UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): July 30, 2024

IMUNON, INC.
(Exact name of registrant as specified in its Charter)

Delaware	001-15911	52-1256615
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

997 Lenox Drive, Suite 100, Lawrenceville, NJ	08648-2311
(Address of principal executive offices)	(Zip Code)

(609) 896-9100
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report.)

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 (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 $0.01 per share	IMNN	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).

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. ☐

Item 7.01. Regulation FD Disclosure.

On July 30, 2024, Imunon, Inc. (the "Company") issued a press release announcing positive topline data from its Phase 2 OVATION 2 trial of IMNN-001 in combination with neoadjuvant and adjuvant chemotherapy in patients with advanced ovarian cancer. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company will host a conference call to discuss the Phase 2 OVATION 2 study data on July 30, 2024 at 8:30 a.m., Eastern Time, and a live audio webcast of the call will be available through the News & Investors – Scientific Presentations section of the Company's website.

Furnished hereto as Exhibit 99.2 is an investor presentation providing an overview of IMNN-001, the Company's lead clinical program, and topline data from the Phase 2 OVATION 2 study.

The information in Item 7.01 of this Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On July 30, 2024, the Company announced positive topline data from its Phase 2 OVATION 2 trial of IMNN-001 in combination with neoadjuvant and adjuvant chemotherapy in patients with advanced ovarian cancer. The following table summarizes the data readout:

		Median time to event, experimental vs control (months)	**Hazard Ratio, experimental vs control**
Overall Survival (secondary endpoint)	ITT n=112	40.5 m vs 29.4	0.74 (0.42; 1.30) pNS
	≥20% of protocol-specified treatments in both arms n=102	45.1 m vs 29.4	0.64 (0.35; 1.19) pNS
	PARP treated patients n=43	NE vs 37.1	0.41 (0.13; 1.28) pNS
Progression Free Survival (primary endpoint)	ITT n=112	14.9 m vs 11.9	0.79 (0.51; 1.23) pNS
	≥20% of protocol-specified treatments in both arms n=102	14.6 m vs 11.9	0.76 (0.48; 1.22) pNS
	PARP treated patients n=31	33.8 m vs 22.1	0.80 (0.31; 2.12) pNS

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of Imunon, Inc., dated July 30, 2024
99.2	Imunon, Inc. Phase 2 OVATION 2 Data Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

IMUNON, INC.

Dated: July 30, 2024

By: */s/ David Gaiero*
David Gaiero
Chief Financial Officer

IMUNON Announces 11.1 Month Increase in Overall Survival in Patients with Newly Diagnosed, Advanced Ovarian Cancer Treated with IMNN-001

- ***Phase 2 OVATION 2 Study of IMNN-001 administered with standard-of-care chemotherapy as first-line treatment demonstrates a hazard ratio of 0.74 in the intent-to-treat patient population compared with the standard-of-care control arm***
- ***Overall survival (OS) was extended by 15.7 months in patients receiving three or more doses of IMNN-001 in the 17-dose protocol***
- ***Patients also receiving maintenance PARP inhibitor therapy demonstrated an OS hazard ratio of 0.41 in the IMNN-001 trial arm with median OS not yet reached at the time of data lock***
- ***Robust and durable benefit of IMNN-001 observed in OS supported by a three-month improvement in the primary endpoint of progression-free survival (PFS)***
- ***IMUNON expects to initiate a registrational study in Q1 2025***

Conference call begins today at 8:30 a.m. Eastern time

LAWRENCEVILLE, N.J. (July 30, 2024) – IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in late-stage development with its DNA-mediated immunotherapy, announces positive topline results from the Phase 2 OVATION 2 Study with IMNN-001 in patients with advanced ovarian cancer. OVATION 2 is a randomized study of IMNN-001 in combination with neoadjuvant and adjuvant chemotherapy (NACT) inclusive of interval debulking or cytoreductive surgery compared with a control arm of standard-of-care NACT alone. IMNN-001 is the Company's interleukin-12 (IL-12) immunotherapy based on its TheraPlas™ technology.

Highlights from patients treated with IMNN-001 plus standard-of-care in a first-line treatment setting include:

- An 11.1 month increase in median OS compared with standard-of-care alone in the intent-to-treat population (ITT).
- A hazard ratio in the ITT population of 0.74, which indicates a 35% improvement in survival.
- Among the approximately 90% of trial participants who received at least 20% of specified treatments per-protocol in both study arms, patients in the IMNN-001 arm had a 15.7 month increase in median OS, representing a further extension of life with a hazard ratio of 0.64, a 56% improvement in survival.
- For the nearly 40% of trial participants treated with a poly ADP-ribose polymerase (PARP) inhibitor, the hazard ratio decreased further to 0.41, with median OS in the IMNN-001 treatment arm not yet reached at the time of database lock, compared with median OS of 37.1 months in the standard-of-care treatment arm.

The PFS results, the trial's primary endpoint, support the OS results with:

- A three-month improvement in PFS compared with standard-of-care alone.
- A hazard ratio in the intent-to-treat population of 0.79, indicating a 27% improvement in delaying progression for the IMNN-001 treatment arm.

"These strong and clinically meaningful Phase 2 results are highly encouraging, suggesting that IMNN-001 may improve the outcomes for women with advanced ovarian cancer. In the near term, we look forward to advancing our therapeutic into a Phase 3 pivotal study as soon as possible," said Stacy Lindborg, Ph.D., President and Chief Executive Officer of IMUNON. "Advancements in treatment options for advanced ovarian cancer in women who require neoadjuvant treatment have been limited over the years, and these patients continue to have poor prognoses. Our goal is for IMNN-001 to play an important role in the treatment regimen for the more than 300,000 women diagnosed with this deadly disease. On behalf of IMUNON, I extend heartfelt thanks to the women who participated in this trial, their families and the investigators."

OVATION 2 evaluated the dosing, safety, efficacy and biological activity of intraperitoneal administration of IMNN-001 in combination with NACT of paclitaxel and carboplatin in patients newly diagnosed with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. Treatment in the neoadjuvant period is designed to shrink the tumors as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three additional cycles of adjuvant chemotherapy to treat any residual tumor. This open-label study enrolled 112 patients who were randomized 1:1 and evaluated for safety and efficacy to compare NACT plus IMNN-001 versus standard-of-care NACT. In accordance with the study protocol, patients randomized to the IMNN-001 treatment arm could receive up to 17 weekly doses of 100 mg/m^2 in addition to NACT.

As a Phase 2 study, OVATION 2 was not powered for statistical significance. Additional endpoints included objective response rate, chemotherapy response score and surgical response.

Sebastien Hazard, M.D., Chief Medical Officer of IMUNON, added, "It is highly gratifying to witness the extraordinary overall survival benefit that IMNN-001 showed in this Phase 2 study further supported by consistency across data, including in progression-free survival and in the patients who received three doses or more of IMNN-001 gaining an additional 15.7 months of life, while the safety profile was tolerable. It suggests that IMUNON's IL-12 gene therapy has a long-term impact on the disease."

Commenting on the study results, Premal H. Thaker, M.D, Interim Chief of Gynecologic Oncology, David & Lynn Mutch Distinguished Professor of Obstetrics & Gynecology, Director of Gynecologic Oncology Clinical Research at Washington University School of Medicine, and the OVATION 2 Study Chair, said, "Typically an increase in survival of six months is considered to be clinically meaningful, and extending survival from 29 months with standard-of-care treatment to 40 months with the addition of IMNN-001 is compelling. Importantly, the extension of survival among IMNN-001 patients also exposed to the new standard that includes PARP inhibitors is even greater. If confirmed in a Phase 3 clinical trial, IMNN-001 could reset the standard of care for women with ovarian cancer."

Charles A. “Trey” Leath, III, M.D., Director, Division of Gynecologic Oncology, Ellen Gregg Shook Culverhouse Chair in Gynecologic Oncology, Professor, Department of Obstetrics and Gynecology at University of Alabama Medical Center, and OVATION 2 Principal Investigator, said, “I (We) have been investigating IMNN-001 since the Phase 1 OVATION 1 Study and continue to be frustrated by the lack of substantial progress in primary treatment options available to treat this disease. The results from this trial demonstrating that IMNN-001 could extend life by one year or longer are provocative and powerful. I believe that should efficacy be confirmed in a pivotal study, IMNN-001 will be quickly incorporated into the care regimen.”

IMUNON plans to hold an End-of-Phase 2 meeting with the U.S. Food and Drug Administration as soon as possible to discuss the protocol for a Phase 3 study, which is anticipated to begin in the first quarter of 2025. IMUNON also plans to present full OVATION 2 Study results at an upcoming medical conference and to submit the results for publication in a peer-reviewed medical journal.

Conference Call and Webcast

IMUNON is hosting a conference call at 8:30 a.m. Eastern time today to discuss OVATION 2 Study results, next steps and to answer questions. Dr. Thaker will be joining management on the call. To participate in the conference call, please dial 833-816-1132 (Toll-Free/North America) or 412-317-0711 (International/Toll) and ask for the IMUNON call. A live webcast of the call will be available here.

Participants are encouraged to preregister for the call here.

The call will be archived for replay through August 13, 2024. The replay can be accessed at 877-344-7529 (U.S. Toll-Free), 855-669-9658 (Canada Toll-Free) or 412-317-0088 (International Toll), using the replay access code 7783601. A webcast of the call will be available here for 90 days.

About IMNN-001 Immunotherapy

Designed using IMUNON’s proprietary TheraPlas platform technology, IMNN-001 is an IL-12 DNA plasmid vector encased in a nanoparticle delivery system that enables cell transfection followed by persistent, local secretion of the IL-12 protein. IL-12 is one of the most active cytokines for the induction of potent anticancer immunity acting through the induction of T-lymphocyte and natural killer cell proliferation. IMUNON previously reported positive safety and encouraging Phase 1 results with IMNN-001 administered as monotherapy or as combination therapy in patients with advanced peritoneally metastasized primary or recurrent ovarian cancer, and completed a Phase 1b dose-escalation trial (the OVATION 1 Study) of IMNN-001 in combination with carboplatin and paclitaxel in patients with newly diagnosed ovarian cancer.

About Epithelial Ovarian Cancer

Epithelial ovarian cancer is the sixth deadliest malignancy among women in the U.S. There are approximately 20,000 new cases of ovarian cancer every year and approximately 70% are diagnosed in advanced Stage III/IV. Epithelial ovarian cancer is characterized by dissemination of tumor in the peritoneal cavity with a high risk of recurrence (75%, Stage III/IV) after surgery and chemotherapy. Since the five-year survival rates of patients with Stage III/IV disease at diagnosis are poor (41% and 20%, respectively), there remains a need for a therapy that not only reduces the recurrence rate, but also improves overall survival. The peritoneal cavity of advanced ovarian cancer patients contains the primary tumor environment and is an attractive target for a regional approach to immune modulation.

About IMUNON

IMUNON is a clinical-stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms to generate safe, effective and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies. IMUNON is developing its non-viral DNA technology across its modalities. The first modality, TheraPlas®, is developed for the coding of cytokines and other therapeutic proteins in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine®, is developed for the delivery of DNA-coded viral antigens that can elicit a strong immunological response.

The Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase 2 development. IMNN-001 works by instructing the body to produce safe and durable levels of powerful cancer-fighting molecules, such as IL-12 and interferon gamma, at the tumor site. Additionally, the Company has entered a first-in-human study of its COVID-19 booster vaccine (IMNN-101). IMUNON will continue to leverage these modalities and to advance the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions, and to further strengthen IMUNON's balance sheet through attractive business development opportunities. For more information, please visit www.imunon.com.

Forward-Looking Statements

IMUNON wishes to inform readers that forward-looking statements in this news release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including, but not limited to, statements regarding the timing for commencement of a Phase 3 trial of IMNN-001, the timing and outcome of the Company's End-of-Phase 2 meeting with the FDA, the timing and enrollment of the Company's clinical trials, the potential of any therapies developed by the Company to fulfill unmet medical needs, the market potential for the Company's products, if approved, the potential efficacy and safety profile of our product candidates, and the Company's plans and expectations with respect to its development programs more generally, are forward-looking statements. We generally identify forward-looking statements by using words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances). Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, uncertainties relating to unforeseen changes in the course of research and development activities and in clinical trials, including the fact that interim results are not necessarily indicative of final results; the uncertainties of and difficulties in analyzing interim clinical data; the significant expense, time and risk of failure of conducting clinical trials; the need for IMUNON to evaluate its future development plans; possible actions by customers, suppliers, competitors or regulatory authorities; and other risks detailed from time to time in IMUNON's filings with the Securities and Exchange Commission. IMUNON assumes no obligation, except to the extent required by law, to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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# # #

Ovation 2, Trial Results in Advanced Ovarian Cancer Patients

Protocol Planned, Phase 2 Data Readout

July 30, 2024

8k Filing

Safe Harbor Statement

Disclosures

For the purposes of this notice, the "presentation" that follows shall mean and include the slides that follow, the oral presentation of the slides by members of management of Imunon, Inc. ("IMUNON" or the "Company") or any person on their behalf, any question-and-answer session that follows such oral presentation, hard copies of this document and any materials distributed at, or in connection with, such oral presentation. The information contained in this presentation is for informational purposes only.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

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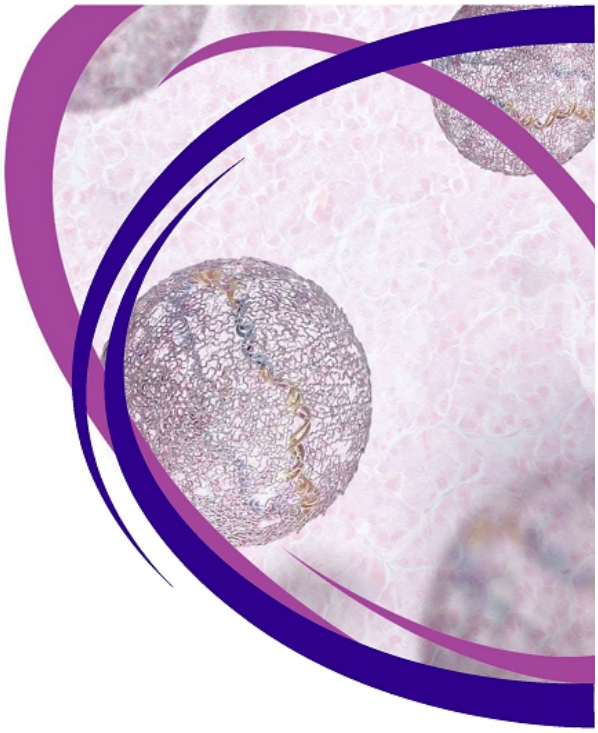
This presentation discusses product candidates that are under clinical study and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these product candidates for the therapeutic use for which such product candidates are being studied.

IMNN-001 and Ovarian Cancer Context



IMNN-001 could reset the standard of care for women with ovarian cancer: Reasons to believe

IMNN-001 allows durable therapeutic and dose-dependent production and release of IL-12 in the Tumor Micro-Environment [1]

- Benefits of IMNN-001 therapy are supported by known long-lived actions of IL-12 recruiting the immune system
- IMNN-001 has Advantages over other Approaches to IL-12 Delivery

Clinical Development has achieved goals specific to each stage

- Phase 1: Dose-dependent biological response (IL-12, IFN-γ) and benefits in clinical efficacy including, objective tumor responses by RECIST, surgical resection score, and chemotherapy response score.
- Phase 2: Improvement in OS and PFS observed with IMNN-001 versus NACT with Magnitude of Overall Survival has grown over time, Consistent with effective Immune therapy:
  - IMNN-001 median survival extended by 38%, 11 month: 40.5 to 29.4 Mo

Across Clinical Development, the safety profile has been without significant safety issues.

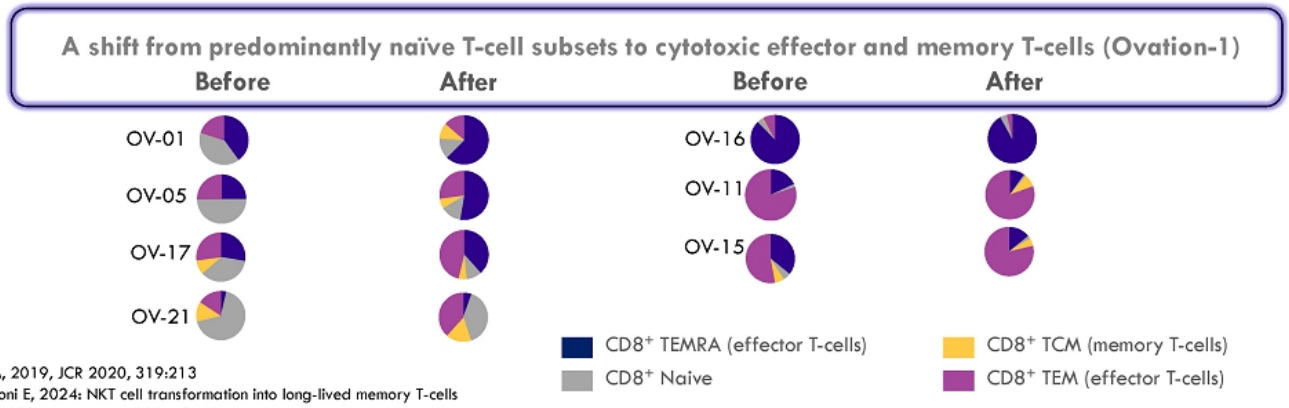
Unmet Patient Need is high

Product Pricing assumptions present a >$1.6B Market Opportunity

1. Thaker et al. doi:10.1158/1078-0432.CCR-21-0360

The OS benefits of IMNN-001 therapy are supported by known long-lived actions of IL-12 on the immune system

- IL-12 promotes activation, proliferation and persistence of cytotoxic T-cells of both innate and adaptive immune system.
  - Innate immune system- cytotoxic natural killer T-cells or NKT cells
  - Adaptive immune system- cytotoxic CD4 and CD8 T-cells
- IL-12 reprograms T-cells and NK T-cells into long-live memory T- cells and NKT cells with durable potent anti-tumor activity.



• Hu M, 2019, JCR 2020, 319:213
• Landoni E, 2024: NKT cell transformation into long-lived memory T-cells
•Zhu Y, 2024, Pharm Res. 203: 107186
•Leleux JA, 2021, PLOS ONE 16: (12)

Potent Immune Mechanisms and Clinical Efficacy Supports Strong R&D Interest in IL-12: Current Strategies to Minimize Serious Systemic Toxicity

- Complete or partial responses to rIL-12 have been observed in:
  - Melanoma[1] Renal carcinoma[1] AIDS-related Kaposi sarcoma[2] Non-Hodgkin's lymphoma[3]
- However, serious systemic toxicity, including deaths, undermines the clinical benefits.
  - Hematological Hepatic
- This is driving strong R&D interest in alternate methods of IL-12 delivery having the potential for minimal systemic toxicity.
  - Targeted rIL-12: CBD-IL-12[4], NHSAb-IL-12[5], tumor protease cleavable[6]
  - Nucleic acids: viral vectors, mRNA[7]
  - Cell-based: CART co-expressing IL-12[8]
- The next 6 months features readouts from 4 IL-12 assets including IMNN (Phase-1 or 2).
  - IMNN-001 is the only one being studied in Ovarian Cancer

1. Atkins MB. et al., Clin Cancer Res 1997. PMID: 9815699
2. Little RF., et al., Blood 2006, 107:4650
3. Younes A., et al., Clin Cancer Res 2004, 10:5432
4. Mansurov A., et al., Nat Biomed Eng- 2020, 4:531
5. Frank SE., et al., Cancer Immunology, Immunotherapy. 2023, 72:2783
6. Mansurov A., et al., Nat Biomed Eng- 2022, 6:819
7. Liu M, Nature Nanotechnology, 2024, 19:565
8. Zhu Y., et al., Pharmacology Res. 2024, 203:107186

IMNN-001 has Advantages over other Approaches to IL-12 Delivery

Comparison with rIL-12

- Physiological profile of IL-12 with durable local increases compared to rapid high systemic increases accompanying serious systemic toxicity following rIL-12.
    - Local increases in IL-12 by IMNN-001will be safer and more effective due to:
        - Enhanced spatiotemporal distribution.
        - Higher drug availability at tumor site.
        - High local levels more effective in reversing tumor-supporting immunosuppression
        - Low CRS risk.
        - Low risk of desensitization often associated with rIL-12 therapy.
    - Durable increase for several days is advantageous over short-lived rIL-12 requiring frequent treatment.

Comparison with mRNA

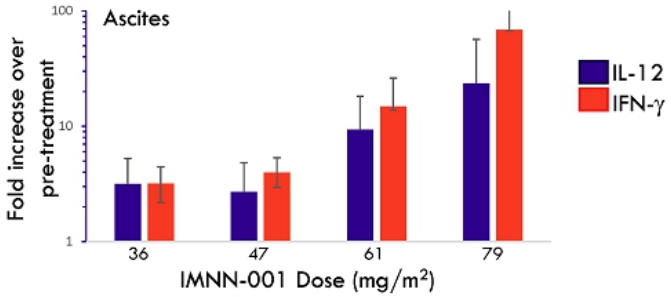
- IMNN-001 provides more durable protein expression.
- IMNN-001 is at advanced development stage potentially going into Phase-3 trial.

OVATION-1 Study in Neoadjuvant Ovarian Cancer

Dose Dependent Biological (IL-12 & IFN-γ) and Clinical Responses Demonstrate POC

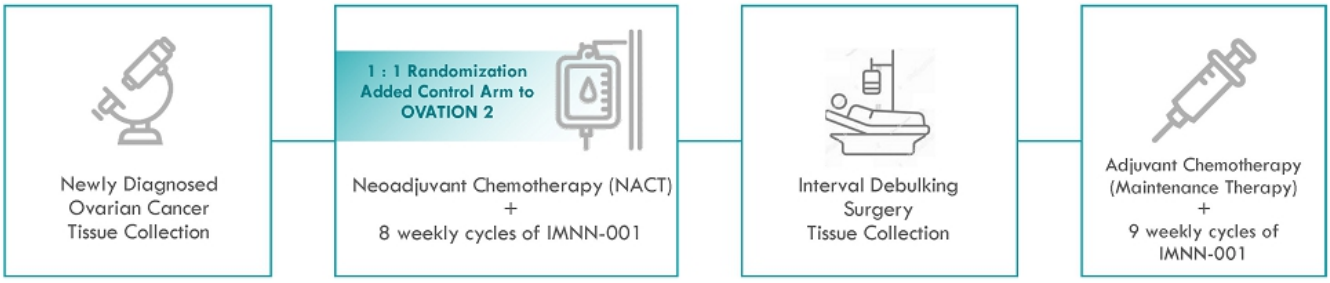
Radiographic Response		Total (n)	Cohort 1 36 mg/m²	Cohort 2 47 mg/m²	Cohort 3 61 mg/m²	Cohort 4 79 mg/m²
Tumor Response	CR	2	1	0	0	1
	PR	10	0	3	3	4
	SD	2	2	0	0	0
Objective Response Rate			67%		100%	
Surgical Resection	R0	9	2	0	2	5
	R1	3	1	2	0	0
	R2	2	0	1	1	0
R0 Resection Rate			33%		88%	
Pathologic Response	cPR	1	1	0	0	0
	Micro	8	1	2	1	4
	Macro	5	1	1	2	1
cPR/micro rate			60%		63%	
Chemotherapy Response Score	CRS 3	5	1	0	2	2
	CRS 2	5	2	1	0	2
	CRS 2	4	0	2	1	1
CRS 3 rate			17%		50%	

Tumor response, surgical outcome, pathologic response, and chemotherapy response score



IMNN-001: OVATION 2 Ovarian Cancer Study

To Determine Efficacy and Biological Activity With NACT in Stage III/IV Patients



Ovarian Cancer Patients (FIGO IIIC & IV)

- 112 patients. **Enrollment completed**
- ITT population contains mix group of BRCA +/- subjects

Primary Endpoint

- Progression Free Survival (PFS). After 80 PFS events or at least 16 months, whichever is longer

Secondary Endpoints

- Overall Survival (OS), ORR, Pathological Response, Chemotherapy response score, Surgical Resection Scores, Biological Response, Safety

With OVATION2, IMUNON Targets a Large Patient Population with High Unmet Needs

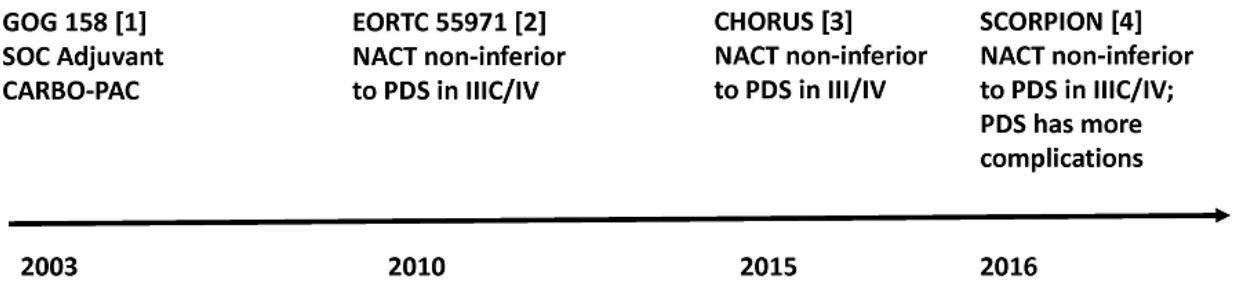
60% of newly diagnosed advanced OC patients and no new treatment in decades

- According to ovarian cancer experts, over 60% of patients are in need for a neoadjuvant treatment ahead of debulking surgery, representing approximately 10,000 new patients in the US every year.
- OVATION-2 population included a large proportion of FIGO Stage IIIC and IV disease, known for their worst prognosis.
- While most studies in 1st line OC exclude ECOG PS 2 patients, these patients were eligible to OVATION-2.
- No new treatment option has been offered to these patients (newly diagnosed advanced ovarian cancer who cannot undergo primary debulking surgery), since chemotherapy.
- The median PFS (12 m) and OS (29m) in the control arm of OVATION-2 confirms the poor prognosis of this population.

Current Standard of Care Established 25 years ago

Overview of Pivotal Trials Defining NACT SOC

In patients with stage IIIC/IV ovarian cancer, neoadjuvant chemotherapy (NACT) followed by interval debulking surgery (IDS) demonstrated non-inferior overall survival (OS) to primary debulking surgery (PDS) followed by chemotherapy in three randomized phase III trials (EORTC 5597 CHORUS and SCORPION). Consequently, NACT is considered a valuable treatment option and is included in international guidelines for patients in whom initial upfront complete resection is not possible or where there is a high risk of perioperative adverse effects.



[1] Ozols et a. J Clin Oncol (2003) 21(17):3194-200
[2] Vergote et al. N. Engl. J. Med. 363, 943–953 (2010)
[3] Kehoe et al. Lancet 386, 249–257 (2015)
[4] Fagotti et al. Eur. J. Cancer 59, 22–33 (2016)

Adding Phase 2 trial to Clinical Development Strategy in Ovarian Cancer Effectively Reduces Risk

Phase 2 trial intended to generate additional clinical data and gain confidence in the clinical effect prior to Phase 3

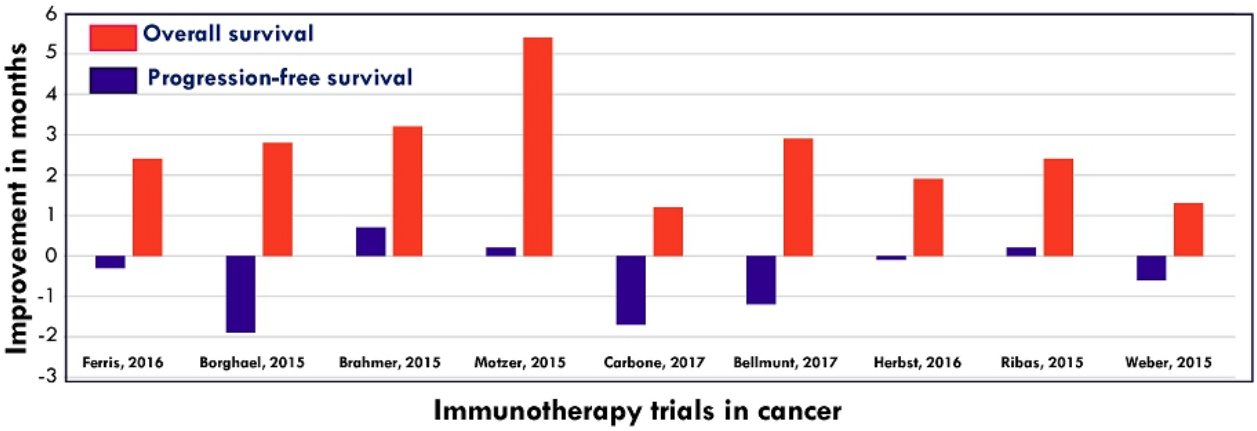
Given interest in Overall Survival, and Progression Free Survival, Phase 2 that are powered for statistical significance end up being Phase 3 trials

2 strategies have been employed in Ovarian Cancer Development:

- Higher Risk Strategy:
  Phase 1 trial (n≈30) → Phase 3 trial, control (n≈300/arm)
- Reduced Risk, IMNN strategy:
  Phase 1 trial (n≈30) → Phase 2 trial, control (n≈50/arm) → Phase 3 trial, control (n≈300/arm)

Regulatory Guidance and evolution of Clinical Trial Practice: single arm vs. control arm

Overall Survival Consistently Shows Greater Protective Effects with Immunotherapies than Progression Free Survival



Adapted from Gyawali B- A comparison of response pattern for PFS and OS following treatment for cancer with PD-1 inhibitors. JAMA Netw Open. 2018 Jun 1;1(2):e180416. doi:

Overall Survival Consistently Shows Greater Protective Effects with Immunotherapies than Progression Free Survival

Meta Analysis from systematic search covering 10 studies, 4,653 patients spanning 8 clinical settings supports importance of OS

JAMA Network Open. 2018;1(2):e180416. doi:10.1001/jamanetworkopen.2018.0416

Table 2. Efficacy Data

		PFS				OS			
Source	Setting	PD-1 Group, mo	Control Group, mo	Difference, mo	Hazard Ratio (95% CI)	PD-1 Group, mo	Control Group, mo	Difference, mo	Hazard Ratio (CI)
Ferris et al,[8] 2016 (Checkmate 141)	Recurrent head and neck	2.0	2.3	−0.3	0.89 (0.70-1.13)	7.5	5.1	2.4	0.70 (97.73% CI, 0.51-0.96)
Borghaei et al,[9] 2015 (Checkmate 057)	Second line, nonsquamous NSCLC	2.3	4.2	−1.9	0.92 (0.77-1.1)	12.2	9.4	2.8	0.73 (96.00% CI, 0.59-0.89)
Brahmer et al,[10] 2015 (Checkmate 017)	Second line, squamous NSCLC	3.5	2.8	0.7	0.62 (0.47-0.81)	9.2	6	3.2	0.59 (95.00% CI, 0.44-0.79)
Robert et al,[11] 2015 (Checkmate 066)	First line, melanoma	5.1	2.2	2.9	0.43 (0.34-0.56)	NR	10.8	NR	0.42 (99.79% CI, 0.25-0.73)
Motzer et al,[12] 2015 (Checkmate 025)	Second line, RCC	4.6	4.4	0.2	0.88 (0.75-1.03)	25	19.6	5.4	0.73 (98.50% CI, 0.57-0.93)
Carbone et al,[13] 2017 (Checkmate 026)	First line, NSCLC	4.2	5.9	−1.7	1.15 (0.91-1.45)	14.4	13.2	1.2	1.02 (95.00% CI, 0.80-1.30)
Bellmunt et al,[14] 2017 (Keynote 045)	Second line, urothelial	2.1	3.3	−1.2	0.98 (0.81-1.19)	10.3	7.4	2.9	0.73 (95.00% CI, 0.59-0.91)
Reck et al,[15] 2016 (Keynote 024)	First line, NSCLC	10.3	6.0	4.3	0.5 (0.37-0.68)	NR	NR	NR	0.60 (95.00% CI, 0.41-0.89)
Herbst et al,[16] 2016 (Keynote 010)[a]	Second line, NSCLC	3.9	4.0	−0.1	0.88 (0.74-1.05)	10.4	8.5	1.9	0.71 (95.00% CI, 0.58-0.88)
Langer et al,[17] 2016 (Keynote 021)[b,c]	First line, NSCLC	13.0	8.9	4.1	0.53 (0.31-0.91)	NR	NR	NR	0.90 (95.00% CI, 0.42-1.91)
After Treatment With Ipilimumab									
Ribas et al,[18] 2015 and Hamid et al,[19] 2016 (Keynote 002)[a,b]	Second line, melanoma	2.9	2.7	0.2	0.57 (0.45-0.73)	13.4	11.0	2.4	0.86 (95.00% CI, 0.67-1.10)
Weber et al,[20] 2015 and Larkin et al,[21] 2018 (Checkmate 037)	Second line, melanoma	3.1	3.7	−0.6	1.0 (0.78-1.44)	15.7	14.4	1.3	0.95 (95.54% CI, 0.73-1.24)

Abbreviations: NR, not reached; NSCLC, non-small cell lung cancer; OS, overall survival; PD-1, programmed cell death 1; PFS, progression-free survival; RCC: renal cell carcinoma.

[a] Only the 2-mg/kg cohort of pembrolizumab has been included in this analysis.

[b] These are the only phase 2 trials in this analysis. All other trials are phase 3.

[c] This is the only trial in which a PD-1 inhibitor was not tested as a single agent, but as a combination with chemotherapy.

Overall Survival HR outpaces PFS by .03 to .25

Difference in OS 1.2 to 5.4 mo.

As OVATION-2 OS Data Mature, the Level of Evidence for a Robust Benefit Increases

Hazard Ratio dropped from 0.86 to 0.74, difference in Median OS increased to 11 months

Overall Survival Parameters	September 2023 Interim Analysis	June 2024 Analysis
Number of Events	37	49
Improvement in Survival (months)	9	11.1
Hazard Ratio	0.86	0.74

$1.6B to $2.1B Market Opportunity in Patients Newly Diagnosed with Advanced Stage Ovarian Cancer

Worldwide diagnoses, yearly: 300,000[1]
US diagnoses each year: 20,000[2]

Population Assumptions, US market: ~9.5k patients treated with IMNN-001

— 80% are Newly diagnosed
— 60% of market captured

Price Assumptions:

- Approved immune checkpoint inhibitors annual treatment[3], $125k-$200k
- Combination therapies using 2 checkpoint inhibitors at $300K.

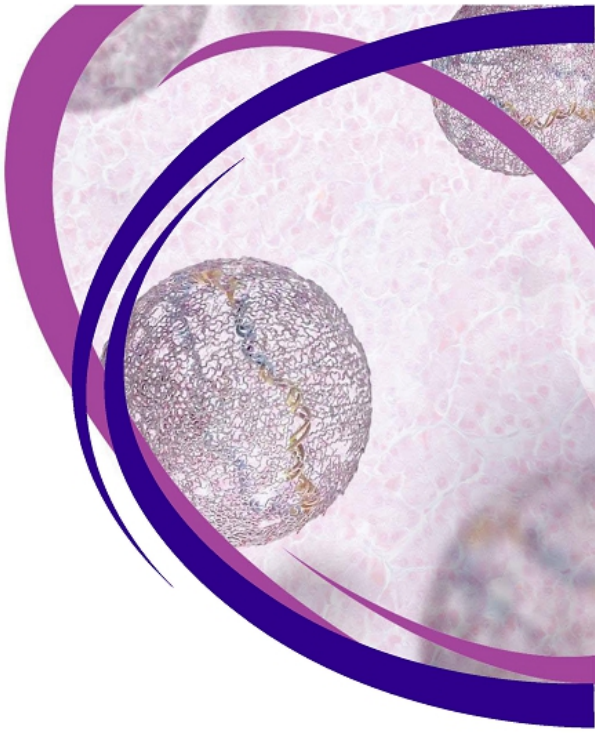
Base IMNN price, annual treatment: $125k/year - $225k/year

Annual Gross Sales $1,653m – 2,124m

1. International Agency for Research on Cancer, 2. American Cancer Society
3. Keytruda, Opdivo, Lenvima, Stivarga, Nexavar

Ovation 2, Trial Results in Advanced Ovarian Cancer Patients

Protocol Planned, Phase 2 Data Readout



Summary: Ovation 2 Advanced Ovarian Cancer Patients Trial Results

If results are replicated in phase 3, we believe that IMNN-001 will be an approved 1st line treatment for Ovarian Cancer that will change the Standard of Care

- An 11-month improvement in Overall Survival by IMNN-001 in intent-to-treat (ITT) population
  - A clinically meaningful improvement in a difficult to treat disease
- A 15.7-month improvement in OS by IMNN-001 in patients receiving at least 20% of protocol-specified treatments in both arms (91% ITT population)
  - Demonstrating greater benefit achieved with higher drug exposure
- The potential for an exceptionally remarkable improvement in the OS benefit by IMNN-001 in patients exposed to standard of care PARP inhibitor therapy (38% of ITT population)
- IMNN-001 treatment also improved progression-free survival (PFS) in intent to treat population (ITT)
  - Benefits in PFS are qualitatively consistent with the OS data
- Consistent with OS improvement, similar PFS improvement was seen in patients receiving at least 20% of protocol-specified treatments, along with evidence of a PFS improvement in first line PARP inhibitor therapy (11.7-month improvement in Median PFS)

Clinical Advisory Committee Summary

Patients who received IMNN-001 in the trial lived longer than those in the control arm

- If they received a PARP inhibitor or if they had at least 20% of treatment in the protocol they did even better

These Phase 2 results are promising and if confirmed in an adequately powered Phase 3 trial could change the standard of care.

Immunotherapies have not been effective in Ovarian Cancer to-date. The novel mechanism of action of IMNN-001 and ability to deliver well tolerated and durable levels of IL-12 in addition to other important cytokines useful to fight cancer could usher in the first Immune based Gene Therapy for Ovarian Cancer.

Ovation 2: Protocol Planned Phase 2 Data Readout Advanced Ovarian Cancer Patients

		Median time to event, Experimental vs Control (months)	Hazard Ratio, Experimental vs Control
Overall Survival (secondary endpoint)	ITT n=112	40.5 vs 29.4	0.74 (0.42; 1.30) pNS
	≥20% of protocol-specified treatments in both arms n=102	45.1 vs 29.4	0.64 (0.35; 1.19) pNS
	PARP treated patients n=43	NE vs 37.1	0.41 (0.13; 1.28) pNS
Progression Free Survival (primary endpoint)	ITT n=112	14.9 vs 11.9	0.79 (0.51; 1.23) pNS
	≥20% of protocol-specified treatments in both arms n=102	14.6 vs 11.9	0.76 (0.48; 1.22) pNS
	PARP treated patients n=31	33.8 vs 22.1	0.80 (0.31; 2.12) pNS

NACT: Neoadjuvant Chemotherapy, **NE**: not evaluable, **pNS**: p-value not significant
Ovation 2 Treatment arms: Experimental: IMNN-001 + NACT; Control arm: NACT