Ampio PHARMACEUTICALS

Ampio Presentation 2019

Forward-Looking Statement

These slides and materials, including any accompanying oral presentation, contain forward-looking statements about our business. You should not place undue reliance on forward-looking statements as these statements are based upon our current expectations, forecasts and assumptions and are subject to significant risks and uncertainties. These statements may be identified by words such as “may,” “will,” “should,” “could,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “forecast,” “continue” or the negative of these terms or other words or terms of similar meaning. Risks and uncertainties that could cause our actual results to differ materially from those set forth in any forward-looking statements include, but are not limited to, the matters listed under “Risk Factors” in our Annual Report on Form 10-K, which is on file with the Securities and Exchange Commission, as well as other risks detailed in our subsequent filings with the Securities and Exchange Commission. These reports are available at www.sec.gov.

Statements and information, including forward-looking statements, speak only to the date they are provided (unless an earlier date is indicated), and we do not undertake any obligation to publicly update any statements or information, including forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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History of drug development

21st Century Cures Act - December 13, 2016

- ***The average cost of a new drug approval is $2,600,000,000***
- ***The average time required for a new drug approval: 10 plus years***
- ***Chances of drug reaching a confirmatory trial are very low***

Ampio is not even close to approaching these numbers in the clinical development of Ampion

Ampion Mechanism of Action Publication Summary

Study Objective	Summary of Findings
Anti-inflammatory effects of HSA and DA-DKP (TNFα, IFNγ)	Bar-Or, et al found that HSA inhibited the production of pro-inflammatory cytokines (IFNγ, TNFα) in activated immune cells; however, when the low-molecular weight ultrafiltrate was removed from HSA, no anti-inflammatory effects were observed. DA-DKP was detected in HSA from multiple vendors, and different concentrations of synthetic DA-DKP (25-500 µM) were shown to inhibit TNFα release in a dose-dependent manner. This study identified early anti-inflammatory properties of < 5 kDa ultrafiltrate of HAS (Ampion) and of the active component DA-DKP. These results were published in the journal of Critical Care Medicine (Bar-Or, 2006).
DA-DKP activity on cytokine production (TNFα, IFNγ, IL-8)	Shimonkevitz, et al. found that DA-DKP decreased production of pro-inflammatory cytokines (IFNγ, TNFα) in T-lymphocytes by increasing phosphorylation of the GTPase Rap-1, which in turn decreased phosphorylated transcription factors involved in the regulation of TNFα and IFNγ gene transcription. Release of an unrelated pro-inflammatory cytokine (IL-8) was not impacted by DA-DKP treatment, suggesting that DA-DKP induction of active Rap-1 impacted the phosphorylation of only selected transcription factor pathways and was not a global effect. These results were published in the Journal of Trauma, Injury, Infection, and Critical Care (Shimonkevitz, 2008).
Ampion anti-inflammatory activity (TNFα inhibition)	Thomas, et al. found that the Low Molecular Weight Fraction of Commercial Human Serum Albumin (LMWF5A), or Ampion, inhibited pro-inflammatory cytokine TNFα in activated immune cells by an average of 37%. Synthetic versions of the individual components were shown to contribute to activity. Multiple studies using this cellular model have been performed at Ampio, and the results from one study are published in the Journal of Immunoassay and Immunochemistry (Thomas, 2016).

References
Bar-Or, et al. Crit Car Med 2006. Vol. 34, No. 6.; Shimonkevitz, et al. Jor Trauma 2008. Vol 64, 35-41.; Thomas, et al. Jor Immuno 2016. Vol 37, 55-67

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Given high unmet need in severe OAK, physician research suggests Ampion has the potential to achieve blockbuster status

- ✓ **OAK affects approximately 200 million people worldwide and increasing.**
- ✓ **OAK affects approximately 35 million people in the United States.**
- ✓ **1 in 2 Americans is expected to develop systemic OAK in their lifetime.**
- ✓ **Prevalence in OAK has increased rapidly and is anticipated to keep growing due to an aging population, increased activity and a rise in obesity.**
- ✓ **China has 300,000,000 million people that have or will have healthcare in the very near future which will increase the demand for OAK treatments.**

References

Campbell Alliance report, Clearview Health Care report

Note: Ampion market share has been adjusted for prescribing habits by specialty (ortho, rheum, pain med), severity (mod/sev), reflect share steal and concomitant use from/with IA steroids and hyaluronic acid, and have been adjusted for access and reimbursement status

Pricing assumes $600 per treatment, 3 treatments per patient per year

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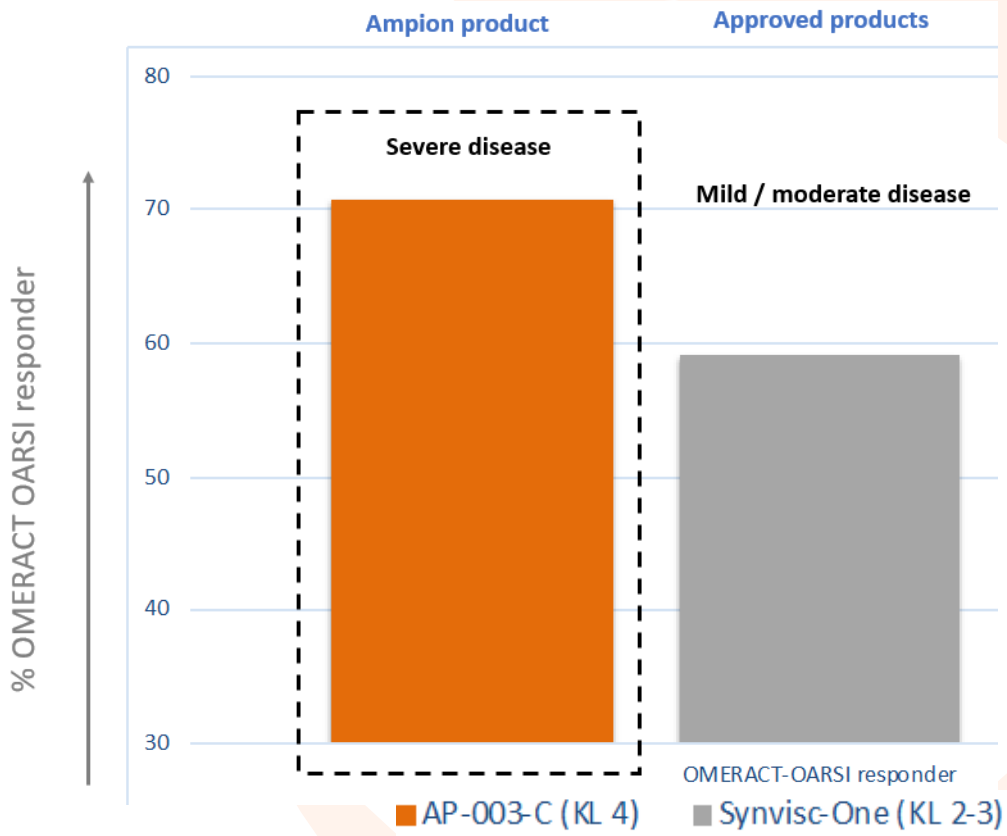
OMERACT-OARSI responder rate in OAK with IA-injection

- **To have commercial potential Ampio must have a therapeutic advantage**
  - **Ampion studies include severely diseased KL 4 patients, where all others FDA-approved IA-injection therapies exclude severely diseased KL 4 patients from pivotal trials**

OMERACT-OARSI responder rate by IA-injection OAK therapy



The comparison being presented is not a head-to-head comparison and involves company generated clinical data compared to published information about separately studied competitor products

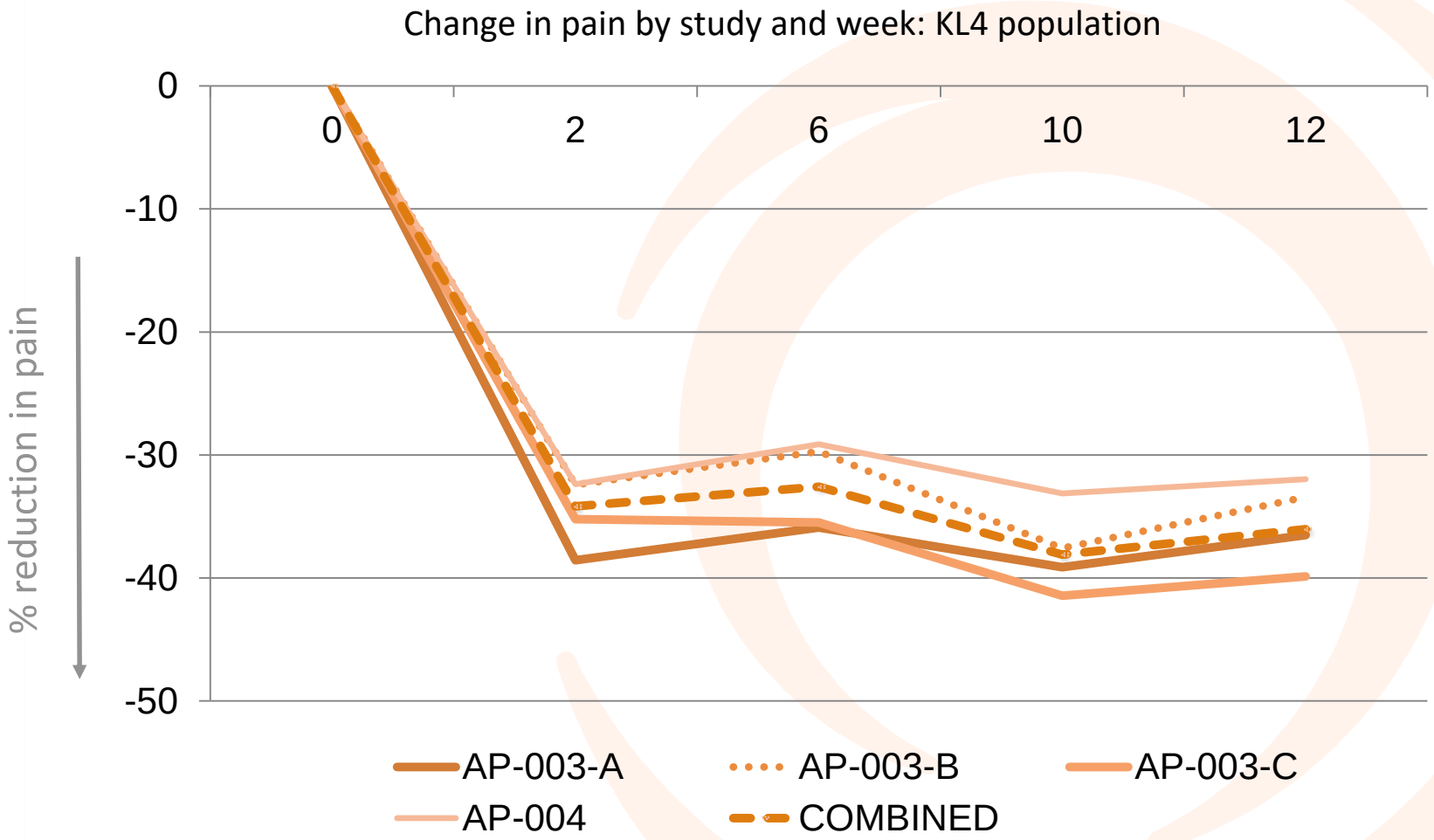
References

Chevalier, et al. Ann Rheum Dis. 2010; 69:113-119.10. Strand et al. Osteoarthritis and Cartilage.. 20 (2012) 350-356.

Cole, et al. Orthopedics. 2018 Jan 1;41(1):e77-e83

Consistent performance in severely diseased patients

Pain reduction with a single injection of Ampion (KL 4)



The FDA will need to review all relevant data in a future BLA submission before any conclusions can be drawn as to the safety or efficacy of the product.

References

Cole, et al. Orthopedics. 2018 Jan 1;41(1):e77-e83.; Bar-Or, et al. PLoS One. 2014 Feb 3;9(2):e87910.; Salottolo, et al. Patient Saf Surg. 2018 Jun 18;12:11; D

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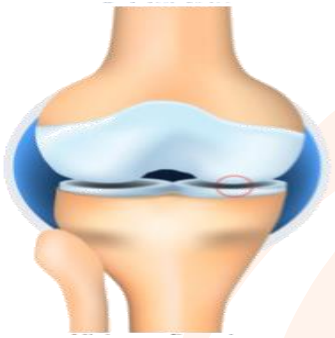
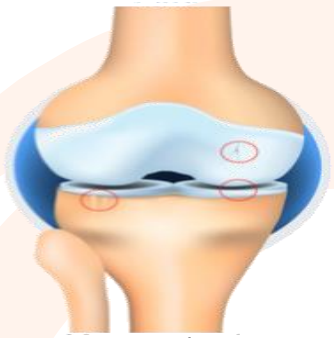
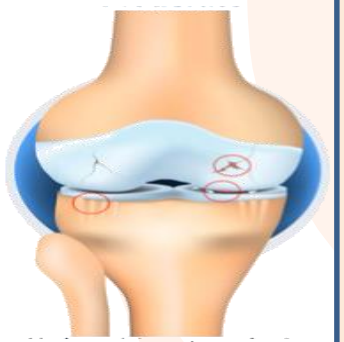
In 2017, FDA stated treatment for KL 4 patients is an unmet medical need



KL Grade 1
Minimum disruption

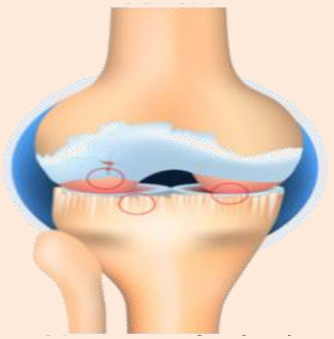


KL Grade 2
Joint-space narrowing. The cartilage begins breaking down. Occurrence of osteophytes



KL Grade 3
Moderate Joint-space reduction
Gaps in the cartilage can expand until they reach the bone

Unmet Need



KL Grade 4
Joint-space greatly reduced. 60% of the cartilage is already lost. Large osteophytes are present

Osteoarthritis Epidemiology Report. DataMonitor, Inc. 2013. 4 Relationship between patient-reported disease severity in osteoarthritis and self-reported pain, function and work productivity. Sadosky et al. Arthritis Research & Therapy 2014.

Special Protocol Assessment

A SPA is a process in which sponsors may ask to meet with the FDA to reach agreement on the design and size of certain clinical trials to determine if they adequately address scientific and regulatory requirements for a study that could support marketing approval. A SPA agreement would indicate concurrence by the FDA with the adequacy and acceptability of specific critical elements of overall protocol design for a study intended to support a future Biologic License Application (BLA). The elements of the study agreed upon in the SPA agreement are critical to ensuring that the trial conducted under the protocol can be considered an adequate and well-controlled study that can support marketing licensure of Ampion. However, a SPA agreement will not indicate FDA concurrence on every protocol detail, and the FDA may still require us to conduct additional clinical trials in the future to support a BLA for Ampion.

Ampion Special Protocol Assessment (SPA) AP-013 trial design

SPA Clinical Trial Design

FDA Concurrence on Trial Design

- Randomized 1:1: Ampion vs saline control
- Double-blind
- Multi-center US sites
- 12-week primary endpoint; 24-week study
- Co-primary endpoints evaluate an improvement in pain and function
- 1,034 patients; 517 per study arm
- **Interim analysis at 724 patients; 362 per study arm**
  - Sample size re-estimation if needed, up to 1,552 maximum total patients; 776 per study arm

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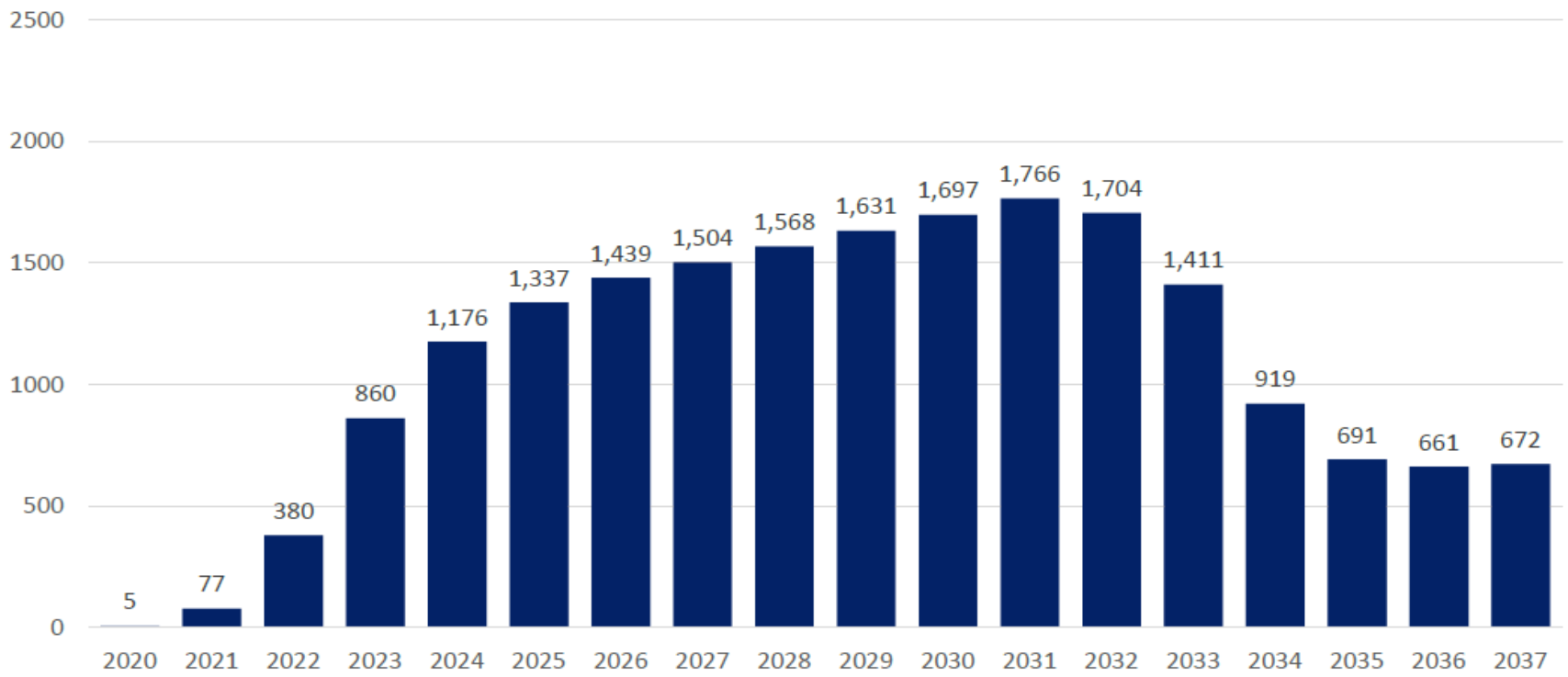
Ampion base case revenue projections

Assuming a price of $1.25 K per injection at launch, Ampion is projected to reach U.S. peak net sales of ~$1.8 B, primarily in the severe OAK population.



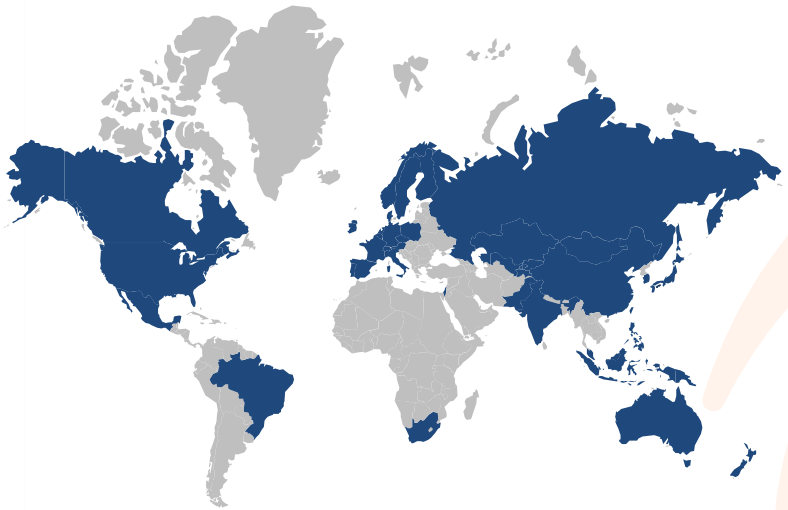
KL 4 knee patients in the United States

The severe OAK population accounts for ~80% of Ampion sales, given that utilization for the moderate population is heavily impacted by market access restrictions

(1) Source: Clearview Healthcare Partners (OA Strategic Assessment – Slide 20)
(2) Source: Physician Survey; Physician Interviews; ClearView Analysis.

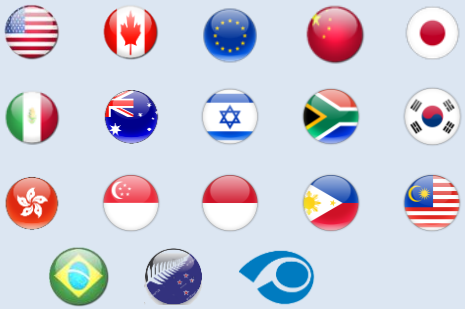
If approved as a "novel biologic," Ampion will receive 12 years of biologic exclusivity and is also protected by a robust IP portfolio with international coverage

Worldwide Patent Coverage



Region	Issued Patents (57)	Pending Patent Applications (35)
US	23	7
Ex-US	34	28

Countries with Patent Protection Granted or Pending



U.S. Patent Portfolio (23)	2000	2005	2010	2015	2020	2025	2030
BLA Exclusivity (expected)					2H 2020 – 2H 2032		
Patent Term Extension (Application made after FDA approval)					Variable depending on patent		
Inflammation (**U.S. 8,916,568**)			2001 – 2021				
Filtrate (**U.S. 8,183,209**)			2004 – 2024				
Degenerative Joint Disease (**U.S. 8,980,834**)				2012 – 2032			

FDA Protections

- **FDA deemed Ampion a "novel biologic". If approved, novel biologics receive 12 years of exclusivity upon approval under the Biologics Price Competition and Innovation Act of 2009 (BPCIA)**

Composition of Matter

- **US 8,916,568 (Inflammation family)**
- **US 6,555,543 (Inflammation family)**
- **US 8,183,209 (Filtrate family)**
- **US 8,969,308 (Filtrate family)**

Method of Use/Treatment

- **US 6,555,543 (Inflammation family)**
- **US 8,268,830 (Inflammation family)**
- **US 8,513,196 (Filtrate family)**
- **US 8,980,834 (Degenerative joint disease family)**
- **US 9,060,968 (Degenerative joint disease family)**
- **US 9,623,072 (Degenerative joint disease family)**

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Ampion manufacturing enables control over operational process and cost for market entry and commercialization Worldwide

- Proprietary process
- Easily transferred to additional manufacturing sites
- 8 billion dollar a year manufacturing potential
- Built to international standards

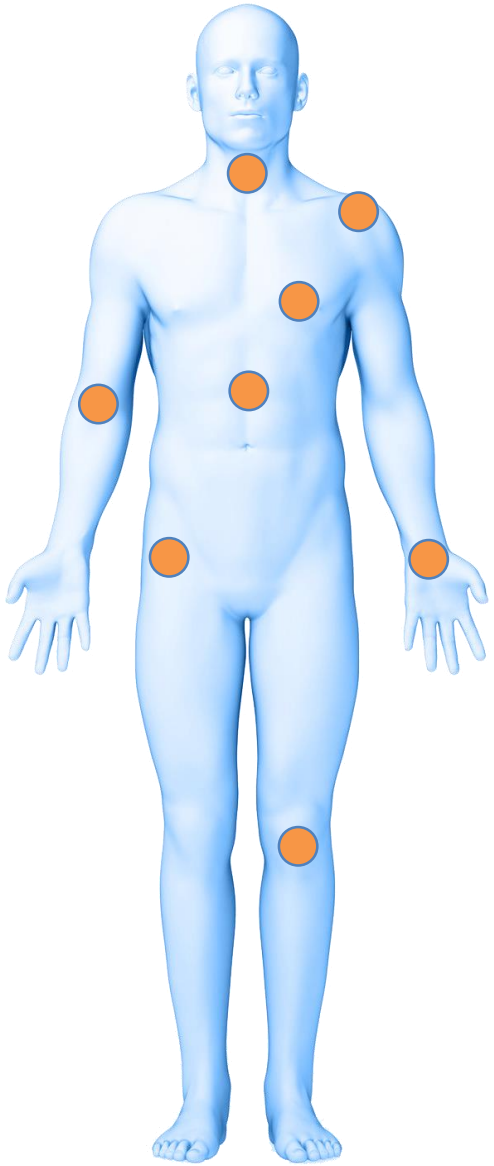
Control over Ampion manufacturing, release, and quality output creates commercial value

Ampio is able to cost effectively manufacture Ampion and achieve estimated COGS of $19.10 per unit for a 9,000 unit batch run

Ampion – Manufacturing Costs For Full Batch (9,000 vials) Processing				
Part Number	**Qty / Batch**	**Cost/Unit**	**Taxes/ Shipping**	**Total**
100 Human Serum Albumin	108 bottles	$198.00	-	$21,384.00
200 Vials	84	$7.19	$0.11	$64,710.11
201 Stoppers	10,000	-	-	-
202 Caps	10,000	-	-	-
300 Fluid Removal	1	$345.00	$71.05	$416.05
302 Vent Filter	1	$508.00	$50.08	$558.08
303 TFF	1	$12,102.00	$548.92	$12,650.92
304 Waste Bag	1	$823.00	$28.90	$851.90
305 Fill Bag	1	$737.05	$5.13	$742.18
306 Sterile Water tee	1	$490.45	$2.50	$492.95
308 Permeate Bag	1	$653.72	$7.60	$661.32
309 Mixing Bag	1	$1,591.00	$103.42	$1,694.42
Sterile Coveralls	~25	$0.47	$0.03	$12.51
Sterile Hood	~25	$0.17	$0.01	$4.53
Sterile Boots	~25	$0.30	$0.02	$7.99
Scrubs	15 sets	$0.32	$0.02	$5.11
307 Sterile Water	1 bag (50L)	$625.00	$25.63	$650.63
313 Syringes	6	$0.72	$0.05	$4.62
Luer Cap	6	$1.59	$0.10	$10.16
Test Kits (PN 800-801) Bowie Dick	1	$15.54	$1.01	$16.55
Sterile Trash Bags	11	$2.33	$0.15	$27.30
Laboratory Testing per lot	1	$1,110.00	-	$1,110.00
ELISA Kits	1	$1,069.00	$42.00	$1,111.00
Total Material Costs*				**$107,122.32**
Labor Costs	13 FTE	$200.00	-	$2,600.00
Overhead/Facility Costs	-	-		$28,471.00
Total Cost per Batch				**$138,193.90**
Price/Unit	9,000			$15.35
Costs from Sharp				$3.75
Total Cost per Unit				**$19.10**

- Total cost to run a batch of Ampion is $171,900
- The commercial price of each batch is over $11M

Other potential indications



The Company seeks to apply the mechanism of action of Ampion to other inflammatory indications, such as:

- Other joints (hip, shoulder, wrist, hand, etc.)
- Sports injuries
- Systemic inflammatory conditions
- Breathing disorders
- Platform technology

** Drug delivery method varies by indication*

Summary of Ampion

- ✓ Large international marketing potential
- ✓ Rapidly growing OAK market
- ✓ Unmet medical need in severe patients
- ✓ International patent protection
- ✓ 12 years FDA exclusivity if approved as a novel biologic
- ✓ In house manufacturing built to international standards
- ✓ Low cost of goods
- ✓ Published scientific support
- ✓ Over 1,000 patients received Ampion treatment in clinical studies with no serious drug related adverse events
- ✓ Only product to seek efficacy in severe KL 4 patients

Next steps

- ✓ Special Protocol Assessment (SPA) was received June 13, 2019 confirming FDA concurrence on trial design for regulatory submission
- ✓ Engage deal discussions
- ✓ Complete AP-013 trial under SPA
- ✓ Set up international distribution through acquisition, partnership and or licensing