

## Athersys Inc. (NASDAQ/ATHX) Buy Rated

September 23, 2020

### Athersys Receives an RMAT Designation for MultiStem in ARDS

We are pleased to see Athersys receive the Regenerative Medicine Advanced Therapy (RMAT) designation for MultiStem in Acute Respiratory Distress Syndrome (ARDS). This follows an RMAT designation for MultiStem in Stroke. Athersys is making progress in the MACOVIA (COVID-ARDS) trial.

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#### Highlights

**RMAT** - The RMAT designation enables sponsors to work closely with the FDA and receive their guidance on expediting the development of their products, including providing advice on generating the evidence needed to support approval efficiently. The RMAT designation invites the company to schedule a Type B meeting with the FDA to discuss multidisciplinary strategic development plans, including expediting manufacturing development for commercialization to support priority review, which could lead to accelerated approval.

**COVID-19:** The U.S. trial is well underway and enrolling patients. The trial is an open-label, single active treatment arm planned to evaluate MultiStem at two dose levels in patients with moderate to severe ARDS associated with COVID-19. If the treatment is well tolerated in this first cohort, the study is designed to further evaluate MultiStem efficacy, safety, and tolerability in this patient population using a robustly powered, double-blind, randomized, and placebo-controlled trial protocol. The primary efficacy endpoint for the MACOVIA study will compare the number of ventilator-free days through day 28 among MultiStem and placebo treatment groups. Secondary objectives of the study are to evaluate 60-day all-cause mortality, time in the intensive care unit, pulmonary function, tolerability, and quality of life (QoL) among survivors through one year of follow-up.

**MAGA - Make Athersys Great (again).** Athersys is working hard to complete current trials in stroke and trauma, as well as the COVID-19 ARDS trial. The goal remains to complete the Master's 2 study next year. Partner Healios is also working to complete the TREASURE (stroke trial) this year and its ONE-BRIDGE ARDS study, which will now include Wuhan Virus patients in Japan.

**Athersys Has Runway.** Athersys raised approximately \$57.6 million, bringing 2Q (June) cash to \$80.7M.

**Valuation.** Our therapeutic models for MultiStem do not include ARDS. We assume a probability of success (PoS) factor across the various other indications. In addition to this, we also apply a 30% risk rate (r) in our Free Cash Flow to the Firm (FCFF), discounted EPS, and Sum-Of-The-Parts (SOP) models. Our price target is derived from these three models, equally weighting and averaged to the nearest whole number. The result is a one-year price target of \$7.00 per share. We caution that models can't predict clinical trial outcomes, but we do suggest that upon success, the company is undervalued.

Current Price	\$1.97
Price Target	\$7.00

Estimates	F2019A	F2020E	F2021E
<b>Expenses (\$000s)</b>	\$ 51,121	\$ 54,166	\$ 46,615
1Q March	\$ 14,705	\$ 15,759	\$ 10,721
2Q June	\$ 14,163	\$ 18,421	\$ 11,188
3Q September	\$ 11,981	\$ 13,597	\$ 11,654
4Q December	\$ 10,272	\$ 6,389	\$ 13,052

	F2019A	F2020E	F2021E
<b>EPS (diluted)</b>	\$ (0.29)	\$ (0.28)	\$ (0.20)
1Q March	\$ (0.09)	\$ (0.10)	\$ (0.05)
2Q June	\$ (0.06)	\$ (0.10)	\$ (0.05)
3Q September	\$ (0.08)	\$ (0.06)	\$ (0.05)
4Q December	\$ (0.06)	\$ (0.03)	\$ (0.05)

	F2019A	F2020E	F2021E
<b>EBITDA/Share</b>	(\$0.29)	(\$0.27)	(\$0.20)
<b>EV/EBITDA (x)</b>	1,173	1,275	1,745

Stock Data			
52-Week Range	\$1.13	-	\$4.38
Shares Outstanding (mil.)	197.4		
Market Capitalization (mil.)	\$389		
Enterprise Value (mil.)	\$345		
Debt to Capital	0%		
Book Value/Share	\$0.19		
Price/Book	8.4		
Average Three Months Trading Volume (K)	13,034		
Insider Ownership	10.1%		
Institutional Ownership	28.4%		
Short interest (mil.)	12.5%		
Dividend / Yield	\$0.00/0.0%		



**We Believe.** Athersys's MultiStem offers great hope for patients suffering from Acute Respiratory Distress Syndrome (ARDS). ARDS occurs when fluid builds up in the tiny, elastic air sacs (alveoli) in your lungs. Severe pneumonia and the new Coronavirus, too, can result in an infection in the lobes of the lungs, triggering an inflammatory cascade that causes death. Data on Athersys Multistem suggest efficacy in treating ARDS independent of the pathogen (or insult) that is the cause.

- Received authorization from the U.S. Food and Drug Administration (FDA) to initiate a Phase 2/3 COVID-19 induced acute respiratory distress syndrome (ARDS) clinical trial; completed site initiation and began enrolling patients in this trial referred to as the MACOVIA study.
- Received FDA authorization to initiate a Phase 2 clinical trial with The University of Texas Health Science Center at Houston (UTHealth) titled MultiStem Administration for Trauma-Related Inflammation and Complications (MATRICS-1); funded by a grant from the Medical Technology Enterprise Consortium (MTEC) and the Memorial Hermann Foundation;
- Announced positive one-year results from an exploratory clinical study of MultiStem cell therapy for ARDS; MultiStem treated patients reported consistent improvement in the quality of life over the one-year evaluation period and showed marked improvements in key clinical metrics, including intensive care unit-free days, ventilator-free days, and mortality compared to placebo, especially in patients with pneumonia-induced ARDS;
- Furthered discussions with the Biomedical Advanced Research and Development Authority (BARDA) to establish a collaboration to advance the MultiStem program;
- Appointed Mr. Ivor Macleod as Chief Financial Officer and Ms. Maia Hansen as Senior Vice President, Operations and Supply Chain, adding their expertise to the leadership team to help plan and execute the strategy as we approach potential product commercialization;
- Initiated new sites for the MASTERS-2 ischemic stroke study while continuing to enroll new patients into the trial;
- Advanced through Japanese partner HEALIOS K.K. (Healios) its ARDS and ischemic stroke programs, with Healios disclosing its intent to finish enrollment of both its ONE-BRIDGE ARDS study and its TREASURE stroke study this year;
- Engaged in partnering discussions with companies interested in MultiStem commercialization rights in Europe and other regions;

**Risks to our thesis include the following:** (1) clinical trial; (2) commercial; (3) employee; (4) financial; (5) intellectual property; (6) partnership; and (7) regulatory. We review these and other risks in the risk section of this report.

**COVID ARDS Trial Design:** The trial is planned as a multicenter study featuring an open-label lead-in followed by a double-blinded, randomized, placebo-controlled Phase 2/3 portion. The primary objectives of the MACOVIA study is to evaluate the safety and efficacy of MultiStem therapy as a treatment for subjects with moderate to severe ARDS due to COVID-19.

- The primary efficacy endpoint will be number of ventilator-free days through day 28 as compared to placebo, a well-established endpoint for ARDS trials that evaluates an intervention's combined impact on survival and liberation from invasive mechanical ventilation.
- The secondary objectives of this study are to evaluate pulmonary function, all-cause mortality, tolerability, and quality of life (QoL) among survivors associated with MultiStem therapy as a treatment for subjects with moderate to severe ARDS due to COVID-19. The study is designed to enroll approximately 400 subjects and will be conducted at leading pulmonary critical care centers throughout the U.S. The first cohort of the study will be open-label, with a single active treatment arm to evaluate the safety of the MultiStem product candidate at two dose levels. The second cohort will be a double-blind, randomized, placebo-controlled run-in phase to evaluate the efficacy of MultiStem. The design of the third planned cohort will be based on analysis of the results of the second cohort. The intent-to-treat population will include all randomized subjects (i.e., subjects from the second and third cohorts).

**We Review Multistem's Prior Program in ARDS.** A few key observations, in our opinion, make this relevant today given the Coronavirus outbreak in China and the world.

1. The data released previously is impressive for a small study and suggests that Multistem has efficacy in ARDS.
2. Multistem works independent of the cause, albeit pneumonia or the coronavirus. As such, it has the potential to be an ideal, first-line defense for patients in respiratory distress.
3. ARDs has a high mortality rate. The treatment protocols are very complex, and one look at the numbers in China tells us the potential to overwhelm the system, any system be it the U.S. or China, is a great risk.
4. ARDS is likely the factor that tips most pneumonia (& likely Coronavirus) patients to a high risk, high mortality outcome.
5. A universal treatment that can limit ARDS could be a life-saver. All indications suggest that Athersys partner Healios is keenly interested. The Japanese media and government are focused on the coronavirus. It is the number one news story in Japan and has been for weeks.
6. Early data not only suggest better outcomes at 28 days, but one-year follow-up also suggests that treated patients are more likely to reestablish the same quality of life versus control patients prior to ARDS.

**Quality-of-Life (QOL) Out to a Year.** Recall that Athersys announced follow-up results from the prior ARDS study of IV (intravenous) MultiStem. These participants were evaluated through 28 days for the primary clinical assessment and again at a one-year follow-up. Of note, the most severe patients seemed to do the best (20% mortality versus 50% on control).

**Key Data Points from the Athersys ARDS study:**

- Previously observed lower mortality for MultiStem-treated subjects compared to placebo (particularly among the prospectively defined subset of more severe ARDS patients) persisted out to one-year of follow-up;
- Day-365 Quality of Life (QoL) outcomes, assessed by the EQ-5D, were meaningfully better among all survivors who received MultiStem treatment compared to those who received placebo;
- Within the prospectively defined group of patients with more severe ARDS, MultiStem treatment was associated with a markedly greater rate of survival and progression to functional independence at one year (i.e., self-care);
- As measured at day-28, MultiStem treatment was associated with a higher mean ventilator-free day (VFD) score of 12.9 vs. 9.2 in the placebo group, and a higher mean intensive care unit (ICU)-free day score of 10.3 vs. 8.1 in the placebo group;
- As measured at day-28, among more severe ARDS patients, mean VFD in the MultiStem subgroup was 14.6 vs. 8.0 in placebo subgroup. Mean ICU-free days were 11.4 vs. 5.9 for MultiStem and placebo recipients, respectively;
- Lower inflammatory cytokine levels at day-7 in the MultiStem group relative to the placebo group, including IFN $\gamma$ , IL-6, and IL-1b among others, suggest the potential for MultiStem treatment to abate the severe inflammatory response associated with ARDS; and
- MultiStem treatment was well tolerated in this very sick ARDS patient population, with no serious adverse events related to administration through one year of follow-up.

**Exhibit 1. The Phase 2 ARDS Trial was a randomized, double-blind, placebo-controlled trial evaluating patients through 28-day clinical assessment with one year follow up.**

<b>All Subjects</b>	<b>MultiStem</b>	<b>Placebo</b>
Number	20	10
Ventilator-free days (mean)	12.9	9.2
(median)	<b>18.5</b>	<b>6.5</b>
ICU-free days (mean)	10.3	8.1
(median)	<b>12.5</b>	<b>4.5</b>
Mortality (d28)	25%	40%
<b>Patients w/ Low pulmonary function: PaO<sub>2</sub>/FiO<sub>2</sub> &lt; 150 mm at baseline</b>	<b>MultiStem</b>	<b>Placebo</b>
Number	8	8
Ventilator-free days (mean)	14.6	8.0
(median)	<b>18.5</b>	<b>3.5</b>
ICU-free days (mean)	11.4	5.9
(median)	<b>12.5</b>	<b>1</b>
Mortality (d28)	25%	50%

Source: Athersys

**Exhibit 2. The Post-hoc analysis of Pneumonia-Induced ARDS, Severe cases –PaO<sub>2</sub>/FiO<sub>2</sub>Ratios at Day 0, Pre-infusion < 150.** Data for severe cases of pneumonia-induced ARDS shows an even greater difference in mortality rate, Vent-free, and ICU-free days between the subjects treated with MultiStem and the patients in the placebo-controlled group.

	<b>MultiStem</b>	<b>Placebo</b>
<b>Day-28 Mortality</b>	20%	50%
<b>Ventilator-free days (mean)</b>	14.8	7.5
<b>Ventilator-free days (median)</b>	<b>18.0</b>	<b>3.5</b>
<b>ICU-free days (mean)</b>	12.0	5.0
<b>ICU-free days (median)</b>	<b>15.0</b>	<b>1.0</b>

Source: Athersys

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## Modeling Assumptions

1. The MultiStem program is the main platform for the company, and we view it as the driver of the company's success. We assume Athersys continues developing the MultiStem program in neurological, cardiovascular, and inflammation and immunological disease areas and that these programs, like the MultiStem platform itself, are prioritized.
2. For the stroke (neurological) indication, we model approximately 800,000 stroke patients in the U.S. and 340,000 in Japan, with 87% of those classified as ischemic, growing at a rate of 0.1% annually since 2017. By factoring in mortality risk, cortical stroke prevalence, and the effective therapeutic treatment window, we arrive at an addressable market population.
3. Hemorrhagic stroke. Success in ischemic stroke sets the stage for Athersys to develop MultiStem in the small side of the stroke market, Hemorrhagic strokes. Here too, the inflammatory response contributes to additional secondary damage. While the complexities of ischemic stroke are challenging, hemorrhagic can be even more complex, and with even fewer options for patients. As such, it makes sense to develop for this indication only after the ischemic market is realized.
4. For the ADRS (immune) indication, we model the addressable population based on the NHLI estimate figure of 70 per 100,000 in the U.S., denoting an approximate 230,000 patients in 2017 growing at 3.1% annually.
5. For the AMI (cardiovascular) indication, we only model for new heart attacks as we believe they are more likely to be amenable to the trophic and anti-inflammatory effects of MultiStem. We anticipate the annual growth rate and mortality rate quoted by the American Heart Association continue to be high, at 11.1% and 15.5%, respectively, a reflection of the increasing obesity epidemic in the U.S. Considering the lengthy nature of cardiovascular trials, we do not begin to model sales until 2022, and we currently anticipate relatively low (8-10%) peak market penetration as cell therapy is not currently a standard of care in hospitals for treating AMI.
6. For the trauma (inflammatory) indication, we model the treatable population based on a reported 2.5 million trauma-related emergency room visits. Approximately 13% of those visits are due to debilitating ailments, leading to hospitalization. The estimation brings us to over 300,000 addressable patients growing at a rate of 3.1% annually.
7. For the GVHD (inflammatory) indication, we do currently assume any revenues in our model, but we show the model as we believe, with additional resources, Athersys may "down the road" re-visit development plans. The population of total U.S. allogeneic stem cell transplants based on 4,265 related and 4,972 unrelated transplants (2017 data) is growing at a rate of 3.1% annually. We estimate 90% of that population to desire prophylactic treatment for GVHD.
8. We model a price for MultiStem at \$25,000 initially, growing at 1% per year. Academic literature estimates that therapies such as tPA in stroke should be priced at \$45,800 based on the quality-adjusted life years (QALY) provided to patients. In this instance, should a therapy allow for successful treatment beyond the three to six-hour therapeutic time window, the literature estimates this therapy should command a higher price. We, therefore, believe our pricing estimates are conservative, considering our belief in the upside therapeutic potential of MultiStem. We have seen examples of other cell (for example, CAR-T) and gene therapies' command prices anywhere between \$100k and \$2.5M; given the blockbuster size of the stroke market, we recognize the therapy must be affordable for the market size.
9. But are also relatively in-line with other allogeneic cell therapies currently on the market, despite the other allogeneic cell therapies not being approved for the same targeted indications.
10. Our sum-of-the-parts model uses the same probabilities as the product models and the same discount rate as the FCFE. We apply a risk factor of 70% for the trauma and AMI clinical programs as they are in earlier stages (neither beyond Phase 2) and have only been tested in a limited number of patients. We anticipate reducing this risk factor should the trials meet our assumptions of producing data in the next year. For royalties and partnerships, we also use 50% because they are dependent on a third party, Healios, and therefore do not provide transparency in terms of timing of cash flows to Athersys. Lastly, the stroke and ARDS indications have a 50% risk factor as a result of the inherent variability associated with stroke and the fact that the current pivotal programs are based on a post-hoc analysis.
11. Discount rate. We use a 30% discount rate to account for the fact that Athersys is not yet a profitable company, with assets still in clinical development and several years from commercialization. For this reason, we add an additional risk premium to the calculated WACC to arrive at our 30% discount rate.





**Valuation.** Our therapeutic models for MultiStem assume a probability of success (PoS) for all the forecast therapeutic indications. We project our model through the year 2030. For modeling purposes, we use a 30% risk rate (r) in our Free Cash Flow to the Firm (FCFF), discounted EPS, and Sum-Of-The-Parts (SOP) models. Our price target is derived from these three models, equally weighting and averaged to the nearest whole number. The result is a one-year price target of \$7.00 per share.

### Exhibit 9. FCFF Model

Average of Metrics	\$	7
FCFF Price Target	\$	8
Year		2020

#### DCF Valuation Using FCFF (mn):

units ('000)	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(45,488)	(54,068)	(46,615)	345,899	762,700	1,369,378	1,983,905	2,656,195	3,257,377	3,893,641	4,569,743	5,291,094
Tax Rate	0%	0%	0%	14%	16%	20%	24%	28%	29%	30%	31%	32%
EBIT(1-t)	(45,488)	(54,068)	(46,615)	297,473	640,668	1,095,502	1,507,768	1,912,460	2,312,738	2,725,549	3,153,123	3,597,944
CapEx	(579)	(637)	(701)	(771)	(848)	(932)	(1,026)	(1,128)	(1,241)	(1,365)	(1,502)	(1,652)
Depreciation	941	1,035	1,138	1,252	1,377	1,515	1,666	1,833	2,016	2,218	2,439	2,683
Change in NWC	(130)	(3,276)	-	-	-	-	-	-	-	-	-	-
FCFF	(44,997)	(50,394)	(46,178)	297,954	641,197	1,096,084	1,508,408	1,913,165	2,313,513	2,726,401	3,154,060	3,598,976
PV of FCFF	(58,495)	(50,394)	(35,521)	176,304	291,851	383,770	406,258	396,362	368,696	334,228	297,427	261,063
Discount Rate	30%											
Long Term Growth Rate	1%											
Terminal Cash Flow	12,534,363											
Terminal Value YE2030	909,220											
NPV	3,739,264											
NPV-Debt	-											
Shares out ('000)	481,414											
NPV Per Share	\$ 8											

Source: Dawson James estimates

Source: Dawson James estimates, company reports

### Exhibit 10. Discounted EPS Model.

Current Year	2020
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 7.48
NPV	\$ 5.42

Discount Rate and Earnings Multiple Varies, Year is Constant							
2030 EPS							
	5.4	20%	25%	30%	35%	40%	45%
Earnings Multiple	10	\$12.08	\$8.03	\$5.42	\$3.72	\$2.59	\$ 1.82
	15	\$18.12	\$12.04	\$8.14	\$5.58	\$3.88	\$ 2.73
	20	\$24.15	\$16.06	\$10.85	\$7.44	\$5.17	\$ 3.64
	25	\$30.19	\$20.07	\$13.56	\$9.30	\$6.46	\$ 4.55
	30	\$36.23	\$24.09	\$16.27	\$11.16	\$7.76	\$ 5.46
	35	\$42.27	\$28.10	\$18.99	\$13.02	\$9.05	\$ 6.37
	40	\$48.31	\$32.12	\$21.70	\$14.88	\$10.34	\$ 7.28
	45	\$54.35	\$36.13	\$24.41	\$16.74	\$11.63	\$ 8.19

Source: Dawson James estimates

### Exhibit 11. Sum of the Parts Model.

Athersys Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales	Term Val
MultiStem Ischemic Stroke (U.S.)	1%	30%	3	50%	\$4,742	\$16,353
NPV						\$3.09
MultiStem Hemorrhagic Stroke (U.S.)	1%	30%	3	50%	\$1,123	\$3,872
NPV						\$0.73
MultiStem GI GVHD	1%	30%	3	50%	\$0	\$0
NPV						\$0.00
MultiStem ARDS	1%	30%	6	50%	\$766	\$2,641
NPV						\$0.23
MultiStem AMI	1%	30%	5	30%	\$5,378	\$18,546
NPV						\$1.25
MultiStem Trauma	1%	30%	6	30%	\$1,743	\$6,010
NPV						\$0.31
Net Margin						40%
MultiStem-Japan Royalties	1%	30%	3	50%	\$423	\$1,460
NPV						\$0.69
MM Shrs OS						481
						\$6.30

Source: Dawson James estimates

## Risk Analysis

**Clinical Risk:** Athersys is an early-stage biotechnology company currently operating with high expenditures and no product revenues. A significant element of the company's valuation is associated with its lead clinical candidate MultiStem. As such, clinical progress with this stem cell product represents the key risk for the company and shareholders.

**Commercial Risk:** There can be no assurances that the pipeline products will be commercialized, and if they receive regulatory approval, there is a risk that Athersys will not be able to reach the projected market share potential.

**Employee Risk:** Athersys has an experienced management team, which plans to ideally bring MultiStem to market within the next three years. The success of the company may depend on the expertise, abilities, and continued services of its senior officers, sales staff, and key scientific personnel.

**Financial Risk:** Athersys has a high burn rate and is currently not a profitable company. The company might face multiple dilutions in the future to raise capital to fund its operations.

**Intellectual Property Risk:** The company may have to defend its patents and technical know-how, and there can be no assurances that the patents will not be infringed upon or will be held as valid if challenged, and the company may infringe on third party's patents.

**Partnership Risk:** The potential benefits from the partnership with Healios are subject to certain milestones, which, if not achieved, may delay commercialization in Japan and fail to provide payments to Athersys.

**Regulatory Risk:** There are no assurances that Athersys' products will be approved in the U.S., Japan, Europe, or other markets.



**Exhibit 12. Income Statement.**

Athersys, Inc. Income Statement (\$ '000)	BI	BN															
ATX: YE Dec. 31	2018A	2019A	1Q20A	2Q20A	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Product Revenue (000's)</b>																	
MultiStem Ischemic Stroke (U.S.)									365,919	732,570	1,099,954	1,468,072	1,836,925	2,206,514	2,576,841	2,947,906	3,319,711
% Chg																	
MultiStem Ischemic Stroke (Japan) - Royalty									12,441	31,134	56,098	87,350	117,104	140,665	164,274	187,929	211,632
% Chg																	
MultiStem Hemorrhagic Stroke (U.S.)									-	-	119,589	239,417	399,427	439,809	480,271	520,814	561,438
% Chg																	
MultiStem ARDS									33,331	68,729	106,289	146,112	188,302	232,967	280,220	330,179	382,967
% Chg																	
MultiStem AMI									77,236	171,619	286,003	423,665	588,365	784,409	1,016,724	1,290,949	1,613,525
% Chg																	
MultiStem Trauma										28,149	87,065	149,607	215,942	286,247	360,703	439,500	522,836
% Chg																	
<b>Total Revenues (Product Sales, Grants &amp; Milestones)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>488,928</b>	<b>1,004,052</b>	<b>1,754,997</b>	<b>2,514,223</b>	<b>3,346,065</b>	<b>4,090,610</b>	<b>4,879,033</b>	<b>5,717,278</b>	<b>6,612,108</b>
Contract revenues from Healios	22,276	5,517		77													
% Chg																	
License Fees - Contract revenues	1,461	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
% Chg																	
Grant Revenues	554	116		7	7	7	21	-	-	-	-	-	-	-	-	-	-
% Chg																	
Pfizer Milestones																	
% Chg																	
<b>Total Revenues (Product Sales, Grants &amp; Milestones)</b>	<b>24,291</b>	<b>5,633</b>	<b>-</b>	<b>84</b>	<b>7</b>	<b>7</b>	<b>21</b>	<b>-</b>	<b>488,928</b>	<b>1,004,052</b>	<b>1,754,997</b>	<b>2,514,223</b>	<b>3,346,065</b>	<b>4,090,610</b>	<b>4,879,033</b>	<b>5,717,278</b>	<b>6,612,108</b>
<b>Expenses</b>																	
COGS (excludes royalties)	-	-	-	-	-	-	-	-	95,297	194,584	339,780	485,374	645,792	789,989	942,952	1,105,870	1,280,095
COGS % Product Sales		20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
R&D	38,656	39,045	12,095	13,767	10,500	5,638	42,000	35,000	36,000	34,920	33,872	32,856	31,871	30,914	29,987	29,087	28,215
R&D % Revs																	
G&A	10,442	11,378	3,664	4,432	2,875	529	11,500	11,615	11,731	11,848	11,967	12,087	12,207	12,330	12,453	12,577	12,703
G&A % Revs																	
Other (depreciation)	855	698		222	222	222											
<b>Total expenses</b>	<b>49,953</b>	<b>51,121</b>	<b>15,759</b>	<b>18,421</b>	<b>13,597</b>	<b>6,389</b>	<b>54,166</b>	<b>46,615</b>	<b>143,028</b>	<b>241,352</b>	<b>385,619</b>	<b>530,317</b>	<b>689,870</b>	<b>833,233</b>	<b>985,392</b>	<b>1,147,534</b>	<b>1,321,013</b>
Oper. Inc. (Loss)	(25,662)	(45,488)	(15,759)	(18,337)	(13,590)	(6,382)	(54,068)	(46,615)	345,899	762,700	1,369,378	1,983,905	2,656,195	3,257,377	3,893,641	4,569,743	5,291,094
Gain from sale of insurance proceeds, net	617																
Oper. Inc. (Loss)	(25,045)																
Oper Margin	NM	NM	NM	NM	NM	NM	NM	NM	71%	76%	78%	79%	79%	80%	80%	80%	80%
Other Income Expense (net)	762	906	115	(35)													
Other Income (loss of unconsolidated affiliate)																	
Equity Earnings (loss) of unconsolidated affiliate																	
Expense from change in fair value of warrants, net																	
Preferred Stock Dividends																	
Change in Warrant valuation																	
Deemed dividend resulting from induced conversion of convert p.stock																	
<b>Pre-tax income</b>	<b>(24,283)</b>	<b>(44,582)</b>	<b>(15,644)</b>	<b>(18,372)</b>	<b>(13,590)</b>	<b>(6,382)</b>	<b>(53,988)</b>	<b>(46,615)</b>	<b>345,899</b>	<b>762,700</b>	<b>1,369,378</b>	<b>1,983,905</b>	<b>2,656,195</b>	<b>3,257,377</b>	<b>3,893,641</b>	<b>4,569,743</b>	<b>5,291,094</b>
Taxes	-	-	-	-	-	-	-	-	48,426	122,032	273,876	476,137	743,734	944,639	1,168,092	1,416,620	1,693,150
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	14%	16%	20%	24%	28%	29%	30%	31%	32%
<b>Net Income</b>	<b>(24,283)</b>	<b>(44,582)</b>	<b>(15,644)</b>	<b>(18,372)</b>	<b>(13,590)</b>	<b>(6,382)</b>	<b>(53,988)</b>	<b>(46,615)</b>	<b>297,473</b>	<b>640,668</b>	<b>1,095,502</b>	<b>1,507,768</b>	<b>1,912,460</b>	<b>2,312,738</b>	<b>2,725,549</b>	<b>3,153,123</b>	<b>3,597,944</b>
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	61%	64%	62%	60%	57%	57%	56%	55%	54%
EPS	(0.18)	(0.29)	(0.10)	(0.10)	(0.06)	(0.03)	(0.28)	(0.20)	1.16	2.31	3.66	4.65	5.45	6.09	6.63	7.08	7.47
Non GAAP EPS (dil)	(0.16)	(0.27)	(0.09)	(0.09)	(0.06)	(0.02)	(0.26)	(0.18)	1.18	2.33	3.67	4.66	5.46	6.10	6.64	7.09	7.48
Wgtd Avg Shrs (Bas) - '000s	136,641	151,696	162,715	191,317	220,143	224,546	199,680	229,353	236,308	243,475	250,859	258,466	266,305	274,381	282,702	291,275	300,108
Wgtd Avg Shrs (Dil) - '000s	136,641	151,696	162,715	191,317	220,143	224,546	199,680	236,000	255,454	276,512	299,305	323,978	350,684	379,592	410,882	444,752	481,414

Source: Dawson James estimates, company reports

Companies mentioned in this report:

Healios (TYO-4593: Not Rated)  
 Mesoblast (MESO: Buy Rated)  
 Pluristem (PSTI: Buy Rated)

Important Disclosures:

**Price Chart:**



Price target and rating changes over the past three years:

- Initiated – Buy – August 26, 2019 – Price Target \$11.00
- Update – Buy – November 7, 2019 – Price Target \$11.00
- Update – Buy – January 14, 2020 – Price Target \$11.00
- Update – Buy – February 11, 2020 – Price Target \$11.00
- Update – Price Target Change – March 17, 2020 – Price Target from \$11.00 to \$12.00
- Update – Buy – March 23, 2020 – Price Target 12.00
- Update – Buy – April 9, 2020 – Price Target 12.00
- Update – Buy – April 13, 2020 – Price Target 12.00
- Update – Buy – April 15, 2020 – Price Target 12.00
- Update – Buy – May 1, 2020 – Price Target 12.00
- Update – Buy – May 5, 2020 – Price Target 12.00
- Update – Buy – May 8, 2020 – Price Target 12.00
- Update – Buy – June 22, 2020 – Price Target 12.00
- Price Target Change - Buy – August 11, 2020 – Price Target 7.00
- Update – Buy – September 23, 2020 – Price Target 7.00

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- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	85%	4	17%
Market Perform (Neutral)	4	15%	1	25%
Market Underperform (Sell)	0	0%	0	0%
Total	27	100%	5	19%

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