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

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of **March, 2023**

Commission File Number: **001-38480**

IMV Inc.

(Name of registrant)

**130 Eileen Stubbs Avenue, Suite 19
Dartmouth, Nova Scotia
B3B 2C4, Canada**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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, thereunto duly authorized.

IMV Inc.

Date: March 16, 2023

By: /s/ Brittany Davison
Name: Brittany Davison
Title: Chief Accounting Officer

Form 6-K Exhibit Index

**Exhibit
Number**

Document Description

[99.1](#)

[IMV Inc. Announces Strategic Update as well as Fourth Quarter and Full Year 2022 Financial and Operational Results](#)



Media Release

IMV Inc. Announces Strategic Update as well as Fourth Quarter and Full Year 2022 Financial and Operational Results

Advanced lead candidate, MVP-S, in two global Phase 2B clinical trials and enhanced the scientific differentiation of the DPX platform

Observed multiple complete clinical responses in relapsed/refractory DLBCL and expect to complete enrollment of stage one in the VITALIZE study in Q2 2023

Accelerated enrollment of stage one in the AVALON study in ovarian cancer expected in Q3 2023

Strengthened financial position with \$9M financing

Retained Stonegate Healthcare Partners, L.L.C. for the exploration of strategic alternatives

Dartmouth, Nova Scotia and Cambridge, Mass. – March 16, 2023-- IMV Inc. (Nasdaq: IMV; TSX: IMV) (“IMV” or “the Company”), a clinical-stage company developing a portfolio of immune-educating therapies based on its novel DPX platform to treat solid and hematologic cancers, today announced alongside the release of its fourth quarter and annual results that it has engaged Stonegate Healthcare Partners, L.L.C (“Stonegate”) to explore strategic alternatives following a review of its business.

“The early Phase 2B clinical data for MVP-S is compelling. To see multiple, confirmed complete responses in such a heavily pre-treated lymphoma population as we have seen in the first group of VITALIZE patients with available scans is very encouraging. Patients need improved treatments for cancer, particularly in the refractory setting,” said Andrew Hall, Chief Executive Officer at IMV. “The market headwinds limiting available capital are, however, very real. Mindful of our environment, we have engaged Stonegate, a long-time partner to IMV, to explore strategic alternatives, so that MVP-S can realize its full clinical potential.”

Recent Clinical Highlights

VITALIZE Phase 2B Study in Relapsed/Refractory DLBCL ("r/r DLBCL")

The VITALIZE study is designed to further evaluate the favorable clinical outcomes observed in the now completed SPiReL Phase 2a study of MVP-S in combination with Merck's anti-PD-1 therapy, KEYTRUDA[®] (pembrolizumab), in patients with r/r DLBCL. In the entire SPiReL study, three complete responses and four partial responses were observed, with 6 of these 7 responses observed in patients with PDL1 biomarker positivity.

In February 2023, IMV announced that in the initial patients on the VITALIZE study, three complete responses have been observed and have been confirmed by at least two scans, one at 70 and one at 140 days. This is in a patient population that is more heavily pre-treated than in the SPiReL trial by at least one line and whose baseline disease is progressing at an extraordinarily rapid rate. Notably, the combination continues to be well tolerated with no serious adverse safety events reported.

Alongside this announcement, Dr. Jeremy Graff, IMV Chief Scientific Officer, presented at the IO360 meeting in NYC, an overview of the DPX platform and the experience of MVP-S in clinical trials. A copy of the presentation is available on the Company's website.

Clinical sites are actively recruiting in North America, Europe, Asia and Australia. Currently 23 out of 30 patients have been enrolled in VITALIZE and the Company expects to complete enrollment in Q2 2023.

AVALON Phase 2B Trial in Platinum-Resistant Ovarian Cancer.

In the third quarter of 2022, IMV initiated the AVALON trial, a phase 2B, single arm trial evaluating MVP-S and intermittent low-dose cyclophosphamide in subjects with platinum-resistant ovarian cancer.

The AVALON trial is a two-stage trial, where the second stage is expressly designed to be registrational. Based on response rates in the 41 patients of stage one in this trial, the Company expects to enroll a total of 110 patients across stage 1 and 2 to have sufficient data to seek accelerated approval from the FDA. Currently 11 out of the 41 patients have been enrolled and acceleration of enrollment continues as additional sites are being opened across Europe and Australia. Enrollment in stage 1 is expected to be completed in Q3 2023.

Expected Upcoming Clinical Milestones

- Q2 2023: Stage 1 enrollment complete for the Phase 2B VITALIZE r/r DLBCL trial (30 patients)
- Q3 2023: Stage 1 enrollment complete for the Phase 2B AVALON platinum-resistant ovarian cancer trial (approximately 40 patients)
- Q3 2023: Preliminary Phase 1 data from the MVP-S and DPX-SurMAGE in non-muscle invasive bladder cancer (NMIBC)

2022 Scientific Highlights

In 2022 the Company further validated that the DPX technology mirrors the way the human immune system coordinates an immune response to cancer by trafficking therapeutic targets directly to the lymph nodes via distinct immune cells. These new data were presented at the AACR and SITC annual meetings.

AACR 2022 Annual Meeting Poster Presentation: NK Cells are Involved in Promoting Anti-tumor Responses to DPX-based Immunotherapy

Consistent with the understood mechanism of action, MVP-S consistently incites a robust and persistent, survivin-specific immune response and promotes T and B cell infiltration into tumor tissues. At the 2022 AACR annual meeting, new data were presented providing the first evidence from preclinical and clinical studies that Natural Killer (NK) cells are also involved in the anti-cancer efficacy of DPX-based therapy.

SITC 2022 Annual Meeting Poster Presentation: DPX-based Immune Education Recruits and Activates Unique Subsets of Antigen Presenting Cells to Drive Immunogenicity of Peptide Antigens

The unique nature of the lipid-in-oil DPX formulation keeps immune educating cargo at the site of injection, ensuring that uptake of the DPX encapsulated cargo is an active process driven by antigen presenting cells (“APCs”) across time. At the 2022 SITC annual meeting, new data was presented highlighting the subset of APCs DPX engages, these APCs are more mature and functional, further validating the uniqueness and differentiation of DPX versus other platform delivery methods.

2022 Operational Highlights

Completion of \$9M public offering: In December 2022, the Company raised gross proceeds of \$9M which IMV intends to use primarily to fund further clinical development of our lead candidate MVP-S.

Achieved milestone to access remaining \$10M under existing debt facility: In June 2022, a \$10M drawdown from our long-term debt facility with Horizon Technology Finance Corporation was made available following the initiation of our Phase 2B AVALON trial in platinum-resistant ovarian cancer.

Restructuring: In September 2022, IMV completed a strategic reorganization to reduce future cash needs and further streamline the organizational focus. The workforce was reduced by approximately one third and the organization is now expressly focused on MVP-S development in Ovarian and DLBCL and further validation of the DPX platform.

New Management Team: At the start of 2022 IMV named Andrew Hall the Corporation’s CEO. In September, Brittany Davison was promoted to Chief Accounting Officer and acting Chief Financial Officer from her previous role as SVP, Finance.

Enhancements to the Board of Directors: Michael Bailey was appointed new Board Chair and appointments of Ms. Shabnam Kazmi and Dr. Saman Maleki as Board Members: Mr. Bailey is Chief Executive Officer of AVEO Oncology, an LG Chem company. He recently led the strategic acquisition of AVEO by LG Chem. He has more than 30 years of pharmaceutical industry experience, having been instrumental in the successful commercial planning and launch of several new medicines across multiple oncology indications. Ms. Kazmi is an experienced CEO and Founder and brings to IMV over 30 years of experience in global biopharma companies such as Bristol-Myers Squibb, Sanofi and Otsuka America Pharmaceuticals. She has deep expertise in oncology, having launched and managed multiple products across both solid tumors and hematology. She currently serves as the CEO of Asellus Ventures, a healthcare advisory and investment firm. Dr. Maleki is an experienced tumor immunologist that brings many years of experience working on various cancers. He is currently an Assistant Professor at Western University and has extensive experience in clinical and pre-clinical operations in oncology.

Share Consolidation: In December, IMV completed a 10 for 1 reverse stock split, supported by an 88% shareholder approval.

Overview of Full Year 2022 Financial Results

As of December 31, 2022, the Company had cash and cash equivalents of \$21.2 million and working capital of \$18.2 million, compared to \$38.6 million and \$37.1 million, respectively on December 31, 2021.

The net loss and comprehensive loss of \$38.0 million (\$4.55 per share) for the year ended December 31, 2022, was \$1.4 million higher than the net loss and comprehensive loss of \$36.6 (\$4.93 per share) for the year ended December 31, 2021.

Research and development expenses were \$23.3 million for the year ended December 31, 2022, compared with \$23.1 million for the year ended December 31, 2021. Research expenses were comparable to the previous year despite increased costs for the Company's Phase 2B trials in r/r DLBCL and ovarian cancer, as a result of the offsetting decrease in manufacturing and development costs for MVP-S and for the phase 2 basket trial, which completed enrollment in 2021.

General and administrative expenses were \$17.0 million for the year ended December 31, 2022, compared with \$16.0 million for the year ended December 31, 2021. This increase was largely attributable to loan interest payments related to our venture debt facility with Horizon, offset by a decrease in salaries, insurance premiums and professional fees.

On March 15, 2022, the number of issued and outstanding Common Shares was 11,711,637 and a total of 5,447,256 shares are reserved for the issuance of common shares upon exercise or redemption of outstanding stock options, warrants and deferred share units.

The Company's audited annual consolidated results of operations, financial condition and cash flows for the year ended December 31, 2022, and the related management's discussion and analysis (MD&A) are available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov as well as on the Company's website at www.imv-inc.com.

Conference Call and Webcast Information

Management will hold a conference call and webcast on Thursday, March 16, 2023, at 8:00 a.m. EST to discuss the Company's 2022 fourth quarter and fiscal year-end financial and operational results.

Financial analysts are invited to join the conference call by registering at this [link](#) prior to the call to receive individual dial-in information.

Other interested parties will be able to access the live audio webcast at this link: <https://ir.imv-inc.com/events-and-presentations>. The webcast will be recorded and will then be available on the IMV website for 30 days following the call.

About IMV

IMV Inc. is a clinical-stage biopharmaceutical company developing a novel class of cancer vaccines based on DPX[®], our immune-educating technology platform. DPX is designed to inform a specific, coordinated and persistent anti-tumor immune response, improving the lives of patients with solid or hematological cancers. DPX can package a wide range of bioactive molecules in a single formulation to incite the tumor-killing function of multiple, distinct immune cell subtypes. IMV's lead therapeutic candidate, maveropepimut-S (MVP-S), is a DPX-based cancer vaccine that delivers antigenic peptides from survivin, a well-recognized cancer antigen commonly overexpressed in advanced cancers. MVP-S also delivers an innate immune activator and a universal CD4 T cell helper peptide. Together, these elements are designed to foster maturation of antigen presenting cells as well as robust activation of CD8 T cell effector and memory function that drive a targeted, sustained immune response. In our clinical trials, MVP-S treatment has been well tolerated and has demonstrated favorable clinical outcomes in multiple cancer indications as well as the activation of a targeted and sustained, survivin-specific anti-tumor immune response. MVP-S is administered in very low doses approximately once every two months, which drives a persistent immune attack on tumor cells. MVP-S is currently being evaluated in Phase 2B clinical trials for advanced r/r Diffuse Large B Cell Lymphoma (DLBCL) and platinum resistant ovarian cancer. IMV is also developing a dual-targeted cancer vaccine candidate leveraging the DPX delivery platform, DPX-SurMAGE. This cancer vaccine combines antigenic peptides for both the survivin and MAGE-A9 cancer proteins to elicit immune responses to these two distinct cancer antigens simultaneously. For more information, visit www.imv-inc.com and connect with us on [Twitter](#) and [LinkedIn](#).

IMV Forward-Looking Statements

This press release contains forward-looking information under applicable securities laws. All information that addresses activities or developments that we expect to occur in the future is forward-looking information. Forward-looking statements use such word as “will”, “may”, “potential”, “believe”, “expect”, “continue”, “anticipate” and other similar terminology. Forward-looking statements are based on the estimates and opinions of management on the date the statements are made. In this press release, such forward-looking statements include, but are not limited to, statements regarding the potential and efficacy of MVP-S, the success of its strategic review process in pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms, the anticipated upcoming milestones and clinical trial outcomes and results with respect to IMV's product candidates, the timing of enrollment in certain of IMV's studies, the potential impact of the VITALIZE and AVALON studies and the anticipated date data from such studies will be available; the Company's ability to advance its development strategy; the prospects for its lead immunotherapy and its other pipeline of immunotherapy candidates; IMV's intended use of proceeds from its December 2022 offering; and the sufficiency of the Company's current cash position to fund operations into the second half of 2023. IMV Inc. assumes no responsibility to update forward-looking statements in this press release except as required by law. These forward-looking statements involve known and unknown risks and uncertainties, and those risks and uncertainties include, but are not limited to, the Company's expected timeline associated with its cash runway and ability to continue as a going concern; the Company's priorities with MVP-S and its DPX delivery platform, the potential for its delivery platform and the anticipated timing of enrollment and results for its clinical trial programs and studies, as other risks detailed from time to time in our ongoing quarterly filings and Form 20-F. Investors are cautioned not to rely on these forward-looking statements and are encouraged to read IMV's continuous disclosure documents, including its current Form 20-F, as well as its audited annual consolidated financial statements which are available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov.

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Source: IMV Inc.

IMV INC.

Consolidated Statements of Loss and Comprehensive Loss

(In thousands of United States dollars, except for share and per share amounts)

	Years ended December 31,	
	2022	2021
	\$	\$
Revenue		
Subcontract revenue	-	-
Interest Income	329	188
Total revenue	329	188
Expenses		
Research and development	23,281	23,080
General and administrative	16,986	16,020
Government assistance	(1,775)	(3,230)
Accreted interest and valuation adjustments	(172)	907
Total operating expenses	38,320	36,777
Net loss	(37,991)	(36,589)
Currency translation adjustment	-	-
Total comprehensive loss	(37,991)	(36,589)
Basic and diluted loss per share	(4.55)	(4.93)
Weighted-average shares outstanding	8,343,455	7,419,844

IMV INC.
Consolidated Statements of Financial Position
(In thousands of United States dollars, except for share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 21,223	\$ 38,616
Accounts receivable	727	602
Prepaid expenses	4,440	6,037
Investment tax credits receivable	1,198	1,135
Total current assets	<u>27,588</u>	<u>46,390</u>
Property and equipment	3,760	3,731
Total assets	<u>\$ 31,348</u>	<u>\$ 50,121</u>
Liabilities and Equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 9,037	\$ 8,607
Current portion of long-term debt	47	73
Current portion of lease obligations	320	265
Warrant liabilities	16	318
Total current liabilities	<u>9,420</u>	<u>9,263</u>
Lease obligation	1,119	1,387
Long-term debt	<u>27,411</u>	<u>17,929</u>
Total liabilities	<u>37,950</u>	<u>28,579</u>
Equity (Deficiency)	<u>(6,602)</u>	<u>21,542</u>
Total liabilities and equity	<u>\$ 31,348</u>	<u>\$ 50,121</u>