

Every raging river, every great lake, every deep blue sea starts ... with a trickle



# Research Update

## **OncoSec Medical Incorporated**

(NasdaqGS: ONCS)

**Report Date: 09/13/21** 

12- 24 month Price Target: \$11.00

Allocation: 4

Closing Stock Price at Initiation (Closing Px: 05/14/20): \$1.92

Closing Stock Price at Price Target Increase (Closing Px: 01/11/21): \$6.81

Closing Stock Price at This Update (Closing Px: 09/13/21): \$2.06

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**Disclosure:** Portions of this report are excerpted from OncoSec's filings, website(s), presentations or other public collateral. We have attempted to identify those excerpts by *italicizing* them in the text.

As a bit of background, we initiated coverage of OncoSec in May (2020) at \$1.90 with a price target of \$6.00. In December (2020) the stock breached our \$6.00 price target and traded through \$8.00 in February (2021). Some may recall, the Company has been a periodic presenter at our past Rocky Mountain Microcap Conferences both before and after we initiated the coverage.

On June 24, 2021, the Company announced the resignation of its CEO Daniel O'Connor and the appointment of Brian Leuthner, the Company's Chief Operating Officer as Interim CEO. Thereafter, on August 16, 2021, OncoSec announced that Mr. Leuthner was also leaving the Company and the board was establishing a "Leadership Committee consisting of three board members, Margaret Dalesandro, Ph.D., Herbert Kim Lyerly, M.D. and Yuhang Zhao, Ph.D., MBA, to lead all development efforts, with a focus on the Company's lead asset, TAVO<sup>TM</sup>".

As a matter of full disclosure, we were fans of CEO Dan O'Connor. In our view, he was a quality CEO on a variety of levels and a high-quality individual as well. We believe his departure is a negative development for OncoSec. Moreover, what is also unsettling is the fact that his replacement, Brian Leuthner, also left the Company less than 30 days after his hiring as the Interim CEO. We will try to unpack that as best we can.

Recall, in late 2019/early 2020, OncoSec was engaged in a proxy fight that essentially focused on the financing direction of the Company, and by extension, the control of the Company. The fight involved competing funding proposals from a Korean company, Alpha Holdings (a prior financier/investor of OncoSec's) and a Chinese company China Grand Pharmaceutical ("CGP"), in conjunction with a "global" company called Sirtex Medical. CGP was/is an investor in Sirtex as well. Briefly, OncoSec management supported the CGP/Sirtex funding proposal for a variety of reasons we will not rehash here, and ultimately that proposal prevailed providing OncoSec with \$30 million of much needed capital. The transaction basically ceded control of the Company to the Chinese enterprise (CGP), which at the time, was viewed by some of those involved in the proxy battle as a "be careful what you wish for" caveat to the capital. While again, we will not dispute the merits and/or necessity of the CGP transaction, our sense is that Mr. O'Connor's departure is rooted in that control.

To be clear, much of our assessment here is speculation from limited information we have been able to ascertain regarding Mr. O'Connor's departure. Frankly, it's disappointing that the street is left to "speculate" on the issues here, but the Company has provided little in terms of providing transparency around the management change(s). To revisit the point, ceding majority control of the Company to a foreign enterprise has its downside and the potential for opacity is certainly an example of that. We concede, majority shareholders, even in public companies, can certainly control much of the narrative, and in this instance, they obviously chose not to elaborate on the minutia of the management changes(s).

The above said, if we look over the direction Mr. O'Connor has taken the Company in the context of other recent developments, we think that exercise might at least provide some insights that might help delineate the direction here. As we noted, we are disappointed at the departure, but absent terminating the coverage because of that event, it seems to us that the question now is "where do they go from here"?

In retrospect, when we first heard the OncoSec story, it was focused on the original (and still most prominent) indication for TAVO, which is "the treatment of documented unresectable melanoma... Stage III or IV". Recall, this endeavor is now reflected in a clinical trial called KEYNOTE-695, in combination with the immunotherapy checkpoint inhibitor Keytruda (Pembrolizumab). Again, to recap, in 2017 the FDA granted OncoSec an Orphan Drug Designation. Orphan Drug status provides incentives to developers and applies to rare diseases affecting fewer than 200,000 people in the U.S. at any point in time. There are several advantages to the designation, one of which is that it may shorten the path to ultimate FDA approval. In short, because many of the indications addressed by the designation have no available treatments, they may be eligible for 'Fastrack' or other accelerated approvals. In OncoSec's case, KEYNOTE-695 addresses melanoma patients for whom available standards of care have failed and the patients are essentially out of options. We would add, OncoSec has specifically been granted Fastrack status for late-stage patients with metastatic melanoma who are refractory to immune checkpoint therapy. Keep in mind, the potential for OncoSec to accumulate enough clinical success to ultimately gain FDA approval through the Orphan

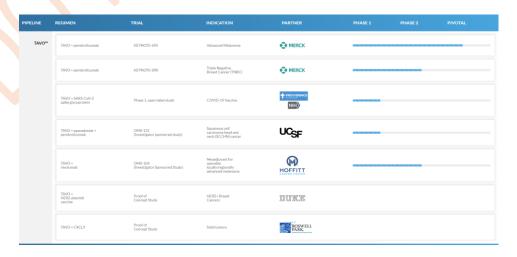
Drug accelerated process, even for the treatment of an initially narrow population of melanomas patients, has driven much of the investment thesis, valuation and associated investment. To that end, the Company has released interim data from the KEYNOTE-695 Phase 2b Clinical Trial that has proven quite promising. Here is a summary of those interim results:

"Achieving an overall response rate of 30% with several complete responses and no serious adverse events is extremely encouraging for checkpoint resistant metastatic melanoma patients who currently rely on systemic administration of immune-stimulating drugs associated with severe toxicity," said Paolo A. Ascierto, M.D., Director of the Unit of Melanoma, Cancer Immunotherapy and Innovative Therapy at the National Tumor Institute Fondazione G. Pascale in Naples, Italy. "The data reported, in addition to its ease of use, demonstrate the potential of TAVO in combination with pembrolizumab as a next-generation intratumoral IL-12 therapy that can induce regression of both locally treated and untreated distant and visceral lesions."

To stop and summarize, here is what we know. Although ongoing, the Company has reported positive interim data from the KEYNOTE-695 trial with Merck's Keytruda. Further, in July (2021) OncoSec announced a Clinical Trial Collaboration and Supply Agreement with Merck to "evaluate the combination of OncoSec's DNA-plasmid interleukin-12 (IL-12) TAVO<sup>TM</sup> (tavokinogene telseplasmid) with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in a global Phase 3 randomized clinical trial, KEYNOTE-C87... KEYNOTE-C87 is intended to support accelerated approval by the U.S. FDA and/or serve as a pivotal study to support a full licensure. Under the terms of the Agreement, Merck will provide KEYTRUDA®, while OncoSec will provide the investigational drug, TAVO<sup>TM</sup>. Each party will be responsible for its own internal costs, with OncoSec covering third party costs. Eligible patients must have Stage III or IV unresectable, metastatic melanoma, and must be refractory to prior checkpoint therapy. KEYNOTE-C87 intends to enroll approximately 400 patients and is planned to be conducted in the U.S., Canada, EU, and Australia".

We think this announcement is highly positive on multiple fronts. First, it essentially represents an extension of KEYNOTE-695. Ostensibly, the results from KEYNOTE-695 continue to support TAVO's ability (in this case in combination with Keytruda) to provide benefit to late-stage melanoma patients who are essentially failing other available treatment options. We submit we are perhaps speculating here, but we assume the emergence of KEYNOTE-C87 is predicated on additional success from interim 695 data. We would note, the news release states that "KEYNOTE-C87 is intended to support accelerated approval and/or a full licensure". Again, trying to take advantage of the Orphan Drug/Fastrack designations to get to commercialization has always been the strategy here, and in addition (much like what has occurred with Keytruda) could one day create a basis for the approval of TAVO for other indications and perhaps ultimately as a monotherapy. That brings us to our more specific topic here, which is the management change and our sense of what may have precipitated it.

Recognize, in addition to KEYNOTE-695, OncoSec has developed a relatively robust clinical pipeline:



From some perspectives, the above pipeline may represent a "double-edged sword" for OncoSec. While most who spend any time in the biopharma space will likely attest, its generally better for a Company in the space to have multiple "shots on goal", the downside of that approach is that with capital typically limited, focusing resources on multiple projects on the face takes resources away from the most promising or at least most imminent project. Succinctly, we think OncoSec's CEO supported the multipronged approach (as illustrated by the pipeline above that he helped build), while the Company's majority investors may have supported focusing on getting TAVO/Keytruda for melanoma (695 and now C87) across the finish line. To edify, while the multipronged approach has clear advantages over the alternative "all the eggs in one basket" approach, it was also likely to require considerably more investment and associated dilution, which we suspect was not palatable to the Chinese. Specifically, R&D grew roughly 36% YoY for F20 vs. F19, and 35% YoY for F21 vs. F20. From a practical standpoint, more capital could ultimately result in that group either putting up more of their own money or losing their majority posture via added dilution. We do not suspect they were particularly interested in the latter. On the other hand, we also suspect Mr. O'Connor may have been quite focused on the benefits of the broader clinical approach. It looks to us like something (someone) had to give, and the departure of *two CEO's* (as well as some additional C-Suite players we are aware of) in a 30-day period suggests to us that majority shareholders must be entrenched in their view.

Unfortunately, as we said, the above is largely our speculation because the Company has provided little in terms of addressing the management change. Frankly, we do not think that approach is appropriate for a public company. As we see it, transparency, typically in the form of financial and other related filings, is one of the major advantages of owning a public company. In that regard, when a public company fails to provide transparency on an issue as important as management, they should not expect the stock to reactive constructively and it has not:



Along with the general uncertainty around any management change (which often include *some* negative elements), and in this case the associated lack of clarity provided around it, we suspect the stock may have also seen some selling from shareholders who (like us) held a positive view of Mr. O'Connor's contributions.

The above said, we/OncoSec, are where we are, so to reiterate, where do we/they go from here?

As we alluded, our expectation is that the focus here will be on devoting resources to the quickest path to commercialization of TAVO, which looks to be KEYNOTE-695 and KEYNOTE-C87. We are not sure how that might impact the rest of the existing pipeline, but we do not expect to see any new clinical endeavors in the foreseeable future. We would add, from a shareholder perspective, that path may in fact be the least expensive and least dilutive, although we still tend to think that continued positive interim results from 695 (which we believe are forthcoming) might provide opportunities that could change the direction here entirely. In our view, the initiation of C-87 may speak to that notion. Frankly, as much as we are not comfortable with the management situation and we *hope* this is not the result of deeper fundamental issues, as we have understood it, focusing on the melanoma trial(s), and the potential of Fastrack/accelerated status, *has always been* the primary path here. However, if we are right about a lesser focus on other indications and/or opportunities, the success/failure of 695 data has perhaps taken on greater import. That may seem obvious, but to play devil's advocate, on the path we have described here, it is certainly possible for instance, that TAVO may illicit better responses in other forms of cancer than melanoma but given the focus on the latter we might conceivably never know that answer.

To reiterate, we view the management change as a bit disconcerting so given the choice we would have preferred that it not roll this way. However, if its basis is something close to what we have speculated here, we get it. In short, we cannot/will not argue that in a scenario where the lead indication is now transitioning to an increasingly more expensive Phase III trial, with a real possibility of Fasttrack accommodation given continued positive results, access to capital and the dilution to support it remain highly topical variables in the path forward. Put another way, in a world where capital is not unlimited, companies must make choices about where they spend limited capital. Those choices are often difficult, and they will almost certainly impact their success or failure.

Lastly, while we are not keen on then management change, we remain constructive on TAVO's potential to address cancer patients who have essentially failed the available standards of care. Further, we view C-87 in conjunction with Merck as another positive data point in support of that thesis. We are hopeful that continued positive interim data from 695 through the balance of 2021 will provide additional support. We reiterate our allocation of 4 and our 12-24 month price target of \$11.00.

### **Projected Operating Model**

Projected Operating Model													
OncoSec Medical Incorporated													
By: Trickle Research	(actual)		(actual)		(actual)		(estimate)		(estimate)		(estimate)		
		10/31/20		1/31/21		4/30/21		7/31/21		<u>Fiscal 2021</u>		Fiscal 2022	
Revenue (net)	\$		\$	_	Ś	_	Ś	_	Ś	_	Ś	_	
Expenses:	\$	-	\$	-	\$	-	\$	-	\$	-	\$	_	
Research and development	\$	9,799,361	\$	8,915,381	\$	7,589,779	\$	7,665,677	\$	33,970,198	\$	32,671,818	
General and administrative	\$	3,240,732	\$	2,110,696	\$	2,847,151	\$	2,875,623	\$	11,074,202	\$	11,792,942	
Loss from operations	\$	(13,040,093)	\$	(11,026,077)	\$	(10,436,930)	\$	(10,541,299)	\$	(45,044,399)	\$	(44,464,761)	
Other income, net	\$	(623)	\$	(440)	\$	962,513	\$	-	\$	961,450	\$	-	
Interest expense	\$	6,134	\$	4,722	\$	1,732	\$	-	\$	12,588	\$	-	
Foreign currency exchange (loss) gain, net	\$	(176,917)	\$	328,592	\$	35,365	\$	-	\$	187,040	\$	-	
Realized loss on sale of securities, net	\$	-	\$	-	\$	-	\$	-	\$	-	\$	-	
Loss before income taxes	\$	(13,223,767)	\$	(10,702,647)	\$	(9,440,784)	\$	(10,541,299)	\$	(43,908,497)	\$	(44,464,761)	
Provision for income taxes	\$	1,500	\$	1,450	\$	-	\$	-	\$	2,950	\$	-	
Net loss	\$	(13,225,267)	\$	(10,704,097)	\$	(9,440,784)	\$	(10,541,299)	\$	(43,911,447)	\$	(44,464,761)	
Basic and diluted net loss per common share	\$	(0.49)	\$	(0.37)	\$	(0.25)	\$	(0.27)	\$	(1.33)	\$	(1.06)	
Weighted average shares basic and diluted		26,771,176		28,676,719		37,335,563		38,943,446		32,931,726		42,033,210	

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There are no letters in the rating system (Buy, Sell Hold), only numbers. The numbers range from 1 to 10, with 1 representing 1 "investment unit" (for my performance purposes, 1 "investment unit" equals \$250) and 10 representing 10 investment units or \$2,500. Obviously, a rating of 10 would suggest that I favor the stock (at respective/current levels) more than a stock with a rating of 1. As a guideline, here is a suggestion on how to use the allocation system.

Our belief at Trickle is that the best way to participate in the micro-cap/small cap space is by employing a diversified strategy. In simple terms, that means you are generally best off owning a number of issues rather than just two or three. To that point, our goal is to have at least 20 companies under coverage at any point in time, so let's use that as a guideline. Hypothetically, if you think you would like to commit \$25,000 to buying micro-cap stocks, that would assume an investment of \$1000 per stock (using the diversification approach we just mentioned, and the 20-stock coverage list we suggested and leaving some room to add to positions around allocation upgrades. We generally start initial coverage stocks with an allocation of 4. Thus, at \$1000 invested per stock and a typical starting allocation of 4, your "investment unit" would be the same \$250 we used in the example above. Thus, if we initiate a stock at a 4, you might consider putting \$1000 into the position (\$250 \* 4). If we later raise the allocation to 6, you might consider adding two additional units or \$500 to the position. If we then reduce the allocation from 6 to 4 you might consider selling whatever number of shares you purchased with 2 of the original 4 investment units. Again, this is just a suggestion as to how you might be able to use the allocation system to manage your portfolio.

For those attached to more traditional rating systems (Buy, Sell, Hold) we would submit the following guidelines.

A Trickle rating of 1 thru 3 would best correspond to a "Speculative Buy" although we would caution that a rating in that range should not assume that the stock is necessarily riskier than a stock with a higher rating. It may carry a lower rating because the stock is trading closer to a price target we are unwilling to raise at that point. This by the way applies to all of our ratings.

A Trickle rating of 4 thru 6 might best (although not perfectly) correspond to a standard "Buy" rating.

A Trickle rating of 7 thru 10 would best correspond to a "Strong Buy" however, ratings at the higher end of that range would indicate something that we deem as quite extraordinary..... an "Extreme Buy" if you will. You will not see a lot of these.