



RELIEF FOR OSTEOARTHRITIS

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EXECUTIVE SUMMARY



Cytonics, founded in 2006, is a **private research and development company** focusing on molecular diagnostic and therapeutic products for **chronic musculoskeletal diseases**.



Our first product was a **biomarker assay** to determine whether painful joints are experiencing breakdown of the articular cartilage, which is the hallmark of osteoarthritis.



We leveraged our understanding of the molecular etiology of osteoarthritis to develop our **APIC system**, a device which uses patients' own blood to treat damaged joints. Over **7,000 patients** treated



Current focus: **Recombinant Protein Drug Development Program**. We are currently developing a novel **drug product "CYT-108"** to eradicate the pain and suffering associated with osteoarthritis once and for all.



We currently have **9 issued international patents**, and **8 patents pending**.

\$1.8M

We were awarded **\$1.8M** in **NIH grants** to pursue our innovative research into discovering treatments for osteoarthritis

\$18M

We have raised over **\$18M** in **funding**, including an investment from **Johnson & Johnson**

\$19M

Seeking to **raise \$19M** in **public and private equity** for the pursuance of **FDA clinical trials**



THE PROBLEM (Osteoarthritis)

Osteoarthritis (OA) is a degenerative disease that erodes the articular cartilage that protects your joints.

Who Suffers From OA?



OVER
27 Million
AMERICANS



25% of adults by
the year 2030

Over 27M Americans currently suffer from OA, and with the **aging population** incidence of OA is projected to reach 25% of the adult population in the US by 2030



OVER
6 Million
ATHLETES

Over 6M Americans are treated for **post-traumatic OA**, which occurs frequently in athletes that experience injury (e.g., **ACL tear**) on the field.



OVER
\$180 Billion Per Year
is spent treating OA

An effective treatment for OA would have a tremendous impact on both **human well-being** and the **economic burden** of the disease, as over \$180B is spent treating OA per year.



THE PROBLEM (Osteoarthritis)

OA is caused by hyperactive proteases, a class of catabolic enzymes that chew away at the cartilage matrix.

A successful treatment must address these molecular forces.

(Cartilage breakdown caused by proteases)

HYPERACTIVE PROTEASES

CURRENT THERAPIES

- ▶ Non-steroidal Anti-inflammatory Drugs (e.g., Advil)

- ▶ Hyaluronic Acid (Essential component of cartilage)

- ▶ Corticosteroids (e.g., Prednisone)

- ▶ Temporary symptomatic relief

- ▶ Treats symptoms, not cause

- ▶ Many side effects

Limited treatment options for OA exist, and the current therapies are all palliative. They address the symptoms, but **fail to address the root cause** of the pain and inflammation, which is cartilage damage due to activity of proteases within the arthritic joint.

OA MARKET

The market for a treatment for OA can be approximated by examining the **sales of TNF-alpha inhibitors**, the class of drugs that treated OA's sister, **Rheumatoid Arthritis (RA)**. The **incidence of OA is 6 times higher than that of RA**, implying that the **market for OA is greater than \$180B**.



**\$30
BILLION**

**RHEUMATOID ARTHRITIS
GLOBAL SALES
(TNF-alpha inhibitors)**



**\$180
BILLION**

**THERAPEUTIC MARKET
(RA x 6 = OA)**

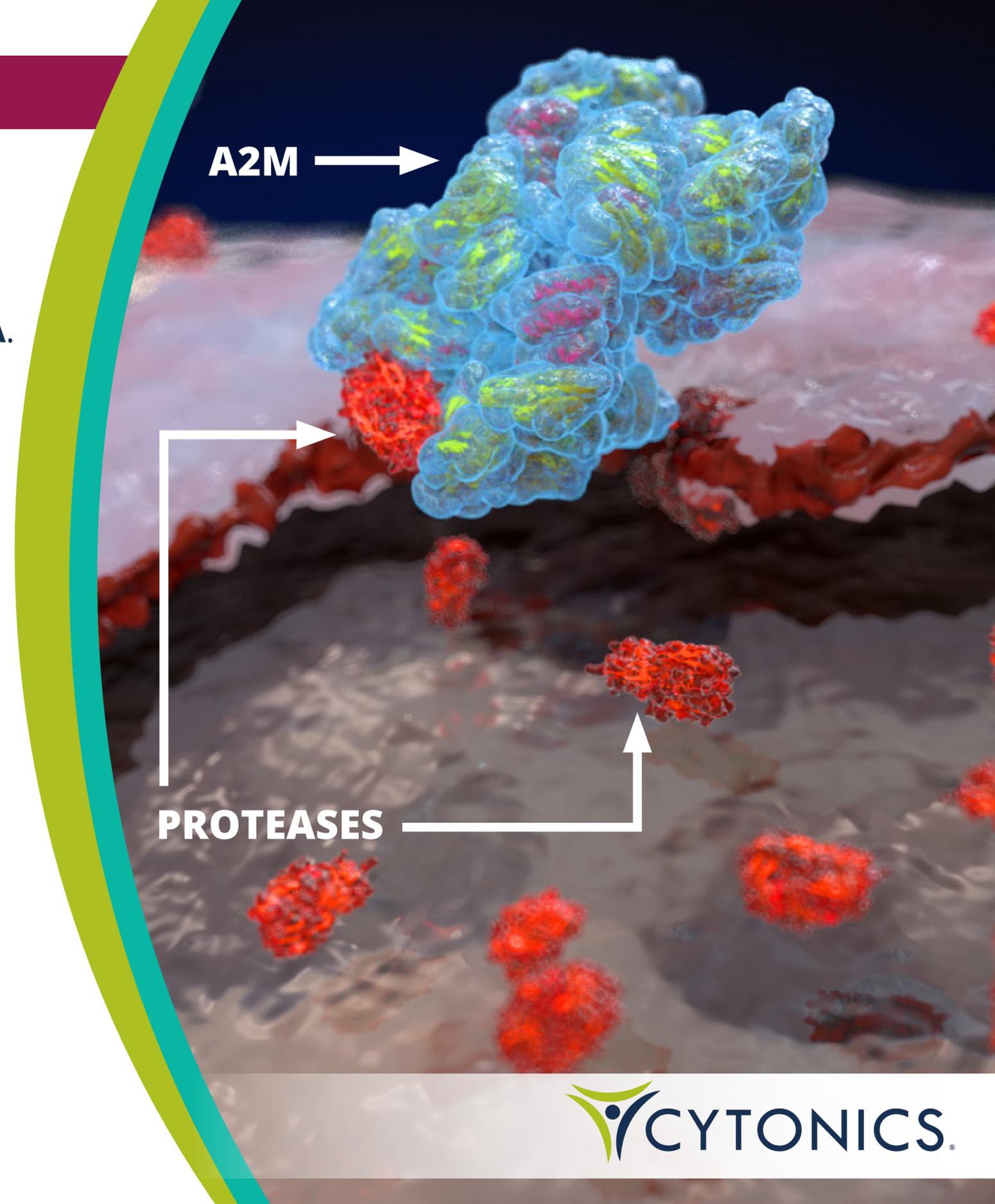
OUR SOLUTION (A2M)

Alpha-2-Macroglobulin (A2M) is a blood serum protein that plays a small role in the clotting cascade. A2M is a well characterized, broad-spectrum **protease inhibitor** that has demonstrated potent inhibitory activity against the **proteases that are upregulated in OA**.

Unfortunately, the levels of naturally occurring A2M are too low to lend any therapeutic benefit to damaged joints. However, we theorized that:



Delivering high concentrations of A2M directly into the joint space could bind to and inhibit the proteases, slowing and eventually halting the progression of OA.



OUR INNOVATION - THE APIC SYSTEM

We developed the **APIC system** to concentrate the **A2M found naturally in the bloodstream**. This is achieved by drawing and centrifuging patient's blood, then filtering out all of the proteins that could cause damage to the joint (such as proteases and inflammatory cytokines).



Our APIC technology is often incorrectly compared to existing PRP (platelet rich plasma) therapies. PRP systems concentrate all the proteins in the blood, delivering a mix of potentially therapeutic and deleterious molecules to the joint.

APIC SYSTEM - Selectively concentrates the **A2M** found within the bloodstream **4-6x above naturally occurring levels**. Our proprietary filtration process **removes the harmful proteins** that remain in PRP formulations.

Our system selectively enriches for A2M, delivering high concentrations of the therapeutic A2M to the joint and eliminating all of the damaging molecules.



OUR INNOVATION - THE APIC SYSTEM



Our APIC system has been used to successfully treat **over 7,000 patients nationwide**



Our technology has been proven to slow cartilage degradation, alleviate pain, eventually halt the progression of OA and allow the body's regenerative mechanisms to heal the damaged tissue.

This observation has been independently verified by a number of academic groups.

"As a busy spine surgeon for the last 25 years the direction that Cytonics is proceeding in attempting to minimize clinical failures through their Autologous Platelet Integrated Concentration (APIC) System is breathtaking and timely."

- Alexander R Vaccaro, MD, PhD, MBA



PHYSICIAN TESTIMONIALS



"I was an early investor in Cytonics as the technology is timely in unraveling the etiology of Low back pain. The future will be assaying for specific biomarkers to determine not only the cause of pain but the potential for improvement with certain interventions. As a busy spine surgeon for the last 25 years the direction that Cytonics is proceeding in attempting to minimize clinical failures through their Autologous Platelet Integrated Concentration (APIC) System is breathtaking and timely."

- Alexander R Vaccaro, MD, PhD, MBA



"I have been using Cytonics' alpha2- macroglobulin kits to treat various joint pains mostly in the knee. This is part of my regenerative medicine practice. I've seen remarkable results such that I have suggested that my wife and my son undergo treatments as well as patients. The treatments were remarkably successful in both of them. I am very pleased and I'm looking forward to having this product available more easily off-the-shelf and approved by insurance. I expect a huge demand for it. Thank you."

- Laurence Rosenfield, MD



"Cytonics' recombinant drug development program is anchored in robust preclinical data indicating that the proteinase inhibitor alpha-2-macroglobulin critically inhibits cartilage breakdown in models of osteoarthritis. Cytonics has developed a lead recombinant drug candidate, a variant of human alpha-2-macroglobulin that possesses a unique and improved bioactivity profile. Cytonics' strategic efforts are exciting as they target the development of a first biologic therapy for patients suffering from osteoarthritis."

- Martin Angst, MD

PATIENT TESTIMONIALS



"[Dr. Scuderi] took out some of my blood and he put it into the centrifuge and they did what they had to do and then he reinjected the A2M protein back into my knee. Before he did the procedure, I could not bend my knee, I could not walk upstairs. I really couldn't do anything. In fact, I was using a brace on my knee just to give me some support because the whole knee felt like it was going to cave in. A few days after the procedure I was walking and we were walking the dogs and the swelling seemed to have been going down."

- Gail Lynn

"I came with Gail when she discovered Dr. Scuderi and what he can do for arthritis. I went for an x-ray. Very simply, he did the same procedure. He took blood from my arm and put it in a centrifuge and got the protein out and injected it in my shoulder. And I've been great. We had nothing but success with this protein shot."

- Robert Lynn



"I partially tore my ACL in a skiing accident in Switzerland. After an unnecessary arthroscopy revealed I was not a candidate for ACL reconstruction, my knee was swollen and stiff for 6 weeks. Then I had a single treatment of Cytonics A2M therapy, APIC. Within 2 days the swelling and stiffness was gone and hasn't returned 6 months later. I was so impressed with these results that I have been evangelizing for APIC treatment to my doctors and friends ever since."

Even if I need another treatment soon, a couple APIC injections per year with no noticeable side effects and no drugs is closer to a miracle-treatment than I imagined possible before my experience with Cytonics' product. Joint injuries can be physically and emotionally debilitating, but medical advancements like this make now the best time in history to tear one's ACL."

Thanks to Cytonics for developing this product!"

- Gabe

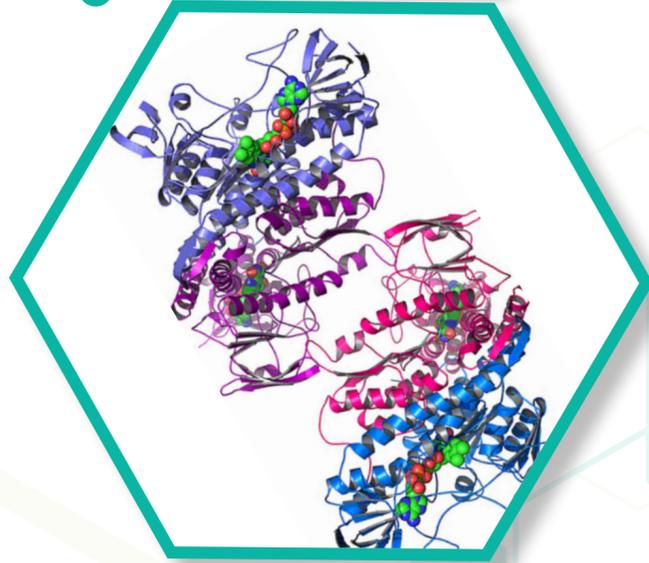
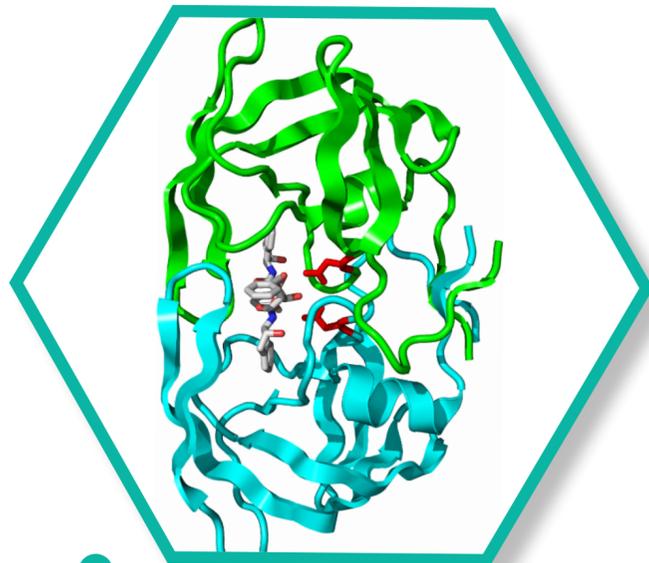
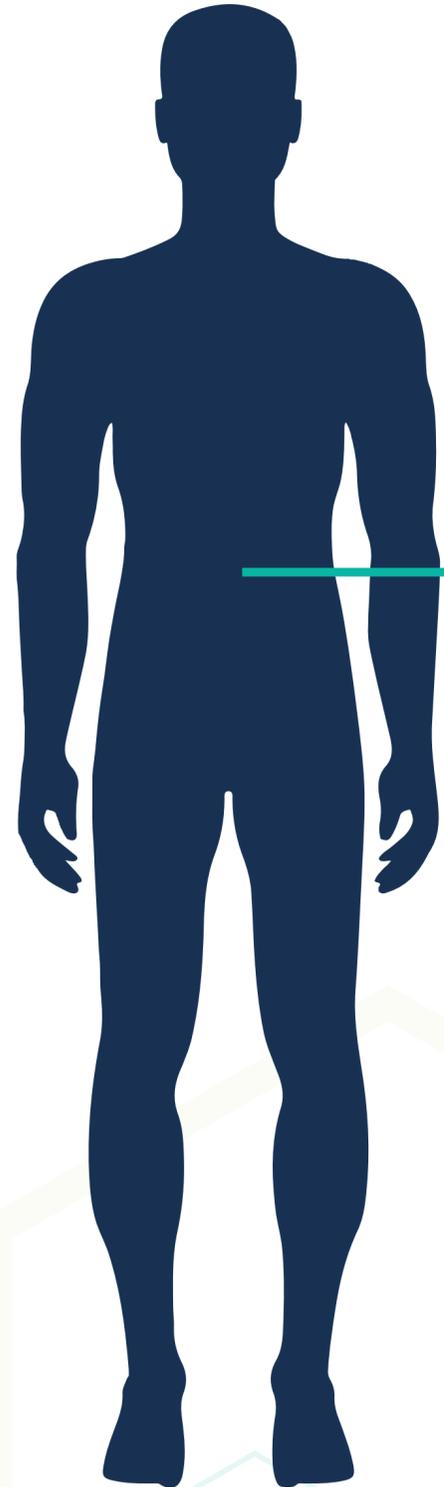


"I suffered prolonged pain from a partial tear in my right Achilles tendon. I am very familiar with this pain as I ruptured and had my left Achilles surgically repaired. After almost eight months of therapy and various treatments, Richard Grossman, MD told me about Cytonics and the available A2M treatment. I received my first injection in April of 2018 and within weeks the large nodule in my Achilles had shrunk significantly. While I was feeling much better and able to start playing basketball and tennis again for the first time in ten months, I still felt a little pain. I went back for a 2nd injection in November of 2018 and the pain has been reduced to only minor pain with NO LIMITATIONS. The A2M therapy has given me my sports and mobility life back and I have recommended this treatment to all of my friends."

- Daryle Bobb



THE NEXT GENERATION – PROTEOMICS



Over the last decade, molecular biologists have made tremendous strides towards **identifying and characterizing the thousands of proteins** that exist in the human body. This line of inquiry gave birth to the field of “**Proteomics.**” Proteomics allows scientists to study the structure and function of proteins, and **discover how they malfunction in diseases.**

Recent innovation in protein engineering has enabled researchers to “**Edit**” **proteins**, giving them **special functions** that result in **therapeutic effects.**

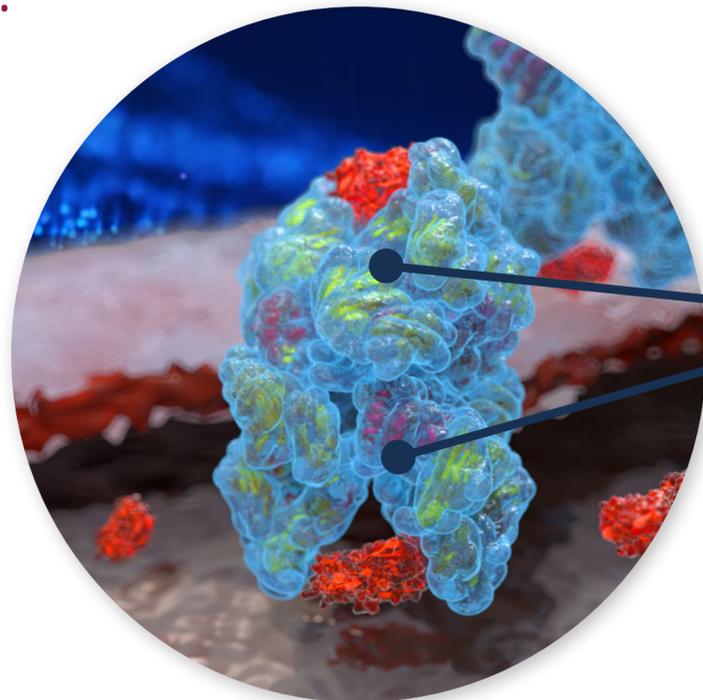
DEVELOPING THE STATE-OF-THE-ART

IMPROVING ON NATURE'S DESIGN

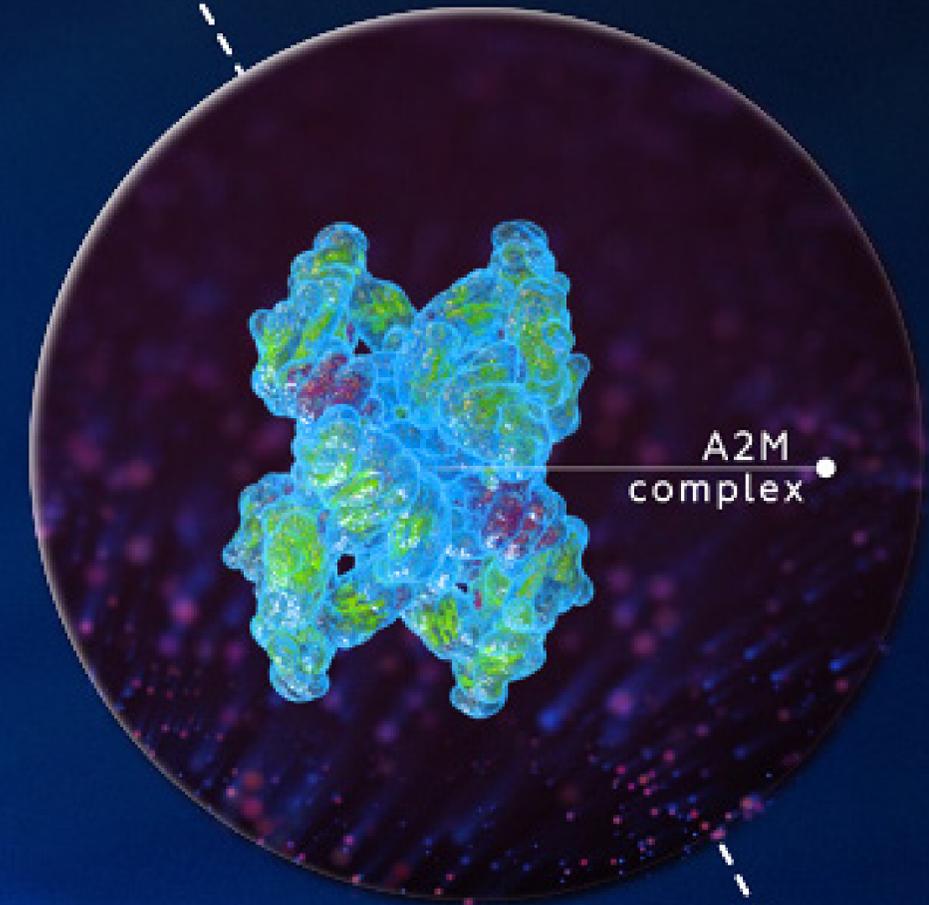
We leveraged our deep understanding of protein engineering to create a **modified A2M protein** - named "**CYT-108**."

CYT-108 was engineered with a special "**bait region**" which is responsible for **trapping the destructive proteases** and rendering them useless.

Our **custom bait region** gives CYT-108 a higher affinity and greater specificity for the classes of proteases that are upregulated in OA, making **CYT-108 much more effective at inhibiting cartilage damage than the naturally occurring A2M**.



BAIT REGIONS



CYT - 108

OUR INNOVATION – CYT-108

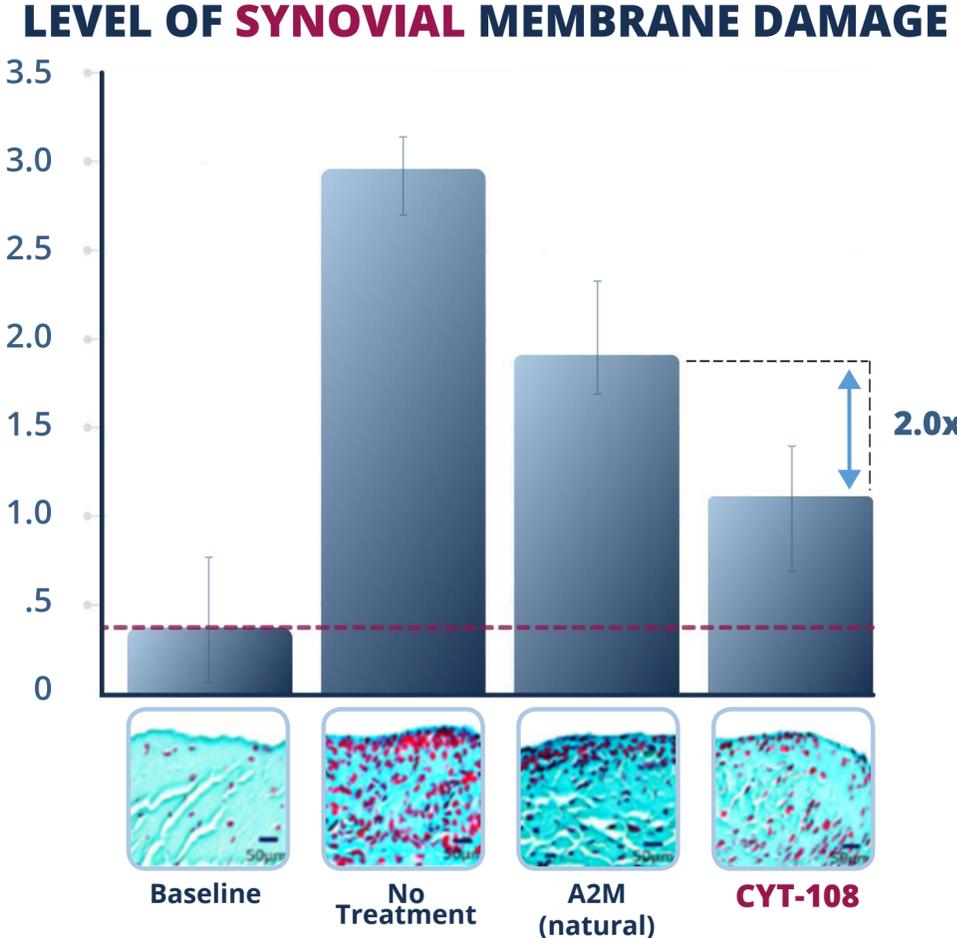
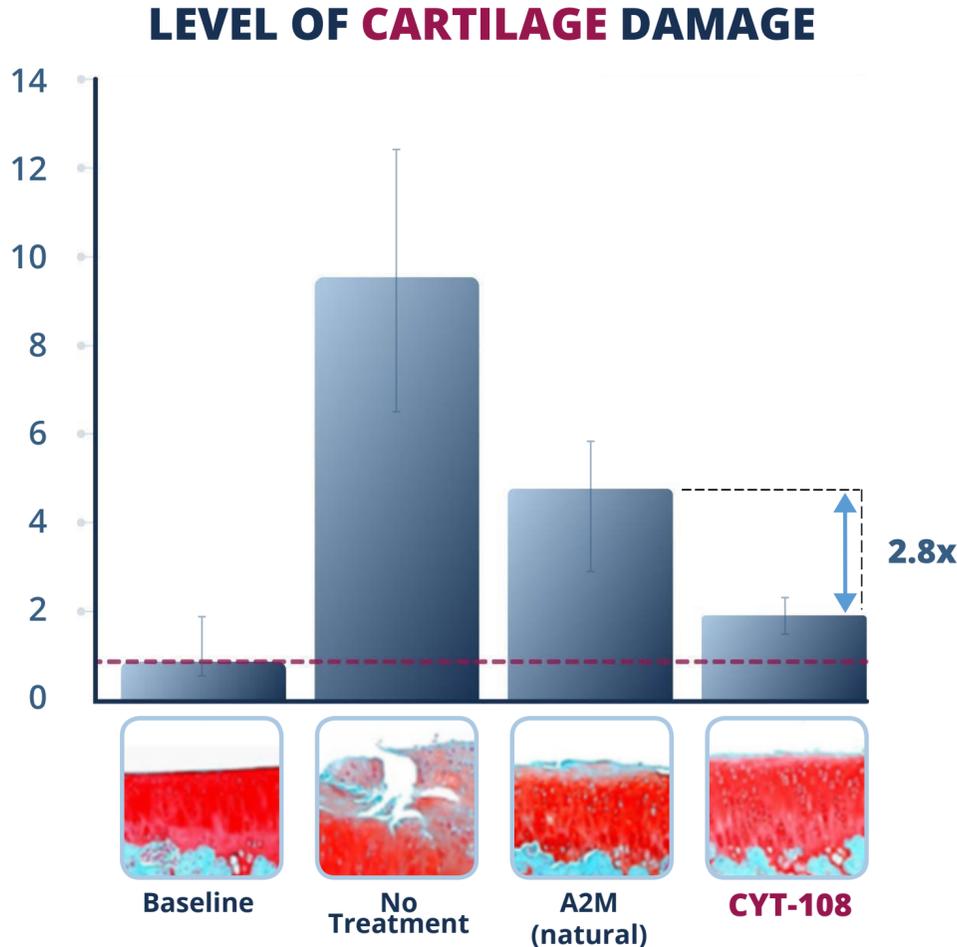
CYT-108 v. NATURAL A2M

Is CYT-108 MORE Effective?



CYT-108 was able to **significantly reduce the damage to the cartilage and the synovial membrane** (the tissue that protects the joint) of rats suffering from post-traumatic osteoarthritis.

CYT-108 is **2-4 times more effective** than the **naturally occurring A2M** at preventing cartilage degradation and synovial membrane damage.



Note: only representative data is shown. Complete dataset published [here](#).

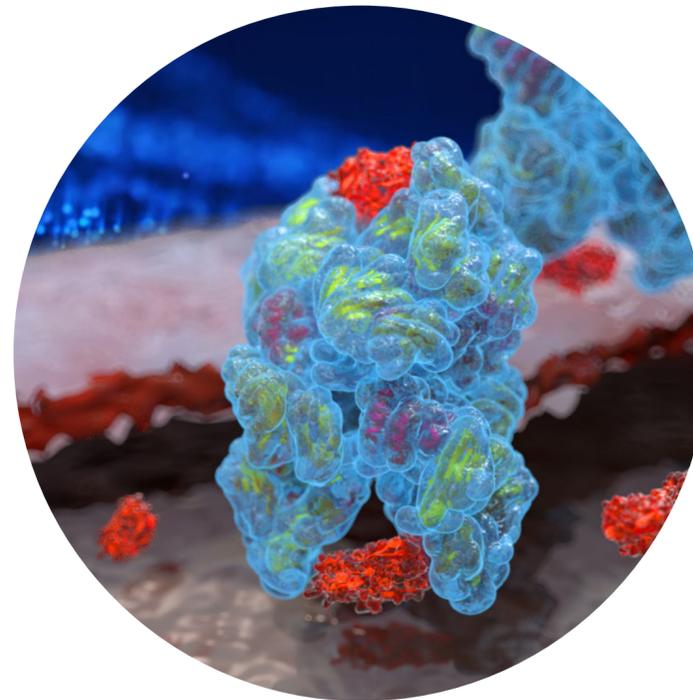
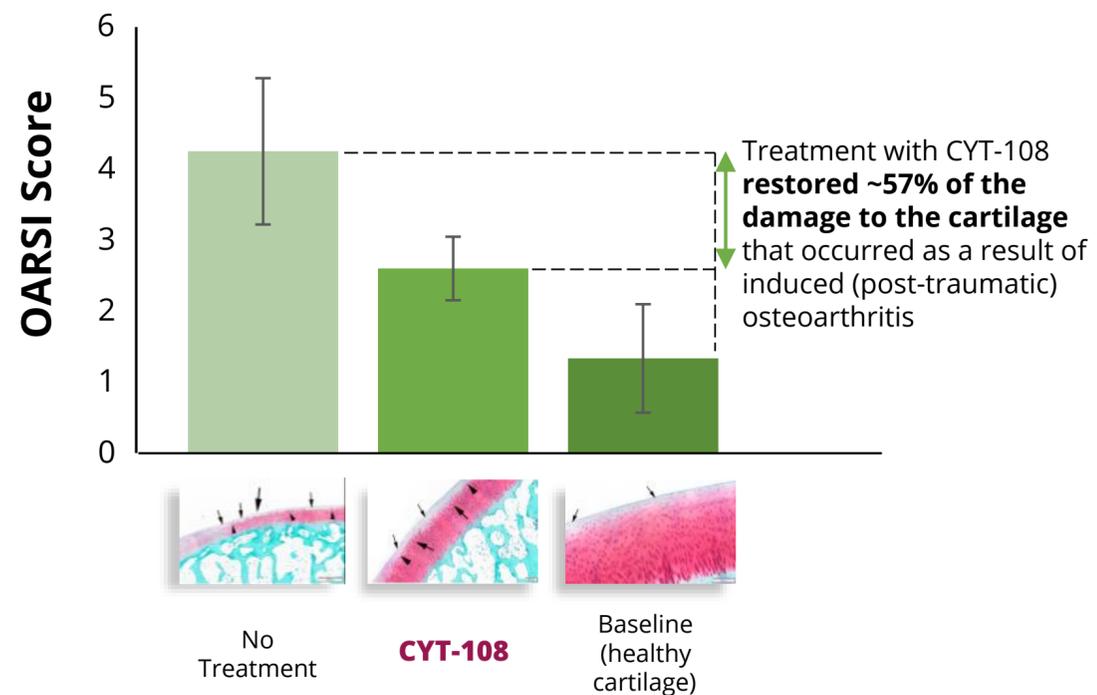


PRECLINICAL STUDY RESULTS – CYT-108 Has Therapeutic Activity Against OA

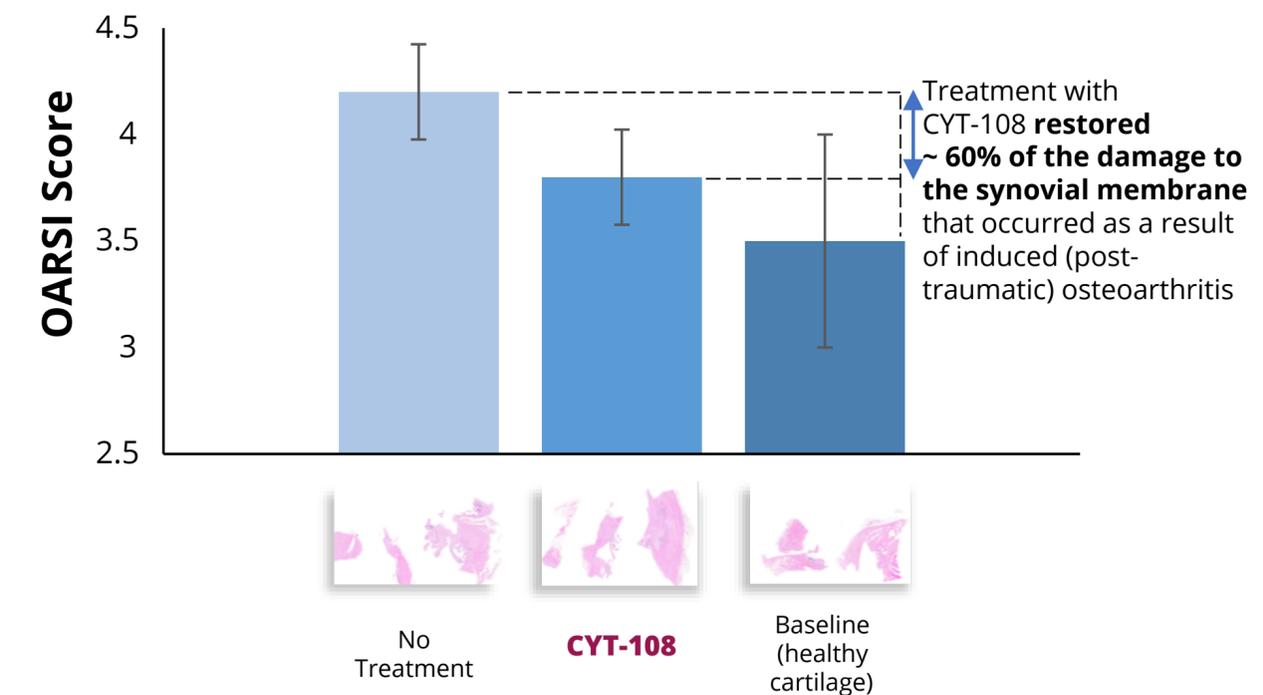
CYT-108 REDUCES CARTILAGE DAMAGE BY 60%

Critical Milestone Achieved Towards FDA Clinical Trials

LEVEL OF CARTILAGE DAMAGE



LEVEL OF SYNOVIAL MEMBRANE DAMAGE

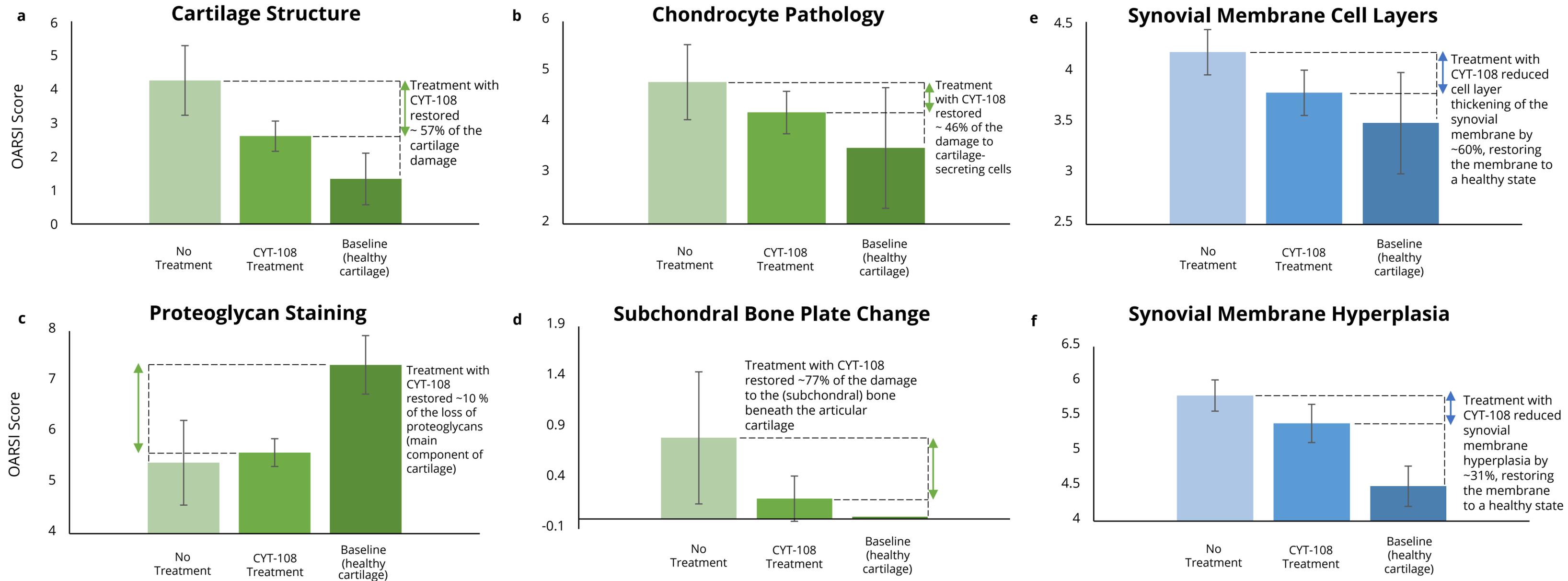


Cartilage and Synovial Membrane damage scored using the standard **OARSI scale**

Note: only representative data is shown. Complete dataset (including 4 additional metrics of cartilage and joint health and an independent review by a pathologist) available upon request.



PRECLINICAL EFFICACY RESULTS – CYT-108 Protects Cartilage and Joint Tissue



Intra-articular injection of our recombinant A2M variant, CYT-108, results in articular cartilage preservation, improved remodeling of the cartilage tissue, recovery of cartilage structure and subchondral bone integrity, and preservation of synovial membrane characteristics in large animal subjects suffering from post-traumatic osteoarthritis. Histopathological grading (modified OARSI scoring system) of the articular cartilage and subchondral bone plate reveals that treatment with CYT-108 results in (a) recovery of ~57% of the damage to the cartilage structure as measured by Safranin-O staining, (b) restoration of ~46% of the damage to chondrocytes (cartilage-secreting cells), (c) enhancement of ~10% proteoglycan content (key component of cartilage), and (d) reduction of ~77% of the subchondral bone plate (bone underneath the cartilage) thickness back to normal levels. Histopathological grading (modified OARSI scoring system) of the synovial membranes of subjects in Groups 1-3 reveals that treatment with CYT-108 results in (e) reduction of ~60% of the pathological accumulation of cell layers in the synovial membrane and (f) reduction of ~31% of synovial tissue hyperplasia (pathological membrane thickening) back to normal levels. Taken together, this data indicates that CYT-108 has therapeutic effect in preserving normal articular cartilage, bone, and synovial membrane physiology when administered to animals suffering from post-traumatic osteoarthritis, and substantially restores the cartilage matrix, underlying subchondral bone, and the synovial membrane back to normal, healthy anatomy and physiology. Error bars +/- SEM.

PRECLINICAL STUDY RESULTS – CYT-108 is Non-Toxic and Safe to Administer

CYT-108 IS SAFE TO ADMINISTER

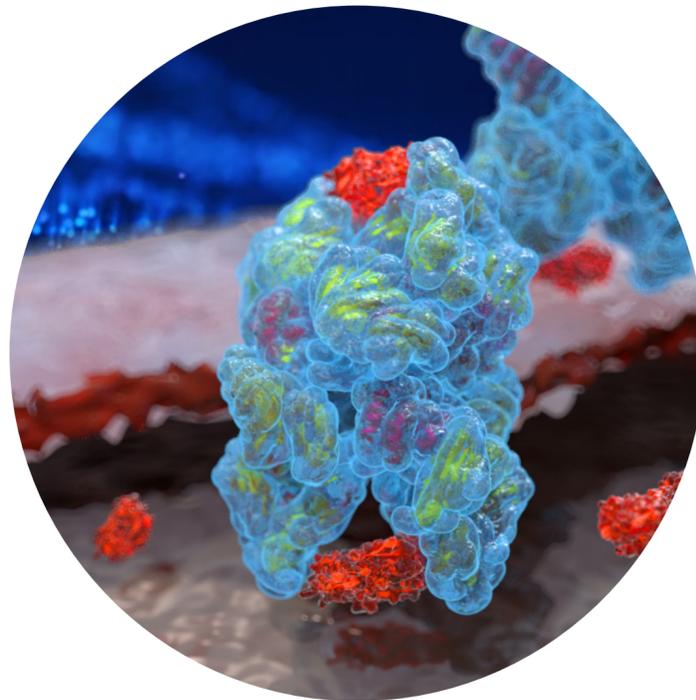
Critical Milestone Achieved Towards FDA Clinical Trials

ORGAN PATHOLOGY

Does administration of CYT-108 affect the health of major organs?

*"...revealed findings consistent with those commonly observed in laboratory subjects, and were **not attributed to treatment with CYT-108.**"*

NO ORGAN DAMAGE



IMMUNOGENICITY

Does administration of CYT-108 cause an immune response?

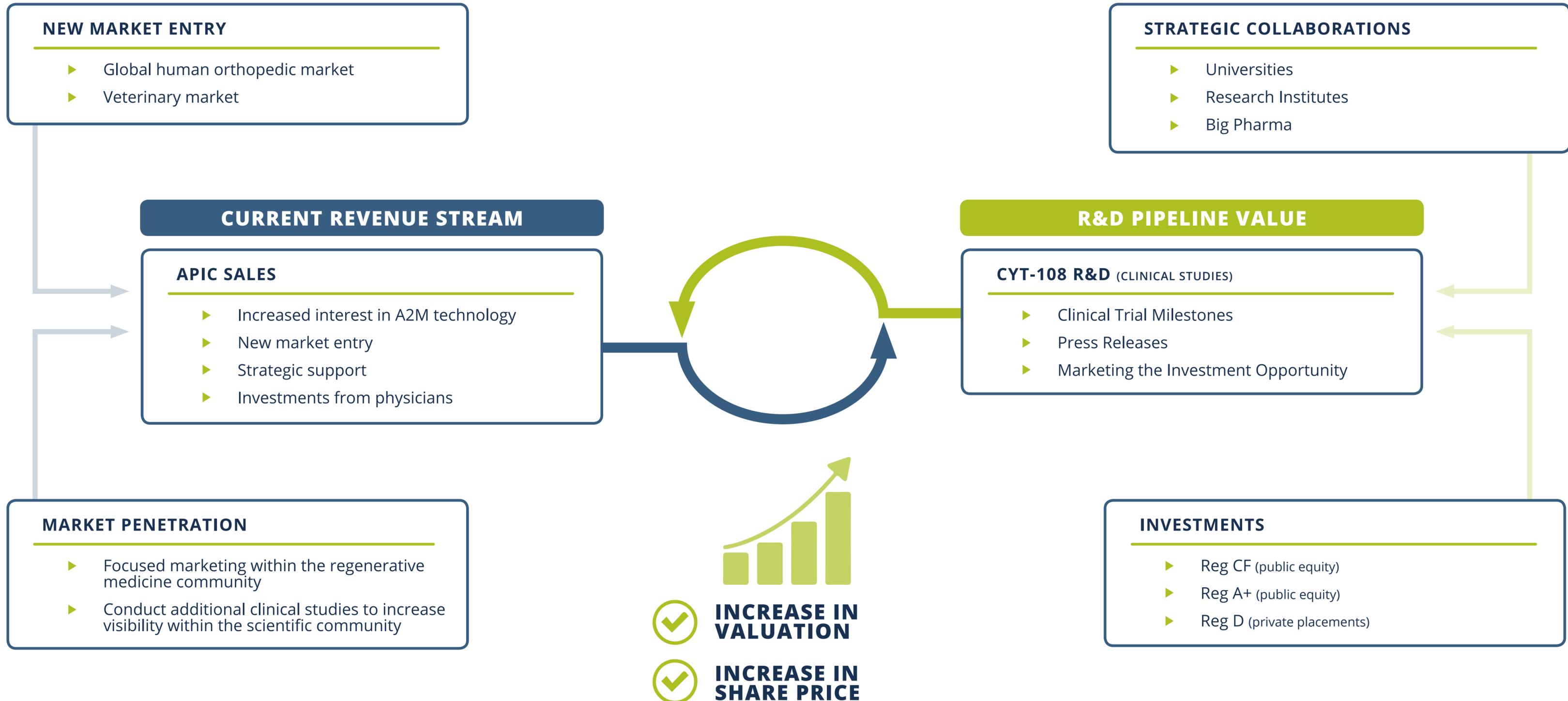
*"...indicating that **none** of the [blood] serum samples showed an immune response [measured by the production of antibodies] as a result of treatment with CYT-108."*

NO IMMUNE RESPONSE

CYT-108 was injected at a **10x proposed dose** to examine the **safety** of the drug when exposed to the systemic circulation

BUSINESS SUMMARY – GROWTH AND INCREASED VALUE

WHAT FACTORS ARE DRIVING THE COMPANY'S GROWTH AND INCREASE IN VALUE?



BUSINESS SUMMARY – APIC FORECAST

HOW DOES THE COMPANY CURRENTLY MAKE MONEY?

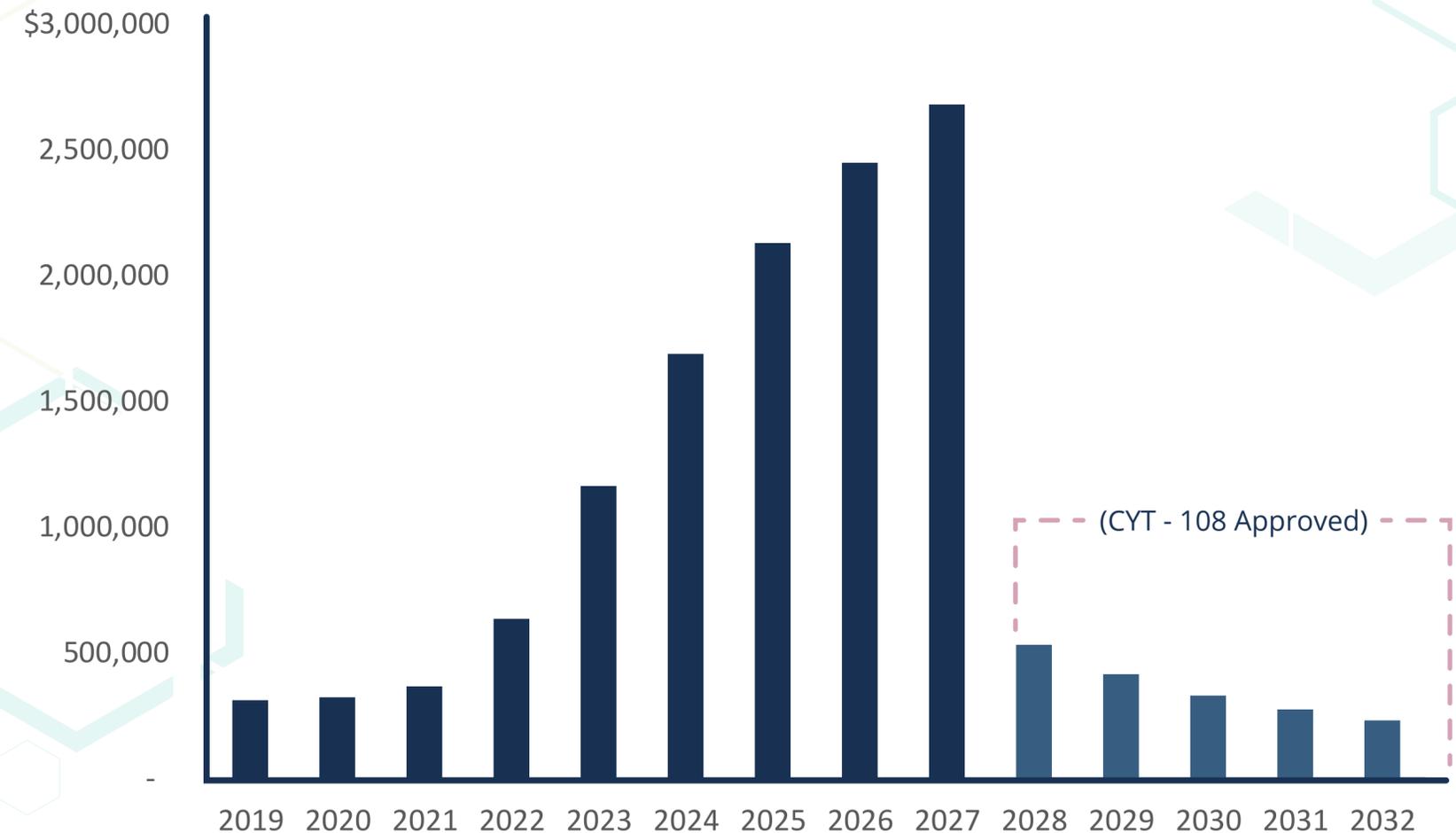
Forecast Parameters and Assumptions

- ▶ Cytonics receives **10% of APIC sales** as royalties.
- ▶ **CYT-108 clinical success will drive APIC sales**, as media attention will increase Cytonics' visibility within the regenerative medicine community.
- ▶ APIC sales will rapidly decline once CYT-108 *if* is approved and hits the market. APIC Sales will be cannibalized by CYT-108, a superior treatment option.

How will we drive future growth?

- ▶ Further penetration into the **human orthopedic market**
- ▶ Expansion into the **veterinary market**
- ▶ Expansion into **global markets**

APIC SALES



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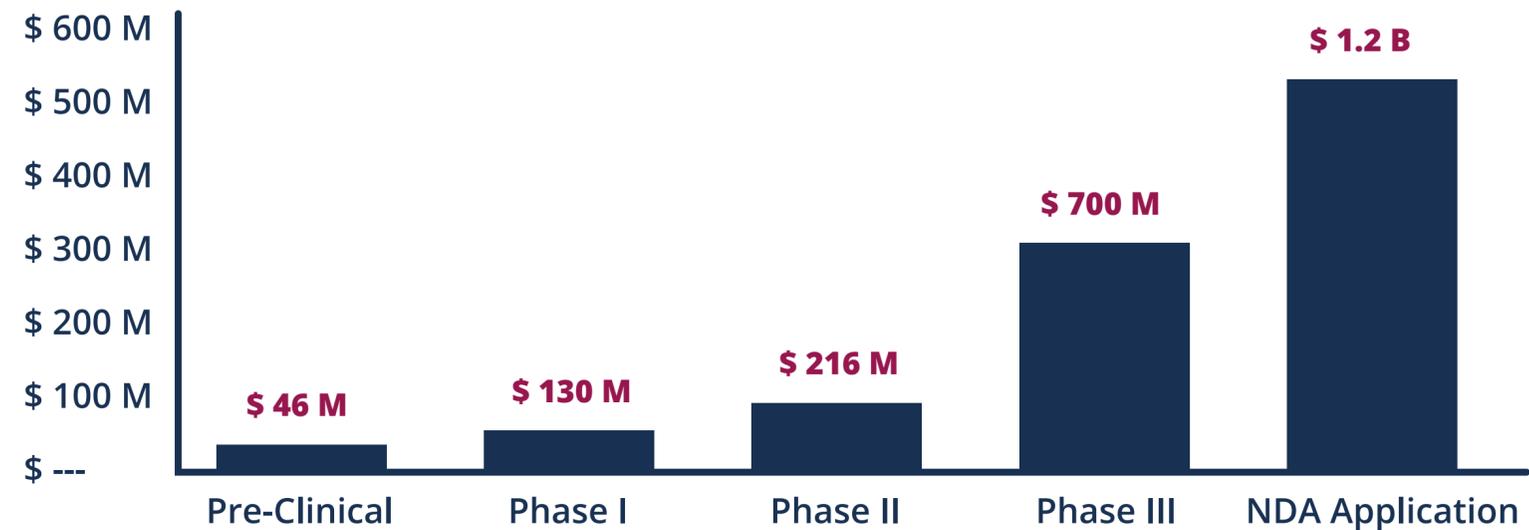


BUSINESS SUMMARY – THE VALUE OF CLINICAL SUCCESS

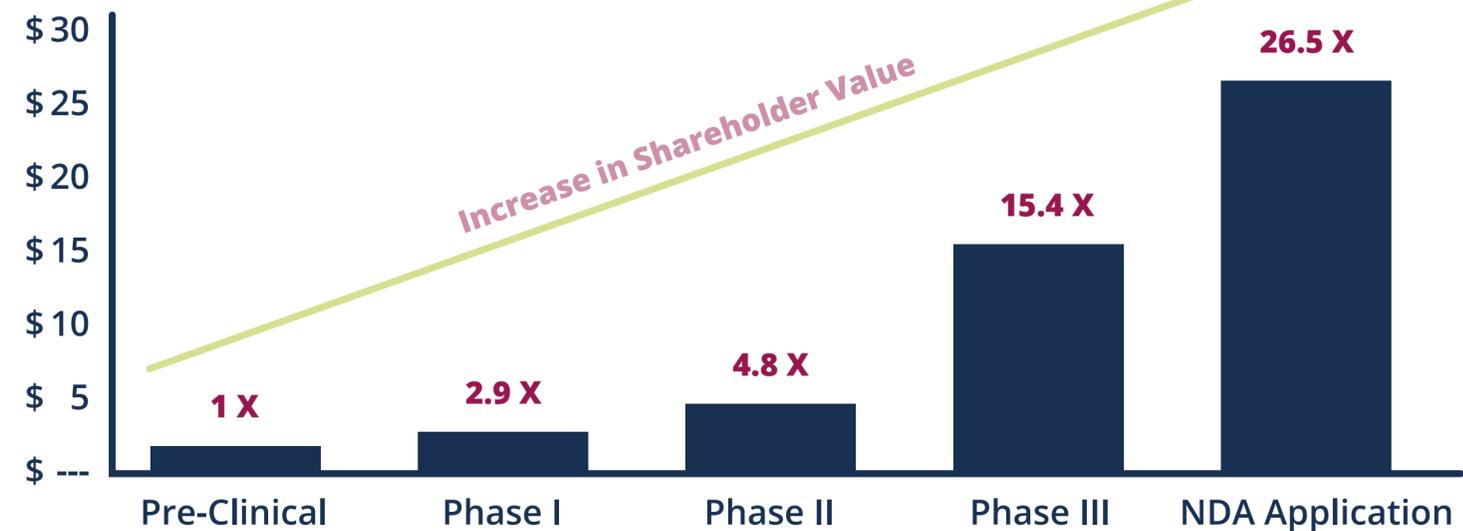
CYT-108 CLINICAL SUCCESS DRIVES VALUATION OF CYTONICS AND INCREASES SHAREHOLDER VALUE

Risk-Adjusted Discounted Cash Flow Assumptions:

- ▶ **Discount rate of 30%**
(this is appropriate for pre-clinical stage biotech)*
- ▶ **2% market capture** (very conservative) in the US human orthopedic market only (does not include expansion into other markets)
- ▶ **\$1,000 per treatment**, avg. 2 treatments per year (Hyaluronic injections cost >\$2,000 each)
- ▶ Cytonics assumes full development cost of bringing CYT-108 to market and producing and selling the drug upon FDA approval
 - ▶ COGS = 15% of revenue (According to a meta-analysis compiled in Biotech Forecasting & Valuation (2016)**. Data was retrieved from company 10-k filings.)
 - ▶ SG&A = 34% (According to an analysis of 35 small- and mid-cap drug companies in the NASDAQ Biotechnology Index in 2015, reported in Biotech Forecasting & Valuation (2016)**)
- ▶ Upon patent expiry, Cytonics' loses 20% of sales per year (Terminal Value in perpetuity)



\$ 1.2 B
After Approval



26.5x
Return After Approval

* <https://www.linkedin.com/pulse/valuation-methodologies-life-science-companies-crean-ph-d-mba/>

**David, Frank S, et al. "The Pharmagellan Guide to Biotech Forecasting and Valuation" Pharmagellan LLC, Pharmagellan, www.pharmagellan.com/book.

BUSINESS SUMMARY – THE VALUE OF CLINICAL SUCCESS

ACQUISITION BY BIG PHARMA MAY OFFER SHAREHOLDERS AN EXIT OPPORTUNITY AND ROI

Biotechnology M&A Activity

- ▶ M&A activity in the biotechnology space is heating up*
- ▶ Low in-house R&D by large pharmaceutical companies has created an attractive environment for buy-outs and licensing opportunities
- ▶ Expiring patents force Big Pharma to acquire novel therapeutics from boutique R&D companies to add to and diversify their pipelines
- ▶ Biotech companies have historically been bought for 10-20x their IPO price

* <https://seekingalpha.com/article/4240702-biotech-bonanza-mergers-acquisitions-theme>

** <https://techcrunch.com/2018/07/28/home-run-exits-happen-stealthily-for-biotech/>

Acquired Company	Valuation at IPO	Post-Acquisition Price	Multiple	Acquiring Company
Receptos	\$ 246,000,000	\$ 7,300,000,000	29.7	Celgene
AveXis	\$ 430,000,000	\$ 8,700,000,000	20.2	Novartis
Kite Pharma	\$ 625,000,000	\$ 11,900,000,000	19.0	Gilead Sciences
Asupex Pharmaceuticals	\$ 270,000,000	\$ 3,500,000,000	13.0	Teva Pharmaceuticals
Foundation Medicine	\$ 486,000,000	\$ 5,080,000,000	10.5	Roche
Kythera Biopharmaceuticals	\$ 225,000,000	\$ 2,100,000,000	9.3	Allergan
ZS Pharma	\$ 300,000,000	\$ 2,700,000,000	9.0	Astrazeneca
Juno Therapeutics	\$ 1,700,000,000	\$ 9,000,000,000	5.3	Celgene
Avg		\$ 535,250,000	\$ 6,285,000,000	14.5



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COMPETITION



STRENGTHS	<ul style="list-style-type: none"> ▶ Small peptide <ul style="list-style-type: none"> ▶ Cheap to manufacture ▶ Formulated from a well-studied, natural protein (Human Serum Albumin). 	<ul style="list-style-type: none"> ▶ Large protein <ul style="list-style-type: none"> ▶ Difficult to replicate <ul style="list-style-type: none"> One of the largest recombinant proteins ever purified. A scientific feat. Due to its large size, CYT-108 is unlikely to diffuse out of the joint cavity and into the bloodstream (this has been validated in small animal studies. We will revalidate in our pre-clinical, large animal study) ▶ We have identified a single mechanism of action (protease inhibition) and characterized the activity of CYT-108 <i>in vivo</i>.
WEAKNESSES	<ul style="list-style-type: none"> ▶ Small peptide <ul style="list-style-type: none"> ▶ Very easy to synthesize and duplicate <ul style="list-style-type: none"> Opportunity to diffuse into the blood stream and have off-target effects ▶ 44% of clinical trial participants experienced an adverse event ▶ No single mechanism of action has been identified ▶ Potential for immunogenicity (the body will recognize the peptide as foreign and mount an immune response) ▶ Only effective for 12 weeks before pain and inflammation return 	<ul style="list-style-type: none"> ▶ Difficult to manufacture due to size ▶ Potential immune response due to breakdown of the protein ▶ A2M is involved in the clotting cascade

SUMMARY (AMPIO)
 Ampio has developed a biologic therapy for treating OA of the knee. Their drug, Ampion, is composed of two amino acids that form the beginning of the albumin protein. Ampio managed to get their drug through Phase 2 clinical trials, however they failed to complete a satisfactory Phase 3 study. Ampio attempted another Phase 3 study, but the FDA found it to be poorly controlled. **Ampio has abandoned OA Phase 3 and PIVOTED TO COVID-19 STUDY - Positive Phase 1 results.**
<https://www.biospace.com/article/releases/ampio-reports-positive-results-for-ampion-treatment-in-covid-19-patients/>

Why has there been no approved therapy?

Big Pharma has failed to develop a treatment for osteoarthritis (OA) because they have adopted a very narrow approach, attempting to imitate the successful discovery of TNF-alpha inhibitors as a treatment for rheumatoid arthritis (RA). Unlike RA, the pathology of OA cannot be distilled down to a single root cause. Big Pharma has failed to appreciate the multi-faceted nature of the disease and develop a therapeutic that tackles all of the causal factors.

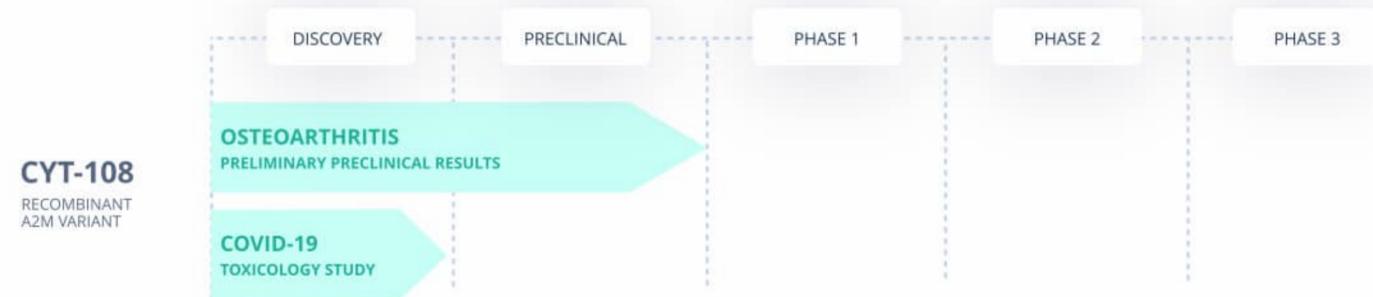
Historically, Big Pharma's focus has been on small molecules instead of biologic therapies (like our recombinant A2M - CYT-108). Biologics have taken off in recent years, and we are on the forefront of this innovation.



DRUG DEVELOPMENT PIPELINE

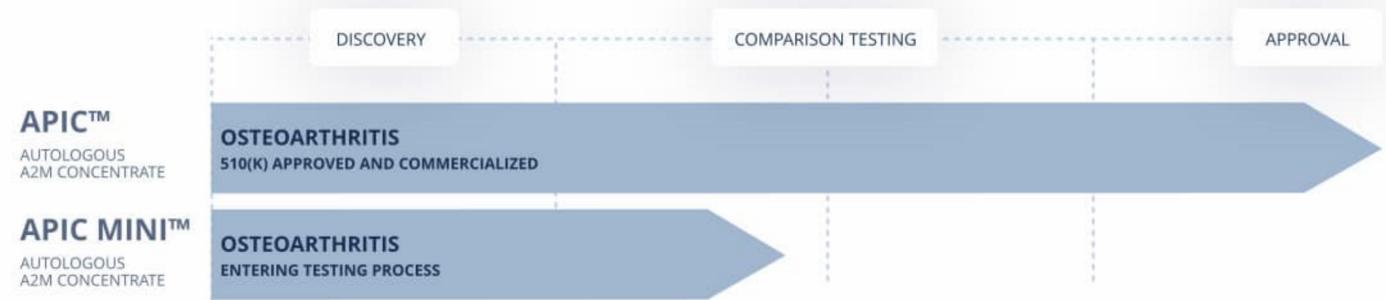
BIOPHARMACEUTICALS

IND (Drug) Pathway to FDA Approval



MEDICAL DEVICES

510(K) Pathway to FDA Approval



DIAGNOSTICS

Clinical Laboratory Test



PATENT STRATEGY SUMMARY

APIC™, FACT™, and Recombinant A2M Variant (CYT-108) Claims

COMPOSITION	
AUTOLOGOUS	RECOMBINANT
Liquid A2M composition <ul style="list-style-type: none"> ▶ GB2501611B ▶ CA 2,865,170 ▶ AU 2013222414 ▶ U.S. 15/910,491 ▶ U.S. 10,265,388 	Non-natural bait region <ul style="list-style-type: none"> ▶ GB2503131B ▶ AU 2015349782 ▶ U.S. 10,400,028 ▶ JP 2017-527277 ▶ U.S. 15/910,477
Non-immunogenic Liquid A2M composition <ul style="list-style-type: none"> ▶ AU 2013222414 	Bait region comprises protease recognition sites <ul style="list-style-type: none"> ▶ GB2503131B ▶ AU 2015349782 ▶ U.S. 10,400,028 ▶ CA 2,967,973 ▶ U.S. 15/910,477
A2M 1.1x higher than sample <ul style="list-style-type: none"> ▶ GB2501611B ▶ AU 2013222414 ▶ U.S. 10,265,388 	Protease Inhibition <ul style="list-style-type: none"> ▶ GB2503131B ▶ U.S. 16/514/591 ▶ EP 3221341

METHODS OF USE / TREATMENT
Method of treating chronic wounds with autologous A2M <ul style="list-style-type: none"> ▶ U.S. Pat. No. 9,352,021
Method of treating chronic wounds with autologous A2M at 1.1x higher than sample <ul style="list-style-type: none"> ▶ U.S. Pat. No. 9,352,021
Method of treating chronic wounds with autologous A2M + non-A2M proteins <ul style="list-style-type: none"> ▶ U.S. Pat. No. 9,352,021
Method of treating chronic wounds with recombinant A2M <ul style="list-style-type: none"> ▶ U.S. Pat. No. 9,498,514
Autologous composition of enriched A2M to treat degenerative joint diseases <ul style="list-style-type: none"> ▶ EP 13751112.7 ▶ U.S. 16/514/591 ▶ CA 2,865,170 ▶ CA 2,967,973 ▶ JP 2017-527277

DEVICES
Flow filtration module + centrifuge <ul style="list-style-type: none"> ▶ GB2522561B

DIAGNOSTICS
Detection of FAC biomarker <ul style="list-style-type: none"> ▶ U.S. 16/514/591

METHODS OF DEVELOPMENT
Engineering recombinant A2M polypeptides <ul style="list-style-type: none"> ▶ U.S. 16/514/591

- ▶ ISSUED
- ▶ PENDING



INVESTMENT OPPORTUNITY



THE OFFERING

\$19M Preferred Stock
Reg A & Reg D

We are seeking to **raise \$19M** through both public and private investment.



USE OF FUNDS

CYT-108 Clinical Trials

Funds will be used to **pursue Phase 1/2 clinical trials** and **manufacturing** for our lead drug candidate, **CYT-108**.



EXIT STRATEGY

- ▶ Uplist to the NASDAQ 2021
- ▶ Strategic Partnerships
- ▶ Acquisition or Out-licensing Opportunities

We will continue to look for **exit opportunities** as the safety and efficacy of the drug is proven in **Phase 1 and 2** clinical trials. **Early liquidity** may be provided via **NASDAQ** listing.



BUSINESS SUMMARY – USE OF FUNDS

TASK	GOAL	COST
GLP PRE-CLINICAL STUDY	Required for approval to conduct human studies	\$ 500,000
GMP PRODUCTION OF CYT-108	Required for use in human studies	\$ 2,000,000
PHASE 1 STUDY	Demonstrate safety and efficacy in humans	\$ 5,000,000
PHASE 2 STUDY APPLICATION & APPROVAL	Begin looking for strategic partnerships and out-licensing opportunities upon approval	\$ 500,000
PHASE 2 STUDY	Dose escalation study to determine optimal dose, demonstrate efficacy, and confirm safety in humans	\$ 11,000,000
		TOTAL
		\$ 19 M

UPCOMING MILESTONES



01

FDA pre-IND Submission for OA

Pre-IND application provides opportunity for dialogue with FDA prior to conducting Phase 1 clinical study for Osteoarthritis. This is critical to designing an effective, efficient human clinical trial

02

FDA pre-IND Meeting for OA

FDA will provide feedback on preclinical data and guidance on GLP preclinical and Phase 1 human clinical trials for Osteoarthritis

03

FDA pre-IND Submission for COVID

Submission of COVID-19 preclinical study proposal and Phase 1 human trial protocol for review and feedback prior to conducting any studies

04

FDA pre-IND Meeting for COVID

FDA will provide feedback on proposed preclinical and Phase 1 human trials for CYT-108 as a treatment for COVID. FDA will also discuss Emergency Use Authorization to expedite the drug approval process for COVID drugs

05

GLP Preclinical Study for OA

Repeat the large animal preclinical study under GLP conditions, as per the FDA's recommendation in the pre-IND meeting (4) for Osteoarthritis held on September 25 (Q3 2020)

06

Preclinical COVID-19 Study

Preclinical study to assess the safety and efficacy of CYT-108 as a therapeutic for COVID-19. Levels of SARS-CoV-2 virus and inflammatory cytokines in the blood and lungs will be measured

07

Reg A Capital Raise Complete

Reg A+ issuance of preferred equity complete. Potential NASDAQ listing following close. Funds will be used to complete drug development, pursue Phase 1 human clinical trials for CYT-108 as a treatment for osteoarthritis, and preclinical studies to assess the safety and efficacy of CYT-108 as a treatment for COVID-19

08

IND Filing for OA human clinical trials

FDA will provide feedback on proposed preclinical and Phase 1 human trials for CYT-108 as a treatment for COVID. FDA will also discuss Emergency Use Authorization to expedite the drug approval process for COVID drugs

09 ★

Phase 1 Trial Begins

Phase 1 human clinical study commences upon FDA acceptance of IND filing. Establishing safety is the primary goal. Efficacy will be scored by measuring a reduction in patient-reported pain



CYTONICS TEAM

Management Team

Gaetano Scuderi, MD – Founder and Chairman, Board Certified Orthopedic Spine Surgeon

Antonio Carvalho, CPA - CEO and CFO, former VP of Finance for Novartis' Global Oncology Division, 25 years' Pharma experience

Joey Bose, MS – President, M.S. Biomedical Engineering (Johns Hopkins University), 10 years' experience in protein engineering

Lewis Hanna, PhD - Chief Scientific Officer, 28 years' experience in protein engineering

Board of Directors

Gaetano Scuderi, MD - Founder and Chairman, Board Certified Orthopedic Spine Surgeon

Antonio Carvalho, CPA - CEO and CFO, former VP of Finance for Novartis' Global Oncology Division, 25 years' Pharma experience

Gordon Ramseier, MBA - Independent Board Member, President and Founder of BCI Life Sciences, 40 years 'Pharma experience

Advisory Board

Vanessa Gabrovsky Cuellar, MD – Orthopedic Surgeon, NYU Hospital

Jason M. Cuellar, MD, PhD – Orthopedic Surgeon, Cedars Sinai Hospital

David Yeomans, PhD - Stanford Research Division Manager

Wayne Olan, MD - Director of Invasive and Endovascular Neurosurgery, George Washington University Medical Center

Thomas San Giovanni, MD - Orthopedic Surgeon, Doctors Hospital (Coral Gables, FL), surgeon for the Miami City Ballet

Martin Angst, MD - Stanford Pain And Anesthesiology Research

Joseph Buckwalter, MD - Orthopedic Surgeon

Geoff Abrams, MD - Orthopedic Surgeon, surgeon for the Chicago Bulls

Raymond Johnson, MBA – CEO of Exit Experts, Harvard Business School, Former President of Cytonics



TEAM BIOGRAPHIES



Gaetano Scuderi, MD **Founder and Chairman of the Board**

Gaetano Scuderi, MD is the Founder of Cytonics Corporation. Dr. Scuderi is a fellowship-trained (UCSD, San Diego, CA) spine surgeon who has practiced medicine since 1993. He was also appointed to Clinical Assistant Professor in the Department of Orthopedic Surgery of Stanford University. He graduated medical school from State University of New York (Buffalo, NY) and completed his Residency at University of Miami School of Medicine (Miami, FL). Dr. Scuderi has published over 45 scientific articles and has lectured world-wide. Dr. Scuderi currently practices orthopedic surgery in Jupiter, FL.

In addition to his clinical practice and his role with Cytonics, Dr. Scuderi is a 4th degree black-belt in Jiu Jitsu and the founder/principle instructor of Scuderi Self Defense (Jupiter, FL). Dr. Scuderi's love for this martial art is only surpassed by his passion for helping the sick and elderly reclaim their mobility and quality of life.



Antonio Carvalho, CPA **CEO and CFO**

Mr. Carvalho has more than 25 years' experience developing, manufacturing, and commercializing innovative products in the pharmaceutical and consumer product industries. He served as Vice President of Finance for the Global Oncology business unit of Novartis Pharmaceuticals, where he had financial oversight for the unit's 20 product launches in a 5 year span. Prior to this role, Mr. Carvalho was the General Manager for Novartis' US Pharmaceutical manufacturing unit. His other roles at Novartis included CFO Latin America, CFO US Ophthalmics, and Vice President and Controller for Novartis' US Pharmaceutical Division. Mr. Carvalho has a BBA in Accounting from Iona College (New Rochelle, NY) and is a Certified Public Accountant.

TEAM BIOGRAPHIES



Joey Bose, MS President

Mr. Bose has over 10 years' experience in biotechnology research development and healthcare investment banking. He began his career as a systems biology researcher at the University of Virginia and Johns Hopkins University, advancing the field of proteomics and elucidating the molecular drivers of cancers. Mr. Bose worked for two boutique healthcare investment banks/consultancies in the south Florida region, bringing his expertise in translational medicine to the deal diligencing team. As President of Cytonics, his primary responsibilities include coordinating capital raising efforts, initiating clinical trials for the company's lead drug candidate (CYT-108), filing and maintaining patent protection of intellectual property, and identifying strategic buyers and out-licensing opportunities for the company. He holds a BS in Biomedical Engineering from the University of Virginia (Charlottesville, VA) and an MS in Biomedical Engineering from Johns Hopkins University (Baltimore, MD).



Lewis Hanna, PhD Chief Scientific Officer

Dr. Hanna has served as Chief Scientific Officer of Cytonics since February 2008. Dr. Hanna has over 28 years' experience in pharmaceutical research and development, specializing in the development of recombinant protein therapies. He has extensive knowledge of protein folding, purification, formulation, large-scale production, quality, and the regulatory requirements to obtain FDA new drug approval. Until 2004, Dr. Hanna was the Director of Process Development at Alexion Pharmaceutical, and prior to that he was a Group Leader at Bristol-Myers Squibb Pharmaceutical Research Institute. He also served a Principal Research Scientist at R.W. Johnson Pharmaceutical Research Institute (Raritan, NJ) for 7 years. Dr. Hanna received his BS degree from Cairo University (Giza, Egypt), received his PhD from City University of New York (New York City, NY), and completed a post-doctoral fellowship at Cornell University (Ithaca, NY).

KEYS TO SUCCESS



MASSIVE MARKET POTENTIAL

FOR EFFECTIVE DIAGNOSTICS AND ORTHOPEDIC PAIN RELIEF THERAPEUTICS

- ▶ \$180B market for effective osteoarthritis treatments



BROAD PATENT COVERAGE

- ▶ World-renowned Wilson Sonsini Patent Attorneys
- ▶ 9 issued international patents, 8 pending



MAJOR BREAKTHROUGH DISCOVERIES

- ▶ Fibronectin-Aggregan Complex biomarker for osteoarthritis
- ▶ Purified one of the largest recombinant proteins to-date



TRACK RECORD OF SUCCESS

- ▶ Over 7,000 patients treated with APIC therapy
- ▶ Successful 510k approval for APIC technology
- ▶ **Critical preclinical data supporting CYT-108**
- ▶ Over \$18M capital raised
- ▶ **J&J large shareholder**
- ▶ \$1.8M NIH grants



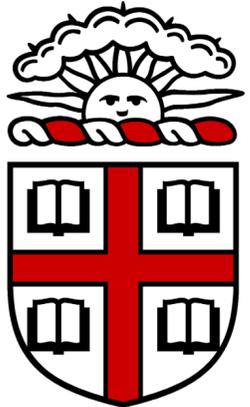
POSSESS CORE COMPETENCIES TO ACHIEVE MILESTONES

- ▶ Hogen-Lovells Regulatory Attorneys
- ▶ Wilson Sonsini Goodrich & Rosati Patent Attorneys

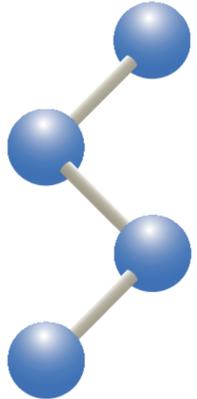


OUTSTANDING TEAM OF MBAs, MDs, AND PhDs

OUR COLLABORATORS



BROWN



THE
SCRIPPS
RESEARCH
INSTITUTE



Stanford
MEDICINE



Jefferson®
University and Hospitals

Beaumont®

HEALTH
SYSTEM



FAU
FLORIDA ATLANTIC
UNIVERSITY



APPENDIX – PUBLICATIONS

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- ▶ Bedi, Asheesh, et al. *"The Effect of Matrix Metalloproteinase Inhibition on Tendon-to-Bone Healing in a Rotator Cuff Repair Model."* Journal of Shoulder and Elbow Surgery, vol. 19, no. 3, 2010, pp. 384–391., doi:10.1016/j.jse.2009.07.010.
- ▶ Browning, Shawn R, et al. *"Platelet-Rich Plasma Increases Matrix Metalloproteinases in Cultures of Human Synovial Fibroblasts."* The Journal of Bone and Joint Surgery-American Volume, vol. 94, no. 23, 2012, doi:10.2106/jbjs.k.01501.
- ▶ Cuellar, Jason M. *"Intradiscal Injection of an Autologous Alpha-2-Macroglobulin (A2M) Concentrate Alleviates Back Pain in FAC-Positive Patients."* Orthopedics and Rheumatology Open Access Journal, vol. 4, no. 2, Mar. 2017, doi:10.19080/oroaj.2017.04.555634.
- ▶ Demirag, Burak, et al. *"The Effect of Alpha-2 Macroglobulin on the Healing of Ruptured Anterior Cruciate Ligament in Rabbits."* Connective Tissue Research, vol. 45, no. 1, 2004, pp. 23–27., doi:10.1080/03008200490278115.
- ▶ Demirag, Burak. *"Enhancement of Tendon-Bone Healing of Anterior Cruciate Ligament Grafts by Blockage of Matrix Metalloproteinases."* The Journal of Bone and Joint Surgery (American), vol. 87, no. 11, Jan. 2005, p. 2401., doi:10.2106/jbjs.d.01952.
- ▶ Gettins, Peter, and Leon W. Cunningham. *"Identification of Proton Resonances from the Bait Region of Human .Alpha.2-Macroglobulin and Effects of Proteases and Methylamine."* Biochemistry, vol. 25, no. 18, 1986, pp. 5011–5017., doi:10.1021/bi00366a007.
- ▶ Luan, Y., et al. *"Inhibition of ADAMTS-7 and ADAMTS-12 Degradation of Cartilage Oligomeric Matrix Protein by Alpha-2-Macroglobulin."* Osteoarthritis and Cartilage, vol. 16, no. 11, 2008, pp. 1413–1420., doi:10.1016/j.joca.2008.03.017.
- ▶ Marynen, P., et al. *"A Genetic Polymorphism in a Functional Domain of Human Pregnancy Zone Protein: the Bait Region."* FEBS Letters, vol. 262, no. 2, 1990, pp. 349–352., doi:10.1016/0014-5793(90)80226-9.
- ▶ Tortorella, Micky D., et al. *"α2-Macroglobulin Is a Novel Substrate for ADAMTS-4 and ADAMTS-5 and Represents an Endogenous Inhibitor of These Enzymes."* Journal Biological Chemistry, vol. 279, no. 17, July 2004, of pp. 17554–17561., doi:10.1074/jbc.m313041200.
- ▶ Zhang, Yang, et al. *"Targeted Designed Variants of Alpha-2-Macroglobulin (A2M) Attenuate Cartilage Degeneration in a Rat Model of Osteoarthritis Induced by Anterior Cruciate Ligament Transection."* Arthritis Research & Therapy, vol. 19, no. 1, 2017, doi:10.1186/s13075-017-1363-4.

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RELIEF FOR OSTEOARTHRITIS

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