

From: John Redaelli Re: My "Public Comment", for the "November IP and Industry Subcommittee Meeting (11/8/2023)

From: John Redaelli (California Resident)

To: Claudette Mandac at cmandac@circm.ca.gov

Re: My "Public Comment" for the [November IP and Industry Subcommittee Meeting](#) (November 8, 2023)

Hello, Claudette...

I hope you are well...Thank You, for this opportunity to present my "Public Comment" to you for the

"November IP and Industry Subcommittee Meeting" (November 8, 2023)...My name is John Redaelli, I live in Huntington Beach, CA...I'm a shareholder in Athersys...I've been following, researching, and investing in the Cell Therapy / Regenerative Medicine sector for over (10) years now...First with, Advanced Cell Technology (ACTC), which became Ocata Therapeutics (OCAT), and later bought out by Astellas... And, now with Athersys...Acting on my own initiative, I'm writing to you in support of consideration by CIRM for a possible buyout of Athersys?...

Currently, Athersys stock (OTC Market: ATHX) is trading at multi-year lows with a market cap of less than a million dollars...Source: finance.yahoo.com/quote/ATHX/

In a recent Athersys PR (Oct. 10, 2023): [Athersys Reports Interim Analysis Results of MASTERS-2 Clinical Study with MultiStem in Ischemic Stroke, Signs Memorandum of Understanding \(MOU\) for Global ARDS License with Healios](#)

(Partial, from the above PR):

Separately, Athersys announces that it has entered into a Memorandum of Understanding (MOU) granting HEALIOS K.K. (Healios) global rights to develop and commercialize MultiStem for the treatment of acute respiratory distress syndrome (ARDS). Under the terms of the MOU, Athersys will receive between \$1.5M and \$4.5M in near term payments with up to \$150 million in potential development and sales milestones and additional royalties. Athersys also expects to receive revenue from the sale of existing clinical doses of MultiStem-- which were manufactured in accordance with its 3D bioreactor process that earlier this year received approval from Japan's Pharmaceuticals and Medical Devices Agency (PMDA)--for Healios to use in its Phase 3 clinical trial in ARDS.

Athersys intends to continue exploring available strategic options. However, in the event Athersys is unable in the near-term to enter into a strategic transaction or obtain adequate financing, it expects to have to file for protection under the bankruptcy laws to

allow the Company to conduct an orderly wind down of operations. In the interim, the Company is streamlining its operations to preserve its capital and cash resources. (END)

And, in another recent Athersys PR (Oct. 3, 2023): [Athersys Licenses its Animal Health Assets to Ardent Animal Health](#)

(Partial, from the above PR):

Under the terms of the agreement, Athersys will receive an initial fee from Ardent in exchange for an exclusive license to Athersys' Multipotent Adult Progenitor Cell (MAPC®) technology for non-human mammal applications in the United States. The agreement includes pre- and post-regulatory approval milestone payments to Athersys, including payments on conditional and full product approval for each species/indication combination. Athersys will also receive tiered, double-digit royalties on commercial sales.

Athersys has also granted Ardent rights of first refusal to be the exclusive distributor for Athersys' novel cryogenic storage system, the Secure Integrated Freezer Unit (SIFU) in the United States animal health space.

(More about SIFU by Athersys

- s23.q4cdn.com/674737627/files/doc_downloads/2023/02/Athersys-SIFU-Overview-1-Page.pdf)

"We're excited to announce this agreement with Ardent based on their proven capabilities in developing stem cell-based treatment options for animals. This agreement recognizes the progress we've made in preclinical research and manufacturing of MAPC for animal health and provides Ardent a solid foundation to build on," stated Dan Camardo, Chief Executive Officer of Athersys. (END)




Separately, upon my review at the CIRM website for funded projects over the years - <http://www.cirm.ca.gov/our-funding/funded-institutions/>

At a cost of \$3,655,904,313.13, for a total of 1396 CIRM funded projects throughout the years, what has been the results?...According to David Jensen, who diligently writes about CIRM at his "The California Stem Cell Report" - "[So far, CIRM has not yet funded a stem cell or gene therapy that is available to the general public.](#)" Oh My God!...If, all the above is true, might we all agree we must find ways to do SO MUCH BETTER?!...

Looking at Athersys again, and their rich promising potential in various indications, in late, and early stage development from their most recent Corporate Presentation pdf (8/25/2023) - s23.q4cdn.com/674737627/files/doc_presentations/2023/Athersys-Corporate-Summary.pdf



Lead Indications

	 Ischemic Stroke	 ARDS	 Trauma
Frequency	~800,000 strokes per year in the US	200,000 cases in the U.S. annually	3 million non-fatal injuries per year 150,000 deaths, and ~2/3 of trauma patients will experience SIRS (Systemic Inflammatory Response Syndrome)
Patient Impact	Leading cause of disability and third highest cause of death	Up to 50% mortality rate One of the leading causes of death in severe COVID cases	Leading cause of death in people under 40 in the U.S
Economic Burden	Over \$55 billion cost to the health care system annually	Leading cause of ventilation and ICU admission	The economic cost of trauma amounts to \$671 billion every year
Treatment Options	Current standard of care includes thrombolytics and mechanical thrombectomy, which reach only 30% of patients	Few effective therapeutic modalities exist to ameliorate this deadly condition	Limited effective treatment options for SIRS (Systemic Inflammatory Response Syndrome)
Addressable Population	43% of all strokes are moderate to severe Ischemic strokes, the focus of our trial with MultiStem	MultiStem is currently being studied in patients with moderate-severe ARDS, 77% of the total ARDS population	We estimate that up to 70% of severe trauma patients admitted to the hospital could benefit from treatment with MultiStem



MultiStem® Cell Therapy Platform: Opportunities Across Serious Unmet Need Indications

PHASE 3	Ischemic Stroke	IND READY	Hemorrhagic Stroke	NONCLINICAL	Parkinson's Disease	NONCLINICAL	Rheumatoid Arthritis
PHASE 2	Trauma	IND READY	Hypoxic Ischemia	NONCLINICAL	Alzheimer's Disease	NONCLINICAL	Congestive Heart Failure
PHASE 2/3	Acute Respiratory Distress Disorder	IND READY	Traumatic Brain Injury	NONCLINICAL	Lysosomal Storage Disorders	NONCLINICAL	Peripheral Vascular Disease
PHASE 2/3	Graft vs Host Disease	IND READY	Spinal Cord Injury	NONCLINICAL	Multiple Sclerosis	DEVELOPMENT	Animal Health: Canine
PHASE 2	Acute Myocardial Infarction	NONCLINICAL	Acute Radiation Syndrome	NONCLINICAL	Alcoholic Hepatitis	DEVELOPMENT	Animal Health: Equine
IND READY	Transplantation	NONCLINICAL	Epilepsy	NONCLINICAL	Wound Healing	DEVELOPMENT	Animal Health: Feline

 Orphan Granted  Orphan Eligible

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Could an argument be made that a potential buy-out of Athersys, if possible, could potentially yield positive results for CIRM, that have yet to be realized to date?...A cell therapy that is available to the general public?...At a small fraction of the cost CIRM has spent on all these grants to date?...Athersys' debt, which is substantial (\$20m?), could possibly be renegotiated with the debt holders, and more beneficial to them in a buyout

versus any money they would receive via bankruptcy?... If, successful, think of the potential value, and INCOME such a buyout could potentially create for CIRM!...

Final Note: If, in fact, California law prohibits stock ownership (and buyouts) of a potential grantee by CIRM, might it be time for CIRM to consider approaching the California legislature, to seek overturning this law?...Not only for the possible purchase of Athersys, but, for other promising companies in the cell and gene therapy sector, that struggle with continuing operations and staying afloat...Only to be lost and forever forgotten...Added to the list of MISSED OPPORTUNITIES...

Thank You, Again, For Allowing Me To Present My Public Comment...

Best Wishes, CIRM...

John Redaelli
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PS. My previous "Public Comments" to CIRM:

www.cirm.ca.gov/wp-content/uploads/2023/09/825-Neuro-Task-Force-Public-Comment.pdf

And...

www.cirm.ca.gov/wp-content/uploads/2023/09/825-Neuro-Task-Force-2nd-Public-Comment.pdf