
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, 2021**

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 17, 2021

By: /s/ Pierre Labbé
Name: Pierre Labbé
Title: Chief Financial Officer

Form 6-K Exhibit Index

**Exhibit
Number**

Document Description

[99.1](#)

[News Release dated March 17, 2021 IMV Inc. Announces Fourth Quarter and Full Year 2020 Financial and Operational Results](#)



IMV Inc. Announces Fourth Quarter and Full Year 2020 Financial and Operational Results

Phase 2B clinical trial in patients with relapsed /refractory DLBCL expected to be initiated in Q2 2021 following guidance received from the FDA

Mavropepimut-S (DPX-Survivac) in combination with Merck's Keytruda® (pembrolizumab) and low dose cyclophosphamide (CPA) shows promising preliminary results in two solid cancer indications in the basket trial

In advanced recurrent ovarian cancer, Mavropepimut-S associated with CPA demonstrates durable clinical benefit exceeding 12 months with limited adverse events

Dartmouth, Nova Scotia – March 17, 2021 – IMV Inc. (the “Company” or “IMV”) (TSX: IMV; NASDAQ: IMV), a clinical-stage biopharmaceutical company pioneering a novel class of immunotherapies, today announced its financial and operational results for the fourth quarter and year ended December 31, 2020.

“Notwithstanding the challenges everyone faced in 2020, IMV’s commitment to provide effective and well-tolerated immunotherapies to patients with hard-to-treat cancer resulted in significant progress on multiple fronts with our lead compound, Mavropepimut-S, and with other DPX-based candidates,” said Fred Ors, Chief Executive Officer at IMV Inc. “We see 2021 as a transformational year for IMV as we are advancing Mavropepimut-S in both relapsed, refractory DLBCL (“r/r DLBCL”), advanced recurrent ovarian cancer. Additionally, we now have encouraging early data in two other solid cancer indications. We continue to explore the power of our versatile delivery platform with new DPX-based cancer immunotherapies, like DPX-SurMAGE, a dual-targeted cancer immunotherapy that is expected to enter clinical trials later this year and DPX-BRAF that is currently evaluated in preclinical studies in animal models.” [Clinical Program Updates](#)

Mavropepimut-S: Phase 2 SPiReL Study in r/r DLBCL

As reported in May 2020, this Phase 2 study in r/r DLBCL met its primary efficacy endpoint. In December 2020, the study's lead investigator, Neil Berinstein, MD, hematologist at Sunnybrook Health Sciences Center provided an update during a poster presentation at the American Society of Hematology Annual Meeting. In November 2020, Dr. Berinstein also presented at *The Society for Immunotherapy of Cancer (SITC) 35th Anniversary Annual Meeting* where he announced the discovery of a potential predictive biomarker.

In his presentation during the annual ASH meeting, Dr. Neil Berinstein described the results from the SPiReL study:

- In the PD-L1+ population (n=7), subjects

- Have significantly higher median Progression Free Survival (PFS) of 230 days, compared to the PD-L1 negative subjects (70 days) with a p-value of 0.007, suggestive of a strong predictive biomarker for this treatment combination,
 - Demonstrated an objective response in six subjects, including three subjects who have completed one-year of study treatment,
 - Demonstrated an ORR and a DCR at both 85.7% in evaluable PD-L1+.
- Peripheral blood was assessed for survivin-specific ELISpot responses in 15 subjects with available samples. All 3 subjects with a CR, and 3 of 4 subjects with a PR, had positive ELISpot responses, while only 1 subject with SD and 1 subject with PD demonstrated survivin-specific ELISpot response suggestive of an association between the clinical responses with the mechanism of action of DPX-Survivac.
 - Treatment was well tolerated. The majority of treatment-related adverse events were grade 1 and 2 severity. A majority of these were injection site reactions associated with the subcutaneous administration of DPX-Survivac.

Based on these results, IMV recently engaged with the FDA which provided productive feedback. The Company is working with Merck to finalize the protocol of the Phase 2b clinical study which is expected to begin in Q2 2021.

Maveropepimut-S: Phase 2 DeCide1 Study in Advanced, Recurrent Ovarian Cancer

Top line data presented in December 2020 demonstrated clinically meaningful activity with long-lasting clinical benefits, and an excellent safety/tolerability profile.

- 15/19 (79%) evaluable subjects demonstrated disease control. Clinical responses were observed across platinum-sensitive, platinum-resistant, and platinum-refractory patients.
- 7/19 evaluable subjects (37%) achieved clinical benefit with partial/stable responses lasting > 6 months, and 5 subjects (26%) achieved clinical benefit with partial/stable responses lasting > 12 months.
- Treatment was well-tolerated with the majority of adverse events being grade 1-2 reactions at the injection site.

IMV is currently analyzing translational data with the goal of better understanding the mechanism of action of Maveropepimut-S and identifying potential predictive biomarkers. Once the analysis of the translational data is completed, the Company will request a meeting with the FDA in the second half of the year to finalize the design of a Phase 2b trial.

Maveropepimut-S: Phase 2 Basket Trial in Multiple Advanced Metastatic Solid Tumors

The objective of this exploratory trial conducted in collaboration with Merck is to identify and select the best solid tumor opportunities for the combination of IMV's T cell therapy with Merck's anti PD-1 checkpoint inhibitor, Keytruda[®], and CPA. Recruitment in five cancer indications follows a Simon two-stage design and each indication has prespecified success thresholds defined by the expected effect of Keytruda[®] as a monotherapy agent in that indication.

The combination therapy is evaluated in patients with metastatic bladder cancer, liver cancer (hepatocellular carcinoma, HCC), ovarian cancer (with and without CPA), non-small cell lung

cancer (NSCLC), and tumors shown to be positive for the microsatellite instability high (MSI-H) biomarker. At the time of this update, 116 subjects were enrolled on the study and sufficient data was available for four of the five indications.

- The combination therapy achieved the thresholds in two indications: metastatic bladder and MSI-H tumor cancers. IMV is pleased to announce that the combination therapy will be further evaluated in these two indications.
- The combination therapy did not meet the prespecified criteria to progress to the next stage in NSCLC and ovarian cancer. The Company will discuss with its partner Merck to decide whether these indications should be further explored.
- In the Hepatocellular Carcinoma (liver) HCC indication, IMV and its partner Merck have decided to adjust some of the enrollment criteria in order to accelerate enrollment rates.
An update will be provided when the enrollment goal is met.

DPX-COVID-19: A DPX-Based Vaccine Against SARS-CoV-2

Due to the evolution of the regulatory landscape, the emergence of new variants and the regulatory approval of vaccines by a number of countries, the Company is currently conducting complementary preclinical studies, including evaluating the impact of new variants, and will provide an update once these preclinical studies are completed.

As the scientific community gains a better understanding of the duration of the protection induced by the current and soon-to-be approved vaccines, their efficacy against new emerging variants and the possible need to revaccinate, the Company's goal is to generate sufficient clinical evidence supporting the claim that DPX-based vaccines, which have a different mechanism of action than traditional vaccines, can represent a compelling long-lasting solution to COVID-19 and to other future pandemics. Once available, IMV intends to submit preclinical study results supporting the Phase 1/2 clinical trial in a peer-reviewed scientific journal.

2020 Operational Highlights

IMV strengthened its financial position in May 2020 with a private placement for gross proceeds of \$25.1 million in addition to gross proceeds of \$40.8 million (US \$30 million) raised under its March and June At-The-Market facilities. This translates to cash and cash equivalents of \$46.4 million at the end of the fiscal year.

Company appointed Andrew Hall, B.Med.Sci., M.Sc. as Chief Business Officer: Mr. Hall joined IMV in November 2020. He brings more than 20 years of executive experience in biopharmaceuticals and life sciences, and has spent his career focused on corporate and portfolio strategy, as well as business development and commercial operations with industry leaders such as Celgene, Merck, Schering-Plough, and Bristol-Meyers Squibb spearheading new product development, analytics and commercial strategy for immunology and inflammation, oncology, women's health, cardiovascular portfolios and more.

Overview of Year-End 2020 Financial Results

As of December 31, 2021, the Company had cash and cash equivalents of \$46.4 million and working capital of \$45.5 million, compared with \$14.1 million and \$13.2 million, respectively as of

December 31, 2019. The increase in cash primarily reflects proceeds from the \$25.1 million private placement completed on May 7th, the 6,841,773 common shares issued for gross proceeds of \$40.8 million (US\$30 million) under its March and June At-The-Market facilities and \$2.3 million from the exercise of 611,888 common share warrants. Based on its current operating plan, IMV expects its current cash position will be sufficient to fund operations for at least the next 12 months.

Research and development expenses were \$26.6 million for the year ended December 31, 2020 compared with \$19.0 million for the year ended December 31, 2019. This increase of \$7.6 million was mainly due to a rise in expenses related to the ongoing basket trial, personnel costs due to an increase in headcount, and pre-clinical development of DPX-COVID-19, which was offset by the increase in government assistance described below.

General and administrative expenses were \$15.2 million for the year ended December 31, 2020 compared with \$10.1 million for the year ended December 31, 2019. This increase was mainly attributable to an increase in insurance premium and, to a lesser extent, an increase in foreign exchange loss and non-cash deferred share unit compensation. These increases were partly offset by a decrease in travel costs due to COVID-19 travel restrictions and a decrease in non-cash stock backed compensation.

Government assistance totaled \$6.7 million for fiscal 2020 compared with \$2.4 million in fiscal 2019. This increase is mainly explained by various government grants for the development of DPX-COVID-19, reimbursed for eligible development expenditures incurred to date.

The net loss and comprehensive loss of \$34.9 million (\$0.58 per share) for the year ended December 31, 2020 was \$7.5 million higher than the net loss and comprehensive loss for the year ended December 31, 2019 and can be further explained by a \$5.1 million increase in general and administrative expenditures, a \$7.6 million increase in research and development expenditures, partly offset by a \$4.3 million increase in COVID-19 specific government funding.

As of March 16, 2021, the number of issued and outstanding common shares was 67,711,045 and a total of 4,997,282 stock options, warrants and deferred share units were outstanding.

The Corporation's audited annual consolidated results of operations, financial condition and cash flows for the year ended December 31, 2020 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/edgar as well as the Company's website at <https://www.imv-inc.com/investors/financial-information/financial-results>.

All dollar amounts noted herein are denominated in Canadian dollars (unless otherwise noted herein)

2021 Expected Milestones

Maveropepimut-S

- Q1 2021: Finalization of clinical protocol and collaboration agreement with partner for Phase 2B clinical trial in r/r DLBCL
 - Q2 2021: Translational and Biomarker analysis update for Ovarian cancer DeCidE1 trial
 - Q2 2021: Initiation of r/r DLBCL Phase 2B trial
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- H2 2021: Meeting with the FDA and final clinical design for a Phase 2B study in Advanced Recurrent Ovarian Cancer
- H2 2021: Updated results for the basket trial.

DPX-SurMAGE

- H2 2021: Initiation of a Phase I clinical study in bladder cancer.

DPX-COVID-19

- Q2 2021: Submission of pre-clinical manuscript.

Conference Call and Webcast Information

Management will host a conference call and webcast today March 17, 2021 at 8:00 a.m. ET. Investment professionals are invited to join the conference call by dialing (866) 211-3204 (U.S. and Canada) or (647) 689-6600 (international) using the conference ID# 8998652. Other interested parties can access the live audio webcast at this link: <https://ir.imv-inc.com/events-and-presentations>.

About IMV

IMV Inc. is a clinical stage biopharmaceutical company dedicated to making immunotherapy more effective, more broadly applicable, and more widely available to people facing cancer and other serious diseases. IMV is pioneering a new class of cancer immunotherapies based on the Company's proprietary delivery platform (DPX). This patented technology leverages a differentiated mechanism of action that generates a targeted and durable immune activation with limited side effects. IMV's lead candidate, Maveropepimut-S, is a T cell-activating immunotherapy that combines the utility of the platform with a novel cancer target: survivin. IMV is currently assessing Maveropepimut-S in advanced ovarian cancer, as well as a combination therapy in multiple clinical studies with Merck. IMV is also developing a DPX-based vaccine to fight against COVID-19. 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 law. 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 the press release, such forward-looking statements include, but are not limited to, statements regarding the FDA potentially granting accelerated regulatory approval of Maveropepimut-S, the potential for synergistic action and results from the use of combined immunotherapies by the Company, the Company's ability to reach agreement with its collaboration partners and the timing of expected results from other Maveropepimut-S's studies with other tumor types. However, they should not be regarded as a representation that any of the plans will be achieved. Actual results may differ materially from those set forth in this press release due to risks affecting the Company, including access to capital, the successful design and completion of clinical trials and the timely receipt of all regulatory approvals to commence, and then continue, clinical studies and trials and the receipt of all regulatory approvals to commercialize its products. 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 ability to access capital, the successful and, generally, the timely completion of clinical trials and studies and the receipt of all regulatory approvals as well as other risks detailed from time to time in our ongoing quarterly filings and annual information form. Investors are cautioned not to rely on these forward-looking statements and are encouraged to read IMV's continuous disclosure documents, including its current annual information form, 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/edgar

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Source: IMV Inc.

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IMV INC.

Consolidated Statements of Loss and Comprehensive Loss

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

	Years ended December 31,	
	2020	2019
	\$	\$
Revenue		
Subcontract revenue	3	59
Interest Income	298	509
Total revenue	301	568
Expenses		
Research and development	26,605	18,986
General and administrative	15,205	10,140
Government assistance	(6,690)	(2,432)
Accreted interest and valuation adjustments	36	1,239
Total operating expenses	35,156	27,933
Net loss and comprehensive loss	(34,855)	(27,365)
Basic and diluted loss per share	(0.58)	(0.55)
Weighted-average shares outstanding	60,305,264	49,653,578

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

	December 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 46,362	\$ 14,066
Accounts receivable	2,012	845
Prepaid expenses	5,645	3,032
Investment tax credits receivable	1,942	1,661
Total current assets	<u>55,961</u>	<u>19,604</u>
Property and equipment	2,839	2,830
Total assets	<u>\$ 58,800</u>	<u>\$ 22,434</u>
Liabilities and Equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 9,240	\$ 6,157
Current portion of long-term debt	1,094	88
Current portion of lease obligations	139	100
Total current liabilities	<u>10,473</u>	<u>6,405</u>
Lease obligation	1,216	1,208
Long-term debt	7,736	8,373
Total liabilities	<u>19,425</u>	<u>15,986</u>
Equity	39,375	6,448
Total liabilities and equity	<u>\$ 58,800</u>	<u>\$ 22,434</u>
