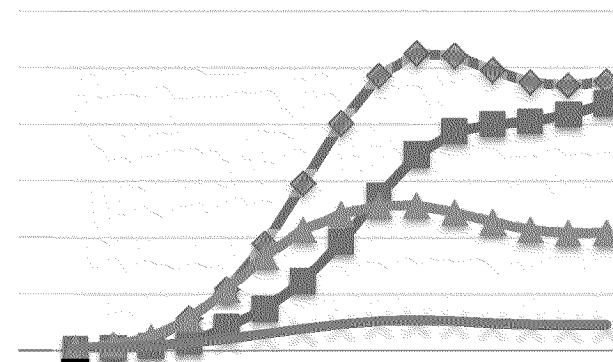


# WW NPV Summary

Scenario	US Peak Net Sales (\$M)	EU Peak Sales (€)	Acquire	Value of Purdue Stock ownership	Purdue Total NPV (\$M)	ROI
1. Blue	640	200	Yes	564	260	60%
2. Red	491	200	Yes	347	43	10%
3. Green	324	200	No	30	83	111%
4. Purple	65	200	No	(2)	(62)	n/a
Total Risk Adjusted					109	54%

## Conclusions:

- The risk adjusted NPV is \$109M
- The NPV is profitable in all scenarios except for trial failure, which is a break even scenario
- Financial risk is mitigated through
  - Acquisition at Purdue's discretion once trial data has been received
  - Stock ownership
  - Retention of ex-US / Canadian rights.



Blue: New code in 2018; Compelling Data; Higher Tip Pricing  
Green: Positive Data; Current 64640 code

Red: Compelling Data; Delayed new code in 2019; Higher Tip Pricing  
Purple: Clinical study failed; cash pay; Higher Tip Pricing



# Myoscience P&L – Peak Sales of \$640M Scenario (Blue Line)

Launch: 2015-Q1

Gross Sales Peak: \$640MM (2025)

LOE: 2029-Q4

Net Sales Peak: \$572MM (2025)

Scenario #1: Compelling comparative data; Higher Tip Price

Scenario:	aA1				Myoscience										US\$MMs				
US\$MMs	Base Year																		
Myoscience (US Only)	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj					
Proforma P&L	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027					
Gross sales	\$ 8.8	\$ 18.8	\$ 34.7	\$ 95.1	\$ 158.4	\$ 247.5	\$ 356.8	\$ 469.3	\$ 568.7	\$ 627.9	\$ 639.6	\$ 621.4	\$ 610.6						
Net sales	-	8.5	17.5	32.1	85.9	141.6	221.3	318.9	419.5	508.1	561.3	571.7	557.2	545.8					
Costs of goods sold (@13.3%)	-	3.6	6.4	12.0	20.8	24.6	32.7	45.1	59.9	72.6	80.2	81.8	79.8	78.2					
Shipping and warehousing (@3.0%)	-	0.3	0.6	1.0	2.9	4.8	7.4	10.7	14.1	17.1	18.8	19.2	18.7	18.3					
Costs of sales (incl. royalties, shipping)	-	3.9	6.9	13.0	23.6	29.3	40.2	55.8	74.0	89.6	99.1	101.0	98.5	96.5					
Gross margin	-	4.6	10.6	19.1	62.3	112.2	181.1	263.1	345.5	418.5	462.2	470.8	458.7	449.3					
Gross margin as % of net sales		54%	61%	60%	72%	79%	82%	83%	82%	82%	82%	82%	82%	82%					
Operating expenses																			
Selling and promotion	5.0	8.1	11.2	15.6	24.5	38.3	55.6	76.1	96.0	112.4	121.5	124.1	124.7	125.7					
Marketing spend	5.0	5.0	5.2	5.4	7.9	12.9	19.6	27.9	36.2	43.4	47.5	47.9	46.2	44.9					
R&D	3.1	6.0	10.2	16.7	25.5	38.0	48.2	57.3	64.0	74.0	76.2	74.0	70.0	60.0					
General and admin (@ 3%incremental+spec)	-	0.3	0.5	1.0	2.6	4.2	6.6	9.6	12.6	15.2	16.8	17.2	16.7	16.4					
Research and development	15.2	22.0	6.6	4.3	9.4	14.4	21.7	29.8	38.8	46.8	51.6	52.6	51.3	50.4					
Total operating expenses	20.2	30.4	18.4	20.9	36.5	57.0	83.9	115.5	147.4	174.5	189.9	193.8	192.7	192.4					
Operating income / (loss)	(20.2)	(25.8)	(7.8)	(1.8)	25.7	55.2	97.2	147.6	198.1	244.0	272.3	277.0	266.0	256.8					
Provision for income taxes (@35.0%)	(7.1)	(9.0)	(2.7)	(0.6)	9.0	19.3	34.0	51.7	69.3	85.4	95.3	96.9	93.1	89.9					
Net income	\$ (13.1)	\$ (16.7)	\$ (5.0)	\$ (1.2)	\$ 16.7	\$ 35.9	\$ 63.2	\$ 96.0	\$ 128.7	\$ 158.6	\$ 177.0	\$ 180.0	\$ 172.9	\$ 166.9					
NPV SUMMARY																			
Operating Cash Flows	\$ (13.1)	\$ (17.8)	\$ (6.2)	\$ (3.1)	\$ 9.5	\$ 28.3	\$ 52.5	\$ 82.9	\$ 115.3	\$ 146.8	\$ 169.9	\$ 178.6	\$ 174.8	\$ 168.5					
Milestones payment	-	-	-	-	-	-	-	-	-	-	-	-	-	-					
Free Cash Flows	\$ (13.1)	\$ (17.8)	\$ (6.2)	\$ (3.1)	\$ 9.5	\$ 28.3	\$ 52.5	\$ 82.9	\$ 115.3	\$ 146.8	\$ 169.9	\$ 178.6	\$ 174.8	\$ 168.5					
Both NPV and IRR are calculated using the base year above, discounted @9% after-tax. No terminal value is assumed.																			
CUMULATIVE																			
Operating Income/(Loss)	\$ (20.2)	\$ (46.0)	\$ (53.7)	\$ (55.5)	\$ (29.8)	\$ 25.5	\$ 122.6	\$ 270.3	\$ 468.3	\$ 712.3	\$ 984.6	\$ 1,261.5	\$ 1,527.5	\$ 1,784.4					
Free Cash Flows, pre-tax	(20.2)	(47.0)	(56.0)	(59.7)	(41.1)	6.6	93.1	227.6	412.3	644.4	909.6	1,185.2	1,453.1	1,711.4					
Free Cash Flows, after-tax	(13.1)	(30.9)	(37.2)	(40.2)	(30.7)	(2.4)	50.1	133.1	248.4	395.1	565.0	743.6	918.4	1,086.9					
Net Present Value	(13.1)	(29.5)	(34.7)	(37.1)	(30.3)	(11.9)	19.4	64.8	122.6	190.2	261.9	331.2	393.3	448.3					



Financial Evaluation: Myoscience iovera

4/9/2014

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# Myoscience P&L – Peak Sales of \$500M Scenario (Red Line)

Launch: 2015-Q1	Gross Sales Peak: \$456MM (2025)					Scenario #2: Delayed compelling data; Higher Tip Price									
Life: 2029-Q4	Net Sales Peak: \$408MM (2025)														
Scenario: <b>US\$MMs</b>	aA2	Myoscience		US\$MMs											
	Base Year	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj
<b>Myoscience (US Only)</b>															
<b>Proforma P&amp;L</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>2024</b>	<b>2025</b>	<b>2026</b>	<b>2027</b>	
Gross sales	\$ 5.7	\$ 11.1	\$ 19.0	\$ 31.5	\$ 77.5	\$ 120.2	\$ 179.6	\$ 254.4	\$ 338.8	\$ 412.0	\$ 456.3	\$ 475.5	\$ 491.0		
Net sales	-	5.5	10.3	17.6	28.5	69.3	107.4	160.5	227.4	302.8	368.3	407.8	425.0	439.0	
Costs of goods sold (@13.9%)	-	2.3	4.5	6.8	11.4	17.6	26.0	28.5	34.4	45.8	52.7	58.4	60.9	63.0	
Shipping and warehousing (@3.0%)	-	0.2	0.3	0.6	0.9	2.3	3.6	5.4	7.6	10.2	12.4	13.7	14.3	14.7	
Costs of sales (incl. royalties, shipping)	-	2.5	4.9	7.3	12.3	19.9	29.6	33.8	42.0	56.0	65.0	72.1	75.2	77.7	
Gross margin	-	3.0	5.5	10.3	16.2	49.4	77.8	126.7	185.4	246.9	303.2	335.8	349.9	361.3	
Gross margin as % of net sales		54%	53%	58%	57%	71%	72%	79%	82%	82%	82%	82%	82%	82%	
Operating expenses															
Selling and promotion	5.0	8.1	8.3	10.3	10.7	18.6	28.0	40.7	55.7	71.1	83.2	89.0	91.4	93.7	
Marketing spend	5.0	5.0	5.0	5.0	2.5	6.2	9.8	14.4	20.1	26.3	31.4	34.0	34.8	35.3	
General and admin (@3% incremental+spec)	-	0.2	0.3	0.5	0.9	2.1	3.2	4.8	6.8	9.1	11.0	12.2	12.8	13.2	
Research and development	15.2	22.0	6.5	3.0	4.3	7.4	10.8	15.6	21.6	28.4	34.3	37.9	39.5	40.8	
Total operating expenses	20.2	30.3	15.1	13.8	15.8	28.1	42.0	61.1	84.2	108.7	128.5	139.2	143.7	147.6	
Operating income / (loss)	(20.2)	(27.3)	(9.6)	(3.5)	0.4	21.3	39.8	65.6	101.2	138.7	174.7	196.6	206.2	213.7	
Provision for income taxes (@35.0%)	(7.1)	(9.6)	(3.4)	(1.2)	0.1	7.5	12.5	22.9	35.4	48.4	61.1	68.8	72.2	74.8	
Net income	\$ (13.1)	\$ (17.8)	\$ (6.3)	\$ (2.3)	\$ 0.3	\$ 13.9	\$ 23.3	\$ 42.6	\$ 65.8	\$ 89.8	\$ 113.5	\$ 127.8	\$ 134.0	\$ 138.9	
<b>NPV SUMMARY</b>															
Operating Cash Flows	\$ (13.1)	\$ (18.4)	\$ (6.9)	\$ (3.2)	\$ (1.2)	\$ 8.4	\$ 18.2	\$ 35.5	\$ 56.8	\$ 79.7	\$ 104.8	\$ 122.5	\$ 131.7	\$ 137.0	
Milestones payment	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Free Cash Flows	\$ (13.1)	\$ (18.4)	\$ (6.9)	\$ (3.2)	\$ (1.2)	\$ 8.4	\$ 18.2	\$ 35.5	\$ 56.8	\$ 79.7	\$ 104.8	\$ 122.5	\$ 131.7	\$ 137.0	
Both NPV and IRR are calculated using the base year above, discounted @9% after-tax. No terminal value is assumed.															
<b>CUMULATIVE</b>															
Operating Income/(Loss)	\$ (20.2)	\$ (47.5)	\$ (57.1)	\$ (60.6)	\$ (60.2)	\$ (38.9)	\$ (3.1)	\$ 62.4	\$ 163.6	\$ 301.8	\$ 476.5	\$ 673.1	\$ 879.3	\$ 1,092.9	
Free Cash Flows, after-tax	(13.1)	(31.6)	(38.5)	(41.7)	(42.9)	(34.6)	(16.4)	19.1	76.0	155.7	260.5	383.0	514.7	651.7	
Net Present Value	(13.1)	(30.0)	(35.9)	(38.3)	(39.2)	(33.8)	(22.9)	(3.5)	25.0	61.7	106.0	153.5	200.3	245.0	



Financial Evaluation: Myoscience iovera

4/8/2014

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# Myoscience P&L – Peak Sales of \$300M Scenario (Green Line)

Launch: 2015-Q1  
Life: 2029-Q4

Gross Sales Peak: \$316MM (2025)  
Net Sales Peak: \$283MM (2025)

Scenario #3: Current 64640 code

Scenario:	aA3	Myoscience												
US\$MMs	Base Year	US\$MMs												
Myoscience (US Only)	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj
Proforma P&L	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Net sales	-	5.7	14.6	32.3	65.0	113.7	170.0	219.2	255.1	280.2	289.8	282.7	266.8	254.4
Costs of goods sold (@27.9%)	-	2.5	6.6	12.7	25.7	37.4	52.5	66.5	78.4	86.1	89.0	86.7	81.8	77.9
Shipping and warehousing (@3.0%)	-	0.2	0.5	1.1	2.2	3.8	5.7	7.4	8.6	9.4	9.7	9.5	9.0	8.5
Costs of sales (incl. royalties, shipping)	-	2.7	7.0	13.8	27.9	41.3	58.2	73.9	86.9	95.5	98.7	96.2	90.7	86.4
Gross margin	-	3.0	7.6	18.6	37.1	72.4	111.8	145.3	168.2	184.7	191.1	186.5	176.1	168.0
Gross margin as % of net sales		53%	52%	57%	57%	64%	66%	66%	66%	66%	66%	66%	66%	66%
Operating expenses														
Selling and promotion	5.0	8.1	11.1	17.0	25.9	39.2	51.7	63.1	72.5	79.4	81.9	83.1	83.5	84.3
Marketing spend	5.0	5.0	5.0	5.0	5.4	9.5	14.3	18.4	21.4	23.5	24.3	23.7	22.4	21.3
General and admin (@3% incremental+spec)	-	0.2	0.4	1.0	1.9	3.4	5.1	6.6	7.7	8.4	8.7	8.5	8.0	7.6
Research and development	15.2	22.0	5.4	3.2	6.4	10.2	15.2	19.6	22.8	25.1	25.9	25.3	23.9	22.8
Total operating expenses	20.2	30.3	16.9	21.1	34.2	52.7	72.0	89.3	103.0	112.9	116.6	116.8	115.4	114.7
Operating income / (loss)	(20.2)	(27.3)	(9.4)	(2.9)	2.9	19.7	39.8	56.0	65.2	71.8	74.5	69.6	60.7	53.3
Provision for income taxes (@35.0%)	(7.1)	(9.5)	(3.3)	(0.9)	1.0	6.9	13.9	19.6	22.8	25.1	26.1	24.4	21.2	18.7
Net income	\$ (13.1)	\$ (17.7)	\$ (6.1)	\$ (1.6)	\$ 1.9	\$ 12.8	\$ 25.9	\$ 36.4	\$ 42.4	\$ 46.7	\$ 48.4	\$ 45.3	\$ 39.5	\$ 34.6

## NPV SUMMARY

Operating Cash Flows	\$ (13.1)	\$ (18.4)	\$ (7.2)	\$ (4.0)	\$ (2.5)	\$ 6.2	\$ 18.3	\$ 29.8	\$ 37.6	\$ 43.3	\$ 47.2	\$ 46.2	\$ 41.6	\$ 36.3
Milestones payment	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Free Cash Flows	\$ (13.1)	\$ (18.4)	\$ (7.2)	\$ (4.0)	\$ (2.5)	\$ 6.2	\$ 18.3	\$ 29.8	\$ 37.6	\$ 43.3	\$ 47.2	\$ 46.2	\$ 41.6	\$ 36.3

Both NPV and IRR are calculated using the base year above, discounted @9% after-tax.

No terminal value is assumed.

## CUMULATIVE

Operating Income/(Loss)	\$ (20.2)	\$ (47.5)	\$ (56.8)	\$ (59.4)	\$ (56.4)	\$ (36.8)	\$ 3.0	\$ 59.0	\$ 124.2	\$ 196.0	\$ 270.5	\$ 340.2	\$ 400.9	\$ 454.1
Free Cash Flows, pre-tax	(20.2)	(48.2)	(59.7)	(63.8)	(65.0)	(52.0)	(19.7)	29.7	80.1	158.5	231.8	302.4	365.2	420.1
Free Cash Flows, after-tax	(13.1)	(31.6)	(38.8)	(42.8)	(45.3)	(39.1)	(20.7)	9.1	46.6	90.0	137.1	183.3	224.9	261.2
Net Present Value	(13.1)	(30.0)	(36.1)	(39.2)	(41.0)	(37.0)	(26.0)	(9.7)	9.1	29.1	49.0	66.9	81.7	93.5



Financial Evaluation: Myoscience iovera

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# Myoscience P&L – Peak Sales of \$60M Scenario (Purple Line)

Launch: 2015-Q1	Gross Sales Peak: \$63MM (2025)													
Life: 2029-Q4	Net Sales Peak: \$57MM (2025)													
Scenario: aA4 Myoscience	US\$MMs													
US\$MMs	Base Year													
Myoscience (US Only)	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj	proj
Proforma P&L	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Gross sales	\$ 1.8	\$ 3.5	\$ 10.0	\$ 17.1	\$ 25.9	\$ 36.1	\$ 46.7	\$ 56.1	\$ 62.0	\$ 65.5	\$ 63.3	\$ 60.2	\$ 56.1	\$ 50.2
Net sales	-	1.7	3.3	10.0	15.5	23.2	32.2	41.8	50.2	56.4	58.5	56.6	52.9	50.2
Costs of goods sold (@25.7%)	-	0.7	1.5	3.1	5.0	7.6	9.1	11.9	14.0	15.8	16.4	15.8	14.8	14.4
Shipping and warehousing (@3.0%)	-	0.1	0.1	0.3	0.5	0.8	1.1	1.4	1.7	1.9	2.0	1.9	1.8	1.7
Costs of sales (incl. royalties, shipping)	-	0.8	1.6	3.4	5.5	8.4	10.1	13.3	15.7	17.7	18.3	17.7	16.6	16.1
Gross margin	-	0.9	1.7	6.5	10.0	14.8	22.1	28.5	34.5	38.7	40.2	38.9	36.3	34.0
Gross margin as % of net sales		53%	51%	65%	65%	64%	69%	68%	69%	69%	69%	69%	69%	68%
Operating expenses														
Selling and promotion	5.0	8.1	8.2	8.3	6.0	8.7	11.8	14.9	17.5	19.2	19.4	18.4	16.8	15.7
Marketing spend	5.0	5.0	5.0	5.0	1.3	1.9	2.7	3.5	4.2	4.7	4.9	4.7	4.4	4.2
R&D	15.2	20.9	5.4	1.7	2.1	2.1	2.9	3.7	4.5	5.0	5.2	5.1	4.7	4.5
General and admin (@3% incremental+spec)	-	0.1	0.1	0.3	0.5	0.7	1.0	1.3	1.5	1.7	1.8	1.7	1.6	1.5
Total operating expenses	20.2	29.1	13.8	10.4	8.6	11.5	15.6	19.9	23.5	25.9	26.4	25.1	23.1	21.7
Operating income / (loss)	(20.2)	(28.2)	(12.1)	(0.8)	1.4	3.3	6.4	8.6	10.9	12.8	13.8	13.7	13.2	12.4
Provision for income taxes (@35.0%)	(7.1)	(9.9)	(4.2)	(1.3)	0.5	1.2	2.3	3.0	3.8	4.5	4.8	4.8	4.6	4.3
Net income	\$ (13.1)	\$ (18.3)	\$ (7.8)	\$ (2.5)	\$ 0.9	\$ 2.2	\$ 4.2	\$ 5.6	\$ 7.1	\$ 8.3	\$ 8.9	\$ 8.9	\$ 8.6	\$ 8.0
NPV SUMMARY														
Operating Cash Flows	\$ (13.1)	\$ (18.5)	\$ (8.1)	\$ (3.4)	\$ 0.2	\$ 1.1	\$ 3.0	\$ 4.3	\$ 6.0	\$ 7.5	\$ 8.7	\$ 9.2	\$ 9.1	\$ 8.4
Milestones payment	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Free Cash Flows	\$ (13.1)	\$ (18.5)	\$ (8.1)	\$ (3.4)	\$ 0.2	\$ 1.1	\$ 3.0	\$ 4.3	\$ 6.0	\$ 7.5	\$ 8.7	\$ 9.2	\$ 9.1	\$ 8.4
Both NPV and IRR are calculated using the base year above, discounted @9% after-tax. No terminal value is assumed.														
CUMULATIVE														
Operating income / (loss)	\$ (20.2)	\$ (48.4)	\$ (60.5)	\$ (64.3)	\$ (62.9)	\$ (59.6)	\$ (54.1)	\$ (44.6)	\$ (31.6)	\$ (20.8)	\$ (7.1)	\$ 6.7	\$ 19.8	\$ 22.7
Free Cash Flows, pre-tax	(20.2)	(48.6)	(60.9)	(65.6)	(65.0)	(62.7)	(57.4)	(50.1)	(40.3)	(28.4)	(14.9)	(0.9)	12.8	25.5
Free Cash Flows, after-tax	(13.1)	(31.7)	(39.7)	(43.1)	(42.9)	(41.8)	(38.8)	(34.5)	(28.6)	(21.1)	(12.4)	(3.2)	5.8	14.2
Net Present Value	(13.1)	(30.2)	(36.9)	(39.5)	(39.4)	(38.7)	(36.9)	(34.6)	(31.6)	(28.1)	(24.5)	(20.9)	(17.7)	(14.9)



Financial Evaluation: Myoscience iovera

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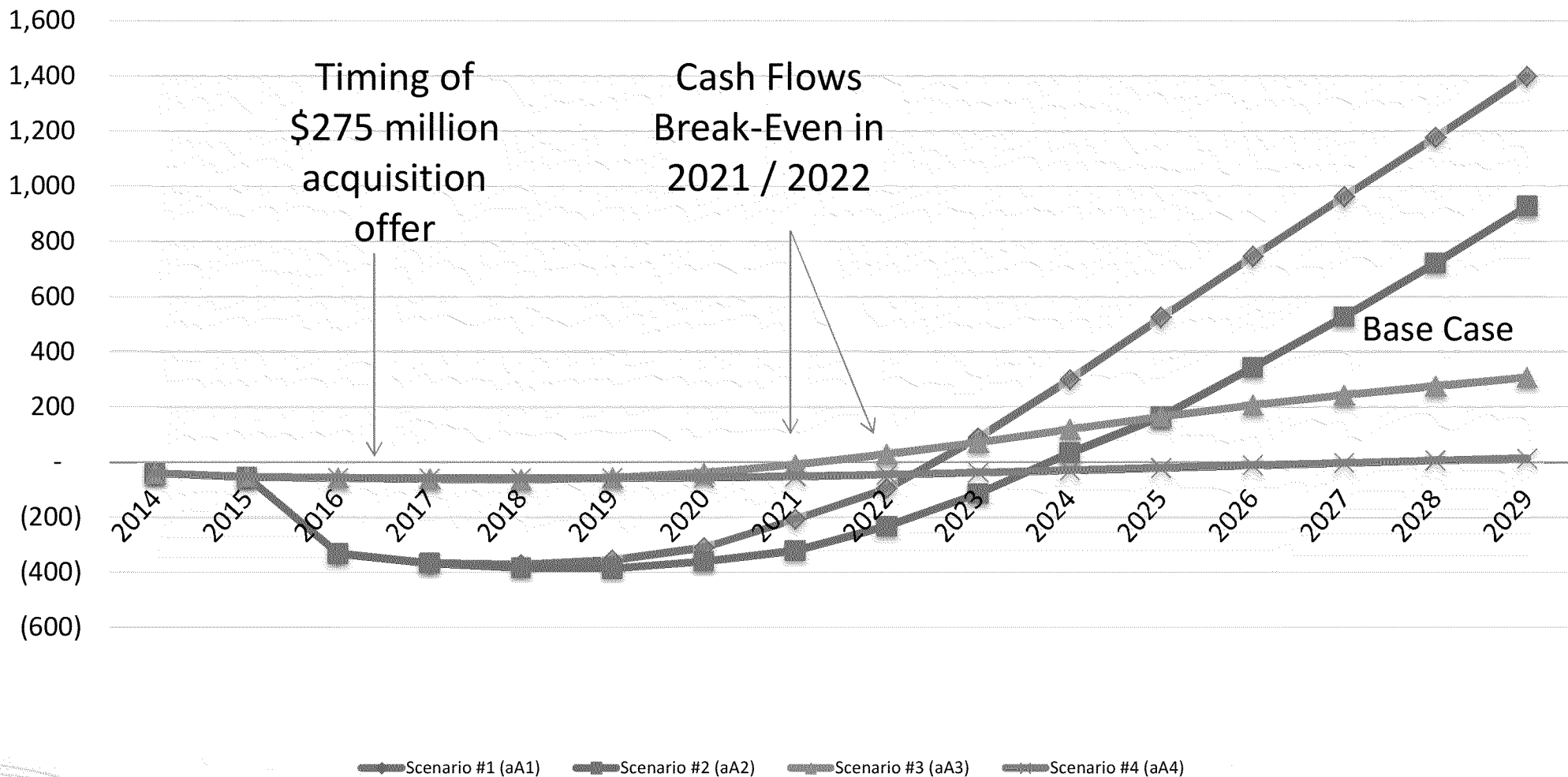
PURDUE-COR-00017079

# Cumulative Free Cash Flows (WW)

Scenario #1: Compelling comparative data; Higher Tip Price  
 Scenario #2: Delayed code; compelling data; Higher Tip Price  
 Scenario #3: Positive data; Current 64640 code  
 Scenario #4: Clinical study failed; cash pay; Higher Tip Price

\$MMs

Net Sales



Financial Evaluation: Myoscience iovera

4/9/2014

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## Risks / Mitigation Plans

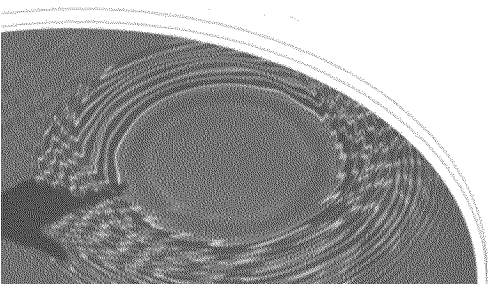
Risk	Mitigation
Disappointing trial results	<ul style="list-style-type: none"> <li>• Trials conducted by Purdue</li> <li>• Purdue not obligated to complete the acquisition</li> </ul>
Trial results delayed	<ul style="list-style-type: none"> <li>• Acquisition option ends after data received for 3 month active comparison trial</li> </ul>
Market access difficulties	<ul style="list-style-type: none"> <li>• HOPE trial to provide pharmacoeconomic data for payers</li> <li>• Work with key medical societies to obtain a unique reimbursement code</li> </ul>
Slow physician adoption	<ul style="list-style-type: none"> <li>• Clinical development plan with clear efficacy and claims</li> <li>• Unique CPT Code should increase payer coverage and therefore, physician usage</li> <li>• New tips developed for additional indications</li> </ul>
Target nerve location difficult	<ul style="list-style-type: none"> <li>• Proper device training for use of the device</li> <li>• Future generation tip to include a nerve finder.</li> </ul>
Safety of repeat procedures	<ul style="list-style-type: none"> <li>• 12 month, open label, repeated use extension trial</li> </ul>
Retention of key personnel	<ul style="list-style-type: none"> <li>• Retention contracts to be implemented for key personnel.</li> </ul>

## Recommendation:

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Complete negotiations with Myoscience under the terms provided in the presentation

Return with fully negotiated contract and recommendation to proceed with staged acquisition of Myoscience





BACK UP SLIDES

# Commercial Assumptions

Factor	Base Position	Upside Position
Physician overstatement of share in market research	50% discount to physician adoption rate	25% Discount to physician adoption rate
Patient share	27% of the physician-reported FCT patient pool at peak 3.4% of the patients who have progressed through all options	30% of the physician-reported FCT patient pool at peak 3.6% of the patients who have progressed through all options
Patient volume	10 procedures per doc building to 13 procedures per doc at peak.	Same
Treatment rate	Three times per year	Three times per year
Tip Price	\$384 based upon facility fee reimbursement rates for intra-articular injections	\$603 based upon parity pricing with SynviscOne
Post-marketing studies	Market adoption slow until studies demonstrate superiority during the <u>first month</u> post-treatment	Market adoption will be slow until studies demonstrate superiority during the <u>first three months</u> post-treatment
Coding	The iovera <sup>9</sup> device can be marketed under existing CPT Code 64640 across all settings of care	New Category I CPT Code specific to FCT will facilitate expanded payer coverage and higher reimbursement rates, especially in the ASC and office settings
Promotion	140 medical device sales reps generating \$2.3M each at peak	180 medical device sales reps generating \$3.5M each at peak
Competitors	No near-term, direct competitors to FCT, but we assume a 50% loss of market share at peak	No near-term, direct competitors to FCT, but we assume a 50% loss of market share at peak
Technology development	Assumes no further technology developments to commercial device	Assumes commercial availability of technology already in development, especially the blunt tip cannula and off-the-shelf or integrated nerve-finding technology



# Regulatory Considerations

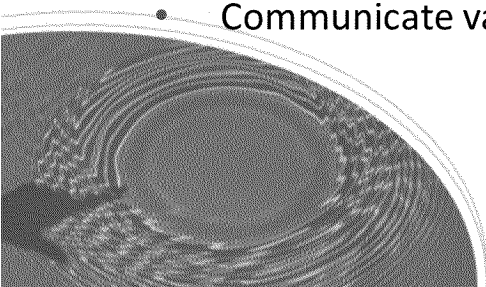
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- Regulatory Approvals
  - US: 510(k) clearance only for “general use” peripheral nerve pain therapy
  - EU: CE mark for aesthetic and pain indications
  - Canada: Approved for aesthetic and pain indications
- Regulatory Limitations
  - No “specific use” in cleared in US for specific pain models
  - FDA regulation/guidance on device promotion is ambiguous and open to interpretation
  - Current limited labelling may lead to issues concerning reimbursement coding
- Regulatory Recommendation:
  - Decision on risk tolerance needed regarding marketing and promotion for uses not clearly delineated in the label in order to formalize regulatory plan of action
  - Request FDA meeting to gain guidance and agreement on Limitations/Options to support specific labeling claims in specific peripheral nerve pain models



# Health Outcomes and Pharmacoeconomics (HOPE)

- Based on the results of the reimbursement evaluation, HOPE is supportive of the current opportunity.
  - The existing CPT code, 64640, allows for sufficient reimbursement in the hospital outpatient department setting.
  - It is possible that physicians may be able to negotiate higher payment rates from commercial (private and Medicare supplemental) payers under the existing CPT code.
  - A new Category 1 CPT code will support higher payment across all settings.
- Potential Risks:
  - Delay in the publication of 5 clinical studies reduces the likelihood of obtaining a new Category 1 reimbursable CPT code.
    - The entire process to obtain a new Category 1 CPT code will take a minimum of 5 years. Requirements for a CPT code include an extensive clinical trial program with 5 published clinical studies.
  - No specific use indication.
    - A specific use indication is needed to demonstrate value to payers proactively.
- Risk Mitigation:
  - Reduce risk of obtaining Category 3 code (a code given to emerging technologies that are not accepted in medical practice) that has a low likelihood of reimbursement by postponing the submission for the request for a new CPT code by a year.
  - Communicate value to payers in response to unsolicited requests.





# Manufacturing/Supply Chain Summary

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- Device consists of 3 components: Hand piece, Smart Tip and Cartridge
- Well documented design process using control & risk mitigation concepts (FEMA analysis) and following US CFR820, ISO 13485-2003 and European CE regs.
- Assembly of each component is entirely manual operation
- Sanmina SCI (San Jose, CA) is contract manufacturer
  - MSA allows for automatic 1 year extensions unless either party terminates with 180 day notice
  - Unexpected termination by Sanmina could adversely effect supply
  - No supply agreements in place with subcomponent suppliers
- Limited manufacturing experience: 1,000 hand pieces; 20,000 Smart Tips
- Continuous incremental improvements of design are ongoing
- Device expensive: Hand piece \$1,430; Smart Tip \$123; Cartridge: \$15.50
  - Current procedure requires 2 to 3 cartridges
- Significant cost savings not attainable until design is stable
- Limited review of customer complaints and device failures



# Myoscience iovera<sup>o</sup>

**Focused Cold Therapy for Treatment of Peripheral Nerve Conditions**

## Financial Evaluation

PRELIMINARY - CONFIDENTIAL

Version C.2, 4/9/2014

Non-Binding Working Draft for Discussion Only

*Disclaimer: Many key assumptions, such as sales forecasts, cost of R&D, probability of approval success, sales force assumptions, are based on very preliminary, last-known good assumptions and with certain modifications. They are subject to change with further market research and due diligence.*