# IMAGIN MEDICAL INC.

# **MANAGEMENT DISCUSSION & ANALYSIS**

# For the Three Months Ended December 31, 2021

# Directors and Officers as of February 16, 2022

**Directors:** Chris Bleck

Ken Daignault Jim Hutchens Kayvon Namvar Kevin Slawin

**Officers:** President & C.E.O. – Jim Hutchens

C.F.O. & Secretary – John Vacha

Contact Names: Jim Hutchens

John Vacha

**Telephone Number:** 833-246-2446

#### Form 51-102-F1

### IMAGIN MEDICAL INC.

#### MANAGEMENT DISCUSSION & ANALYSIS

For the Three Months Ended December 31, 2021

### 1.1 Date of This Report

# February 16, 2022

This Management's Discussion & Analysis ("MD&A") of Imagin Medical Inc. for the three months ended December 31, 2021 has been prepared based on information available to us as of February 16, 2022. This discussion should be read in conjunction with the Condensed Interim Consolidated Financial Statements of the Company and notes attached thereto for the three months ended December 31, 2021 included herewith, all of which are available at the SEDAR website at www.sedar.com.

This MD&A includes certain statements that may be deemed "forward-looking statements". All statements in this discussion, other than statements of historical facts, that address activities and events or developments that the Company expects, are forward-looking statements. Although the Company believes the expectations expressed in such forward-looking statements are based on reasonable assumptions, such statements are not guarantees of future performance and actual results or developments may differ materially from those in the forward-looking statements. Factors that could cause actual results to differ materially from those in forward-looking statements include product development timing, government regulatory approvals, hospital reimbursement, continued availability of capital and financing and general economic, market or business conditions. Investors are cautioned that any such statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking statements. Reported currency is stated in Canadian dollars.

# 1.2 Overall Performance

#### **Description of Business**

Imagin Medical Inc. is incorporated in the Province of British Columbia. On February 9, 2016, the Company completed the acquisition of BSS Life Sciences Inc. ("BSS"). BSS holds the intellectual property rights to a proprietary imaging technology developed for extremely accurate visualization of cancers. In connection with the acquisition, the Company changed its name to Imagin Medical Inc. and now focuses on research, development and commercialization in the device/instrumentation medical technology industry.

On December 23, 2021, the shareholders approved the plan of pursuant to Division 5 of Part 9 of the British Columbia Business Corporations Act whereby the Company will continue from the jurisdiction of the BCBCA and become domesticated in Delaware

pursuant to the General Corporation Law of the State of Delaware. As of the date of this report, the Company is still in the process of completing this transition.

## License Agreement

By way of a Licence Agreement dated May 20, 2015, BSS was granted an exclusive, nontransferable, royalty-bearing license by Lawrence Livermore National Security, LLC (LLNS), to use LLNS's patents and intellectual property rights to manufacture and sell products and services pertaining to *in vivo* imaging applications.

Under the License Agreement, BSS must:

- complete a commercial prototype by December 31, 2016 (first prototype completed);
- complete submissions for United States Food and Drug Administration ("FDA") approval by March 31, 2023;
- achieve first commercial sales ("FCS") in the United States within one year of achieving the FDA approval; and
- achieve gross cumulative sales revenues from the sales of licensed products of at least \$10,000,000 within the first three years of achieving FCS.

The sales requirements may be amended and/or extended at the written request of BSS to LLNS, based upon legitimate business reasons specified in reasonable detail in such written request.

BSS must pay certain fees to LLNS for the licence, being (all amounts are in US dollars):

- (i) a nonrefundable issue fee of \$100,000 payable as follows:
  - \$10,000 upon the date of execution of the Agreement (June 22, 2015; paid);
  - \$30,000 by November 22, 2015 (paid);
  - \$30,000 by January 22, 2016 (paid); and
  - \$30,000 by March 22, 2016 (paid).
- (ii) an earned royalty of 3% of net sales, subject to minimum annual royalties of:

Calendar year	Minimum annual royalty	Due date
2017	\$5,000	February 28, 2017 (paid)
2018	\$10,000	February 28, 2018 (paid)
2019	\$10,000	February 28, 2019 (paid)
2020	\$5,000	February 28, 2020 (paid)
2021	\$5,000	February 28, 2021 (paid)
2022	\$5,000	February 28, 2022 (paid)
2023	\$5,000	February 28, 2023
2024 and thereafter	\$25,000	February 28, 2024

(iii) a nonrefundable U.S. Maintenance Patent Fee of \$45,000 to be paid as follows:

- \$15,000 on or before February 28, 2016 (paid);
- \$15,000 on or before February 28, 2019 (paid); and
- \$15,000 on or before February 28, 2023

## The Technology

Imagin Medical is a surgical imaging company focused on establishing a new standard of care in visualizing cancer during minimally invasive surgeries (MIS). The Company's first product, the i/Blue Imaging<sup>TM</sup> System, is based on advanced optics and light sensors and employs patented ultrasensitive imaging technology. The Company believes the i/Blue System, with easy-to-use imaging options, will significantly improve surgeons' ability to visualize cancerous cells for more accurate resection. The Company's initial focus is bladder cancer.

The i/Blue Imaging System is a device external to the body that attaches to an endoscope to emit both white and blue light during MIS. When used in combination with contrast agents, cancerous cells, including premalignant lesions and tumor tissue along the margins, begin to fluoresce within an hour or less. The i/Blue Imaging System provides the option to display, in real-time, the white and blue light images side-by-side. This advancement eliminates the surgeon's need to switch back and forth between the white and blue light images when locating and then resecting the cancer as needed with current technology.

Imagin's i/Blue Imaging System is comprised of two key, state-of-the-art components:

- The i/Blue Control Unit: contains a dual wave-length light source, a twochannel camera control unit, data recorder and power supply modules that allow simultaneous displays of white and blue light illumination in the interior of the bladder.
- Dual View Camera Handpiece: includes sophisticated optical filters that split
  the image into white and blue light channels, allowing simultaneous display of
  corresponding images on the surgical monitor. This patented technology
  compatible with most endoscopes on the market today and offers multiple realtime viewing options/images that better enable the surgeon to visualize and
  resect the cancer.

Benefits of the i/Blue Imaging System

- Simultaneous side-by-side white and blue light images
- No toggling back and forth between images
- Shows cancer in context within the bladder
- Enables surgeons to better visualize cancerous cells for more accurate resection
- Compatible with most endoscopes on the market
- Appropriate for physicians' offices

Future Development - Disruptive Technology / Multiple Markets

Imagin intends to build on the i/Blue technology, which currently works with hexaminolevulinate hydrochloride (HAL), and adapt it to other U.S. Food and Drug Administration (FDA) approved contrast agents, such as Indocyanine green (ICG). These additional products will expand Imagin's market potential, facilitating entry into multiple endoscopic procedures, such as laparoscopic (general and gynecology), colorectal and thoracic.

Imagin is actively pursuing opportunities to acquire or distribute additional products such as disposable scopes, cancer biopsy devices and other products to complement its portfolio.

## The Strategy

Imagin Medical will differentiate the bladder cancer imaging market by improving surgical technique that will lead to improved resections. This will be accomplished by the providing white and blue light images simultaneously, side-by-side on the monitor. Additionally, Imagin will be the low-cost producer and allow the company to make solid margin and price the i/Blue System at a significant discount from current products.

Imagin will continue to strengthen relationships with urologists and key opinion leaders, as well as engage in market development activities through virtual meeting, events, and demonstrations over the coming months. An example of this was the successful webinar showcasing the i/Blue Imaging System that included interviews and commentary from leading urologists and a financial analyst from CNBC regarding the on-going excitement in the healthcare environment. It remains Imagin's plan to differentiate the MIS surgical imaging market by focusing on state-of-the-art, easy-to-use, practical and cost-effective cancer visualization systems.

Once the i/Blue Imaging System is commercially available for urological indications, Imagin will focus on expanding the product platform from bladder cancer to laparoscopic (abdominal), thoracic and other minimally invasive procedures. The Company will partner with manufacturers of contrast agents that are already FDA-approved or in their final phase (Phase III) of FDA approval.

Imagin plans to add complementary products to expand its product portfolio. Because the i/Blue technology is adaptable to most endoscopes currently on the market, the Company will be of strategic interest to existing dominant endoscope manufacturers.

The Company continues to plan for commercialization via initial marketing programs, future participation in trade shows and focus groups with key opinion leaders, along with the development of physician champions and Centers of Excellence. While the 2021 AUA meeting transitioned to a virtual meeting due to Covid, the Company was able to achieve all of its goals by scheduling video meetings with Key Opinion Leading physicians and Investors to showcase the i/Blue System.

#### Intellectual Property

The Company, through its wholly owned subsidiary (BSS Life Sciences) has secured an exclusive license from Lawrence Livermore National Security, LLC (LLNS) to

commercialize the technology invented by Dr. Stavros Demos. This license agreement includes three issued patents and one pending patent application on technology related to exclusive spectroscopic imaging for cancer and other medical applications. These include:

- 1. Issued U.S. Patent 7,149,567 Near-Infrared Spectroscopic Tissue Imaging for Medical Applications.
- 2. Issued U.S. Patent 7,257,437 Autofluorescence Detection and Imaging of Bladder Cancer Realized Through a Cystoscope.
- 3. Issued U.S. Patent 8,285,015 Simultaneous Acquisition of Differing Image Types.
- 4. Issued U.S. Patent 10,182,708 Simultaneous Acquisition of Differing Image Types.

Based on product refinement and development since the completion of the University of Rochester study and the innovative work being completed at Lighthouse Imaging, Imagin intends to file additional patent that the Company anticipates will broaden its intellectual property portfolio.

## Product Development and Regulatory Approval

In 2021 the Company eliminated non-essential expenses in all areas of its business. Costcutting measures, including company-wide salary reductions remained in place, as well as virtual operational meetings. Imagin, as well as our partners, supply channels and consultants, were affected by the current pandemic, pushing out product completion by approximately nine months into late 2022.

In the past 12 months the Company has made significant progress in product development. The i/Blue System has successfully transitioned from the development stage to manufacturing with Lighthouse Imaging, our contract manufacturer, who will finalize the product design, move to pre-production units and pilot builds. Lighthouse has moved forward with documentation, as well as key device performance characteristics that have met technical design specifications using various testing techniques including, but not limited to, analytic design calculations, measurements of physical characteristics and testing by independent laboratories. Data from these independent lab tests is being combined with data from internal testing, engineering calculations, component suppliers and competitive device analysis, all of which will become the basis of the Company's documentation requirements and will be included with Imagin's FDA submission.

The Company intends to conduct the first-in-human usability studies to demonstrate fluorescence now that medical institutions have resumed clinical trials and products have become available. The Company's plan is to showcase an i/Blue Imaging System with the final optics design too a select group of key urologists during the American Urology Association meeting in New Orleans this coming May.

Imagin believes that the imaging quality and cost reduction goals for the i/Blue Imaging System will be achieved and make blue light cystoscopy more accessible to hospitals and patients. The product will be highly manufacturable with a modular design that will become a basic platform for Imagin's current and future applications.

As previously reported, the Company met with the FDA twice to proactively discuss the i/Blue System's regulatory path. The content and feedback from these meetings have been instrumental as the Company continues to refine its regulatory strategy and complete the formal FDA Pre-Market Approval (PMA) submission. Imagin will ensure that the i/Blue System will be in compliance with FDA and international requirements, i.e., Quality System Regulation ISO 13485:2016 and Quality Management System (QMS).

## Highlights from July 1, 2021 up to the date of this report

The Company announced the following:

- Announced that Kayvon Namvar joined Imagin's Board of Directors as Chair of the Audit Committee. Mr. Namvar serves as a Principal at RNA Capital Advisors, a financial and strategic advisory firm, and as Vice President, Finance & Strategic Analysis at Hawthorne Effect, Inc., a healthcare technology company focused on clinical trials. He has expertise in forecasting, valuation, and transaction advisory support in the life sciences, healthcare, and technology industries. Kayvon holds a Bachelor of Science degree in Business Administration from the University of Southern California.
- Announced that Kevin Slawin, M.D. joined Imagin's Board in August 2021, has assumed the role of Chairman. Dr. Slawin, a leading uro-oncologist, is the founder of Rapha Capital Management, LLC, a venture capital firm focused on identifying and managing strategic investments in early-stage biotechnology companies. Dr. Slawin brings knowledge of bladder and prostate cancer to Imagin as the Company advances the i/Blue Imaging System for bladder cancer visualization to commercialization.
- Announced it closed a new convertible note offering totaling US\$3 million in three tranches by Rapha Capital BioVentures Fund I, LP (RCBVFI) to support the clinical development of Imagin's lead product, the *i/Blue* TM Imaging System.

As at the date of this report, the Company reported a share structure as follows:

- Issued and Outstanding 9,996,879
- Options granted 527,500
- Finance warrants 24,940,250
- Finder's warrants 52,790

#### 1.3 Selected Annual Information

The highlights of financial data for the Company for the two most recently completed financial years are as follows:

	30-Sep-21	30-Sep-20
(a) Loss before other items		
(i) Total loss	\$11,345,197	\$4,352,095
(ii) Loss per share – basic	\$1.26	\$0.53
(iii) Loss per share – diluted	\$1.26	\$0.53
(b) Net loss		
(i) Total loss	\$11,473,412	\$4,376,849
(ii) Loss per share – basic	\$1.27	\$0.53
(iii) Loss per share – diluted	\$1.27	\$0.53
(c) Total assets	\$774,515	\$219,400

Loss per share was calculated using the post-consolidated weighted average of 9,049,948 in the year ended 2021 and 8,927,096 in the year ended 2020.

## 1.4 Results of Operations

# Discussion of Operations and Financial Condition

The following should be read in conjunction with the condensed interim consolidated financial statements for the three months ended December 31, 2021 and notes attached hereto.

During the three months ended December 31, 2021, the Company reported a net loss of \$1,322,484 (December 31, 2020 – \$562,260). The increase in the net loss is related to the issuance of convertible notes during the year, and the related revaluation of the fair value of the embedded derivative and interest expense. The Company recorded a convertible note expense of \$535,760, which is the main reason for the increase in loss.

The Company incurred the following major expenditures:

- 1. Legal & accounting Total \$141.927 (December 31, 2020 \$104,138) increased by \$37,789. The increase is related to legal fees incurred in connection with the convertible debt plus the increase in compensation effective September 1, 2021.
- 2. Management fees Total \$110,608 (December 31, 2020 \$146,476). The decrease of \$35,868 is related to the decrease in compensation of the CFO effective September 1, 2021.
- 3. Product Development Total \$432,100 (December 31, 2020 \$208,894); increased by \$223,206. These expenses are primarily related to the work performed by outsourced design and engineering, regulatory, FDA, legal and quality consultants for the design and development of the i/Blue system and associated FDA & regulatory plans.

The Company also reported receivables and prepaids for a total amount of \$399,963 (September 30, 2021 – \$385,821). The amount is broken down as follows:

	31-Dec-21	30-Sep-21
GST Receivable	\$ 2,049	1,256
Trust account	1,700	1,700
Prepaid expenses *	396,214	382,865
	\$ 399,963	385,821

<sup>\*</sup> The Company was billed in advance for services ranging from six months to a year with respect to services primarily related to raising capital and public relations. In addition, the Company had to make a deposit of US\$275,000 (Cdn\$357,972) to Lighthouse Imaging, the contract manufacturer for the Company's i/Blue Imaging System.

#### **Shareholders Communication and Travel**

For the three months ended December 31, 2021, the Company reported shareholder communication and travel expenses totaling \$19,882 (December 31, 2020 – \$94,356) and is broken down as follows:

	31-Dec-21	31-Dec-20
Communication & information	\$ 14,776	\$ 76,132
Conferences	-	9,915
Telephone & website	868	1,222
Travel & entertainment	4,314	7,087
	\$ 19,958	\$ 94,356

Communication & information expenses relate to an increase in investor outreach to promote investor awareness of the progress the Company has made towards bringing the i/Blue System to market. This included digital marketing campaigns, technical articles and investor outreach.

#### **Summary of Quarterly Results**

The following is a summary of the Company's financial results for the eight most recently completed quarters:

	Q1 31-Dec-21	Q4 30-Sep-21	Q3 30-Jun-21	<b>Q2 31-Mar-21</b>
	IFRS	IFRS	IFRS	IFRS
Net loss	(1,322,484)	(8,163,540)	(434,788)	(2,312,824)
Per Share	(0.14)	(0.90)	(0.05)	(0.26)
	Q1 31-Dec-20	Q4 30-Sep-20	Q3 30-Jun-20	Q2 31-Mar-20
	IFRS	IFRS	IFRS	IFRS
Net loss	(562,260)	(689,057)	(582,805)	(1,744,702)
Per Share	(0.06)	(0.08)	(0.07)	(0.21)

Loss per share was calculated using the post-consolidated weighted average for the above eight quarters.

# 1.5 Liquidity

The Company has no current operating income or cash flow. In management's view, given the nature of the Company's operations, the most relevant financial information relates primarily to current liquidity, solvency, and planned expenditures. The Company's financial success will be dependent on continuing to raise operating capital and successful clinical trials that validate the Company's technology. Such activities may take time to complete, and the amount of resulting income is difficult to determine.

#### *Convertible Note #1:*

During the previous fiscal year, the Company issued convertible notes (the "Notes") in the aggregate of US\$2,900,500. The notes bear interest at 10% annually, payable semi-annually in arrears, and mature 18 months following the date of issue, unless repurchased, redeemed or converted. The Notes are convertible at the holder's discretion into common shares at a conversion price of US\$0.40 per share.

In connection with the issuance of the Notes, the Company issued 3,625,625 warrants exercisable at US\$0.50 and 3,625,625 warrants exercisable at US\$0.60. All warrants are exercisable for five years from the date of issue.

#### Convertible Note #2:

Also, during the previous fiscal year, the Company closed a second convertible note offering totaling US\$3,000,000. This offering will be received in three tranches, with the first tranche of US\$500,000 having been received during the year. This note matures 24 months following the date of issue, unless earlier repurchased or converted, and bears interest at the rate of 10% per annum, payable on maturity or conversion. The outstanding principal balance, plus any unpaid interest, will automatically convert into common shares of the Company upon the completion of not less than US\$2,000,000 in financings by the Company, at a conversion price of US\$0.40.

Upon receiving the first tranche of US\$500,000, the Company issued to the note holder 15,775,000 warrants, exercisable at US\$0.40 per share, and expiring five years from the date of issue.

During the three months ended December 31, 2021, the Company received US\$500,000 as full payment of the second tranche of the US\$3,000,000 convertible note. Subsequent to the quarter, the Company received US\$1,250,000 as partial payment of Tranche 3.

# Cash and cash equivalents

	31-Dec-21	30-Sep-21
Cash deposits	\$ 46,672	\$ 265,664
Total cash and cash equivalents	\$ 46,672	\$ 265,664

Included in the December 31, 2021 amount above is US\$30,654 converted to Canadian dollars and quarter end rate of 1.2677.

#### Credit Risk

Credit risk arises from cash held with banks and financial institutions. The maximum exposure to credit risk is equal to the carrying value of the financial assets. The Company's cash is held with Canadian and US banks.

#### Currency Risk

Currency risk is the risk to the Company's earnings that arises from fluctuations of foreign exchange rates and the degree of volatility of these rates. The Company faces certain foreign exchange risks related to expenses incurred in U.S. dollars, a currency which may appreciate against the Canadian dollar, the Company's reporting currency. Additionally, net working capital balances denominated in non-reporting currencies are also subject to fluctuations in value. The Company mitigates these threats by limiting its exposure to such balances where their expenditure in the same non-reporting currency is not imminent.

#### Commitments

The Company has certain commitments related to the license agreement with Lawrence Livermore National Security. Please refer to Sections 1.2 Overall Performance – License Agreement.

# 1.6 Capital Resources

The Company has no capital resources.

## 1.7 Off Balance Sheet Arrangements

There are no off-balance sheet arrangements to which the Company is committed.

#### 1.8 First Quarter

The first quarter result does not differ significantly from other the previous quarter.

# 1.9 Transactions with Related Parties

During the three months ended December 31, 2021, the Company paid and/or accrued \$194,967 (<u>December 31</u>, 2020 – \$224,265) to directors and officers or companies controlled by directors and officers of the Company, for management, accounting, and directors' fees incurred by the Company.

	 31-Dec-21	31-Dec-20
Management fees	\$ 110,608	146,476
Accounting fees	78,859	76,289
Directors fees	5,500	4,500
Total	\$ 194,967	224,265

Included in accounts payable as at December 31, 2021 are fees due to directors and officers in the amount of \$351,952 (September 30, 2021 – \$333,749), which are non-interest bearing, unsecured, and payable on demand. Fair value cannot be reliably determined.

	31-Dec-21	30-Sep-21
Unpaid Management fees (CEO)	\$ 254,569	254,569
Unpaid Accounting fees (CFO)	57,383	44,680
Directors fees	40,000	34,500
Total	\$ 351,952	333,749

During the three ended December 31, 2021 and 2020, the Company did not grant any stock options to directors and officers.

Effective September 1, 2021, the Company reduced the annual compensation of the CEO from US\$450,000 to US\$350,000 and increased the annual compensation of the CFO from US\$225,000 to US\$250,000. Both executive officers will receive 6 months of severance in the event of a change of control, severance, termination or constructive dismissal.

#### 1.10 Proposed Transactions

N/A

## 1.11 <u>Critical Accounting Estimates</u>

In preparing financial statements, management has to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. Based on historical experience, current conditions and expert advice, management makes assumptions that are believed to be reasonable under the circumstances. These estimates and assumptions form

the basis for judgments about the carrying value of assets and liabilities and reported amounts for revenues and expenses. Different assumptions would result in different estimates and actual results may differ from results based on these estimates. These estimates and assumptions are also affected by management's application of accounting policies. Critical accounting estimates are those that affect the consolidated financial statements materially and involve a significant level of judgment by management.

#### 1.12 Financial and Other Instruments

The carrying value of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities and convertible debt (debt host) approximate their fair values due to the short maturity of those instruments. The embedded derivative within the convertible note is carried measured at fair value.

#### **1.13 Other**

As of the date of this report, the Company reported the following:

Disclosure of Outstanding Share Capital:
Common Shares

9,996,876

Disclosure of Outstanding Stock Options:
Incentive Stock Options

527,500

Disclosure of Outstanding Share Purchase Warrants:

Warrants

Fully diluted

24,993,040

35,517,416

#### **Disclosure Controls and Procedures**

It should be noted that pursuant to Multilateral Instrument 52-511 (adopted by the British Columbia Securities Commission on November 23, 2007), that the officers of the Company are no longer required to certify the effectiveness of disclosure controls and procedures used by the Company, as was required in previous filings under National Instrument 52-109. Accordingly, the new forms of certificate to be signed by the Company's Chief Executive Officer and Chief Financial Officer contain the following Note to Reader:

In contrast to the certificate required under National Instrument 52-109 Certification of Disclosure in Issuers' Annual and Filings (NI 52-109), this Venture Issuer Basic Certificate does not include representations relating to the establishment and maintenance of disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as defined in NI 52-109. In particular, the certifying officers filing this certificate are not making any representations relating to the establishment and maintenance of:

- (i) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation;
- (ii) a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP.

The issuer's certifying officers are responsible for ensuring that processes are in place to provide them with sufficient knowledge to support the representations they are making in this certificate.

Investors should be aware that inherent limitations on the ability of certifying officers of a venture issuer to design and implement on a cost-effective basis DC&P and ICFR as defined in NI 52-109 may result in additional risks to the quality, reliability, transparency and timeliness of and annual filings and other reports provided under securities legislation.

# **Subsequent Events**

Subsequent to the three months ended December 31, 2021:

• The Company received US\$1,250,000 as part of Tranche 3 of the Convertible Debt #2.

Additional information relating to the Company is on SEDAR at www.sedar.com.