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): November 15, 2022 (November 14, 2022)

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	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 November 14, 2022, Imunon, Inc. (the "Company") held a conference call to discuss its financial results for the quarter and nine months ended September 30, 2022 and provide a business update. Attached as Exhibits 99.1 and 99.2 are the conference call script and the Company's November 2022 corporate presentation.

The information in this report, including the exhibits hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. Such information shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Imunon, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The exhibits contain forward-looking statements which involve certain risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Please refer to the cautionary note regarding forward looking statements in Imunon's SEC filings.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Script from third quarter earnings teleconference held November 14, 2022
99.2	Imunon, Inc. Corporate Presentation – November 2022
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: November 15, 2022

By: */s/ Jeffrey W. Church*
Jeffrey W. Church
Executive Vice President and Chief Financial Officer

IMUNON, Inc.

Third Quarter 2022 Conference Call

Monday, November 14, 2022
11:00 a.m. Eastern time

Operator

Please stand by. Good morning. My name is Marlise and I will be your operator today. At this time, I would like to welcome you to IMUNON's third quarter 2022 financial results conference call. All lines have been placed on mute to prevent any background noise. Following the speakers' prepared remarks there will be a question-and-answer session. At that time, you may press star one on your phone to ask a question. Please keep in mind, if you are using a speaker phone, you must release your mute function to allow the signal to reach our equipment. Again, that's star one to ask a question during the Q&A session.

I would now like to turn the call over to Kim Golodetz. Please go ahead.

Kim Golodetz

Thank you, and good morning everyone. This is Kim Golodetz with LHA.

Welcome to IMUNON's third quarter 2022 financial results and business update conference call. As has been IMUNON's practice and as noted by the operator, prepared remarks will be followed by a question-and-answer session.

During today's call management will be making forward-looking statements regarding IMUNON's expectations and projections about future events. In general, forward-looking statements can be identified by terminologies such as expects, anticipates, believes or other similar expressions. These statements are based on current expectations and are subject to a number of risks and uncertainties, including those set forth in the company's periodic filings with the Securities and Exchange Commission. No forward-looking statements can be guaranteed, and actual results may differ materially from such statements. In particular, there is significant uncertainty about the duration and impact of the COVID-19 pandemic. This means results could change at any time, and the contemplated impact of COVID-19 on IMUNON's operations, financial results and outlook is the best estimate based on the information for today's discussion.

I also caution that the content of this conference call is accurate only as of the date of the live broadcast, November 14th, 2022. IMUNON undertakes no obligation to revise or update comments made during this call, except as required by law.

With that said, I would like to turn the call over to Dr. Corinne Le Goff, President and Chief Executive Officer. Corinne?

Corinne Le Goff

Thank you, Kim, and good morning, everyone.

Joining me today is Jeffrey Church, our Chief Financial Officer. In addition, Dr. Khursheed Anwer, our Chief Scientific Officer and Dr. Nicholas Borys, our Chief Medical Officer, will be available during the Q&A session to answer your questions regarding our development programs with PLACCINE, our prophylactic vaccine modality, and GEN-1, our IL-12 immunotherapy for the treatment of advanced Ovarian Cancer.

Today I am going to spend most of my time speaking about PLACCINE, as our recent progress in developing this modality has been extraordinarily robust.

PLACCINE is one of IMUNON's DNA-based platform technologies that relies on DNA delivery with novel synthetic delivery systems that are independent of viral vectors or devices. DNA vectors encompass molecular elements that are designed to improve the immune response by targeting multiple antigens of a pathogen or multiple variants of the same antigen. IMUNON has produced a family of DNA vaccine vectors expressing one or more SARS-CoV-2 surface antigens and we have demonstrated expression of the encoded genes. This promising vaccine approach has broad applicability in infectious diseases and also in oncology.

We have been conducting preclinical proof-of-concept studies on a DNA vaccine candidate targeting the SARS-CoV-2 virus in order to validate our modality. To date, we are delighted with the results, which bode well for our ability to broaden applications to other pathogens.

But before I dive into the data, I want to start by telling you why I am excited about the potential of our DNA-based vaccine modality.

First, the market opportunity is very large. Vaccines are the most powerful and cost-effective way to protect the health of billions of people around the world.

Before COVID, the global market for preventive vaccines was about $35B, roughly shared between four key players (Sanofi, Merck, GSK and Pfizer). The market grew to $61B in 2021 and is expected to reach $125B in 2028. New viruses are being discovered all the time. In fact, over the past 40 years, 80 new pathogenic viruses have been discovered, for an average of 2 new viruses per year. When it comes to the development of vaccines, if you consider all the viruses known to mankind from 100 years ago, commercial vaccines have been approved for only 4% of them.

So clearly there is a large addressable market providing significant room for new technologies. And that brings me to my second point: I believe that DNA has the potential to be an entirely new class of vaccines. In particular, our PLACCINE modality has the potential to represent a viable alternative to current commercial vaccines.

Current vaccine technologies -- attenuated virus, protein sub-unit, mRNA and viral DNA vector vaccines have shortcomings that we want to address. There are five important attributes that regulators and governments around the world want to see in the next generation of prophylactic vaccines and we are addressing each with our technology:

1. **Durability of protection**: DNA antigen expression is more durable, longer lasting than mRNA and induces a robust immunological response
2. **Breadth of protection**: our multi-valent vector increases the breadth of immune response and allows for combination vaccines
3. **Transmission advantage**: DNA has a greater capability to induce T cell activity against infected cells. We have the option in our vector for co-expression of immune modifiers to further strengthen the immune response and decrease the risk of viral shedding.
4. **Safety and convenience**: our synthetic delivery systems present no risk of genotoxicity – there is no virus involved, or risk of cytotoxicity – there also is no device needed, which improves treatment compliance and makes it very convenient to handle immunization campaigns with suitability for potential pandemic control.
5. **Flexible manufacturing**: we are developing a truly versatile platform enabling rapid response to changing pathogens, much better stability and shelf-life than mRNA at workable refrigerated temperatures versus deep-freeze temperatures, which simplifies handling and distribution

The data we've generated to date is extremely encouraging.

In proof-of concept mouse immunogenicity studies we have demonstrated robust IgG, neutralizing antibody and T-cell responses with our PLACCINE vaccines. The data also demonstrated the ability of our PLACCINE vaccines to protect a SARS-CoV-2 mouse model in a live viral challenge. In the study, mice were vaccinated with a PLACCINE vaccine expressing the SARS-CoV-2 spike antigen from the D614G variant, the Delta variant or a combination vaccine expressing both variants. All three vaccines were found to be safe and elicited IgG responses and inhibited viral load by 90-95%. The key exciting finding is that our bivalent vaccine was equally effective against both variants of the SARS CoV-2 virus we tested. The murine model data also suggest that our approach provides not only flexibility, but also the potential for efficacy that is at least comparable to benchmark mRNA commercial vaccines with durability of protection expected to exceed six months.

These encouraging results from the mouse study formed the basis of a non-human primate challenge study. The partial results from this ongoing study were reported last month. In the study, we are examining a single plasmid DNA vector containing the SARS-CoV-2 spike antigen from the D614G variant that is formulated with a synthetic DNA delivery system and administered by intramuscular injection.

We vaccinated Cynomolgus monkeys with either the PLACCINE vaccine or a commercial mRNA vaccine three times over 84 days. Analyses of blood samples for IgG and neutralizing antibodies showed evidence of immunogenicity both in PLACCINE and mRNA vaccinated subjects. In a head-to-head comparison, the protection efficiency as measured by viral clearance following challenge with the SARS-CoV-2 virus was equivalent between PLACCINE and the commercial mRNA vaccine. We look forward to the completion of this study and the final report by the end of this year. Also of importance, in an ongoing stability study the physio-chemical properties and immunogenicity of the PLACCINE vaccine did not change during storage at 4° Celsius for up to six months. It is a clear advantage over mRNA vaccines with respect to transport and flexibility.

So, what is next for PLACCINE?

Given the highly encouraging data to date, and the potential for key commercial advantages over existing vaccines, we have moved to broaden and strengthen the platform and we entered into an agreement with Acuitas Therapeutics to evaluate our PLACCINE nucleic acid constructs formulated with their proprietary lipid nanoparticle delivery system, or LNP. Acuitas is known for its LNP systems for mRNA vaccines, having worked with Pfizer/BioNTech on their commercial vaccine. Our work with Acuitas will focus on various LNP formulations for gene expression and immunogenicity in murine models. The combinations of our technologies will expand our delivery portfolio, thereby enabling us to pursue a broad spectrum of formulation capabilities and delivery modalities with greater potential to improve currently available vaccines against a multitude of pathogens and also to develop novel cancer vaccines.

Now that our proof-of concept studies using SARS-CoV-2 have yielded highly promising results, we are considering an option to developing a multivalent PLACCINE DNA vaccine as a SARS-CoV-2 booster vaccine and expanding PLACCINE vaccine to other pathogens.

With respect to developing a SARS-CoV-2 booster vaccine and selecting the next pathogens for development, last week we held a "tech watch" with The Biomedical Advanced Research and Development Authority, the division of HHS responsible for strategic preparedness and response. Our discussion with BARDA focused on the characteristics of PLACCINE for developing the vaccines of the future.

Our presentation was very well received. There was a clear reaction that IMUNON has made real progress making plasmid vaccines more effective. They were impressed with our ability to make DNA technology a potential strong contender in further vaccine development.

While our near-term plan is to request a pre-IND meeting for a Covid booster based on the next variants of interest, we also plan to file a second IND for another pathogen. We are looking for BARDA's input on the vaccines of the future and hope to receive some non-dilutive funding from them to apply to our development programs.

I've used the term "vaccines of the future," and that is exactly what our vision is – to be the provider of safe and effective vaccines of the future that are superior to current vaccines in durability and breadth of protection, stability at workable temperatures, speed in manufacturing process that allows for quick response to changing pathogens, and have better compliance for mass immunization by not requiring a device or virus.

Now let's turn to our clinical oncology program, which utilizes GEN-1 developed from our TheraPlas modality. GEN-1 is a DNA plasmid that is administered into the abdomen of patients to induce cells to manufacture the potent natural immuno-modulating agent interleukin-12 (or "IL-12"). Our clinical studies have established that GEN-1 produces IL-12 and is favorably impacting the tumor microenvironment. These data were published in the *Journal of Cancer Clinical Research* in 2021 and are the basis of the OVATION 2 Study.

The OVATION 2 Study is designed to determine how safe and active GEN-1 is in patients with advanced ovarian cancer who will be undergoing neoadjuvant chemotherapy (or NACT). NACT is designed to shrink tumors as much as possible for optimal surgical removal. Following surgery, another three cycles are administered to address any remaining tumor. In the OVATION 2 Study GEN-1 is added to standard-of-care NACT to boost the natural immune response to the cancer. OVATION 2 is a randomized Phase II study that compares patients treated with standard NACT against patients who get standard NACT plus GEN-1. The results of this study will help us determine the course of registration for GEN-1 in ovarian cancer. As previously announced, 110 patients from more than 20 centers in the U.S. and Canada have been enrolled in this study.

It's important to note that since the OVATION 2 Study was initiated several years ago, a new class of drugs called PARP inhibitors have been approved that benefit ovarian cancer patients who have a specific gene mutation called BRCA positive or HRD. In our study, when we focus on the BRCA negative patients, who have not received a PARPi we can see that GEN-1 is providing a progression-free survival benefit. Please note this data is interim and is not statistically significant, but it serves as a basis for our interest in continuing evaluating BRCA negative population and initiating combination studies with other therapies such as Avastin or checkpoint inhibitors.

The interim data has been reviewed by our independent data and safety monitoring board and experts in the field of ovarian cancer. They agree that the safety of GEN-1 is acceptable, and that the data supports continuation of our clinical studies and exploration of combination regimens. We expect topline data from the OVATION 2 Study in mid-2024. This timing, however, depends on how quickly patients progress in their disease.

As previously announced, we are working in partnership with the Breakthrough Cancer Foundation, with MD Anderson Cancer Center and three other major centers to initiate a combination study of GEN-1 with Avastin in patients who are newly diagnosed with advanced ovarian cancer. The preclinical data supporting this combination is very exciting and is being prepared for submission at an upcoming cancer conference in 2023. We hope to enroll our first patient in the first half of 2023.

We are also preparing a Phase I/II study with GEN-1 in combination with checkpoint inhibitors. This is also the result of exciting preclinical data that should be published in the coming months. The FDA has accepted this protocol. Nevertheless, in consideration of the need to conserve capital, we might delay the start of this study.

So, as I have just described, we have a thoughtful and thorough plan for GEN-1 for the treatment of advanced ovarian cancer.

Before I turn the call over to Jeff Church for his review of our very strong financial position, I want to impress upon you that our long-term vision calls for the creation of a new category of medicines based on our plasmid DNA technology across a broad array of human diseases. We are starting in immuno-oncology and infectious diseases, and we will continue to invest to fully characterize the platform and to advance the technological frontier of plasmid DNA.

Now I will turn the call over to Jeff.

Jeffrey Church

Thank you, Corinne.

Details of IMUNON's third quarter 2022 financial results are included in the press release we issued this morning and in our Form 10-Q, which we filed today before the market opened.

IMUNON ended the third quarter of 2022 with $43.4 million in cash, investments, restricted cash, and accrued interest receivable. Along with future planned sales of the Company's State of New Jersey Net Operating Losses, we believe we have sufficient capital resources to fund our operations into early 2025 – at our current spending rate.

Over the past four years and without any dilution to our shareholders, we have raised over $16 million from NOL sales, and we have a further $3.5 million of unused NOLs available for sale over the 2022 - 2024 time period. We are in an excellent position with respect to liquidity to support operations through several important value-creating milestones.

Let me now turn to our third quarter and year-to-date financial results…

For the quarter ended September 30, 2022, IMUNON reported a net loss of $6.1 million, or $0.87 per share, and this compares with a net loss of $5.4 million, or $0.94 per share, for the third quarter of 2021.

Operating expenses were $6.3 million for the third quarter of 2022, which is up $1.1 million, or 21%, from the third quarter last year. Breaking this down by line item:

Research and development expenses were $2.4 million, down slightly from $2.5 million a year ago.

- R&D costs associated with the development of the PLACCINE DNA vaccine platform as well the GEN-1 OVATION 2 Study increased to $1.5 million for the quarter, up slightly from $1.3 million a year ago.

- Costs associated with the OPTIMA Phase III study were $0.1 million in the current quarter, which represented expenses associated with closing out this discontinued study.
- Other clinical, CMC and regulatory costs were $0.8 million in the third quarter, compared with $1.0 million for the comparable period of 2021.

General and administrative expenses were $3.9 million for the third quarter of 2022, compared with $2.7 million in the third quarter of 2021. This $1.2 million increase is primarily attributable to higher legal costs to defend various lawsuits filed after the announcement of OPTIMA Phase III study results in 2020 and higher compensation expenses resulting from the CEO succession plan announced in July 2022. Offsetting these higher G&A expenses are lower non-cash stock compensation expenses.

We had non-operating income of $26 thousand for the third quarter of 2022, versus non-operating expense of $300 thousand a year ago, with the improvement largely attributable to lower interest expense under our loan facility with Silicon Valley Bank and higher income from invested capital in the current quarter.

On a year-to-date basis, net cash used for operating activities was $18.1 million, and this compares with $11.4 million for the same period in 2021. The increase was primarily due to the one-time payment of $4.5 million in interest expense related to the sale and subsequent redemption of $30 million of Series A & B convertible redeemable preferred stock in the first quarter of 2022, and another $100 thousand in costs related to the Special Meeting of Shareholders held in February 2022. This Special Meeting of Shareholders was necessary to ensure that the Company had an adequate number of authorized shares to continue funding our R&D initiatives.

Excluding these one-time expenditures, cash used in operations was $13.5 million for the first nine months of 2022, which is in line with our projections. Cash provided by financing activities was $6.3 million during the first nine months of 2022, which resulted from a registered direct stock offering in April 2022 that was priced at the market with no warrants. We also received net proceeds of $1.4 million from the sale of NOLs in February 2022. Our projected cash utilization for the balance of 2022 is approximately $5 million for the fourth quarter of 2022.

I will now turn the call back over to Corinne.

Corinne Le Goff

In closing, I want to mention that since I joined IMUNON back in the summer, I have been so highly impressed by the commitment of our talented scientists, clinicians and staff to bring a new class of medicines to patients and the medical community. In doing so, we will also create great value for our shareholders.

Thank you all for your time this morning. I trust we conveyed our excitement about the potential for our platform technologies. We look forward to keeping you informed of our progress. Please note that we will be participating in Alliance Global Partners' virtual conference on November 30th and December 1st. Please contact AGP if you would like a one-on-one meeting. And we hope to see some of you in San Francisco as we prepare to hold one-on-one meetings concurrent with the JP Morgan Healthcare Conference during the second week of January. Please contact our IR firm LHA to schedule a meeting.

We will speak with you again when we report our 2022 fourth quarter financial results in March. Have a nice afternoon.

# # #


IMUNON
Corporate Presentation
November 2022
Nasdaq: IMNN
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Safe Harbor Statement

This presentation and any statements made during any presentation or meeting contain forward-looking statements related to Imunon, Inc. ("Imunon") under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These statements may be identified by the use of forward-looking words such as "anticipate," "planned," "believe," "forecast," "expected," and "intend," among others. There are many factors that could cause actual events to differ materially from those indicated by such forward-looking statements. Such factors include, among other things, unforeseen changes in the course of research and development activities and in clinical trials; possible changes in cost, timing and progress of development, preclinical studies, regulatory submissions; Imunon's ability to obtain and maintain regulatory approval of any of its product candidates; possible changes in capital structure, future working capital needs and other financial items; changes in approaches to medical treatment; introduction of new products by others; success or failure of our current or future collaboration arrangements, possible acquisitions of other technologies, assets, or businesses; the ability to obtain additional funds for operations; the ability to obtain and maintain intellectual property protection for technologies and product candidates and the ability to operate the business without infringing the intellectual property rights of others; the reliance on third parties to conduct preclinical studies or clinical trials; the rate and degree of market acceptance of any approved product candidates; possible actions by customers, suppliers, potential strategic partners, competitors, and regulatory authorities; compliance with listing standards of The Nasdaq Capital Market; and those risks listed under "Risk Factors" as set forth in Imunon's most recent periodic reports filed with the Securities and Exchange Commission, including Imunon's Form 10-K for the year ended December 31, 2021.

While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and Imunon does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.

Developing new medicines that harness the building blocks of life to work in harmony with the body's immune system

- Leveraging **innovative plasmid DNA platform** with proprietary synthetic delivery systems and multiple potential indications
- Initial clinical focus is on **immuno-oncology** and **infectious diseases**
- Development of the PLACCINE modality in prophylactic vaccines, with **strong evidence of immunogenicity and durability of protection in a SARS-CoV-2 proof-of-concept model**
- Phase II trial underway with GEN-1 (**IL-12 immunotherapy) for the localized treatment of advanced ovarian cancer**; Fast Track and Orphan designations received; plans for combination studies to address a multibillion-dollar market
- Focus on **continued platform innovation** and discovery
- **Strong balance sheet** supports strategy into 2025 and robust news flow of value-creating activities in pursuit of building a **fully integrated** biotech company

Experienced Management Team

Corinne Le Goff, PharmD
MBA President, CEO and Director

Nicholas Borys, MD
Executive Vice President and Chief Medical Officer

Khursheed Anwer, PhD
MBA Executive Vice President and Chief Scientific Officer

Jeffrey W. Church
Executive Vice President, CFO & Corporate Secretary

Anthony Recupero, PhD
Vice President Business Development

IMUNON Next Generation DNA Plasmid Technology Platform

Proprietary Synthetic Delivery System (No Virus, No Device)

Vaccine Modality: PLACCINE

- DNA Plasmid vectors engineered for next generation vaccine technology
- Designed for multiple antigens/epitopes with co-expression of immunomodulators

Self-assembling Synthetic Nanocarriers

SARS-CoV-2

Multivalent Vaccine for COVID-19

Preclinical Development Stage

Gene Therapy Modality: TheraPlas

- Delivers DNA Plasmids Coding for Therapeutic Proteins
- Multiple development programs on-going

Synthetic Polymeric Nanoparticle Cholesterol conjugated

GEN-1 Immunotherapy

Localized Interleukin-12 Immunotherapy

Phase II Evaluation in Advanced Ovarian Caner
Orphan Drug Designation: U.S. and EU
Fast Track Designation

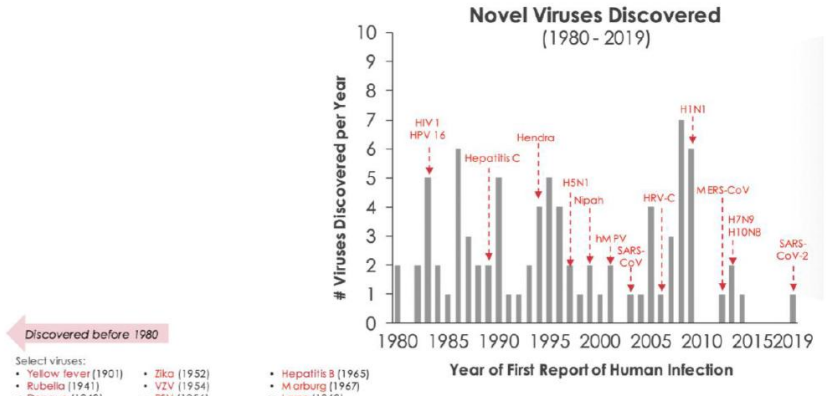
IMUNON's Pipeline of DNA-based Transformative Medicines

Platform	Program	Indication(s)	Discovery	IND enabling	Phase 1	Phase 2
TheraPlas	**IL-12 (OVATION)** Intraperitoneal (IP)	Advanced Ovarian, Fallopian Tube or Primary Peritoneal Cancer	GEN-1			
	IL-12 IP in combination with **bevacizumab**	Advanced Ovarian, Fallopian Tube or Primary Peritoneal Cancer	GEN-1			
PLACCINE	**Multicistronic SARS-Cov2.** Proof-of-Concept	COVID-19 Booster	PL-COV			
	Prophylactic Vaccine	Infectious Disease target	PL-X			
	Therapeutic Vaccine	Cancer target	PL-Z			

PLACCINE SARS-CoV-2 PROOF OF CONCEPT PROPHYLACTIC VACCINES PROGRAM

More than 80 Pathogenic Viruses Discovered since 1980

Less than 4% have a vaccine commercially available



Discovered before 1980

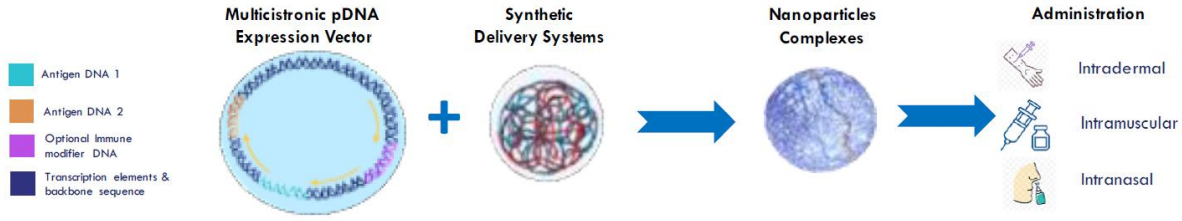
Select viruses:

- Yellow fever (1901)
- Rubella (1941)
- Dengue (1943)
- PIV3 (1950s)
- Chikungunya (1952)
- Zika (1952)
- VZV (1954)
- RSV (1956)
- CMV (1956-1957)
- EBV (1964)
- Hepatitis B (1965)
- Marburg (1967)
- Lassa (1969)
- Ebola (1976)

Sources: Institute of Medicine (US) Forum on Microbial Threats (2009); Medscape Medical News (2008); Lederberg, J. *Emerging Infectious Diseases from the Global to the Local Perspective: A Summary of a Workshop of the Forum on Emerging Infections* (2001); National Institute of Health (US) Biological Sciences Curriculum Study (2007); Holshue, M. *et al NEJM* (2020); Bush, L. *Emerging...and Re-emerging Infectious Diseases* (2015); Gibbs, A.J. *Virology* (2009); CDC Zika Overview; CDC Ebola About; Plotkin, S.A. *Clinical Infectious Diseases* (2006); Woolhouse, M. *et al. Phil Trans R Soc* (2012); WHO H7N9 China Update (2018); Tapparel, C. *et al. Virology* (2013); Hepatitis B Foundation. History Page; Ho, M. *Med Microbiol Immunol.* (2008); Nature. Dengue Viruses Page; Brauberger, K. *et al. Viruses* (2012); FDA approved vaccine list; CDC RSV Overview; Hendrickson, K.J. *Clinical Microbiology Reviews* (2003); Andersson, J. Herpes (2000); WHO Chikungunya Overview; CDC Varicella Overview; Xu, Y. *et al. Infect Genet Evol.* (2015); CDC Lassa Fever Overview

PLACCINE Platform: Powering the Next Generation of Vaccines

By addressing the shortcomings of current nucleic acid, viral vector and protein subunit vaccines

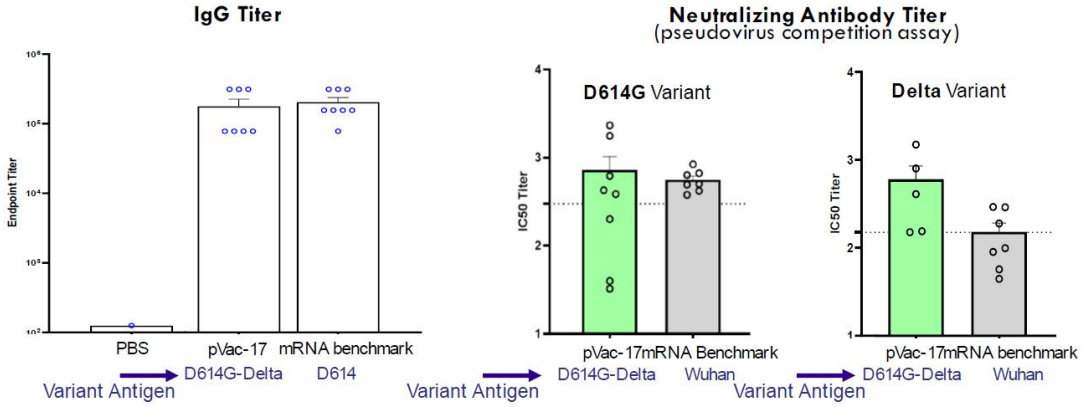


❑ **Durability of Protection**	Durable antigen expression induces robust immunological response
❑ **Breadth of Protection**	Multicistronic vectors increase the breadth of immune response and allows for combination vaccines
❑ **Transmission Advantage**	Strong T-cell activity. Option for co-expression of potent immune modifiers increases the immune response and lowers the risk of viral shedding
❑ **Safe and Convenient**	Synthetic delivery systems present no risk of genotoxicity - no virus, or cytotoxicity - no device. Convenient handling for pandemic control.
❑ **Flexible Manufacturing**	Truly versatile platform enables rapid response to changing pathogens. Stability and long shelf-life at normal refrigerator temperatures simplifies handling and distribution.

Bivalent PLACCINE Vaccine Produces Stronger Neutralizing Immune Response than mRNA Benchmark

Multicistronic vector: **pVac-17**

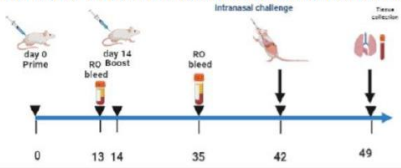
- Spike antigen: **D614G, Delta**
- Formulation: **PLACCINE**
- 125 µg DNA
- IgG & nAB titer (day 35)



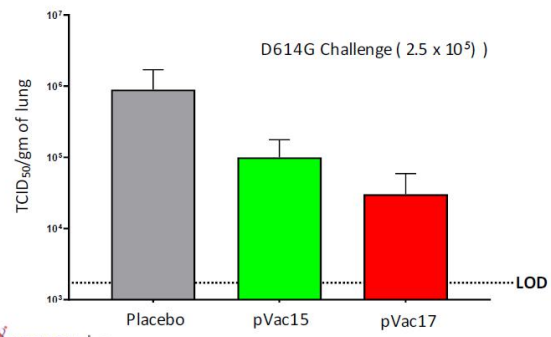
Over 90% Protection From Live Viral Challenge

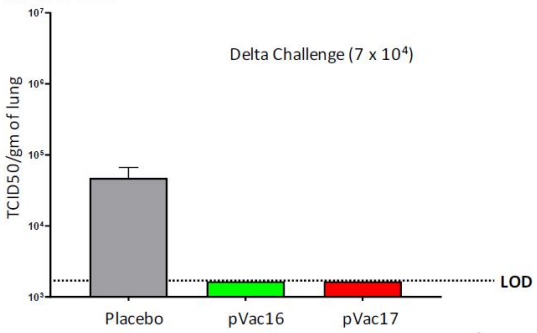
Activity of PLACCINE-SARS-CoV-2 Vaccines in hACE2:K18 SARS-CoV-2 Model

- pVac-15- D614G
- pVac-16- Delta
- pVac-17- D614G - Delta
- Formulation: PLACCINE
- Dose- 125 µg DNA



TCID50 Tissue Culture Infection Dose

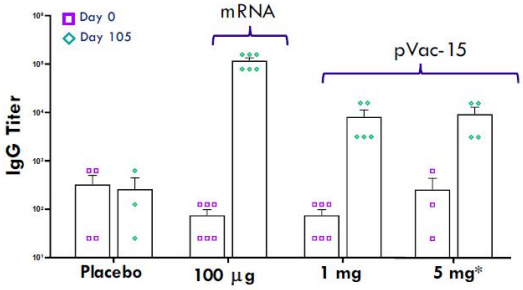


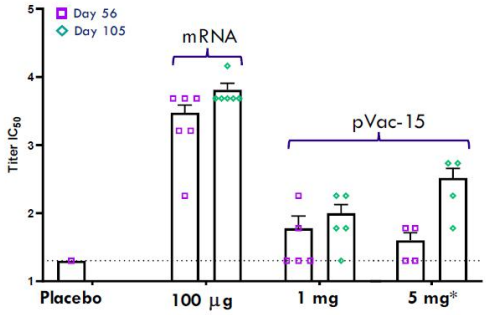


Monovalent PLACCINE Vaccine is Immunogenic in Cynomolgus Monkeys

PLACCINE Subjects Showed IgG and neutralizing Antibody Response

- Single antigen vector — **pVac-15 (D614G)** in PLACCINE
- Comparator mRNA — **Commercial mRNA Vaccine** (LNP)
- Dosing schedule — Day 1, 28, 84
- IgG titer — Day 105 (21 days after 3rd dose)

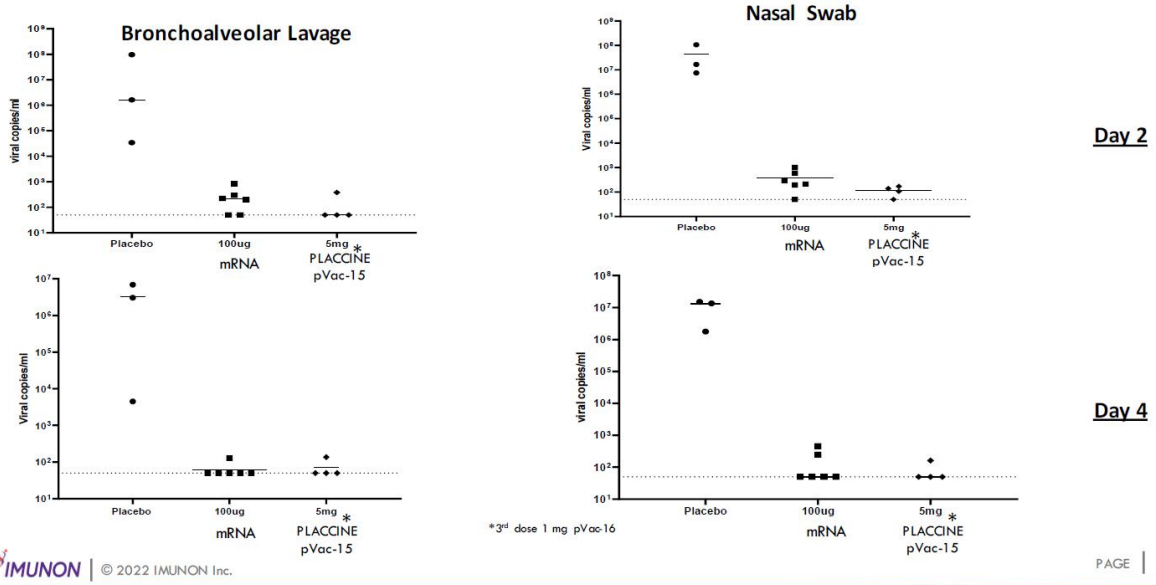




*3rd dose for this group was changed to pVac-16 at 2 mg dose

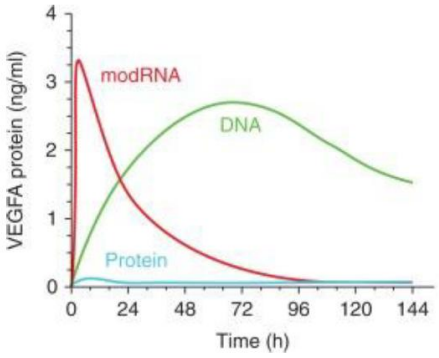
Viral Clearance by PLACCINE is Comparable to mRNA Vaccine

Clearance efficiency comparable to mRNA vaccine by PCR assay : >99% clearance

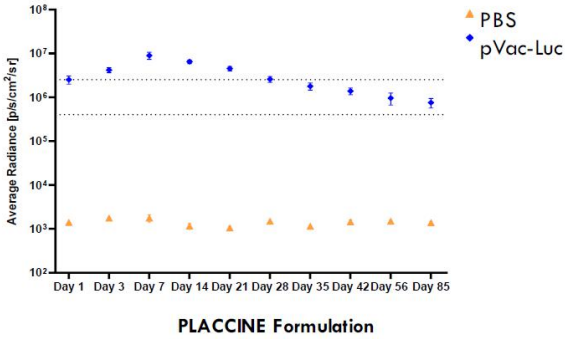


*3rd dose 1 mg pVac-16

pDNA Yields More Durable Antigen Expression than the Protein or modified mRNA



Chien KR Cold Spring Harb Perspect Med 2015;5:a014035

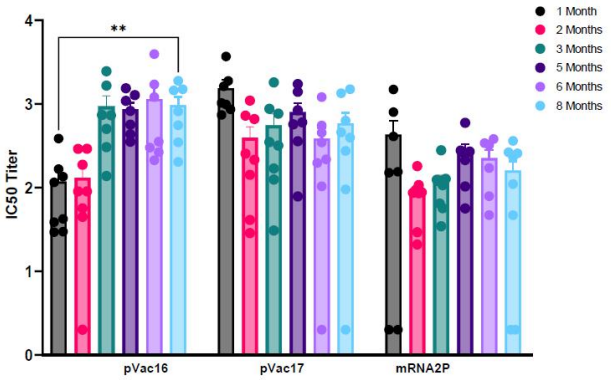


Durable Neutralizing Antibody Response to PLACCINE-SARS-CoV-2 Vaccines

Evidence of Durability For 8 Months (Ongoing Study)

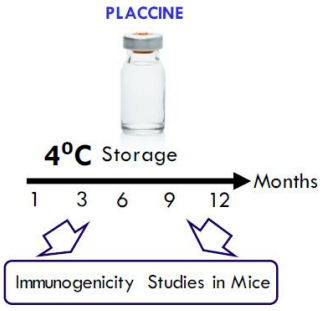
- Vectors: **pVac-16** (Delta), **pVac-17** (D614G -Delta)
- 125 µg DNA
- IgG titer (2, 3, 5 months)

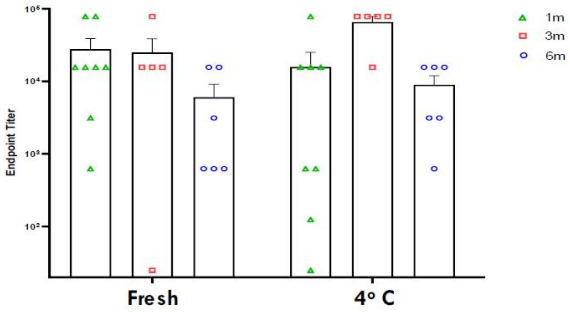
nAB Assessment by a Delta Pseudo Lentivirus Assay



PLACCINE is Stable at 4°C for Six Months or Longer

Vector: pVac-17 (D614G-Delta)
Formulation: PLACCINE

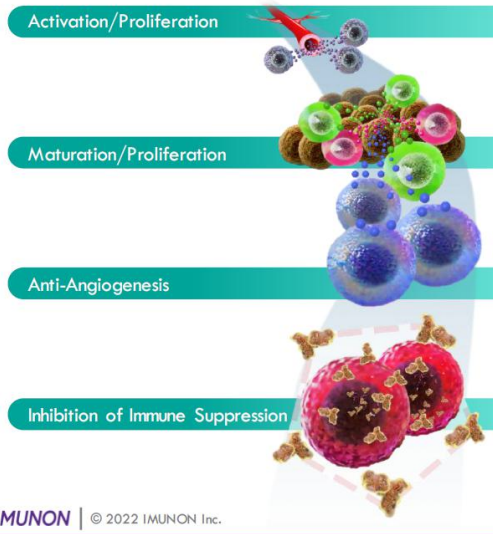




GEN-1 IL-12
IMMUNO-ONCOLOGY PROGRAM

IL-12: A Powerful Immune-Modulating Agent

Interleukin-12 Can Induce Anti-cancer Immunity Through Multiple Mechanisms



Activation/Proliferation

Stimulates the proliferation of CD-8 positive T-cells and natural killer (NK) cells and their cytotoxic activity against the tumor

Maturation/Proliferation

Shifts the differentiation of naive CD-4 positive T-cells toward a TH-1 phenotype, further enhancing the immune response – Turns "cold" tumors into "hot" tumors

Anti-Angiogenesis

Promotes cellular production of the potent immune mediator IFN-γ and TNF-α. IFN-γ promotes the expression of anti-angiogenic molecules, halting the growth of new blood vessels that supply oxygen to the tumor

Inhibition of Immune Suppression

IL-12 inhibits regulatory T-cells that suppress immune responses by "hiding" the tumor from the body's immune system

First Target: Ovarian Cancer

Epithelial ovarian cancer (EOC) is insidious and usually diagnosed late at an advanced stage. Though EOC initially responds to treatment, the recurrence rate is high. Recent treatments delay progression but overall survival has not improved. Hence there is a need for effective therapy for patients with EOC.

20,000 cases diagnosed each year in U.S.
13,000 deaths

Standard of care has remained **stagnant for decades**

80% diagnosed in late stage (III/IV)

50% will die within 5 years of diagnosis

225,000 cases per year Globally
> 100,000 Patients in the U.S. alone

5th leading cause of cancer mortality in women

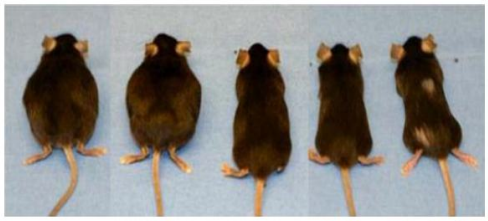
GEN-1 has the potential to revolutionize today's standard of care

Sources: Cancer Statistics, American Cancer Society; Globocan; SEER database. CDC

Survival Benefit of GEN-1 in an ID-8 Mouse Ovarian Cancer Model

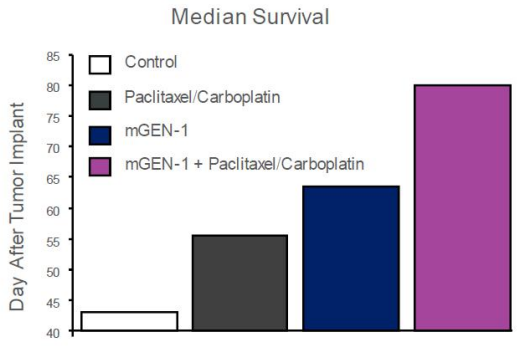
Dose dependent effects of intraperitoneal mGEN-1:

- Reduction in tumor ascites
- Reduction in tumor weight
- Improvement in survival



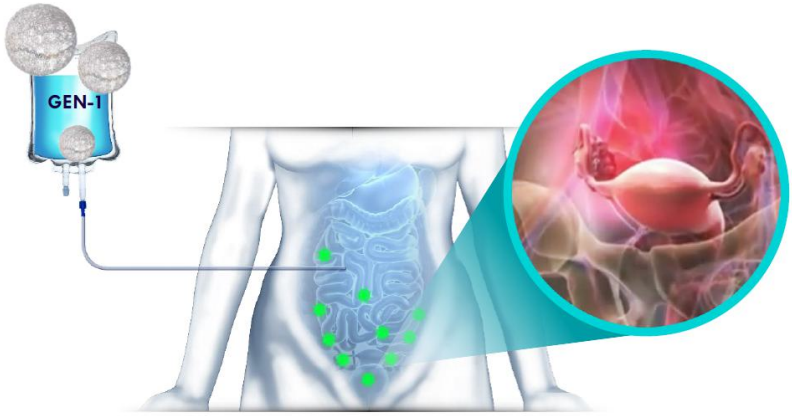
0 10 50 250 No implant

mGEN-1 Dose (µg/treatment)



GEN-1 Targets the Micro-Environment of Ovarian Cancer

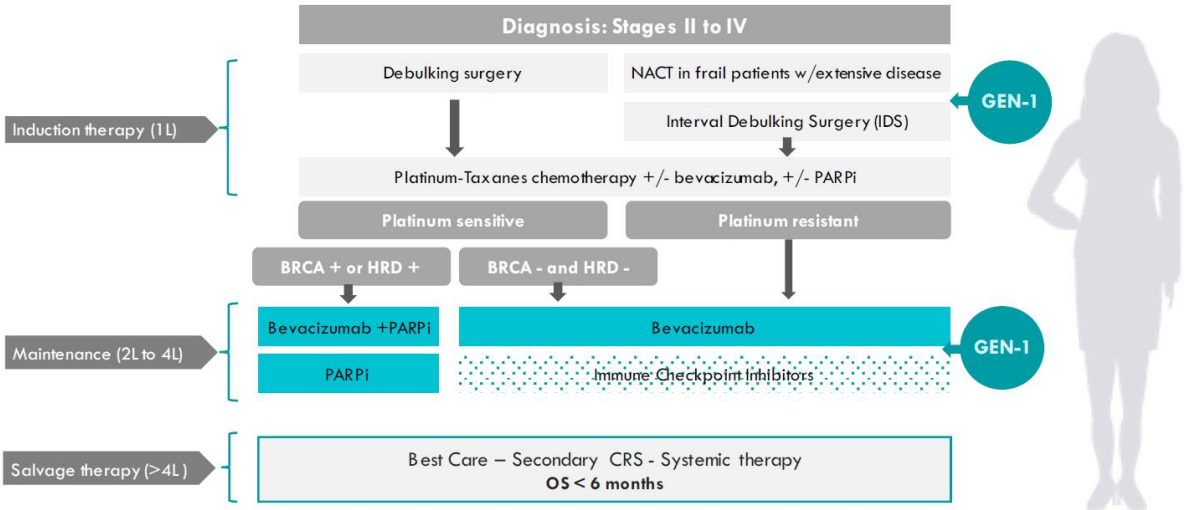
Local production of safe and durable levels of a powerful anti-cancer immune agent, IL-12



Local Expression of IL-12 Favors
Immune Modulation in Tumor Microenvironment

- Intracavity infusion of GEN-1 has demonstrated durable and local expression of IL-12 in the peritoneum
- No supraphysiological increases in IL-12 commonly associated with the bolus rIL-12 minimizes excessive systemic exposure of IL-12, thereby giving a favorable safety profile to GEN-1

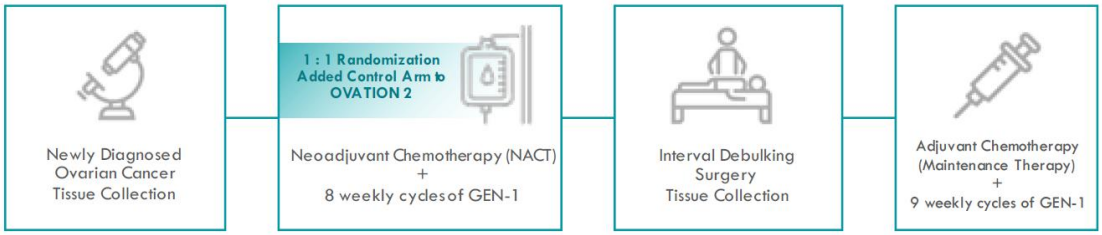
As an Immuno-oncology Agent, GEN-1 has the potential to play a key role in new combination strategies



Sources: NCCN Clinical Practice guidelines – Ovarian Cancer, Version 2.2020. JNCCN.org, Vol.19 Issue 2, Feb. 2021
Annals of Oncology doi:10.1093/mdz104

GEN-1 OVATION 2 Ovarian Cancer Study

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



Ovarian Cancer Patients (FIGO IIIC & IV)

- 110 patients. **Enrollment completed**
- 50% of expected primary endpoint data collected
- ITT population contains mix group of BRCA +/- subjects (BRCA + have much longer time to PFS due to PARPi)

Primary Endpoint

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

Secondary Endpoints

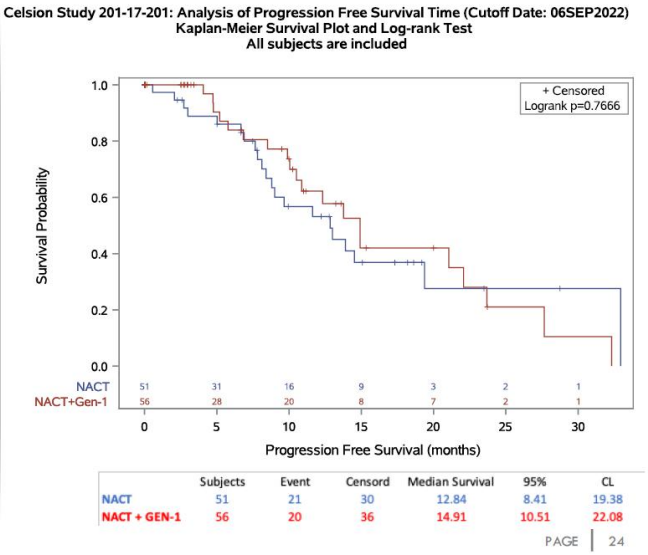
- Clinical Response (ORR), Pathological Response, Surgical Resection Scores (R0, R1, R2), Biological Response, Safety

Interim OVATION 2 Data suggest that GEN-1 is Safe and Active

ITT population: PFS benefit likely confounded by PARPi positive impact (50% of events)

ITT population	NACT ONLY	NACT + GEN-1
Interval Debulking Surgery (n=70) R0 Resection Rate	56%	68%
Median Time to Progression (mos.) 50% of events	12.8	15.0
Chemotherapy Response Score of CRS3	17%	31%

- HR 0.91 (95% CL, 0.49-1.70) *P*=0.767



	Subjects	Event	Censord	Median Survival	95%	CL
NACT	51	21	30	12.84	8.41	19.38
NACT + GEN-1	56	20	36	14.91	10.51	22.08

Interim OVATION 2 Data Indicates Subjects on GEN-1 who are BRCA-/HRP May Have Improved PFS

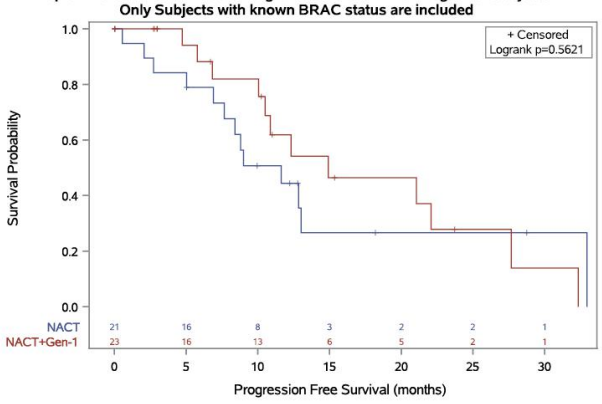
Sub-population of patients with the greatest medical need

Targeted Therapy Approach

HRP (homologous recombination proficient with no BRCA 1/2 mutations)

- Early data suggests 3-month improvement in this identified subgroup of interest
- About **45% of ovarian cancer patients** are not getting a clinical benefit from PARP inhibitors
- HR 0.79 (95% CI, 0.35-1.77) *P*=0.563

Celsion Study 201-17-201: Analysis of Progression Free Survival Time (Cutoff Date: 06SEP2022)
Kaplan-Meier Survival Plot and Log-rank Test for BRAC "Negative" Subjects
Only Subjects with known BRAC status are included

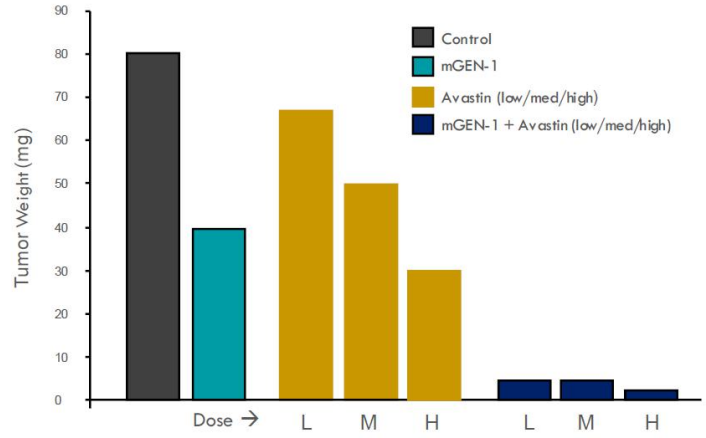


	Subjects	Event	Censored	Median Survival	95%	CL
NACT	21	13	8	11.63	6.899	
NACT + GEN-1	23	12	11	14.91	10.05	27.66

HR 0.79 (95% CI, 0.35-1.77) *P*=0.56

Synergistic Antiangiogenic Effect of GEN-1 with Avastin in Ovarian Cancer

SKOV-3 Ovarian Cancer in Nude Mice

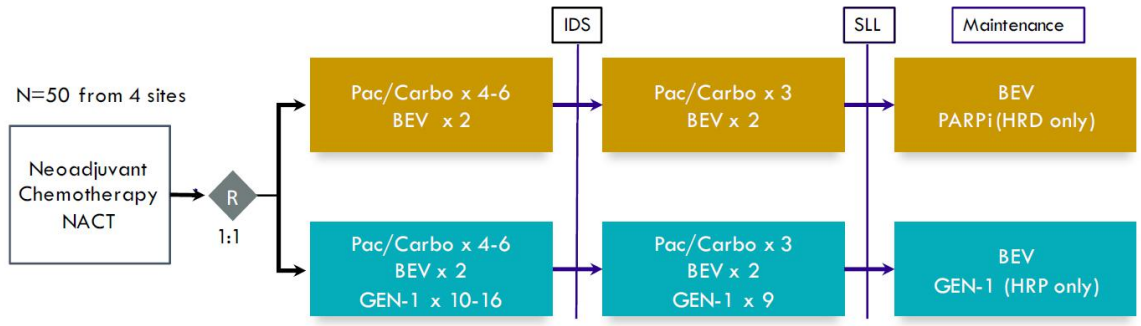


Key Rationale for Combination of GEN-1 with Avastin®

- Synergistic efficacy potential of VEGF level reduction by Avastin and VEGF production inhibition by GEN-1
- Efficacy improvement of low dose Avastin by GEN-1 combination improves its therapeutic index and cost

New Phase 2 Study in Combination with bevacizumab

Avastin (BEV) + GEN-1 Study Design in Advanced Epithelial Ovarian Cancer. Accepted by the FDA.



Primary Endpoint = Second Look Laparotomy (SLL)

Secondary = Progression-Free Survival (PFS)

Interval Debulking Surgery (IDS)

Summary of Development Programs

GEN-1 offers a novel way to harness the powerful immunological properties of IL-12: the "Master Switch" to the body's immune system.

- Five completed ovarian cancer trials demonstrate **biologic and clinical activity**
- Safety and activity signals in Phase I; Mechanism of action confirmed
- **OVATION 2 offers new hope for ovarian cancer patients.** Interim data are promising, with potential of a targeted therapy approach in BRCA negative sub-group
- One new phase 2 trial will explore **combination strategy with VEGF inhibitors**

PLACCINE SARS-CoV-2 Proof Concept has demonstrated that our multicistronic formulated plasmid DNA platform can produce a robust immune response.

- **Evidence of IgG, neutralizing antibody and T-cell responses and protection against live virus challenge**
- Activity demonstrated with both single & bicistronic vectors
- **Immune quality is comparable to commercial mRNA vaccine benchmark**
- Evidence of **8-month durability** (ongoing study)
- Evidence of **6-month stability at 4°C** (ongoing study)
- Non-Human Primate study in progress

Milestones & Financials

Upcoming Key Milestones: Robust Flow of Value Creating Activities

2H 2022	1H 2023	2H 2023	1H 2024
GEN-1 OVATION 2 ORR & Surgical Data	Initiation of GEN-1 P2 Combo trial with bevacizumab	GEN-1 OVATION 2 Interim Data	GEN-1 OVATION 2 Topline Results
NHP SARS-Cov2 Data	PLACCINE SARS-Cov2 Booster IND	PL-X Pre-clinical Challenge Data	Interim results GEN-1 P2 Combo trial with bevacizumab
PLACCINE Next Pathogen Target		PL-Z POC Data	PL-X IND filing

Strong Balance Sheet Supports Upcoming Milestones

Cash Runway into 2025

Cash + Investments @ 9/30/2022	$43.4 million
Projected NOL sales – 2022-2024	+ $3.5 million
Total	**$46.9 million**
Estimated cash usage/quarter (2022)	**~$5 million**
Cash Runway at current spending	**Into 2025**

Common shares outstanding @ 9/30/2022	7.1 million
+ Stock Options	0.9 million
+ Warrants	0.2 million
Fully diluted shares outstanding	**8.2 million**
Market Capitalization	**$12 million**
Avg Daily Trading Volume	**~ 50,000**

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