ONCOSEC MEDICAL Inc
Form 10-K
October 19, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended July 31, 2018

OR

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission file number 000-54318

ONCOSEC MEDICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Nevada	**98-0573252**
(State or other jurisdiction	(I.R.S. Employer
of incorporation or organization)	Identification Number)

24 North Main Street
Pennington, NJ 08534

3565 General Atomics Court, Suite 100
San Diego, CA 92121
(Address of principal executive offices) (Zip Code)

(855) 662-6732

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	**Name of Exchange on which Registered:**
Common Stock, par value $0.0001 per share	**Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes [ ] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [ ] Accelerated filer [ ]

Non-accelerated filer [ ] Smaller reporting company [X]

Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [ ] No [X]

The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of January 31, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $63,514,594, computed by reference to the price at which the registrant's common stock was last sold on such date, as reported by the Nasdaq Capital Market. Shares of common stock held by the registrant's officers and directors and holders of 10% or more of the outstanding shares of the registrant's common stock have been excluded from this calculation because such persons may be deemed to be affiliates of the registrant; however, this determination of affiliate status is not, and shall not be considered, a determination of affiliate status for any other purpose.

As of October 19, 2018, there were 59,213,947 outstanding shares of the Company's common stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for the 2018 Annual Meeting of Stockholders, which is expected to be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended July 31, 2018, are incorporated by reference in Part III of this Annual Report on Form 10-K to the extent stated herein.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND OTHER MATTERS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. Forward-looking statements relate to future events or circumstances or our future performance and are based on our current assumptions, expectations and beliefs about future developments and their potential effect on our business. All statements in this report that are not statements of historical fact could be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “expects,” “plans,” “intends,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the nega terms or other comparable terminology. The forward-looking statements in this report include statements about, among other things: the status, progress and results of our clinical programs; our ability to obtain regulatory approvals for, and the level of market opportunity for, our product candidates; our business plans, strategies and objectives, including plans to pursue collaboration, licensing or other similar arrangements or transactions; our expectations regarding our liquidity and performance, including our expense levels, sources of capital and ability to maintain our operations as a going concern; the competitive landscape of our industry; and general market, economic and political conditions.

Some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- the success and timing of our clinical trials, including safety and efficacy of our product candidates, patient accrual, unexpected or expected safety events, and the usability of data generated from our trials;
- our ability to successfully file and obtain timely marketing approval from the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory agency for one or more Biologics License Applications, or BLAs, or New Drug Applications, or NDAs;
- our ability to obtain and maintain marketing approval from regulatory agencies for our products in the U.S. and foreign countries;
- our ability to adhere to ongoing compliance requirements of all health authorities, in the U.S. and foreign countries;
- our ability to obtain and maintain adequate reimbursement for our products;
- our ability to obtain the desired labeling of our products under any regulatory approval we might receive;
- our plans to develop and commercialize our products;
- the successful development and implementation of sales and marketing campaigns;
- the loss of key scientific or management personnel;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;

our ability to successfully compete in the potential markets for our product candidates, if commercialized;

regulatory developments in the United States and foreign countries;

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- the rate and degree of market acceptance of any of our product candidates;
- new products, product candidates or new uses for existing products or technologies introduced or announced by our competitors and the timing of these introductions or announcements;
- market conditions in the pharmaceutical and biotechnology sectors;
- our available cash and investments;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our ability to obtain additional funding;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to maintain license agreements for our licensed product candidates;
- the success and timing of our preclinical studies, including those intended to support an Investigational New Drug, or IND, application;
- the ability of our product candidates to successfully perform and advance in clinical trials;
- our ability to obtain and maintain authorization from regulatory authorities for use of our product candidates for initiation and conduct of clinical trials;
- our ability to manufacture and supply our products, gain access to products we plan to use in combination studies and the performance of and reliance on third-party manufacturers and suppliers;
- the performance of our clinical research organizations, clinical trial sponsors, and clinical trial investigators; and
- our ability to successfully implement our strategy.

Forward-looking statements are only predictions and are not guarantees of future performance, and they are subject to known and unknown risks, uncertainties and other factors, including the risks described under “Risk Factors” in Part I, Item IA of this report and similar discussions contained in the other documents we file from time to time with the Securities and Exchange Commission, or the “SEC.” Moreover, we operate in a rapidly evolving industry in which new risks and uncertainties continuously emerge, and it is not possible for us to predict all of the risks we may face or assess the impact of all uncertainties or other factors on our business or the extent to which any factor or combination of factors could cause actual results to differ from our current expectations, assumptions or beliefs. In light of these risks, uncertainties and other factors, the forward-looking events and circumstances described in this report may not occur and our results, levels of activity, performance or achievements could differ materially from those expressed in or implied by any forward-looking statements we make. As a result, you should not place undue reliance on any of our forward-looking statements. Forward-looking statements speak only as of the date they are made, and unless required to by law, we undertake no obligation to update or revise any forward-looking statement for any reason, including to reflect new information, future developments, actual results or changes in our expectations.

We qualify all of our forward-looking statements by this cautionary note.

* * * * *

Unless the context indicates otherwise, all references to OncoSec, our Company, we, us and our in this report refer to OncoSec Medical Incorporated and its consolidated subsidiaries.

We own registered trademark rights in the United States to ImmunoPulse®, and we have filed applications in the United States and in certain foreign jurisdictions to register trademark rights to ImmunoPulse, OncoSec and NeoPulse. Other service marks, trademarks or trade names used in this report are the property of their respective owners. We do not use the ® or ™ symbol in each instance in which one of our registered or common law trademarks appears in this report, but this should not be construed as any indication that we will not assert our rights thereto to the fullest extent permissible under applicable law.

We make available, free of charge, on our website, www.oncosec.com, our reports on Forms 10-K, 10-Q, 8-K and amendments thereto, as soon as reasonably practical after we file such materials with the SEC. Any information that we include on or link to our website is not, and should not be considered, part of this report.

PART I

ITEM 1. BUSINESS

Overview

We are a biotechnology company focused on designing, developing and commercializing innovative therapies and proprietary medical approaches to stimulate and to guide an anti-tumor immune response for the treatment of cancer. Our core platform technology, ImmunoPulse®, is a drug-device therapeutic modality comprised of a proprietary intratumoral electroporation delivery device. The ImmunoPulse® platform is designed to deliver plasmid DNA-encoded drugs directly into a solid tumor and promote an immunological response against cancer. The ImmunoPulse® device can be adapted to treat different tumor types, and consists of an electrical pulse generator, a reusable handle and disposable applicators. Our lead product candidate, ImmunoPulse® IL-12, uses our electroporation device to deliver a plasmid DNA-encoded interleukin-12 ("IL-12"), called tavokinogene telseplasmid ("TAVO"), with the aim of reversing the immunosuppressive microenvironment in the treated tumor. The activation of the appropriate inflammatory response can drive a systemic anti-tumor response against untreated tumors in other parts of the body. In February 2017, we received Fast Track designation from the U.S. Food and Drug Administration ("FDA") for TAVO in metastatic melanoma, which could qualify TAVO for expedited FDA review, a rolling Biologics License Application review and certain other benefits.

Our current focus is to pursue our study of TAVO in combination with KEYTRUDA® (pembrolizumab) for melanoma patients who are definitive anti-PD-1 non-responders. The trial is referred to as the PISCES/KEYNOTE-695. In May 2017, we entered into a clinical trial collaboration and supply agreement with a subsidiary of Merck & Co., Inc. ("Merck") in connection with the PISCES/KEYNOTE-695 study. Pursuant to the terms of the agreement, both companies will bear their own costs related to manufacturing and supply of their product, as well as be responsible for their own internal costs. We will sponsor the study and be responsible for external costs. The PISCES/KEYNOTE-695 study is currently enrolling patients and we plan to provide a topline preliminary data update at The Society for Immunotherapy of Cancer ("SITC") 2018. This study is a registrational-directed, Phase 2b open-label, single-arm, multicenter study in the United States, Canada and Australia.

We are also pursing development in triple negative breast cancer ("TNBC"). On May 8, 2018, we entered into a second clinical trial collaboration and supply agreement with Merck with respect to a Phase 2 study of TAVO in combination with KEYTRUDA® to evaluate the safety and efficacy of the combination in patients with inoperable locally advanced or metastatic TNBC, who have previously failed at least one systemic chemotherapy or immunotherapy. This study is referred to as KEYNOTE-890. Pursuant to the terms of the agreement, both companies will bear their own costs related to manufacturing and supply of their product, as well as be responsible for their own internal costs. We will sponsor the study and be responsible for external costs. The KEYNOTE-890 study is opened for enrollment. The study is a Phase 2 open-label, single-arm, multicenter study in the United States and Australia.

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We intend to continue to pursue other ongoing or potential new trials and studies related to TAVO, in various tumor types including melanoma, TNBC and head and neck cancers. In addition, we are also developing our next-generation electroporation device and applicator, including advancements toward prototypes, pursuing discovery research to identify other product candidates that, in addition to IL-12, can be encoded into propriety plasmid-DNA, delivered intratumorally using electroporation. Using our next-generation technology, our goal is to reverse the immunosuppressive mechanisms of a tumor, as well as to expand our ImmunoPulse® pipeline. We believe that the flexibility of our propriety plasmid-DNA technology allows us to deliver other immunologically relevant molecules into the tumor microenvironment in addition to the delivery of plasmid-DNA encoding for IL-12. These other immunologically relevant molecules may compliment IL-12's activity by limiting or enhancing key pathways associated with tumor immune subversion.

Cancer Immunotherapy Treatments: Background

Many traditional modalities for treating cancer have limited clinical efficacy and are frequently associated with significant negative side effects. Immunotherapy, a relatively new therapeutic modality that has received significant attention in recent years, focuses on modulating the immune system to treat cancer rather than directly killing the cancer cells. Systemic delivery of immune-modulating proteins, such as interleukin-2 and interleukin-10, or IL-2, and IL-10, has shown early indications of efficacy, but with significant mechanism-based toxicity.

Recent attention has also focused on the development of monoclonal antibody drugs, which target critical "immune checkpoint" proteins and augment anti-tumor immunity. Therapies using monoclonal antibodies, such as anti-CTLA-4 (cytotoxic T-lymphocyte-associated protein-4), anti-PD-1 (program cell-death-1) and anti-PD-L1 (programmed death-ligand-1), are being developed for the treatment of several cancers and have been approved for the treatment of multiple sold tumor cancers. Although these new immuno-oncology agents have shown clinical benefit for patients with late-stage cancer across multiple tumor types, only a small subset of the overall patient population responds to these therapies. Certain tumors are able to evade the immune system. We believe that when tumors do not have any immune cells inside (immune desert) or surrounding the tumor (immune excluded), immune checkpoint therapies are less effective or ineffective. These tumors are sometimes referred to as "cold" tumors.

We believe that if we can convert an inactive, or "cold," tumor with a low frequency of tumor infiltrating lymphocytes, or TILs, that limit the anti-tumor response and remove the interferon signature, into an active, or "hot," tumor that can activate the anti-PD-1 or anti-PD-L1 pathway, then we can potentially increase the number of patients who respond to these therapies. We believe our TAVO platform addresses this objective, as it has the potential to reshape the tumor microenvironment in patients with an immunologically cold tumor into a highly-inflamed tumor with a fully engaged PD-1 / PD-L1 axis. The immunological components that enable this conversion relates to the intratumoral delivery of TAVO, which increases the density of TILs, and in the presence of an anti-PD-1 antibody, adaptive resistance can be neutralized allowing for the maximal T cell cytotoxicity.

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There is a significant unmet medical need for patients who may not respond well to these therapies on their own. In particular, for patients who have “cold” tumors and would be unlikely to respond to an immune checkpoint therapy alone, our focus is to develop a therapeutic that has the ability to directly modulate the microenvironment of the tumor by stimulating a local immune reaction through the intratumoral delivery of IL-12 or other immune-modulating molecules. This immune cascade allows anti-tumor immune cells to infiltrate the lesion, turning the tumor “hot” and ultimately generates a productive systemic immune response. In doing so, we believe intratumoral delivery of immune-modulating molecules, such as IL-12 provides a strong biological rationale for treatment in combination with immune checkpoint inhibitors, such as anti-PD-1 or anti-CTLA-4.

CLINICAL PROGRAMS

Our Lead Product Candidate: TAVO

Our lead product candidate, TAVO, is a drug-device combination. The drug consists of a plasmid construct called tavokinogene telseplasmid, or TAVO, with plasmid DNA-encoded, IL-12, and is delivered into a tumor using our proprietary electroporation device. Our clinical data indicates that the in vivo gene transfer of plasmid DNA-encoded IL-12 using electroporation is well-tolerated and anti-tumor activity has been observed after a single cycle of treatment. Importantly, regression in distant, non-injected/non-electroporated lesions has also been observed (“abscopal effect”) in different solid cancers.

Our Clinical Pipeline

MELANOMA

Melanoma is a deadly form of skin cancer with rapidly rising incidences both in the U.S. and internationally. The National Cancer Institute ("NCI") Surveillance, Epidemiology and End Results ("SEER") Program estimates that 87,110 new melanoma cases were diagnosed in 2017, representing 5.2% of all new cancer cases in the U.S. Overall, the five-year survival rate for melanoma, regardless of disease stage, is high (91.7%); however, according to SEER 2017, for patients who present with metastatic disease and receive systemic treatment, the five-year survival rate is considerably lower at less than 20%. Despite recent advances in therapy, advanced metastatic melanoma continues to present a major and increasing burden with significant morbidity and mortality.

PISCES/KEYNOTE-695 Study (OMS-103) (ongoing)

The PISCES/KEYNOTE-695 study is a Phase 2b, open-label, single-arm, multi-center study of TAVO in combination with an intravenous anti-PD-1 antibody, Merck's KEYTRUDA®, in patients with histological diagnosis of melanoma with progressive locally advanced or metastatic disease defined as stage III/IV.

PISCES/KEYNOTE-695 study enrolled its first patient in December 2017 and is actively enrolling patients in the United States, Canada and Australia across 19 sites.

PISCES/KEYNOTE-695 enrollment criteria with respect to anti-PD-1 checkpoint failure is highly restrictive. In order to be considered an anti-PD-1 checkpoint failure, all patients must have Stage III or Stage IV metastatic melanoma, be refractory to anti-PD-1 monoclonal antibodies, namely KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab), as either monotherapy or in combination with other approved checkpoint inhibitors or targeted therapies according to their approved label, and must have relapsed as documented disease progression within 24 weeks of the last dose of anti-PD-1 monoclonal antibodies according to RECIST v1.1, measured by radiologic assessment, with confirmation of progression by second assessment. Patients can have with no intervening therapies between failure of anti-PD-1 therapy and the TAVO / KEYTRUDA® combination treatment. Patients that are BRAF eligible must receive and progress following BRAF treatment. The primary endpoint of the study, by blinded independent central review, is to assess the best overall response rate (BORR) during 24 weeks of TAVO in combination with KEYTRUDA® in patients with unresectable or metastatic melanoma.

PISCES/KEYNOTE-695 is a registration enabled clinical trial. In order to be eligible for accelerated approval, the TAVO / KEYTRUDA® combination must treat a serious condition and provide a meaningful advantage over available therapies. In early 2017, and prior to the commencement of the study, the Company reviewed the patient inclusion criteria and other study requirements with FDA so that KEYNOTE-695 could be submitted to FDA for accelerated approval. In light of this review, we strictly defined the patient population to be enrolled in

PISCES/KEYNOTE-695 to include only those patients who have definitively failed prior anti-PD-1 checkpoint therapy, as determined by the above-described rigor, and who have exhausted all available treatment options.

We plan to provide a topline preliminary data update at the Society for Immunotherapy of Cancer ("SITC") 2018. Based on the preliminary tumor response data and safety profile observed to date, we have eliminated the formal interim Simon stage 1 analysis. The distinguishing feature of the Simon 2-stage design is sample size minimization. Phase 2 clinical trials using this design enroll a relatively small number of patients to allow a preliminary assessment of a new intervention before conducting a larger trial. Since preliminary tumor responses and correlative immunological data have been observed, we believe that eliminating the formal analysis and expanding the sample size is warranted. We believe that this may also accelerate the completion of the study and avoid any unwarranted interruption in continuous enrollment which may occur. We are planning to increase the number of patients to be enrolled from 48 to approximately 80 patients. We believe this will provide for a more robust data set and may further enhance our ability to seek an accelerated approval, should the final data results support doing so. We continue planning to complete enrollment of all patients by mid-2019.

Lastly, based on the outcome of the study and feedback from FDA, we plan to file for accelerated approval with the FDA for this patient population by the end of 2019 or early 2020.

OMS-102 (completed)

OMS-102 was an open-label, multi-center, Phase 2 trial of TAVO and KEYTRUDA® (pembrolizumab) in patients with advanced, metastatic melanoma. In August 2015, we enrolled the first patient in our Phase 2 investigator-sponsored clinical trial led by the clinicians at the University of California, San Francisco, or UCSF. Huntsman Cancer Institute in Utah was the second clinical site. The primary endpoint of this study was to assess the anti-tumor efficacy of the combination of TAVO and KEYTRUDA® in patients with stage III/IV metastatic melanoma whose tumors are characterized by low frequency of $CD8^+/PD\text{-}1^+/CTLA\text{-}4^+$ TILs (tumor infiltrating lymphocytes). The primary endpoint of the study was best overall response rate by RECIST of the combination regimen. Recent data suggests that patients whose tumors are lacking TILs or $CD8^+$ T-cells at the tumor margin or generally have a low frequency of $CD8^+/PD\text{-}L1^+/CTLA\text{-}4^+$ TILs are unlikely to respond to anti-PD-1 therapies such as KEYTRUDA®, while tumors with a frequency of $CTLA\text{-}4^+/PD\text{-}L1^+/CD8^+$ >20% in the tumor are likely to have a clinical benefit. Therapies, such as TAVO, that promote TIL generation and PD-L1 positivity play an important role in augmenting the clinical efficacy of the anti-PD1/PD-L1 agents.

Initial data were presented in February 2017 at ASCO-SITC and the trial stopped enrolling patients in September 2017, allowing the Company to progress on PICSES/KEYNOTE-695. The final data was selected for prominence at SITC 2017 and was presented during the oral poster session. The overall response rate in the 22-patient population was 43% by RECIST v1.1. at week 24 (best overall response rate was 50% by clinical assessment), with one Grade-3 adverse event of cellulitis that resolved with antibiotics. Based on these results, we believe the combination of TAVO and KEYTRUDA® demonstrated efficacy in this low TIL metastatic melanoma patient population and was well-tolerated. Further, long-term follow up has shown responses with significant durability, with all patients who experienced a response remaining in responding status. To date only one patient has required additional surgery to maintain remission.

OMS-100 (completed)

OMS-100 was an open-label Phase 2 trial of TAVO monotherapy in patients with metastatic melanoma. On December 5, 2014, we released top-line six-month data from a Phase 2 repeat dose trial of TAVO in patients with stage III/IV metastatic melanoma. We will present final data at the Melanoma Bridge Conference in 2018. This study is now locked with the data collected at 6 clinical centers. Thirty (30) patients with stage III/IV melanoma received up to four cycles of TAVO delivered by electroporation on days one, five and eight of each 12-week cycle. Of the 28 patients in the study who were evaluable, an objective response rate of 35.7% (10/28 patients) was observed. Five patients (17.9%) had a CR, 5 patients (17.9%) had a PR, 12 patients (42.9%) had SD. Of the distant untreated and assessed lesions that decreased in longest dimension by ≥ 30%, 17.4% (20/115) were assessed. Of the 26 patients with ≥ 1 assessed lesion, 12 patients (46.2%) had ≥ 1 assessed distant lesion with major regression (≥ 30%). Two patients were not evaluated due to not having evaluable distant untreated lesions. Other clinical endpoints included objective response rate, local and distant lesion regression, duration of response, overall survival and safety. The results of this study demonstrated that multiple treatment cycles of TAVO were well-tolerated, with no treatment-limiting toxicities. The majority of adverse events were localized to the treatment site and were Grade-1 or -2 in severity.

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In order to continue to acquire clinical and immune correlational data on melanoma patients treated with TAVO, the protocol of the OMS-I100 study was amended in February 2014 to enroll up to an additional 30 patients. Enrollment in OMS-I100 Addendum was completed in March 2016. The study is now completed and the Company plans to present final data at the Melanoma Bridge Conference being held on November 29 – December 1, 2018. These data were selected for an oral presentation and will include new data demonstrating that local treatment with TAVO alone led to whole-body immune responses associated with regression of untreated lesions in almost half of the 50 patients treated on the study.

Following this trial, a retrospective analysis of the patients who went on to receive an anti-PD-1/PD-L1 therapy was conducted. Results from this retrospective analysis suggested that TAVO primes and enhances response rates to PD-1/PD-L1 blockade. Specifically, of the 29 patients who completed TAVO, 14 subsequently received an anti-PD-1/PD-L1 treatment. Overall, five of these 14 patients (36%) experienced a complete response and four patients experienced a partial response (29%), for an overall response rate of 65% (75% without intervening therapies). Two patients experienced stable disease (14%) and three patients experienced progressive disease (21%). We believe this retrospective sequential data could suggest combinatorial potential of an immune-priming effect with TAVO prior to anti-PD-1/PD-L1 therapy. Data from this retrospective analysis formed the clinical rationale for conducting OMS-I102.

OMS-104 (planned)