

March 21, 2019



# IMV Inc. Announces 2018 Year-end Financial and Operational Results and Provides Updates on Key Clinical Programs

- *Attained multiple milestones in DECIDE1/2 clinical program in advanced ovarian cancer*
- *Achieved initial positive data from phase 2 clinical trial in DLBCL with Merck*
- *Initiated a phase 2 basket trial across five indications under a collaboration with Merck*
- *Listed on Nasdaq and changed Corporation name to better reflect inherent value proposition*
- *Will host conference call tomorrow morning at 8 a.m. ET*

DARTMOUTH, Nova Scotia--(BUSINESS WIRE)-- IMV Inc. (Nasdaq: IMV; TSX: IMV), a clinical stage immuno-oncology corporation, today released its financial and operational results for year ending December 31, 2018.

“IMV made significant advances in 2018,” said [Frederic Ors, Chief Executive Officer](#). “Foundational changes, including shifting the name of the corporation to IMV and listing on Nasdaq, are enabling us to access to a larger pool of investors and allow us to better communicate our value proposition globally. However, the evolution of our clinical program is an even more important accomplishment: we entered into a collaboration with Merck across five tumor types; opted, based on DECIDE clinical data, to pursue DPX-Survivac as a monotherapy in ovarian cancer; and published studies clearly demarcating the T cell-activating novel mechanism of action of our DPX platform. With these milestones achieved, we are looking forward to a strong 2019 in which we will continue to advance our pipeline, drive value for investors, and support unmet patient needs.”

IMV will host a conference call and webcast tomorrow at 8 a.m. ET. The dial-in number for the conference call is (844) 461-9932 (U.S. and Canada) or (636) 812-6632 (international) using the conference ID: 9647179. A live audio webcast will be available through IMV’s website on the ‘Events and Presentations’ page at <https://ir.imv-inc.com/events-and-presentations>. The webcast will be recorded and available on the IMV website for 30 days following the call.

## **Recent Clinical Updates & Expected Milestones**

**Phase 1b/2 DPX-Survivac monotherapy and combination trial in ovarian cancer (DECIDE)**

The first 13 patients with advanced recurrent ovarian cancer have been enrolled in the phase 2 portion of the study. Six patients were randomized on DPX-Survivac monotherapy and seven were randomized on the DPX-Survivac/epacadostat combination. The Corporation is planning to provide an update on the preliminary clinical data by the end of Q1 2019.

Enrollment of an additional 15 patients in a population with lower tumor burden is ongoing and the corporation is planning to provide another clinical update on this cohort in Q2 2019.

### **Phase 2 Study in Combination with KEYTRUDA® in Relapsed/Refractory DLBCL (SPIREL)**

Seven patients have been enrolled and treated across four different clinical sites in Canada. Additional patients are being screened and IMV expects to report updated clinical data in Q2 2019.

### **Phase 2 Basket Trial in Combination with KEYTRUDA® in Multiple Solid Tumors**

Screening and enrollment of patients is ongoing at multiple clinical sites across the U.S. and Canada for patients with bladder, liver (hepatocellular carcinoma), ovarian, or non-small cell lung (NSCLC) cancers as well as tumors shown to be positive for the microsatellite instability high (MSI-H) biomarker. The first patients have been dosed in the ovarian and lung cancer cohorts. IMV expects to report preliminary clinical results on several of the solid tumor indications before the end of 2019.

## **2018 Highlights**

### ***Clinical Programs - DECIDE1/2 Advanced Ovarian Cancer Trial***

- Updated Phase 1b data shared via an [oral presentation at the 2018 ASCO Meeting](#) and topline data from the first two Phase 1b dosing cohorts highlighted at the 2018 [ESMO-IO Meeting](#)
  - Based on these data, [IMV opted to develop DPX-Survivac as a monotherapy](#) in certain ovarian cancer patients defined by BTB (baseline tumor burden), an indication of tumour size
  - Additional analyses were conducted that correlated DPX-Survivac's novel MOA - the level of T cell infiltration - with clinical response
- [Met with the U.S. Food and Drug Administration](#) (FDA) and submitted an updated DECIDE trial protocol; in addition, IMV discussed with the FDA the need for accelerated approvals in advanced ovarian cancer and received guidance on clinical design considerations for different lines of therapy and platinum-sensitive and resistant patients

### ***Additional Clinical Highlights***

- First clinical data obtained from the combination of [DPX-Survivac and mCPA with Keytruda® \(SPIREL Trial\)](#), which came from an investigator-sponsored phase 2 trial in patients with persistent or recurrent/refractory DLBCL; data from the combination signaled significant anti-cancer activity in three of the first four evaluable patients as well as a tolerable safety profile

- Announced a [collaboration with Merck in a phase 2 basket trial](#) evaluating the safety and efficacy of DPX-Survivac, low-dose cyclophosphamide, and Keytruda® (pembrolizumab) in patients with select advanced or recurrent solid tumors across five different indications: bladder, liver (hepatocellular carcinoma), ovarian, or non-small cell lung (NSCLC) cancers as well as tumors with the microsatellite instability high (MSI-H) biomarker

### **R&D Milestones**

- [Research published in the Journal of Biomedical Science](#) demonstrated the association between IMV's proprietary immune-targeted delivery technology and enhanced efficacy in slowing tumor progression
- [New data presented at the 2018 AACR Meeting](#) highlighted the novel MOA underscoring the Corporation's T cell-activating DPX technology and the potential for heightened anti-cancer activity of combination therapies based on IMV's proprietary delivery platform

### **Operational Highlights:**

- **Completion of two public offerings:** In February 2018 and in March 2019 for a total of approximately \$43.9 million
- **Nasdaq listing and share consolidation:** IMV's common shares commenced trading on the Nasdaq Stock Market LLC on June 1, 2018
- **Corporate name change:** Because the MOA of DPX-based candidates signals a new class of immunotherapies that is differentiated from vaccines, IMV leadership changed the corporation's name from Immunovaccine to IMV to better reflect the true potential of its therapeutic candidates
- **Addition of Julia P. Gregory and Dr. Markus Warmuth to the Corporation's Board of Directors:** Ms. Gregory is a seasoned biotechnology executive, having served as Chief Executive Officer and of ContraFect Corporation and the immuno-oncology company Five Prime. Dr. Warmuth brings to the Board more than 20 years of drug discovery experience with a strong focus on targeted therapy and immuno-oncology programs
- **Expansion of management team:** IMV named [Joseph Sullivan as the Corporation's first Senior Vice-President, Business Development](#). Mr. Sullivan brings with him over 25 years of global pharmaceutical experience with Merck & Co. Inc. to IMV
- **Opening of new facility in Dartmouth, Nova Scotia:** Nearly tripling the functional workspace, the new premises feature upgraded facilities and equipment as well as increased laboratory size to support long-term growth
- **Cash position:** As of December 31, 2018, cash and cash equivalents and short-term investments were \$14.9 million (excluding the \$29.5 million financing completed in March 2019) compared to \$14.9 million as of December 31, 2017

### **Overview of Year-End 2018 Financial Results**

The net loss and comprehensive loss of \$21,935,000 (\$0.50 per share) the year ended

December 31, 2018 was \$9,908,000 higher than the net loss and comprehensive loss for the year ended December 31, 2017.

Research and development expenses increased by \$6,914,000 for the year ended December 31, 2018, compared to 2017. These increases are mainly due to higher enrollment in the phase 1b/2 Incyte trial in ovarian cancer; milestone payments for the phase 2 study in DLBCL; and expenses related to the initiation of the basket trial. The increase is also attributable to manufacturing activities to support the increased clinical activity, which included purchasing raw materials and contract manufacturing organization costs.

General and administrative expenses increased by \$2,039,000 for the year ended December 31, 2018 compared to 2017. This increase is mainly due to the various expenses related to the Nasdaq listing (legal, audit and consulting fees as well as listing fees) that are non-recurring expenses, the filing of a shelf prospectus, the increase in insurance premiums following the Nasdaq listing, consulting and professional fees, regulatory fees, the increase of the rent, lease interest accretion, and utilities related to the new facility.

Business development and investor relations expenses increased by \$781,000 for the year ended December 31, 2018 compared to 2017. These increases are mainly explained by the hiring of a Senior Vice President, Business Development in January 2018 and a Senior Director of Investor Relations and Communications in November 2018.

At December 31, 2018, the Corporation had cash and cash equivalents of \$14,895,000 (excluding the \$29.5 million financing completed in March 2019) and working capital of \$12,247,000, compared with \$14,909,000 and \$13,627,000, respectively at December 31, 2017. For the year ended December 31, 2018, IMV's cash burn rate, defined as net loss for the period adjusted for operations not involving cash (interest on lease obligation, depreciation, accretion of long-term debt, stock-based compensation and DSU compensation), was \$18.4 million. IMV expects research and development expenditures to increase over time due to the continuing development of product candidates and other clinical, preclinical, and regulatory activities.

As of March 21, 2019, the number of issued and outstanding common shares was 50,594,260 and a total of 2,008,057 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, 2018 and the related management's discussion and analysis (MD&A) are available on SEDAR at [www.sedar.com](http://www.sedar.com) and on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar).

## **About IMV**

IMV Inc. is a clinical stage biopharmaceutical corporation 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 immunotherapies based on the Corporation's proprietary drug delivery platform. This patented technology leverages a novel mechanism of action that enables the programming of immune cells *in vivo*, which are aimed at generating powerful new synthetic therapeutic capabilities. IMV's lead candidate, DPX-Survivac, is a T cell-activating immunotherapy that combines the utility

of the platform with a target: survivin. IMV is currently assessing DPX-Survivac as a monotherapy in advanced ovarian cancer, as well as a combination therapy in multiple clinical studies with Merck. Connect at [www.imv-inc.com](http://www.imv-inc.com).

## 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 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 DPX-Survivac. 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 Corporation, including access to capital, the successful design and completion of clinical trials and the receipt and timely receipt of all regulatory approvals. 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, our ability to access capital, the successful and timely completion of clinical trials, the receipt of all regulatory approvals and 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](http://www.sedar.com) and on EDGAR at [www.sec.gov/edgar](http://www.sec.gov/edgar).*

IMV INC.

Unaudited Interim Condensed Consolidated Statements of Loss and Comprehensive Loss

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

	Year ended December 31	
	2018	2017
	\$	\$
<b>Revenue</b>		
Subcontract revenue	82	33
Interest Income	401	189
Total revenue	483	222
<b>Expenses</b>		
Research and development	12,852	5,938
General and administrative	7,241	5,202
Business development and investor relations	2,002	1,221
Government assistance	(1,062)	(1,078)
Accreted interest	1,385	966
Total operating expenses	22,418	12,249

<b>Net loss and comprehensive loss</b>	(21,935)	(12,027)
<b>Basic and diluted loss per share</b>	(0.50)	(0.31)
Weighted-average shares outstanding	43,766,951	38,656,771

IMV INC.

Unaudited Interim Condensed Consolidated Statements of Financial  
Position

(Expressed in thousands of Canadian dollars except for per share amounts)

	December 31, 2018	December 31, 2017
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 14,895	\$ 14,909
Accounts receivable	1,337	261
Prepaid expenses	2,699	838
Investment tax credits receivable	1,111	461
Total current assets	20,042	16,469
Property and equipment	2,883	563
Total assets	\$ 22,925	\$ 17,032
<b>Liabilities and Equity</b>		
Current liabilities		
Accounts payable and accrued liabilities	\$ 7,575	\$ 2,760
Amounts due to directors	49	21
Current portion of long-term debt	81	61
Current portion of lease obligations	90	--
Total current liabilities	7,795	2,842
Lease obligation	1,308	--
Deferred share units	1,436	1,371
Long-term debt	8,069	6,476
Total liabilities	18,608	10,689
Equity:		
Share Capital	90,152	70,113
Contributed Surplus	6,504	6,375
Warrants	415	674
Deficit	(92,754)	(70,819)
Total equity	4,317	6,343
Total liabilities and equity	\$ 22,925	\$ 17,032

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Source: IMV Inc.