OpSens, Inc.

First Quarter 2021 Financial Results

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CORPORATE PARTICIPANTS

Robert Blum – *Lytham Partners*

Louis Laflamme – *Chief Executive Officer*

Robin Villeneuve – *Chief Financial Officer*

PRESENTATION

Operator
Good day and welcome to the OpSens, Inc. Reports First Quarter Fiscal Year 2021 Financial Results Conference Call. All participants will be in a listen-only mode. Should you need assistance, please signal a conference specialist by pressing the star key followed by zero. After today's presentation, there will be an opportunity to ask questions. To ask a question, you may press star then one on a touchtone phone. To withdraw your question, please press star then two. Please note this event is being recorded.

I would like now to turn the conference over to Robert Blum with Lytham Partners. Please go ahead.

Robert Blum
Thank you very much and thank you all for joining us today for the OpSens First Quarter Fiscal 2021 Conference Call.

With us on the call representing the company today are Louis Laflamme, OpSens' President and Chief Executive Officer; and Robin Villeneuve, OpSens' Chief Financial Officer.

At the conclusion of today's prepared remarks, we will open the call for a question-and-answer session.

Before we begin with prepared remarks just a couple of comments. Today's call will contain forward-looking statements that are based on current assumptions and subject to risks and uncertainties that could cause actual results to differ materially from those projected and the company undertakes no obligation to update these statements, except as required by law. Information about these risks and uncertainties are included in the company's filings, as well as periodic filings with regulators in Canada, and the United States, which you can find on SEDAR and the OpSens website.

Today's discussion will include adjusted financial measures which are non-IFRS measures. They should be considered as a supplement to and not a substitute for IFRS financial measures.

Finally, today's event is being recorded and will be available for replay through both the webcast and conference call dial-in information provided in the press release.

With that said, let me turn the call over to Louis Laflamme, President and Chief Executive Officer for OpSens. Louis, please proceed.

Louis Laflamme
Thank you, Robert, and good morning to all of you. We are excited to speak with you today for our first quarter fiscal 2021 conference call.

As many of you are aware, this is just our second investment community conference call. We conduct our first call in November where we spent some added time providing background on the business and on our strategies. We will try to keep our prepared remarks a bit more brief going forward and allow additional time for your questions.

With that said, I continue to be very pleased with the achievements made by the team at OpSens over the past quarter as we achieved solid double-digit top-line growth and profitability both on a net income and EBITDA basis. Specifically, revenue was up 19% during the first quarter at $8.3 million while improving the profitability of the company with net income increasing by $2.5 million. Considering we are still dealing with the impacts from the COVID-19 pandemic that has caused temporary closure of several cardiology laboratories, these positive results clearly reflect the continued confidence of our customers and partners in our team, products and leading-edge technologies. As we look to the future of OpSens, we continue to accelerate the medical development activities in preparation for our entry in the aortic stenosis market for the transcatheter replacement of the aortic valve, more commonly referred to as TAVR or TAVI. Our next generation guidewire will provide the medical community will innovative first-of-its-kind technology for the improved treatment of cardiovascular disease that will allow us to compete in the fastest-growing market in cardiology, a $4 billion global market opportunity growing more than 40% per year.

So with the solid financial performance during the first quarter within our commercialized operation, and continued progress in our TAVR development program, we are laying the foundation for a successful fiscal 2021 and beyond. We continue to remain highly optimistic about the long-term prospects for OpSens to deliver life-changing medical technology to improve patient outcomes.

Let’s dive a bit deeper into what some of the key drivers were during the first quarter. Sales within our coronary artery stenosis measurement line of business, FFR and dPR, were $5.3 million during the first quarter, an increase of 23%. We saw strong continued adoption in the US where sales were up 31%. This is a direct result of our concentrated efforts to expand and enhance our market share in the US and the first quarter’s results clearly show the results of those efforts are gaining traction.

As we discussed last quarter, we recently signed the first of what we expect to be a series of Group Purchasing Organization, or GPO contracts, to expand our presence in the US. The three-year contract with a major GPO will provide its medical facilities immediate access to the OptoWire and our services to all their 50 members across the US. We believe this recognition is a validation of OptoWire’s ability to improve efficiency and reduce cost in the treatment of coronary artery stenosis. We are currently working on negotiating with other GPOs and expect to be signing additional GPO contracts in the coming year to enhance our market share in the US.

Another key effort is to widely educate the medical community on the benefits of the OptoWire that will lead to increasing the number of hospitals utilizing the OptoWire in their suite of services for the improved treatment of cardiovascular disease. It’s important to note that only a small portion of the increase during the first quarter is related to the new GPO contract which was signed in the previous quarter. We hope that continued growth from the GPO agreement, coupled with greater overall awareness and usage will drive solid growth in the US going forward.

Sales in EMEA were up 15% while Japan was up 33% during the quarter. The increase in Japan was generated in part by sales of OptoMonitor III units. As previously stated, we continue to work through the transition period with our partners to facilitate the conversion from OptoWire II to OptoWire III in these regions.

As we look to the rest of the year, while there continues to be headwinds, effects from the pandemic, our teams are in constant communications with our partners and physicians, they generally have a positive outlook for fiscal year 2021 for a ramp-up in OptoWire procedures. Overall, we believe we will continue to see growth within the coronary artery stenosis regimen business with continued growth in North America, EMEA and Japan.

Transitioning to our business partnerships. As most of you are aware, several companies are integrating OpSens sensors into their product used in medical integration of our pressure sensor into their medical applications. Overall, when we include our coronary artery stenosis business plus the contributions from Abiomed for their ventricular assist device, our medical segment sales were $7.3 million during the first quarter.

Let's now discuss the performance of our industrial segment. Please recall in this segment we are leveraging our optical technology and knowledge through our fully-owned subsidiary called OpSens Solutions to offer key solutions in optical temperature, pressure, strain, and other parameters for various industries including aerospace, nuclear and power electronics. During the quarter, OpSens Solutions achieved its highest quarterly revenues since 2016 at $1 million compared to $528,000 in the comparative quarter. These revenues were mainly generated in aerospace and power electronics application for temperature and pressure measurement. While I do not expect this doubling of revenues in the industrial sector to be a trend at this time, we are making significant efforts to bring to market key product application within our industrial division that can be actual drivers for revenues, profitability, and long-term value creation.

Let us transition to our lead development program now and recap for just a moment. As we look to capitalize on the expertise we acquired in the development of the OptoWire product for cardiology, we developed a strategic plan to launch a commercial product for the TAVR. In multiple studies, minimally invasive TAVR is shown to be non-inferior or superior to open chest surgical aortic valve replacement, including reduction in hospital stay and decrease in death for both high and low risk patients. These are critical elements in managing healthcare costs and improving patient outcomes. This is the fastest-growing segment in cardiology, expected to grow at a 43% compound annual growth rate between 2019 through 2025 to reach $8 billion US driven by an aging population, better clinical outcomes and openness to new evidence that people of all heart conditions benefit from this minimally-invasive treatment.

Our TAVR guidewire allows for a single wire to diagnose and deliver the valve, reducing complications, saving time and money through its flawless connectivity capabilities. In fact, it would be the industry's first guidewire that can deliver the valve and allow for continuous pressure measurement. This concept has been very well-received by a panel of international LK experts and we believe our TAVR guidewire can be a game-changer for the treatment of cardiovascular disease.

While only a few months have passed since our last call, let me remind all of you where we are on the development pathway. We have recently completed key milestones for the project, including the completion of multiple animal studies of the TAVR guidewire before starting our first in-man trial. The first in-man trial is expected to happen at the end of the summer 2021. We are highly focused on rapid delivery of this product and ultimately to the market with an expectation to receive regulatory approvals to the market as early as 2022.

Just to recap a bit before I turn it over to Robin, I am pleased with the overall progress made during the first quarter of fiscal 2021. Total revenue was up 19%, led by 31% growth in coronary artery stenosis revenues in the US. Every region we operate in showed growth during the quarter. We achieved profitability on a net income basis and our cash balance remained strong, increasing by $1.3 million during the quarter. We believe we are ticking the boxes on a number of key commercialization initiatives to grow OptoWire across the globe, including the introduction of OptoWire III outside North America, as I mentioned, along with the signing of key GPO contracts and overall adoption and improved utilization by hospitals in the US.

And perhaps most importantly, we continue to make progress on the development of the industry's first TAVR guidewire that has the ability to allow for a single wire to both diagnose and deliver the valve for the treatment of aortic valve stenosis as we look to enter this potential $8 billion and rapidly-growing segment in cardiology. I continue to believe we are on pace for a very exciting fiscal 2021 with a number of value creation milestones in store.

Let me now turn the call over to Robin for a review of the first quarter 2021 results. Robin?

Robin Villeneuve
Thank you, Louis, and thanks to everyone joining us on the call. The company reported sales of $8.3 million in the first quarter of fiscal 2021 compared with $7 million in the same period of fiscal 2020, an increase of 19%.

Sales in the medical segment, which encompass both our coronary artery stenosis measurement line of business, FFR, dPR, and OEM, which is mainly our agreement with Abiomed for integration of our pressure sensor into their Impella pump, totaled $7.3 million. This was an increase of about $875,000 or 13%. FFR-related sales were up 24% while the OEM sales were down about $191,000.

Sales in the industrial segment totaled $1 million during the first quarter, compared to sales of $528,000 for the same period last year. While longer term we believe we will see substantial growth in our industrial segment, we don’t believe we will repeat the $1 million level again in the second quarter.

When you look at gross margins, they were flat compared to the year-ago first quarter at 56% but up compared to 53% during all of fiscal 2020. We expect to see our gross margin increase when we will have fully implemented OptoWire III in EMEA and Japan.

From an operating expenses standpoint, we continue to efficiently manage the business, with overall operating expenses decreasing by $1.3 million during the first quarter of fiscal 2021 compared to the first quarter of fiscal 2020. The decrease is largely explained by lower sales and marketing expenses, when compared to last year, related to the adjustment of the size of our direct sales force in the US due to COVID-19.

Also, please note we did recognize a non-refundable contribution under the CEWS, or Canada Emergency Wage Subsidy program, for an amount of just under $500,000. You will see this recognized under other income on the income statement.

Adjusted EBITDAO, which we define as net earning loss plus financial expenses, depreciation of PP&E and right-of-use-assets, amortization of intangible assets, and stock-based compensation cost was a positive $1.3 million in the first quarter of 2021, compared with the loss of $1.2 million in the first quarter of 2020, a $2.5 million improvement.

Looking at net income, we had a profit of $0.6 million in the first quarter of 2021, compared with a net loss of $1.9 million in the year-ago first quarter. The $2.5 million improvement is due to a $0.8 million increase in gross margin as a result of an increase in sales, a $1.2 million decrease in operating costs, and the $500,000 subsidy from the Canadian government.

Finally, we have $12.2 million in cash on the balance sheet and working capital is at $17.5 million as of November 30, 2020. These are both improvements from the August 31, 2020 period.

With that, I will turn the call over to Louis.

Louis Laflamme
Thank you, Robin. So, in conclusion, I want to thank all of our employees for their hard work and dedication and our shareholders for their continued support. We had a very strong first quarter and I believe we are positioned for a continuation of strong operational results and development milestones through fiscal 2021.

With that said, let me now turn the call over to your questions. Operator?

QUESTIONS AND ANSWERS

Operator
We will now begin the question-and-answer session. To ask a question, you may press star then one on your touchtone phone. If you are using a speakerphone, please pick up your handset before pressing the keys. If at any time your question has been addressed and you would like to withdraw your question, please press star then two. At this time, we will pause momentarily to assemble our roster.

Our first question comes from Jeffrey Cohen with Ladenburg Thalmann. Please go ahead.

Jeffrey Cohen
Hi, Louis, and Robin. How are you?

Louis Laflamme
Very good and you, Jeff?

Jeffrey Cohen
Good. I just want to fire through five or six questions. Did you have any large one-time orders to note for the quarter?

Louis Laflamme
No. In the medical device business, as you know, usually it’s a good quantity of small orders, so nothing that would be relevant. It’s more really our regular business that happens in the medical.

In the industrial, there was maybe one order for approximately $350,000 that was, let’s say, a very positive surprise. It is in an exciting application but as per se it was a single non-recurring order.

Jeffrey Cohen
Got it. Okay. Nice rebound on the gross margins versus Q4. We continue to anticipate full-year 2021 in line with this quarter that you reported. Would that be okay? Does that seem aggressive or not?

Louis Laflamme
No, sure. We think that there is room to do better. I mean, we are comfortable with your current anticipation but as we increase the rollout of the OptoWire III in the Japanese and the European market, this should help us to see even higher margin.

Jeffrey Cohen
Got it. Can you give us any guesstimate from the field on dPR traction and dPR usage if you were trying to guesstimate out there? Is it being used and what percent of cases do you think?

Louis Laflamme
It’s a little bit difficult for us because when we sell the OptoWire devices, we don’t know if they are going to do FFR or dPR. But based on the feedback that we get from our customers, we think that the dPR users in the US is broadly 75% or 80% of our volume, while we may be in the position where it’s more 50/50 in Europe. And in Japan, our perception is that it’s probably 80% being FFR. But, at the end of the day for us, as you know, it’s the same device that is being used, the same monitor, so at OpSens we have the duty to provide the choice to our customers and I think that what they appreciate is that they can adapt their procedure based on their needs.

Jeffrey Cohen

Got it. Could you talk a little bit about the US commercial force currently that's in place at end of Q1?

Louis Laflamme
I mean, we don't disclose the number of our sales force. What we can say is that right now we feel we are properly covering our existing customers. We probably expect to add a certain number of person throughout—maybe five additional person down the road as we get a better picture of the vaccine success and seeing the cardiologists working on their backlog of patient following the COVID-19 situation.

Jeffrey Cohen
Yes, got it. And then finally, as far as the top line goes, we're still anticipating year-over-year '21 over '20 top-line growth of call it mid-teens at the moment, which looks moderately linear and sequential in growth throughout the four quarters. Does that seem reasonable to you or would you guide us one way or another or talk a little bit about the cadence for the year?

Louis Laflamme
Well, we don't disclose, as you know, a current time forecast to the Street. This being said, when we look at the results of Q1, I mean, we are pleased with our results but there is multiple areas where we think we could have done even better. Again, COVID-19 has been a headwind but—I mean, COVID-19 has been negatively impacting our growth. We are expecting to see growth for the Q2, Q3, and Q4.

Jeffrey Cohen
Got it. And then on the opex front, Robin, I think we're a point or two from a flat line on the total opex for '21 versus 2020. It looked like 2020 over 2019 was down, total opex down 3.5%, so I think we're thinking of from that to a flat line. Does that also seem reasonable at this point in time?

Robin Villeneuve
Yes, on the opex side, we will have higher expenses in the R&D related to our TAVR project because we will start the manufacturer of the VNV products. So, we will have higher expenses than the Q1 for sure.

Jeffrey Cohen
Got it. Okay, that does it for me. Nice read it.

Louis Laflamme
In general, if I can add that from an SG&A standpoint, we feel that the Q1 results was fairly representative of what you can expect overall in the year. As Robin mentioned, clearly as we are very excited to manufacture currently devices for the VNV on the TAVR project, this will generate some increased costs for Q2.

Jeffrey Cohen
Got it. Thanks for taking the questions.

Louis Laflamme
Thank you, Jeff.

Operator
Our next question will come from Doug Miehm with RBC Capital Markets. Please go ahead.

Doug Miehm
Hello, Louis. Hi, Robin.

Louis Laflamme

Good morning, Doug.

Doug Miehm
Good morning. I guess what's left is just a few questions on the situation around the TAVR product. Now you indicated that you're going to start your first in-man studies probably at the end of the summer but could you tell us how many patients you expect to review in those trials?

Louis Laflamme
Sure. So, we had the opportunity to sat with the FDA. The expectation that they have is to see OpSens doing a 20 patient first in-man study to demonstrate the safety of the device. So, we think that this can be done fairly rapidly in the context where we are working with centers of adding significant volume. So, we don't see 20 patients being a long study and the study that we need to do, there is no follow-ups, since it's only the safety during the procedure.

So, we are going to give our best to perform this as soon as we can and as rapidly as we can because we think it will be a significant value driver for us. Today, the feedback that we get from top [indiscernible] leaders in the field is that there is a very strong need for the concept that we are bringing. So for us, we think it's very strategic.

Doug Miehm
Okay. Perfect. That's a nice segue into my next question with respect to the marketplace today. The physicians are calling for a product like this. Perhaps you could tell us what is available in the market today and why they would prefer a product like this.

Louis Laflamme
Well, today, I would say that the TAVR procedures are being performed with either the SAFARI from Boston Scientific or the Confida from Medtronic. Those wires are wires that can only deliver the valve. In the case of OpSens concept, we are going to be able to have the same [indiscernible] performance to deliver the valve, but at the same time we will be able to measure in a continuous manner pressure to display that to the physician using the OptoMonitor and also to calculate some algorithm that will give the opportunity for the physician to appreciate if they get the pressure, the gradient, the [indiscernible] that they want from their valve implementation.

Doug Miehm
Perfect. And then finally, just in respect to the introduction in this product, perhaps in 2022, but we don't exactly know, is it your intention to introduce that using your own sales force or would you expect this to be part of a future licensing agreement?

Louis Laflamme
I mean, there is always some interest around a licensing agreement. It is a possibility but I would say that the current plan where OpSens is driving the full control is to use the existing sales channel that we have. So, we have a direct sales force in North America. We have distributors in EMEA and Japan, and we think this sales channel can be used to efficiently deliver our TAVR product to the field. When we decided to develop this product, the concept of putting another product in the bag of our sales people was something important, especially in the context where this product can be sold to the same customer. And, we think it will make us more relevant for our customers, more relevant also with our GPO's discussion, and on top of that it will make easier the path of bringing our [indiscernible] managers to profitability.

So, at this time, I would say we still have to evaluate both options but we are very comfortable with both in the context of the benefit that we will get from each option.

Doug Miehm
Okay. Thanks very much.

Operator
As a reminder, if you have a question, please press star then one to be joined into the queue. Our next question comes from Justin Keywood with Stifel. Please go ahead.

Justin Keywood
Good morning, and thanks for taking my call. I just had a couple of questions of clarification just around the comments on growth and the sales and marketing expenses. So, if I heard correctly, you expect growth this year for each of the quarters. I guess my first question, is that sequential growth or year-over-year?

Louis Laflamme
It's both. So, we think we will grow sequentially and we will also grow with the comparative year.

Justin Keywood
Okay, thank you. And then the comments on, and if I heard this correctly, the sales and marketing being relatively flat, is that correct?

Louis Laflamme
I mean, you can expect a certain increase in sales and marketing expenses, but this increase won't be significant in the overall consolidated figures of OpSens.

Justin Keywood
Okay. And, if I interpret, is that just executing on maybe pent-up orders that were perhaps deferred from last year where you don't need that extra sales and marketing expense? Would that be a correct interpretation?

Louis Laflamme
I mean, we are doing both. I mean, we are serving our existing customers but the plan for OpSens is also based on adding new accounts, new partners. The GPO initiative is also a way to expand our customer base and as we get more success with this, we will increase our sales force, which will generate some additional expenses but overall for the full year, based on the total revenue that we are doing, it won't be major.

Justin Keywood
Okay. And what would be the indicator that you're looking out for to increase the sales and marketing team again? Given still a dynamic situation with the coronavirus, is there any metric that you would look to, to possibly increase your sales force again?

Louis Laflamme
Well, obviously the virus is having some impact on this decision and after that, our capability to properly serve our new GPO partners and our customers and also the speed of opening new accounts. So those are indicators that will make our decision easy to add additional people.

Justin Keywood
Okay, understood. Thank you for taking my questions.

Louis Laflamme

Thank you, Justin.

CONCLUSION

Operator
This concludes our question-and-answer session. I would like to turn the conference back over to Louis Laflamme for any closing remarks.

Louis Laflamme
Okay, so, thank you to all participants of this second conference call of OpSens on earnings. We really appreciate your presence and we think that the next few quarters will be very exciting for us. So, thanks for attending and looking forward to being in contact with you.

Operator
The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.