
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **November 9, 2020**

ONCOSEC MEDICAL INCORPORATED

(Exact Name of Registrant as Specified in Charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

000-54318
(Commission
File Number)

98-0573252
(IRS Employer
Identification No.)

**3565 General Atomics Court, Suite 100
San Diego, California 92121**

**24 North Main Street
Pennington, NJ 08534-2218**
(Address of Principal Executive Offices)

(855) 662-6732
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	ONCS	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 8.01 Other Events.

On November 9, 2020, OncoSec Medical Incorporated announced new positive interim data from its KEYNOTE-695 registration-enabled Phase 2b clinical trial evaluating TAVO™ (tavokinogene telseplasmid), a DNA plasmid-based interleukin-12, in combination with KEYTRUDA® (pembrolizumab) in rigorously defined anti-PD1 checkpoint resistant metastatic melanoma patients. A copy of such press release is being furnished as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as part of this report:

Exhibit Number	Description
99.1	<u>Press Release issued by OncoSec Medical Incorporated, dated November 9, 2020.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ONCOSEC MEDICAL INCORPORATED
(Registrant)

Date: November 13, 2020

By: /s/ Daniel J. O'Connor
Name: Daniel J. O'Connor
Title: Chief Executive Officer and President



**OncoSec Announces Positive Interim Data from
KEYNOTE-695 Trial in Anti-PD-1 Checkpoint Refractory
Metastatic Melanoma at SITC 2020**

- 30% overall response rate (ORR) and 6% complete response (CR) rate achieved —
- 35% ORR achieved in patients with Stage IV M1c or M1d disease —
- TAVO + pembrolizumab demonstrated durable responses for up to two years —

— Data selected for Poster Walk discussion and will be additionally presented at SITC Symposium on November 11, 2020 at 7:30 a.m. ET and at a Company Investor & Analyst Day on November 12, 2020 at 8:30 a.m. ET —

PENNINGTON, N.J. and SAN DIEGO, November 9, 2020 /PRNewswire/ — OncoSec Medical Incorporated (NASDAQ:ONCS) (the “Company” or “OncoSec”) today announced new positive interim data from its KEYNOTE-695 registration-enabled Phase 2b clinical trial evaluating TAVO™ (tavokinogene telseplasmid), a DNA plasmid-based interleukin-12 (IL-12), in combination with KEYTRUDA® (pembrolizumab) in rigorously defined anti-PD1 checkpoint resistant metastatic melanoma patients.

TAVO + KEYTRUDA led to a 30% ORR in the first 54 out of 100 planned patients. This interim investigator assessed ORR is much higher than the primary efficacy endpoint for the study, which is a 20% ORR determined by blinded independent review. The data were selected for a Poster Walk discussion and will be additionally presented in the virtual Poster Hall on Wednesday, November 11 and Friday November 13 and as part of a Company Symposium on November 11th at the Society for Immunotherapy of Cancer (SITC)’s 35th Anniversary Annual Meeting.

“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. 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,” 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.

Key highlights of KEYNOTE-695 include:

- Of the first 54 out of 100 planned patients evaluated by investigator-assessed RECIST v1.1:
 - ORR was 30% (95%CI [18.0%, 43.6%]) (16/54)
 - Complete response rate was 6% (3/54)
 - All responses were confirmed by scans taken no earlier than after 6 months on study
 - 9% (5/54) patients had 100% reduction of target lesions
 - ORR was 35% (n=6/17) in patients with Stage IV M1c/M1d disease
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- ORR was 40% (n=6/15) in patients with prior exposure to ipilimumab
- Median duration of response (mDOR) is currently 12.2 months (95% CI, 5.6-NE)
- Median study follow-up was 13.5 months
- Excellent safety profile resulting from intratumoral treatment approach
 - Only 5.4% Grade 3 treatment-related AEs
 - No grade 4/5 treatment-related AEs
- This study enrolled rapidly progressing patients with a short interval of 1.2 months (median) between the last dose of anti-PD-1 and study treatment

Adil Daud, M.D., a Professor of Medicine at The University of California, San Francisco, Director of the Melanoma Clinical Research, and lead author of the study added, “the TAVO-electroporation (TAVO-EP) delivery system works by optimizing cellular uptake of DNA-based IL-12 in the tumor microenvironment, leading to local, sustained production of IL-12 in the tumor, where it matters, with negligible systemic exposure. This recruits and primes immune cancer-fighting cells in the tumor leading to systemic immune responses without systemic toxicity. The totality of the safety and efficacy data establishes TAVO-EP as a best-in-class intratumoral therapy.”

Daniel O’Connor, Chief Executive Officer of OncoSec, added “Patients with recurrent metastatic melanoma are in great need of effective treatment options. We believe this data demonstrates not only strong levels of efficacy, but also very low treatment related adverse events with the TAVO + pembrolizumab combo. This, combined with its ease of administration to accessible lesions within minutes in an outpatient setting, plus TAVO’s low-cost/simple manufacturing process and its off-the-shelf availability, build a strong case that the TAVO + pembrolizumab combination, in a real-world setting, could equip clinicians with more options for their patients.”

OncoSec also announced pre-clinical data showing that CORVax12 triggers an immune response against the SARS-CoV-2 virus. CORVax12 combines OncoSec’s novel DNA-encodable vaccine immuno-stimulant IL-12 expression platform, TAVO™ with the National Institute of Health (NIH)’s COVID-19 “spike” protein. On November 3, the Company announced FDA clearance of its Investigational New Drug (IND) application for a first-in-human Phase 1 trial to evaluate the safety and immunogenicity of CORVax12.

Mr. O’Connor continued, “Older adults or immuno-compromised patients, such as cancer patients, may not receive adequate protection from any one of the seven vaccine candidates currently being tested in humans in the U.S. The addition of our proprietary IL-12 delivery system may optimize the immune response to these vaccines and better protect these vulnerable populations. We believe that CORVax12 represents a second-generation vaccine that has the potential to contribute to the eradication of COVID-19.”

Additionally, the company presented preclinical data in murine models of triple negative breast cancer (TNBC) demonstrating that intratumoral injection of TAVO followed by electroporation prior to anti-PD-1 therapy led to complete tumor regression and long-term survival in a significant proportion of mice.

Additional details about the poster presentations, Symposium and Investor & Analyst Day are as follows:

Oral Poster Walk Presentation (by invitation only) and General Poster Presentation

Title: Durable responses and immune activation with intratumoral electroporation of pIL-12 plus pembrolizumab in actively progressing anti-PD-1 refractory advanced melanoma: KEYNOTE 695 interim data

Poster #: 799

Date/Time: Wednesday, Nov. 11, from 5:15-5:45 p.m. EST and Friday, Nov. 13, from 4:40-5:10 p.m. EST. at the virtual Poster Hall.

Presenter: Adil Daud, M.D., HS Clinical Professor, Department of Medicine (Hematology/Oncology), University of California, San Francisco (UCSF); Director, Melanoma Clinical Research, UCSF Helen Diller Family Comprehensive Cancer Center

Company Symposium

Event Name: DNA Plasmid-Based IL-12 Delivered Intratumoral Electroporation: Achieving Meaningful Tumor Response while Avoiding Systemic Toxicities

Date/Time: Thursday, Nov. 12, 2020 from 7:30 – 8:30 a.m. ET

Presenters:

- Paulo Ascierto, M.D., Director Dept. of Melanoma, Cancer Immunotherapy, Development Therapeutics, Ist. Naz. Tumori IRCCS Pascale
- Deborah Charych, Ph.D., Founder and Chief Technology Officer at RayzeBio
- Richard Heller, Ph.D., Professor at University of South Florida
- Michael Pritchett, D.O. and M.P.H., Director of Thoracic Oncology; Director, Chest Center of the Carolinas; FirstHealth of the Carolinas; Pinehurst Medical Clinic Pulmonary & Critical Care Medicine
- Chris Twitty, Ph.D., Chief Scientific Officer (moderator)

OncoSec Live Investor & Analyst Day Webcast

Date/Time: Wednesday, Nov.11, 2020 from 8:30-10:30 a.m. ET

Presenters:

- Tara Mitchell, M.D., Penn Medicine
- Adil Daud, M.D., University of California San Francisco
- Alain Algazi, M.D., University of California, San Francisco
- Matteo Carlino, M.D., University of Sydney
- Rohit Joshi, M.D. Calvary Central Districts Hospital
- Bernard Fox, Ph.D., Earle A. Chiles Research Institute

Additional Poster Presentations

Title: Intratumoral plasmid IL-12 expands CD8+ T cells and induces a clinically validated CXCR3 signature in triple-negative breast cancer

Poster #: 789

Date/Time: Wednesday, November 11, 2020 from 5:15–5:45 p.m. ET and Friday, November 13 from 4:40–5:10 p.m. ET

Session: Virtual Poster Hall

Presenter: Erika J. Crosby, Ph.D., Department of Surgery, Duke University Medical Center

Title: Preliminary evaluation of a novel coronavirus vaccine (CORVax) using electroporation of plasmid DNA encoding a stabilized prefusion SARS-CoV-2 spike protein alone or with transfection of plasmid IL-12

Poster #: 480

Date/Time: Thursday, November 12, 2020 from 4:50–5:20 p.m. EST and Saturday, November 14 from 1–1:30 p.m. ET

Session: Virtual Poster Hall

Presenter: Shawn M. Jensen, Ph.D., Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute, Providence Portland Medical Center

Copies of the posters will be archived and available in the Investors section of the Company's website at www.oncosec.com. The live video webcast of the Investor & Analyst day call will be accessible under Events and Presentations in the Investors section of the Company's website. The archived audio webcast will be available on the OncoSec website following the call and will be available for 30 days.

About KEYNOTE-695

KEYNOTE-695 is OncoSec's registration-directed Phase 2b trial (NCT#03132675) evaluating TAVO™ (tavokinogene telseplasmid), a DNA plasmid-based interleukin-12 (IL-12) + KEYTRUDA® (pembrolizumab) in patients with rigorously confirmed anti-PD-1 checkpoint resistant metastatic melanoma. The trial aims to enroll up to 100 patients with refractory, locally advanced or metastatic disease defined as unresectable Stage III/IV metastatic melanoma that had definitively progressed on a full-course of anti-PD-1 treatment with KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab). TAVO™ has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for the treatment of metastatic melanoma following progression on KEYTRUDA or OPDIVO.

About TAVO™

OncoSec's gene therapy technology combines TAVO™ (tavokinogene telseplasmid), a DNA plasmid-based interleukin-12 (IL-12), with an intra-tumoral electroporation gene delivery platform to achieve endogenous IL-12 production in the tumor microenvironment that enables the immune system to target and attack tumors throughout the body. TAVO™ has demonstrated a local and systemic anti-tumor response in several clinical trials, including the pivotal Phase 2b trial KEYNOTE-695 for metastatic melanoma and the KEYNOTE-895 Phase 2 trial in triple negative breast cancer (TNBC). TAVO™ has received Orphan Drug and Fast-Track Designation by the U.S. Food & Drug Administration (FDA) for the treatment of metastatic melanoma following progression on KEYTRUDA or OPDIVO.

About Advanced Metastatic Melanoma

Metastatic melanoma refers to stage IV melanoma, which has typically spread through the lymph nodes to distant sites in the body such as the liver, lungs, bones and brain. Every year, approximately 100,000 adults in the United States are diagnosed with metastatic melanoma. Due to this metastatic tumor burden, stage IV melanoma is often very difficult to treat. Available treatment options frequently combine surgery with immunotherapy or targeted therapy. The 5-year survival rate for metastatic melanoma is approximately 25%.

About Metastatic Triple Negative Breast Cancer (TNBC)

Metastatic triple negative breast cancer (mTNBC) is an aggressive type of breast cancer with a high recurrence rate within the first five years following diagnosis, which accounts for 10-20% of all breast cancers. Unlike some other breast cancers, mTNBC does not express estrogen or progesterone receptors or human epidermal growth factor receptor 2 (HER2), and it does not respond to existing cancer drugs designed to target these markers. mTNBC is difficult to treat and there are very few FDA approved treatment options for these patients, which mostly rely on surgery, radiation, and chemotherapy. The 5-year survival rate for these patients is approximately 11%.

About CORVax12

CORVax12 is the only DNA vaccine that uses an immune stimulant to promote an immune response against the SARS-CoV-2 virus. The CORVax12 vaccine approach combines the co-administration of TAVO™ (plasmid IL-12) with a DNA-encodable version of the SARS-CoV-2 spike or “S” glycoprotein to enhance immunogenicity of the component developed by scientists at the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center. CORVax12 is designed to drive a coordinated vaccine response, capable of drawing upon the innate and adaptive humoral and cellular arms. This multi-pronged innate, adaptive and cellular immune response has the potential to generate a robust anti-viral response.

About OncoSec Medical Incorporated

OncoSec Medical Incorporated (the “Company,” “OncoSec,” “we” or “our”) is a late-stage biotechnology company focused on developing cytokine-based intratumoral immunotherapies to stimulate the body’s immune system to target and attack cancer. OncoSec’s lead immunotherapy investigational product candidate – TAVO™ (tavokinogene telseplasmid) – enables the intratumoral delivery of DNA-based interleukin-12 (IL-12), a naturally occurring protein with immune-stimulating functions. The technology, which employs electroporation, is designed to produce a controlled, localized expression of IL-12 in the tumor microenvironment, enabling the immune system to target and attack tumors throughout the body. OncoSec has built a deep and diverse clinical pipeline utilizing TAVO™ as a potential treatment for multiple cancer indications either as a monotherapy or in combination with leading checkpoint inhibitors; with the latter potentially enabling OncoSec to address a great unmet medical need in oncology: anti-PD-1 non-responders. Results from recently completed clinical studies of TAVO™ have demonstrated a local immune response, and subsequently, a systemic effect as either a monotherapy or combination treatment approach along with an acceptable safety profile, warranting further development. In addition to TAVO™, OncoSec is identifying and developing new DNA-encoded therapeutic candidates and tumor indications for use with its new Visceral Lesion Applicator (VLA), to target deep visceral lesions, such as liver, lung or pancreatic lesions. For more information, please visit www.oncosec.com. TAVO™ is a trademark of OncoSec Medical Incorporated.

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KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

Risk Factors and Forward-Looking Statements

This release, as well as other information provided from time to time by the Company or its employees, may contain forward-looking statements that involve a number of risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Forward-looking statements provide the Company’s current beliefs, expectations and intentions regarding future events and involve risks, uncertainties (some of which are beyond the Company’s control) and assumptions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. These statements may include words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “should,” “will” and “would” and similar expressions (including the negative of these terms). Although we believe that expectations reflected in the forward- looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. The Company intends these forward-looking statements to speak only at the time they are published on or as otherwise specified, and does not undertake to update or revise these statements as more information becomes available, except as required under federal securities laws and the rules and regulations of the Securities Exchange Commission (“SEC”). In particular, you should be aware that the success and timing of our clinical trials, including safety and efficacy of our product candidates, patient accrual, unexpected or expected safety events, the impact of COVID-19 on the supply of our candidates or the initiation or completion of clinical trials and the usability of data generated from our trials may differ and may not meet our estimated timelines. Please refer to the risk factors and other cautionary statements provided in the Company’s Annual Report on Form 10-K for the fiscal year ended July 31, 2020 and subsequent periodic and current reports filed with the SEC (each of which can be found at the SEC’s website www.sec.gov), as well as other factors described from time to time in the Company’s filings with the SEC.

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