Long Ideas | Healthcare

Aytu BioScience: The Moonshot Continues To Orbit Awaiting The Next Giant Steps

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Summary

- Initial details from the FDA-approved trial for the Healight medical device published by Cedars-Sinai show that UVA therapy may be a safe and effective treatment for severe SARS-CoV-2 infection.
- Cedars-Sinai and Aytu BioScience are working with the FDA to confirm the next steps on the advancement of this technology, including a more comprehensive trial and possibly an Emergency Use Authorization.
- Solid progress advancing the promising Healight technology and the highly-anticipated merger confirmation with Neos Therapeutics expected on March 18th should help propel Aytu's share price to a more rational valuation.

In the Q4 2020 earnings call last September, Josh Disbrow, CEO and Chair of Aytu BioScience (NASDAQ:AYTU) referred to the potential of the new Healight Platform Technology as a “moonshot” due to its innovative and groundbreaking potential. Fast forward two quarters later and Aytu investors finally received at least partial news they have been longing to hear when initial details of the first phase of the FDA-approved trial for Healight were published. The pre-print publication titled "Endotracheal application of ultraviolet A light in critically ill severe acute respiratory syndrome coronavirus-2 patients: A first-in-human study", addresses the first key question of whether UVA therapy can be a safe and effective treatment for severe SARS-CoV-2 infection. The answer, quite simply, is yes. The more compelling long answer from the Cedars-Sinai doctors leading the study is more nuanced:

> “Under specific and monitored settings, endotracheal UVA light therapy may be an effective treatment for SARS-CoV-2 infection. Endotracheal UVA light therapy appears to be well tolerated in critically ill patients with SARS-CoV-2 infection.”

What exactly did the trial measure and achieve? Readers should dive into the details but to summarize (from a layman’s perspective), five critically ill patients with various characteristics and symptoms were enrolled in the trial for a similar five days of treatment:

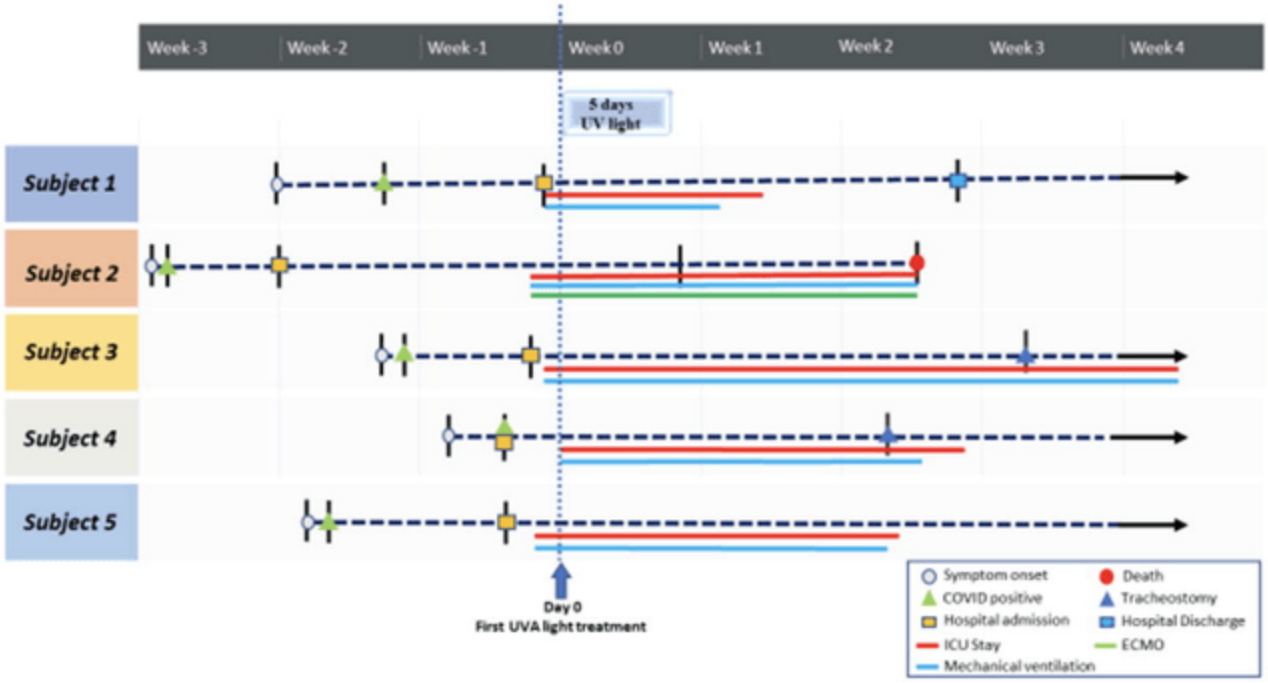
Subject	**1**	**2**	**3**	**4**	**5**
Age	65	38	64	62	54
Gender	M	M	M	F	F
Race/ Ethnicity	White/ Hispanic	White/ Hispanic	White/ Persian	African American	White/ Hispanic
BMI	26.0	36.3	25.5	35.4	34.0
PMH	Type 2 DM	Prediabetes	Type 2 DM, HTN	Mechanical mitral valve, HTN, Dyslipidemia	Type 2 DM
Symptom onset to intubation (days)	14	18	11	5	10
ETT size (mm)	7.5	8.0	8.0	7.5	7.5
PaO_2/FiO_2	70	51	50	50	82
Vasopressor use	+	+	+	+	+
ECMO	-	+	-	-	-
SOFA score/predicted mortality	8/33.3%	8/33.3%*	14/95.2%	8/33.3%	7/21.5%
SAPSIII score/predicted mortality	62/34%	62/34%*	85/67%	68/43%	57/26%

*Note that SOFA and SAPSIII scores do not account for the need for ECMO

BMI, Body mass index; ECMO, Extracorporeal membrane oxygenation, DM, Diabetes mellitus; ETT, Endotracheal tube; HTN, Hypertension; PMH, Past medical history; SAPSIII, Simplified Acute Physiology Score III; SOFA, Sequential organ failure assessment.

Source: medRxiv preprint

The risk of mortality from COVID-19 (based on the SOFA and SAPSIII scores) for the five patients ranged from a one-in-five chance to as high as a 95% risk of death. Despite suffering from severely critical conditions, the trial saw meaningful clinical improvements in 4 out of 4 patients (the fifth was unable to be measured - thoughts and prayers go out to the family and friends of the patient who passed away during the trial from factors not related to the Healight technology). The timeline and key activities for the trial subjects were as follows:



Source: medRxiv preprint

To fully appreciate why Healight is possibly so consequential, just consider that for Patient #3, Healight eliminated > 99% of the Covid-19 viral load in just five days. This patient appeared to be near-death when enrolled in the Cedars-Sinai study. It appears that Healight likely saved his life.

The device itself is relatively straightforward and described very succinctly in this instructional video (provided along with the pre-trial findings) that also explains how the device is employed in treatment. Another positive development from the release of this enlightening information is the implication that the challenges securing the appropriate patents and trademarks for the technology must have been achieved. The Healight prototype was developed by Sterling Medical Devices, a highly-regarded U.S. medical device engineering firm, and contains a base unit with a “controller” and other supporting components. Attached to it by the “umbilical”, is the UV light catheter, which delivers the therapy to the patient through a connection using a double-swivel multi-access port (developed by Halyard Health, GA) to maintain a closed-loop system.

Source: instructional video

What can investors and other interested stakeholders expect in terms of the next steps? Because the sample size was so small with limited controls, more comprehensive trials are needed to confirm to what extent UVA therapy improves clinical outcomes for COVID-19 and other illnesses. There now must be conclusive evidence that the Healight technology, not other factors, is responsible for the improved conditions shown in the first few patients.

In his press release of March 8th Josh Disbrow, CEO and Chair of Aytu, said, "we look forward to continuing discussions with the FDA on the advancement of this technology." This may mean that Aytu is currently seeking accelerated FDA approval under the Emergency Use Authorization (EUA) designation. Sterling Medical Devices has an unblemished track record supporting its clients in this pursuit. As stated on their website:

> "Involvement in over 1,100 projects, none of which failed to receive FDA regulatory approval upon submission."

The FDA also has the "Breakthrough Devices Program" available for certain medical devices that provide more effective treatment/diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the Program is to provide patients and health care providers expedited access to these products by speeding up their development, assessment, and review while preserving public health and upholding safety standards and regulations. Aytu has enlisted the help of several prominent external legal and regulatory resources to support their journey through this cumbersome, complex, and often time-consuming maze.

In December of last year, our team of researchers uncovered information that suggested the Cedars-Sinai team, having concluded the initial feasibility study described earlier, maybe working on a next phase to enroll another, much larger cohort of patients for a comprehensive trial (this has not been publicly confirmed by either Aytu or Cedars-Sinai). Given the recent surge in Covid-19 cases in the Los Angeles area where the trial is located, a few possible scenarios can be speculated on:

1. Cedars-Sinai might have been able to complete enrollment very quickly and may already be well underway in the "Phase 2" of the Healight trial, executing on a similar timeline to the initial phase and may actually be in the final stages of full data acquisition now; or
2. Healight was deployed by Cedars-Sinai on a "compassionate use" basis during the recent COVID-19 surge in L.A. from December through March, possibly in lieu or in advance of a formal Phase 2 trial; or
3. Cedars-Sinai resources were stretched too thin during the recent surge to do any further Healight trials until the extreme conditions could abate.

In any case, what is unknown is whether the pre-print findings from Cedars-Sinai are enough to secure a EUA from the FDA for widespread use in other critically ill Covid-19 patients. We do know that even if there is a EUA, Cedars-Sinai will need to perform separate trials for other endpoint applications (such as Ventilator-Associated Pneumonia) prior to commercialization for those other applications. We also don't know how many Healight platform devices have been produced already and are available for deployment, or if modifications are required to the current prototype before further usage.

Current and Future Valuation

Truly rough estimates for the price of the Healight base device start at around $100k (based on other state-of-the-art medical devices), while the catheters (it is unclear if they are single-use or reusable) may sell for anywhere from $10k to over 25k. Please note though that these "guesstimates" are thumb-in-the-air and for illustrative purposes only but let's use those numbers to re-visit some simple but straightforward math I wrote about in an earlier article. There are currently between 250-300k VAP cases in the U.S. per year. Across the U.S. there are 6,150 hospitals. If Healight were to prove successful, you could envision every hospital having at least one Healight device but possibly more, perhaps 5 - 10. That would be a multi-billion-dollar market opportunity just in the U.S. alone. Then there is the global market to consider!

In his recent PR, CEO Disbrow provided this assessment of the latent opportunity:

> "There may be additional anti-infective applications for Healight beyond COVID-19, so having this initial proof of concept data gives us a great deal of enthusiasm for the potential of this investigational device."

The potential markets are incredibly compelling when you think about patients that have chronic infections, chronic rhinosinusitis, chronic bacterial infections, and chronic bronchitis, to name a few. These are patients who typically run the gamut with respect to the number of antibiotic courses that they've already undergone. There is also the daily cost of an Intensive Care Unit (ICU) patient to consider. The ability to add something as effective as Healight to reduce viral and bacterial load, and potentially improve outcomes to the point of minimizing the number of days within the ICU (i.e. getting patients discharged faster) could save the healthcare system a lot of effort and cost. The value proposition there is enormous for what is currently a very expensive, resource-intensive in-patient treatment. There is also a huge number of patients with severe respiratory illnesses that show up at emergency rooms every day, many more that end up in the ICU, so the market opportunity gets even larger.

According to The 2019 National and State Healthcare-Associated Infections Progress Report,

> “Healthcare-associated infections (HAIs) are complications of healthcare and linked with high morbidity and mortality. Each year, about 1 in 25 U.S. hospital patients are diagnosed with at least one infection related to hospital care alone; additional infections occur in other healthcare settings. Many HAIs are caused by the most urgent and serious antibiotic-resistant (AR) bacteria and may lead to sepsis or death. CDC uses data for action to prevent infections, improve antibiotic use, and protect patients.”

If Healight can be effective in treating any or all of the top HAIs, it will become a truly revolutionary invention and live up to its billing as a “moonshot”. Aytu has a "first-mover advantage" with this technology, indirect patent protections, and the additional benefit of human trial regulatory requirements for approval that any competing device will need to overcome. Talk about a deep "moat"!

As you can imagine on such huge news as the promising trial findings, the Aytu share price must have shot through the roof in this hyper-charged market, especially given the low 18 million share float (after the reverse split in December). Well, not exactly. The Aytu share price initially had a big spike when the PR hit the airwaves but despite a promising surge of volume, the market makers quickly drove the price back down the next day to the depressed / suppressed value it hovers at currently.

Source: Seeking Alpha

The one-month chart illustrates the ongoing frustration felt by many shareholders in a stock that seems to be fully controlled by certain stakeholders who appear to be in no hurry to have it truly reflect its fair value. The current Aytu market cap of around $140 million just barely accounts for the annual revenue run rate of $55 - 60 million of the company on a stand-alone basis, along with its $62 million cash-on-hand. With a Y-o-Y annual revenue growth rate of almost 500%, you would reasonably expect more future value priced into the shares, and that's without any consideration for the revenue opportunities from Healight.

Investors in Aytu, along with those in Neos Therapeutics, Inc. (NEOS), are eagerly awaiting the results of the shareholder vote on their blockbuster merger agreement, to be announced in a special meeting on March 18th. With Neos stockholders set to receive 0.1088 shares of Aytu stock in the acquisition, the two share prices appear to be under aggressive "market management" so they align somewhat leading to that transaction to mitigate arbitrage opportunities. If the vote in favor of the combination is confirmed, the new entity (to be named "Aytu BioPharma") will have an immediate annual revenue run rate of over $100 million on just a Pro-forma basis. A "very rough" crunching of data from the most recent Income Statements for each entity shows this enticing potential:

NEOS-AYTU	NEOS Q3 / 2020	AYTU Q2 / 2021	AYTU-NEOS COMBINED
Consolidated Statement of Operations	*3-mths to Sept. 30*	*3-mths to Dec. 31,*	*Quarterly*
Revenues:			
Net product sales	12,535	15,147	27,682
Cost of goods sold	5,120	5,998	11,118
Gross profit	7,415	9,149	16,564
Research and development expenses	1,310	287	1,597
Selling and marketing expenses	4,844	12,853	17,697
General and administrative expenses	4,177	1,585	5,762
	15,451	20,722	32,528
Loss from operations	(2,916)	(5,575)	(8,491)
Interest expense	(2,005)	(3)	(2,757)
Other income (expense), net	12	(3,692)	14
Loss before income taxes	(4,909)		(4,909)
Income tax expense	2		2
Net loss	(4,911)	(9,525)	(14,436)
Wgt'd. Avg. Common Shares O/S	49,755,094	13,282,000	24,000,000
Net loss per share	($0.10)	($0.72)	($0.60)

Source: Author's Research

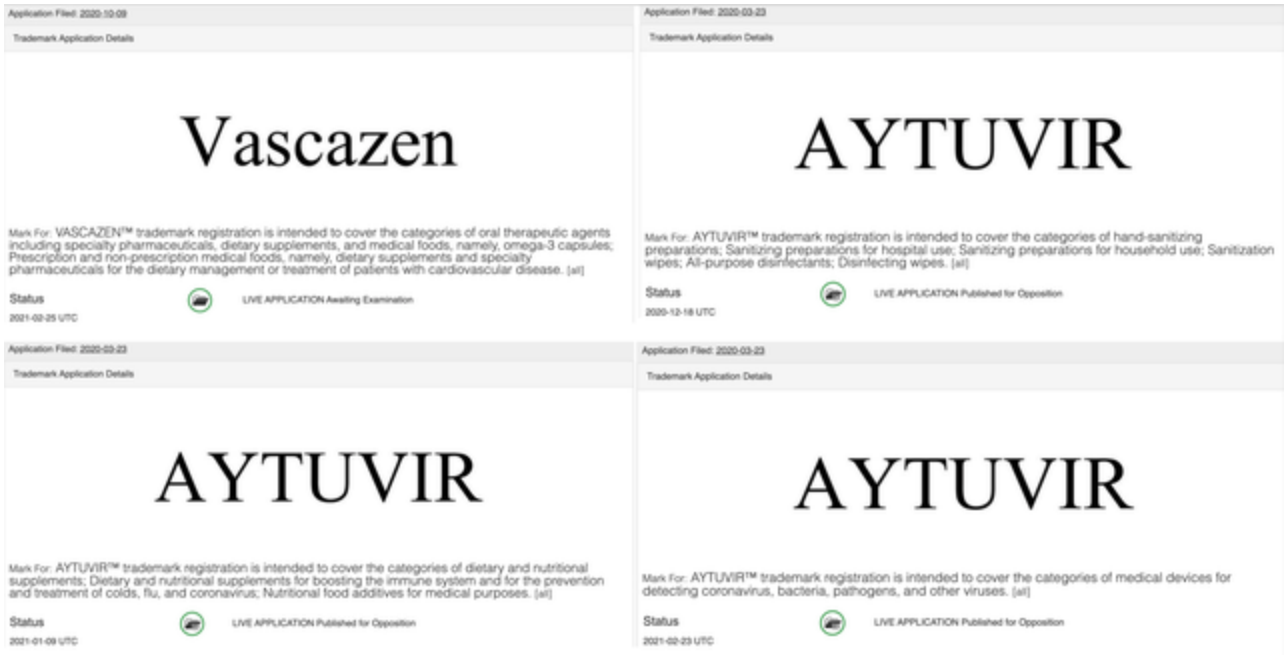
Neos and Aytu are both dynamic, commercial-stage pharma's with well-established multi-brand portfolios who will be able to leverage common platforms and networks for up-sell / cross-sell opportunities. As the combined income statements above show, the stated objective of an estimated $15 million in synergy savings should achieve an accelerated path to profitability by 2022. There is also the Neos pipeline drug that is under development to treat roughly 1.4 million U.S. patients suffering from chronic sialorrhea.

Last month H.C. Wainwright's Vernon Bernardino provided an updated share price target for Aytu "BioPharma" of $24, which doesn't include Healight . The plan is to re-assess the share price target once more is known and confirmed with the new technology.

Source: H.C. Wainwright

With a low float (around 24 million shares post-merger), the lifting of pandemic restrictions, and an expected economic resurgence in the U.S. and globally, I am comfortable with an Aytu share price of between $25 and $35 in 2021 (without Healight), a roughly 5x gain from current levels based on moderate growth and expedited efficiencies. Factor in successful Healight progress and we should be talking about a share price in the triple digits.

Don't forget, there are still a number of very interesting trademarks that Aytu has filed for which we have yet to hear any details about:



Source: USPTO

Research into recent SEC filings suggests that many former institutional shareholders in Aytu were “fortunate” enough to exit their positions “in and around” the time of the 1-for-10 reverse split Aytu executed in December. There can be a quarter lag in filing so exact timing is difficult to pinpoint. It is suspected that part of the share price malaise in 2021 is to indirectly encourage those institutions to re-invest at discounted levels. These are all theoretical musings though to try to justify an inexplicably low valuation. In any case, the rough projections of pre and post-merger institutional holdings show steady improvement according to data pulled from Fintel (which can often be somewhat “fluid”):

OUTSTANDING SHARES - SUMMARY (as of 03-11-21)

AYTU	#	Comment	Shares	% Own.
Institutions	114	As Per Fintel	6,364,433	36%
Public Shares		Non-institutional (calculation)	11,518,460	64%
Total Float		As Per Fintel	17,882,893	100%
NEOS	**#**	**Comment**	**Shares**	**% Own.**
Institutions	64	As Per Fintel	12,723,691	26%
Public Shares		Non-institutional (calculation)	37,034,631	74%
Total Float		As Per Fintel	49,758,322	100%
NEOS		*Convert existing Neos shares to Aytu (@ .1088)*	*5,413,705*	*100%*
Institutions		Apply previous percentage	1,384,338	26%
Public Shares		Apply previous percentage	4,029,368	74%
New Aytu Float		**Post-Merger Close**	**23,296,598**	**100%**
Institutions	178	Apply new, aggregate percentage	7,748,771	33%
Public Shares		Apply new, aggregate percentage	15,547,828	67%

Source: Fintel and Author’s Research

If the Aytu and Neos leadership and stakeholders were successful in convincing institutional investors to get back on board over the last few months, the proof will start to appear in new SEC filings next quarter. If institutional ownership post-merger can climb above the 50% level, the incentive for and pressure on the leadership to sustain an increased share price will be much greater and lift all boats.

Conclusion

There are many critical questions that still need to be answered, starting first and foremost with proving unequivocally through a more comprehensive trial(s) that Healight works effectively on multiple endpoints. Additional questions investors need to have addressed to determine future value include: how much of the manufacturing, distribution, and support will Aytu take on directly, or are they looking to outsource much of it; is licensing to a partner still being seriously considered (as has been mentioned by Mr. Disbrow) as a possible approach to expedite the commercialization of Healight; and finally, but very importantly, what time frame will Healight become available to the first clients?

Another completely baffling mystery associated with this potentially groundbreaking medical development is how it has been almost completely ignored by mainstream media. How are the myriad media outlets not churning out reams of coverage on this novel treatment that is showing extremely good results, both for Covid-19 and other illnesses? Even if just from a strictly human interest angle. There are certainly many theories on this but it is well overdue to put those all to rest and give this scientific achievement its time in the sun. In the meantime, investors will just have to amuse themselves with the endless and inane focus on the "meme stocks" and other mind-numbing shenanigans.

Investors have been faithfully waiting for Aytu to deliver on the promise and potential that the company presented well over a year ago following the merger with Innovus and the acquisition of the Cerecor products. With all of the immediately pending developments, is April the month that the Aytu share price will finally reflect a fair valuation, trade freely in an environment of strong execution, greater transparency, good governance, and promises kept? Investors will find out soon enough.

This article was written by

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