine enteritis (calf scours), causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death.

- Leading pathogens causing scours:
  - Rotavirus
  - Coronavirus
  - *E. coli*

- Reasons to prevent scours:
  - Prevent death (lost profits).
  - Calves that contract scours are likely to be less productive cows (less milk and growth).
  - Calves that scour are more susceptible to other diseases later in life (increased costs to the farmer).

The cost of scours to the U.S. dairy and beef industries is approximately $741 million. *

* ImmuCell Investor Presentation

Scours | First Defense

- Original format approved in 1991.
- First Defense is an effective tool to prevent scours in newborn calves caused by Rotavirus, Coronavirus, and *E.coli*.
- Manufactured from hyperimmunized cows' colostrum (antibody rich milk that a cow produces immediately after giving birth) utilizing proprietary vaccine and milk protein purification technologies.
- Provides bovine antibodies that newborn calves need but are unable to produce on their own immediately after birth. First Defense is administered directly after birth to provide immediate immunity.
- Tri-Shield format introduced in 2017 adds protection against rotavirus. This additional claim has allowed ImmuCell to compete more effectively against vaccine competitors.

Scours | First Defense

First Defense is more effective at preventing scours than competitor vaccine products.

Historically, the most common tool to help combat scours has been to vaccinate the mother cow (dam) with a scours vaccine and deliver the antibodies that she produces in her milk to the newborn.

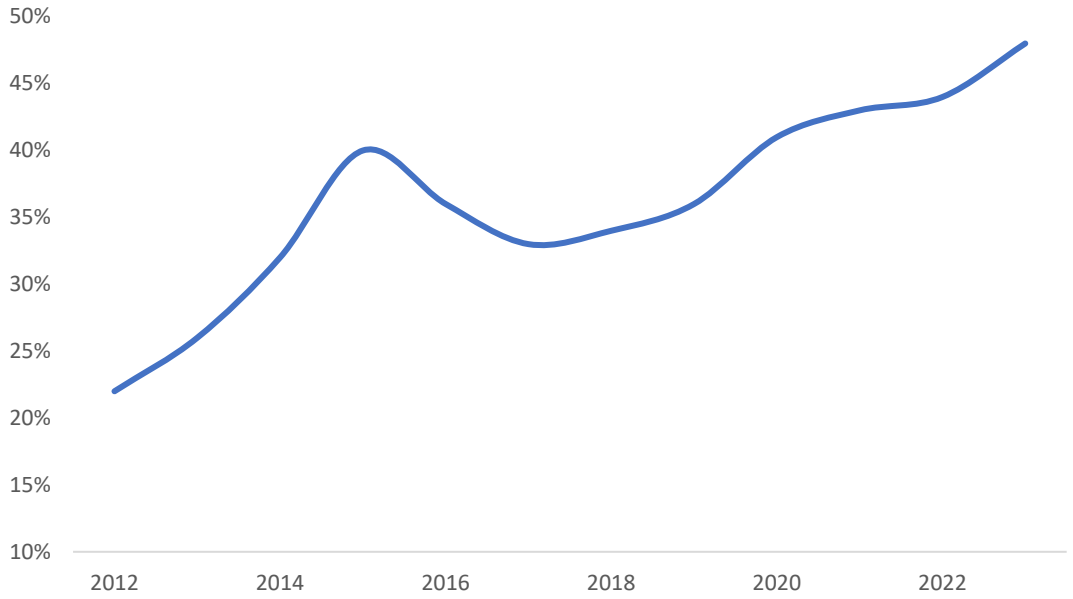
- ☒ Only 80% of animals respond to a vaccine. This leaves 20% of the calf crop unprotected when the scour prevention program relies on scour vaccines.
- ☑ First Defense removes the variability associated with a scour vaccine response and instead provides a direct measured level of pre-formed antibodies to the calf, protecting each with an equal level of scours protection.
- ☒ Reliance on a dam-level (mother cow) scours vaccine requires that money be spent before it is known whether the cow is carrying a viable, valued calf.
- ☑ With First Defense, that investment can be targeted to the calves that are most critical to the operation.

The unique ability of the First Defense to provide immediate immunity generates a dependable and competitive return on investment for dairy and beef producers.

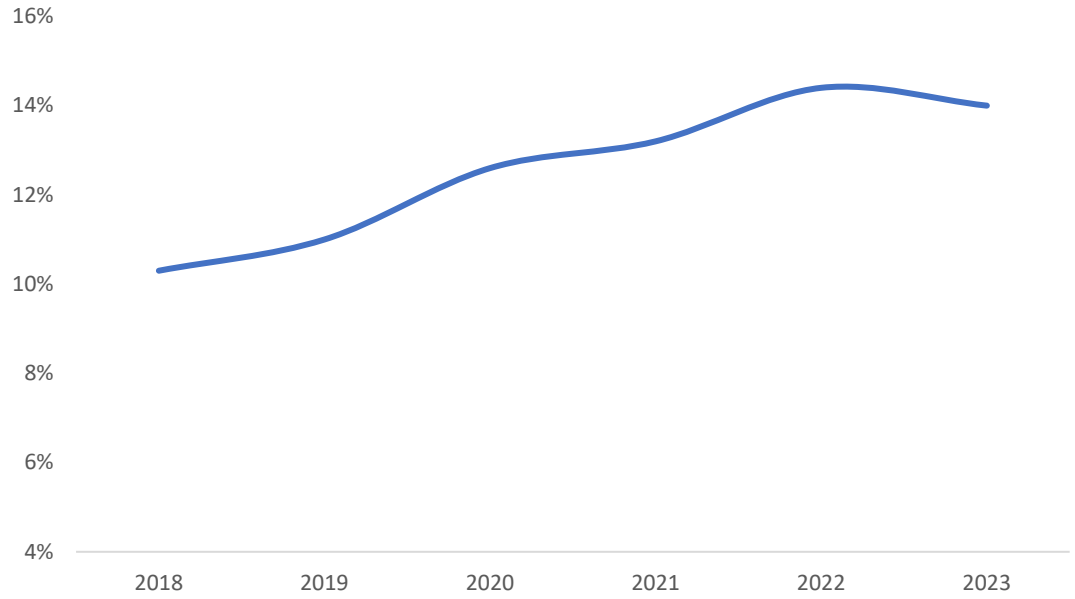
First Defense is Winning U.S. Market Share

The market is learning that the best preventative for scours may not be a vaccine, but a measured dose of pre-formed antibodies from First Defense.

Calf-Level Market Share



Total U.S. Market Share



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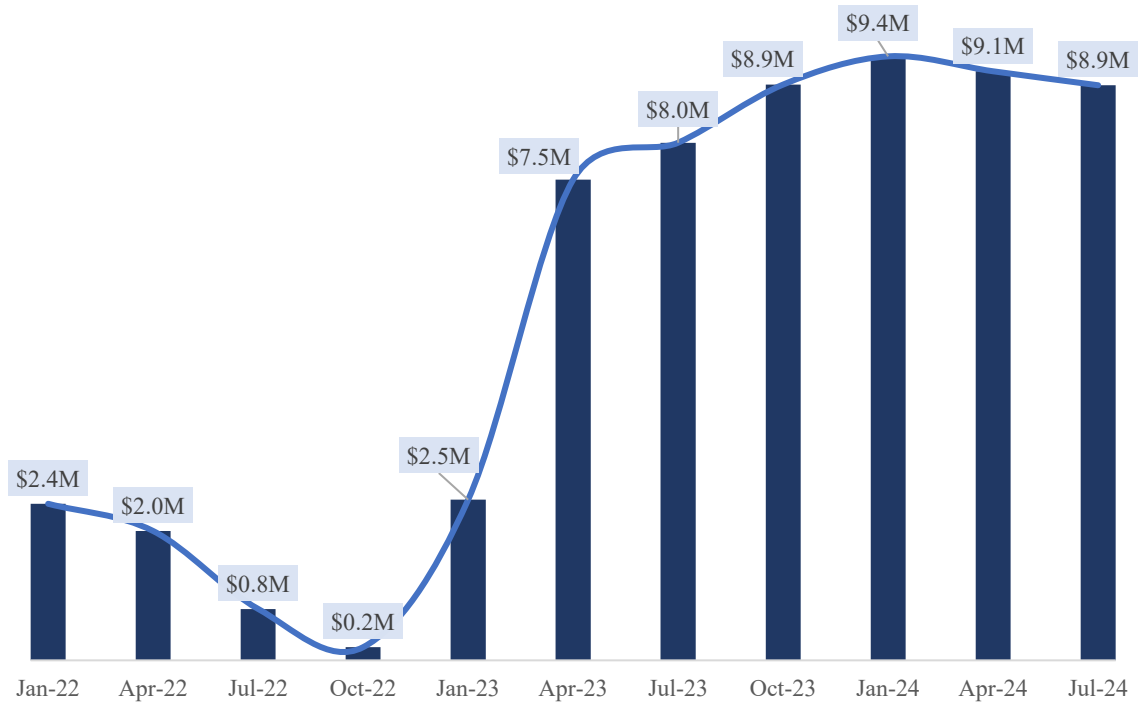
Source: ImmuCell 10-K.

First Defense

First Defense product <u>demand has not been permanently damaged</u> by production issues.

- During production issues, the company's approach was to take care of their largest customers first by shipping available product directly to them. This appears to have protected product demand.
- $8.9M backlog as of June 30, 2024. Prior to contamination issues, the company historically did not operate with a substantial backlog.
- Backlog has remained strong following an 8% price increase for First Defense products in November 2023.
- Backlog indicates customer demand and loyalty has been sustained; customers are coming back as supply ramps up.

Backlog



Source: ImmuCell public filings.

First Defense | Historical Financials

Pro-forma First Defense	2016	2017	2018	2019	2020	2021	2022	2023
Revenues	9.54	10.43	10.99	13.72	15.07	18.93	18.41	17.29
% Change YoY	-7%	9%	5%	25%	12%	25%	-4%	-6%
Cost of Goods Sold	4.12	5.21	5.79	6.98	8.29	10.41	10.75	13.45
% of Rev	43%	50%	53%	51%	55%	55%	58%	78%
Gross Profit	5.42	5.22	5.19	6.74	6.86	8.66	7.65	3.84
% Change YoY	-13%	-4%	-1%	30%	2%	26%	-12%	-50%
% Gross Margins	57%	50%	47%	49%	45%	45%	41%	22%
Sales and Marketing Expenses	1.94	1.94	1.94	1.94	1.94	1.94	1.87	2.45
Product Development Expenses	0.1	0.1	0.1	0.1	0.1	0.025	0.066	0.01
Total Operating Expenses	2.04	2.04	2.04	2.04	2.04	1.965	1.936	2.46
Operating Income	3.38	3.18	3.15	4.70	4.82	6.695	5.714	1.38
% Operating Margins	35%	30%	29%	34%	32%	35%	31%	7.98%
Plus: D&A	0.783	0.885	1.501	2.248	2.328	2.469	2.495	2.74
EBITDA	**4.163**	**4.065**	**4.651**	**6.948**	**7.148**	**9.164**	**8.209**	**4.12**
% EBITDA Margins	44%	39%	42%	51%	47%	48%	45%	24%

Mastitis

Mastitis is inflammation of a cow's mammary gland caused by infection. It's the most prevalent disease affecting cows, costing the U.S. dairy industry approximately $2 Billion in economic loss each year.

Mastitis can:

- Reduce milk production and quality. (Farmers are paid less for lower quality milk.)
- Shorten the shelf life of dairy products.
- Increase the risk of other health issues in cows, like reduced fertility and culling.

There are two main types of mastitis:

- **Subclinical Mastitis:** This form shows no visible signs in the milk, but milk quality is still compromised, and milk production can decrease. This is the most common form, often going undetected.
- **Clinical Mastitis:** This form presents with visible abnormalities in the milk, such as flakes, clots, or pus, and the cow might show signs of illness like fever or lethargy.

Treatment options:

- **Clinical Mastitis:** currently, the only available treatment is with the use of antibiotics. This requires the cow's milk to be dumped / meat withheld during this time until the antibiotics are clear from its system. (Lost profits)
- **Subclinical Mastitis:** currently, treatment involves forms of management practices. Due to the cows milk still being salable it is not considered economically feasible to treat with antibiotics, which require the milk to be discarded.

Mastitis | Re-Tain

Re-Tain is a potentially revolutionary product developed by ImmuCell specifically for treating subclinical mastitis in lactating cows that requires zero milk discard and meat withhold.

- **Antibiotic-free:** Unlike many conventional mastitis treatments, Re-Tain **doesn't contain antibiotics**. This reduces the risk of antibiotic resistance in the human food chain, a growing concern in animal agriculture. **No requirement for milk discard or meat withhold.**

- **Bacteriocin-based:** The active ingredient in Re-Tain is **nisin**, a naturally occurring **bacteriocin**. Bacteriocins are proteins produced by certain bacteria that have antimicrobial properties, meaning they can kill or inhibit the growth of other bacteria.

- **Targeted action:** Nisin specifically targets and disrupts the cell membranes of **gram-positive bacteria**, which are commonly associated with mastitis in cows.

Re-Tain offers an antibiotic-free and potentially more sustainable solution for treating subclinical mastitis in lactating cows, contributing to both animal health and responsible antibiotic use in the dairy industry.

Mastitis | Re-Tain

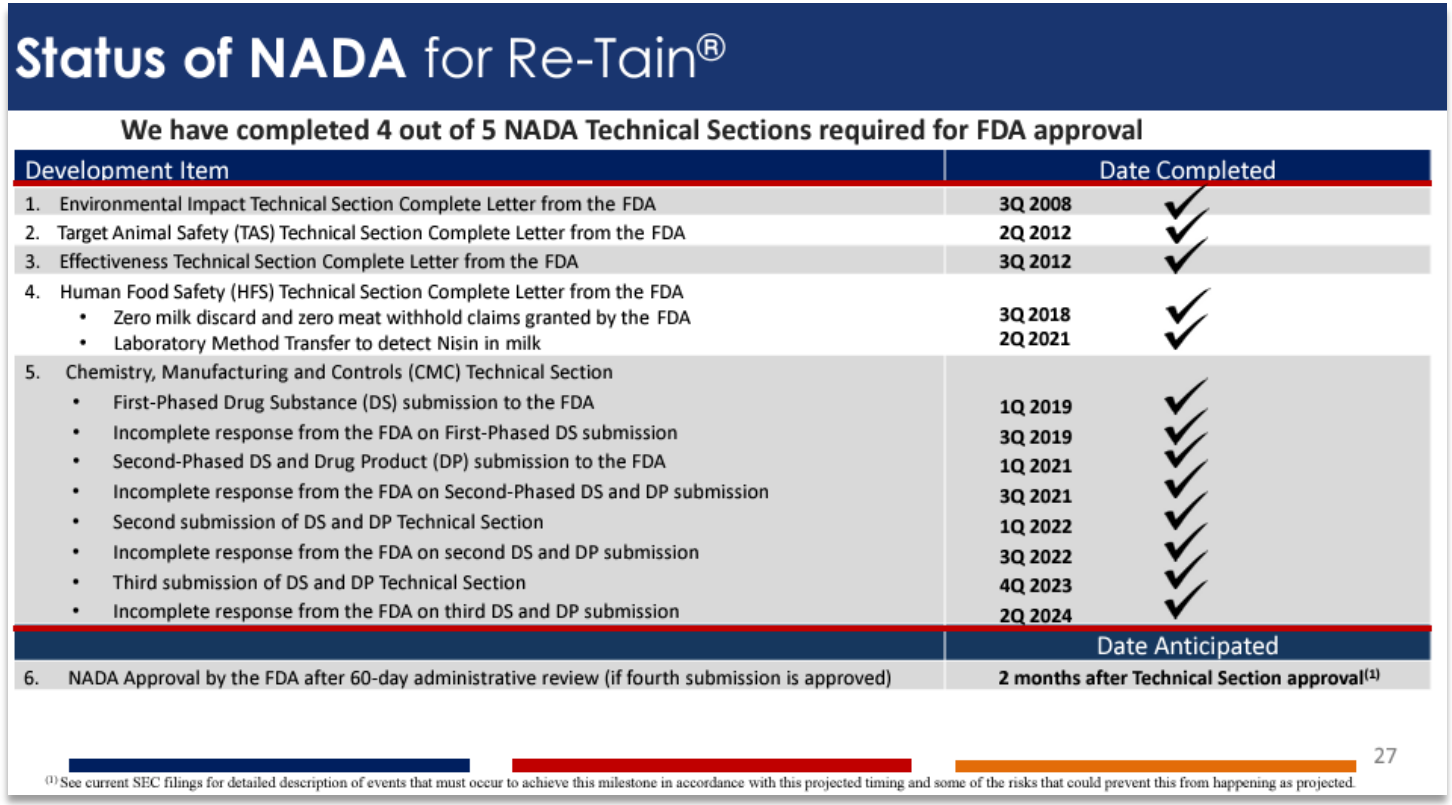
Completed construction of a Nisin production facility in 2018 for approximately $21M in anticipation of Re-Tain FDA approval.

- The facility has an initial annual production capacity sufficient to meet at least $10 million in sales of Re-Tain at current production yields.
- Most company product development expenses are due to operating and maintaining the facility until commercialization.
  - Upon FDA approval and commercialization of Re-Tain, these expenses will be recategorized as costs of good sold.
- Gross margin for Re-Tain is expected to be in line with managements 40% target.

Company owned 16,202 square foot Re-Tain production facility at 33 Caddie Lane in Portland, Maine.

Re-Tain will likely change the way Mastitis is treated and is a much larger addressable market than Scours. An eventual approval will create a path to a doubling of revenue for ImmuCell.

Re-Tain FDA Timeline



Status of NADA for Re-Tain®

We have completed 4 out of 5 NADA Technical Sections required for FDA approval

Development Item	Date Completed
1. Environmental Impact Technical Section Complete Letter from the FDA	3Q 2008 ✓
2. Target Animal Safety (TAS) Technical Section Complete Letter from the FDA	2Q 2012 ✓
3. Effectiveness Technical Section Complete Letter from the FDA	3Q 2012 ✓
4. Human Food Safety (HFS) Technical Section Complete Letter from the FDA	
• Zero milk discard and zero meat withhold claims granted by the FDA	3Q 2018 ✓
• Laboratory Method Transfer to detect Nisin in milk	2Q 2021 ✓
5. Chemistry, Manufacturing and Controls (CMC) Technical Section	
• First-Phased Drug Substance (DS) submission to the FDA	1Q 2019 ✓
• Incomplete response from the FDA on First-Phased DS submission	3Q 2019 ✓
• Second-Phased DS and Drug Product (DP) submission to the FDA	1Q 2021 ✓
• Incomplete response from the FDA on Second-Phased DS and DP submission	3Q 2021 ✓
• Second submission of DS and DP Technical Section	1Q 2022 ✓
• Incomplete response from the FDA on second DS and DP submission	3Q 2022 ✓
• Third submission of DS and DP Technical Section	4Q 2023 ✓
• Incomplete response from the FDA on third DS and DP submission	2Q 2024 ✓
	Date Anticipated
6. NADA Approval by the FDA after 60-day administrative review (if fourth submission is approved)	**2 months after Technical Section approval**(1)

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(1) See current SEC filings for detailed description of events that must occur to achieve this milestone in accordance with this projected timing and some of the risks that could prevent this from happening as projected.

*ImmuCell Company Presentation

- Final phase towards FDA approval. This is now the fourth submission of this section.
- Per management comments:
  - First submission was a trial run with zero expectation of approval.
  - Second submission resulted in additional questions from the FDA.
  - Management states the FDA had only minor questions following the third submission and expect an abbreviated review period of less than the typical 180 days for the fourth submission.
- Response from the FDA expected by the end of FY25Q1.

Base Case Estimate

2025E	Bear	Base	Bull
Revenue *($ in millions)*	22.00	27.50	32.40
EBITDA	2.36	6.95	9.27
Multiple	10x	12x	12x
Price Target	3.01	10.65	14.20
Current Price	3.60	3.60	3.60
% upside	-16.35%	195.79%	294.55%

Base case: Assumes 10% growth from $25M of Revenue in FY24. Gross Margin increases to 40%. Re-Tain is not approved, and the company discontinues pursuing approval. Operating expenses reduce to $6.75M as the company focuses exclusively on the Scours segment.

Bull case: Assumes 12% growth from $27M of Revenue in FY24 plus $2.7M of Revenue from the Mastitis segment following Re-Tain FDA approval. Operating expenses total $6.39M.

Bear case: Assumes no growth from $22M of Revenue in FY24. Re-Tain FDA approval is not achieved, and the company continues to pursue approval with historical operating expenses and no revenue from the Mastitis segment. Total operating expenses are $8.04M.

*Federal net operating losses (NOLs) of $17.8M available to offset future income taxes.

Base Case Model

	2021	2022	2023	2024E	2025E	2026E
Revenues	19.24	18.57	17.47	25.00	27.50	29.43
% Change YoY	25%	-3%	-6%	43%	10%	7%
Cost of Goods Sold	10.59	10.91	12.68	16.25	16.50	17.66
% of Rev	55%	59%	73%	65%	60%	60%
Gross Profit	8.66	7.65	3.87	8.75	11.00	11.77
% Change YoY	26%	-12%				
% Gross Margins	45%	41%	22%	35%	40%	40%
Sales and Marketing Expenses	2.5	3.19	3.07	3.20	3.36	3.53
Product Development Expenses	4.17	4.5	4.4	3.50	1.00	0.50
Administrative Expenses	1.73	2.26	2.15	2.30	2.39	2.49
Total Operating Expenses	8.4	9.95	9.62	9.00	6.75	6.52
Operating Income	0.26	-2.30	-5.75	-0.25	4.25	5.25
% Operating Margins	1%	-12%	-33%	-1%	15%	18%
Plus: D&A	2.469	2.495	2.74	2.7	2.7	2.7
EBITDA	**2.729**	**0.195**	**-3.01**	**2.45**	**6.95**	**7.95**
% EBITDA Margins	14%	1%	-17%	10%	25%	27%

Assumptions:

- Revenue grows 43% in FY24 as production issues have been rectified. $25M represents 83% of First Defense production capacity. FY25 revenue growth reverts to more historical growth of 10% and then levels off to 7% in FY26.
- Expect Gross Margins to reach target of 40% in FY24Q4 from increased capacity utilization and biological yield.
- FY24 operating expenses are lower due to cost cuts combined with lower product development expenses for Re-Tain. FY25 and FY26 assume Re-Tain is not approved and operating expenses are reduced as approval is no longer pursued.

Valuation Matrix

	FY-2025E EBITDA					
	$2	$4	$6	$8	$10	$12
8.00	16	32	48	64	80	96
10.00	20	40	60	80	100	120
12.00	24	48	72	96	120	144
13.00	26	52	78	104	130	156
14.00	28	56	84	112	140	168

	FY-2025E EBITDA					
	$2	$4	$6	$8	$10	$12
8.00	-58%	-16%	26%	68%	111%	153%
10.00	-47%	5%	58%	111%	163%	216%
12.00	-37%	26%	89%	153%	216%	279%
13.00	-32%	37%	105%	174%	242%	311%
14.00	-26%	47%	121%	195%	268%	342%

Why Does the Opportunity Exist

- Nanocap (<$50M Market Cap).
- Obscured earnings.
- No analyst coverage.
- No known research / writeups (Twitter “X”, VIC, etc.).
- Long term shareholder fatigue due to operational issues and Re-Tain FDA approval delays.

Risks

- Additional contamination events.
  - *This risk will always exist with the production of a biological process. The company determined their supply farms as the source of the contamination. This was likely caused by insufficient labor on farms following the pandemic combined with increased demand which led to diminished quality control. The company believes they have mitigated this risk from reoccurring (large scale contamination) by increasing the number of farms that supply colostrum and implementing new quality control procedures. Additionally, manufacturing at less than full capacity to allow for preventative maintenance and thorough cleaning will further mitigate contaminations.*

- Expected margin improvement never materializes.
  - *We see this as unlikely given that margin deterioration was caused by contamination events resulting in inefficient capacity utilization. With large contamination issues rectified and capacity utilization normalizing we expect margins to follow. See slide 33 for the Bear Case model.*

- Re-Tain is not approved, and the company continues to pursue FDA approval (higher operating expenses).
  - *There is a genuine risk the company will continue to pursue approval following a non-approval from the FDA. We believe the company is more likely than not to move forward without the opportunity of Re-Tain following a fourth non-approval due to the growth and profitability of First Defense. This assumption is based on our own beliefs following conversations with the company and their recognition of the company's value creation opportunity they have with First Defense.*

Conclusions

First Defense is a more effective product at preventing scours with durable competitive advantages that is taking market share from vaccine competitors.

Production issues of First Defense have been resolved. FY24 six-month results indicate record revenue of $12.73M with a strong backlog pointing to continued growth.

FDA comments for Re-Tain are expected by FY25Q1. Irrespective the outcome, we believe this will serve as a catalyst for lower operating expenses and less obscured financials moving forward.

ImmuCell (ICCC) is a compelling asymmetric opportunity that offers 100-200% returns over the next 6-12 months based on conservative assumptions.

Appendix

Shelf Registration / At The Market Offering

- In early April, ImmuCell filed a shelf offering for up to $20M including an $11M At The Market Offering (ATM).

- Poor timing and communication have resulted in the offering overshadowing positive Q1 results.

- We believe the company was influenced by their bankers to file an offering for $20M.
  - Our conversations with management following the filing indicates the company does not need capital as a going concern.
  - Their plan is to potentially raise $1-$3M to further increase annual First Defense production capacity from approximately $30 million to $40 million.
  - Considering the demand and market share growth opportunity of First Defense, the investment to increase capacity will likely lead to an increase of $4.5M of operating income for the Scours segment of the business.
  - Accounting for dilution, this has the potential to increase earnings per share an additional +37% more rapidly than if internally funded from cash flows.

- We believe the potential dilution is worth the increase in earnings it will provide.

Bear Case Model

	2021	2022	2023	2024E	2025E	2026E
Revenues	19.24	18.57	17.47	22.00	22.00	22.44
% Change YoY	25%	-3%	-6%	26%	0%	2%
Cost of Goods Sold	10.59	10.91	12.68	14.74	14.30	13.46
% of Rev	55%	59%	73%	67%	65%	60%
Gross Profit	8.66	7.65	3.87	7.26	7.70	8.98
% Change YoY	26%	-12%				
% Gross Margins	45%	41%	22%	33%	35%	40%
Sales and Marketing Expenses	2.5	3.19	3.07	3.15	3.15	3.15
Product Development Expenses	4.17	4.5	4.4	4.40	2.50	2.50
Administrative Expenses	1.73	2.26	2.15	2.30	2.39	2.49
Total Operating Expenses	8.4	9.95	9.62	9.85	8.04	8.14
Operating Income	0.26	-2.30	-5.75	-2.59	-0.34	0.84
% Operating Margins	1%	-12%	-33%	-12%	-2%	4%
Plus: D&A	2.469	2.495	2.74	2.7	2.7	2.7
EBITDA	**2.729**	**0.195**	**-3.01**	**0.11**	**2.36**	**3.54**
% EBITDA Margins	14%	1%	-17%	0%	11%	16%

Assumptions:

- Revenue growth of 26% in FY24, a slower growth rate than the base case. FY25 revenue assumes no growth.
- Gross margins fail to reach managements target of 40% until FY26.
- Operating expenses remain high as Re-Tain is not approved and the company continues to pursue approval.

Bull Case Model

	2021	2022	2023	2024E	2025E	2026E
Revenues	19.24	18.57	17.47	27.00	32.40	37.26
% Change YoY	25%	-3%	-6%	55%	20%	15%
Cost of Goods Sold	10.59	10.91	12.68	17.55	19.44	20.49
% of Rev	55%	59%	73%	65%	60%	55%
Gross Profit	8.66	7.65	3.87	9.45	12.96	16.77
% Change YoY	26%	-12%				
% Gross Margins	45%	41%	22%	35%	40%	45%
Sales and Marketing Expenses	2.5	3.19	3.07	3.20	3.50	3.75
Product Development Expenses	4.17	4.5	4.4	3.50	0.50	0.50
Administrative Expenses	1.73	2.26	2.15	2.30	2.39	2.49
Total Operating Expenses	8.4	9.95	9.62	9.00	6.39	6.74
Operating Income	0.26	-2.30	-5.75	0.45	6.57	10.03
% Operating Margins	1%	-12%	-33%	2%	20%	27%
Plus: D&A	2.469	2.495	2.74	2.7	2.7	2.7
EBITDA	**2.729**	**0.195**	**-3.01**	**3.15**	**9.27**	**12.73**
% EBITDA Margins	14%	1%	-17%	12%	29%	34%

Assumptions:

- Revenue grows 55% in FY24 as production issues have been rectified and product demand returns. $27M represents 90% of First Defense production capacity. FY25 First Defense revenue growth reverts to more historical growth of 10% and then levels off to 7% in FY26. $2.7M and $5.5M of Re-Tain revenue in FY25 and FY26, respectively.
- Gross margins exceed management target in FY26 from increased efficiencies along with the addition of Re-Tain revenue.
- FY25 operating expenses are lower than base case due to Re-Tain product development expenses being reclassified as COGs.
- Re-Tain sales increase operating income and EBITDA in FY25 and FY26.