Healthcare

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Sernova Corp. (SVA.TO) Rating: Buy

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Shields Up!; Conformal Coating Protects Transplanted Islet Cells From Immune Surveillance

Stock Data			10/27/2023
Price			C\$0.74
Exchange			TSX
Price Target			C\$6.00
52-Week High			C\$1.28
52-Week Low			C\$0.68
Enterprise Valu	ıe (M)		C\$197
Market Cap (M)		C\$224
Shares Outstar	nding (M)		303.3
3 Month Avg V	olume		64,017
Short Interest (M)		0.09
Balance Shee	t Metrics		
Cash (M)			C\$27.20
Total Debt (M)			C\$0.00
Total Cash/Sha	are		C\$0.09
EPS (C\$) Dilute	ed		
Full Year - Oct	2021A	2022E	2023E
1Q	(0.01)	(0.02)A	
2Q	(0.01)	(0.02)	
3Q	(0.01)	(0.02)	
4Q	(0.01)	(0.02)	
FY	(0.03)	(80.0)	(80.0)
Revenue (C\$M			
Full Year - Oct	2021A	2022E	2023E
1Q	C\$0.0	C\$0.0A	
2Q	C\$0.0	C\$0.0	
3Q	C\$0.0	C\$0.0	
4Q	C\$0.0	C\$0.0	
FY	C\$0.0	C\$0.0	C\$0.0

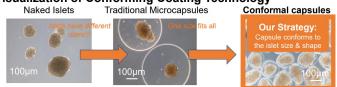


Preclinical data show conformal coating is a safe and effective way of improving islet cell transplant into the Cell Pouch. This morning, Sernova reported preclinical data related to its conformal coating immune protection technology program at the IPITA, IXA, and CTRMS Joint Congress '23. We remind investors, the conforming coating technology was developed to protect islet cells following transplant into the company's Cell Pouch device, and reduce dependency on immunosuppressive medications. The process is also predicted to increase the safety and efficacy of the strategy, without altering cell function, in T1D patients. Key takeaways, per the study authors, include:

- The final conformal coating exhibits significantly improved cell compatibility and overall biocompatibility.
- Coated islets were tested, in combination with the Cell Pouch, in a syngeneic animal model of T1D to assess the safety and efficacy of the combined product.
- Biocompatibility of coated islets in the Cell Pouch was confirmed histologically demonstrating healthy islets within the vascularized tissue matrix; moreover, normal physiological transfer of glucose-stimulated insulin from the conformal coated islets within was confirmed.
- A series of studies using conformal coated islets, using the Cell Pouch, in an allogeneic rat model of T1D established the optimal conditions to achieve diabetes reversal.
- Significant progress has been achieved in manufacturing of the coating scale up equipment; a significant step towards preparing for clinical endeavors.

Although this morning's disclosure pertains primarily to pilot studies, protocol refinements, and formulation optimizations, we believe these data are particularly compelling. Sernova and its collaborators have a history of conducting comprehensive preclinical and investigational work to establish the Cell Pouch's activity in T1D and metabolic diseases. These results are another nice addition this growing body of work. The conformal coating technology has the potential to significantly enhance the islet cell translation protocol. If success in clinical trials, the conformal coating could boost the safety and longevity of the company's treatment strategy, provide even more clinical benefit for patients, and increase the value of the device and the procedure, in our opinion.

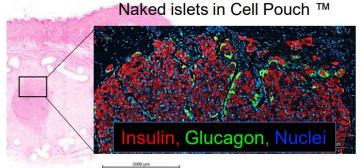
Visualization of Conforming Coating Technology



Source: Tomei A., IPITA, IXA, and CTRMS Joint Congress '23 presentation.

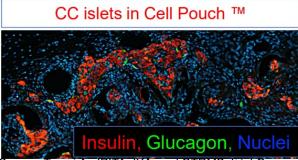
Using histology and immunofluorescence, investigators compared the function of 'naked' vs. conformal coated (CC) islets in the cell pouch. Compared to naked islets (top panel), CC islets appear to produce similar amounts insulin and other metabolic molecules critical in blood sugar regulation (bottom panel). These results suggest the conformal coating technology is not negatively affecting islet cell function in the device.

'Naked' Islet Cells Within the Cell Pouch



Source: Tomei A., IPITA, IXA, and CTRMS Joint Congress '23 presentation.

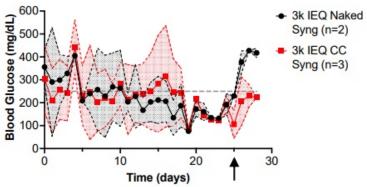
Conformal Coated Islet Cells Within the Cell Pouch Functional Normally



Source: Tomei A., IPITA, IXA, and CTRMS Joint Congress '23 presentation.

- To better evaluate the function of coated islets, a series of animal transplant experiments were conducted using islet cells and Sernova's Cell Pouch device.
- These preclinical experiments demonstrate translated conformal coated islets are effective at potentially treating diabetes. It should also be noted, in our opinion, although in animals, the inclusion of CC islets led to no discernable safety or tolerability issues.
- The data below support already robust evidence bolstering the Cell Pouch device's potential to treat T1D in a safe and effective manner. The conformal coating appears to only make this case stronger by protecting from immunosurveillance and reducing the dependency on immunosuppresive agents.

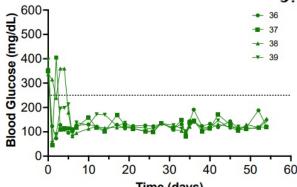
Conformal Coated Islet Cells Improve Blood Glucose Levels in a Syngeneic Rat Model



Source: Tomei A., IPITA, IXA, and CTRMS Joint Congress '23 presentation.

- In an optimized transplant protocol, abatacept is included with the islet transplantation into the Cell Pouch.
- We remind investors, a major goal of developing the conformal coating technology is to reduce the number of and time on immunosuppressive agents following islet cell transplant.
- Here, investigators demonstrate the addition of a single immunomodulating molecule is sufficient to maintain improvements to blood glucose, weight gain, and C-peptide levels (data not shown) following transplant.

Conformal Coated Islet ells Reverse Diabetes Using an Optimized Protocol



Time (days)
Source: Tomei A., IPITA, IXA, and CTRMS Joint Congress '23 presentation.

Cell Pouch Phase 1/2 trial continues a steady march forward. Last week, Sernova provided an interim look and lessons learned from its ongoing Phase 1/2 clinical trial assessing its Cell Pouch device in Type 1 diabetes (T1D) and hypoglycemia unawareness during an oral presentation at the IPITA, IXA, and CTRMS Joint Congress. Recall, this study consists of two cohorts: Cohort A and Cohort B. Cohort A utilizes the 8-channel Cell Pouch device (n=6), while Cohort B employs an 10-channel device (>50% greater capacity compared to 8-channel; n=7) in tandem with a better-tolerated immunosuppressive regimen. The primary objective of the study is to better assess the safety and tolerability profile of allogeneic islet transplantation into a pre-vascularized Cell Pouch in patients experiencing T1D, impaired hypoglycemia awareness, and a history of severe hypoglycemic episodes. Key takeaways from the trial thus far, per the authors, include:

- 5/6 (83%) patients in Cohort A discontinued insulin therapy following islet transplantation into the Cell Pouch and modest islet top-up via portal vein (post-transplant follow-up periods ranging from 6 months to 3.5 years).
- 6/6 (100%) patients achieved HbA1c values in the non-diabetic range (<6.5%);
- 6/7 planned patients of Cohort B have received the higher capacity 10-channel Cell Pouch and 5/7 of panned patients have received a first islet transplant.
- Stable fasting and stimulated serum C-peptide levels were observed following a single islet transplant into the 10-channel Cell Pouch in the first assessable Cohort B patient that subsequently achieved insulin independence with a modest portal vein top up. The same patient showed modest but favorable improvements in HbA1c.
- Implantation with both the 8-channel and 10-channel cohorts were well tolerated.
- For additional data and analysis from this presentation refer to our previous note: <u>Efficacy Matures in T1D With Continued Striking Insulin Independence</u>; <u>Reiterate Buy</u>

Moreover, as part of the presentation, the company highlighted numerous aspects of protocol optimization learned from Cohort A that can be applied to Cohort B (i.e., optimal suspension technique and islet density for most robust results). We believe these observations should help increase the likelihood of the trial's success and improve the device's overall efficacy and safety profile. We are particularly interested in how the 10-channel device can improve on the 8-channel with a capacity to accommodate higher islet dose at target concentrations that is predicted to lead to insulin independence. The updated data from this presentation, in our opinion, are encouraging and indicative of the Cell Pouch's potential. Despite early clinical evaluation, the signals of a favorable safety profile in tandem with impressive response rates support Sernova's strategy and justify further investigation, in our opinion. We are encouraged by the trial's progress and look forward to data and updates in the near future that we believe should provide welcome guidance related to the design, initiation, and timeline of a possible Phase 3 pivotal study.

Valuation and risks to price target achievement. We reiterate our Buy rating and C\$6 price target; we also believe visibility for the company should increase around its opportunities around its Cell Pouch system across multiple indications starting with T1D in driving insulin independence in patients. To this end, we value Sernova on the proverbial low-hanging fruit addressing hypoglycemic unawareness patients being monitored by their physicians. We project that the Cell Pouch system could reach the market in the U.S. in 2027, and assign a 25% chance of success on sales of \$2.3 billion; importantly these peak sales are based on a very low approximate 2.1% market penetration in the hypoglycemic unawares population. We believe the market could be significantly larger with the broader T1D population and the continuing dramas surrounding insulin supply and its costs. Currently, the data support, at the minimum, a two-year, cell implant impact on insulin independence, which we believe has a significant impact on the broader healthcare costs of T1D patients. Our price target is based on our clinical net present value (NPV) model, which allows us to flex multiple assumptions affecting a drug's potential commercial profile. Factors that could impede reaching our PT include failed or inconclusive clinical trials, the inability of the company to secure adequate funding to progress its drugs through the development pathway or the occurrence of dilutive capital raises.

(CDN\$ in millions except per share data) - October fiscal year

Profit & Loss	2019A	2020A	2021A	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Licensing and R&D revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Milestone revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Product and Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	151.2	600.1
Other revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	151.2	600.1
CoGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	18.1	72.0
Gross Profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	133.1	528.1
Gross margin	0%	0%	0%	0%	0%	0%	0%	0%	88%	88%
G&A	2.0	2.5	2.3	9.2	9.7	11.4	13.9	16.4	18.4	21.2
R&D	2.0	2.8	4.6	13.4	15.0	19.9	23.5	27.0	33.7	45.5
Other op ex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ЕВІТ	(4.0)	(5.3)	(6.9)	(22.6)	(24.6)	(31.3)	(37.4)	(43.4)	80.9	461.4
EBIT margin	nm	54%	77%							
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Amortization Intangibles	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA	(4.0)	(5.3)	(6.9)	(22.6)	(24.6)	(31.3)	(37.4)	(43.4)	80.9	461.4
EBITDA margin	nm	54%	77%							
Non operating expenses	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Interest Income/Other	0.0	(0.1)	(0.0)	0.0	0.0	0.0	0.1	0.3	0.3	0.3
Interest expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBT	(4.0)	(5.3)	(7.0)	(22.5)	(24.6)	(31.3)	(37.3)	(43.1)	81.2	461.7
EBT margin	nm	54%	77%							
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	20.3	115.4
Net Income	(4.0)	(5.3)	(7.0)	(22.5)	(24.6)	(31.3)	(37.3)	(43.1)	81.2	461.7
Participation of preferred stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income to common	(4.0)	(5.3)	(7.0)	(22.5)	(24.6)	(31.3)	(37.3)	(43.1)	60.9	346.3
net margin	nm	40%	58%							
Number of shares - basic	175.9	197.3	245.5	266.4	292.0	301.5	309.3	350.0	355.4	368.0
Number of shares - diluted	175.9	197.3	245.5	266.4	292.0	301.5	309.3	350.0	362.0	385.0
EPS - basic	(0.02)	(0.03)	(0.03)	(80.0)	(80.0)	(0.10)	(0.12)	(0.12)	0.17	0.94
EPS - diluted	(0.02)	(0.04)	(0.03)	(80.0)	(80.0)	(0.10)	(0.12)	(0.12)	0.17	0.90
Source: SEC filings and H.C. Wainwright estimates.										

Source: SEC filings and H.C. Wainwright estimates.

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Quarterly P&L	Jan	Apr		Jul			Oct	Jan	Apr		Jul			Oct
October fiscal year - CDN\$	Q1'21A	Q2'21A	H1'21A	Q3'21A	9M'21A	Q4'21A	FY'21A	Q1'22A	Q2'22E	H1'22E	Q3'22E	9M'22E	Q4'22E	FY'22E
Licensing and R&D revenue	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Milestone revenue	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Product and Royalties	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Other revenues	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Revenues	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Gross Profit	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Gross margin	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
G&A	0.49	0.57	1.05	0.68	1.73	0.57	2.3	2.29	2.30	4.59	2.31	6.90	2.31	9.2
R&D	0.68	1.11	1.79	0.96	2.75	1.89	4.6	3.17	3.23	6.40	3.41	9.81	3.54	13.4
Other op ex	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBITDA	(1.2)	(1.7)	(2.8)	(1.6)	(4.5)	(2.5)	(6.9)	(5.5)	(5.5)	(11.0)	(5.7)	(16.7)	(5.9)	(22.6)
EBITDA margin	((,	(===,	(,	(333)	(,	nm	(,	(,	(,	(,	(,	(,	nm
Non operating expenses	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Net Interest Income/Other	(0.33)	0.01	(0.32)	0.01	(0.31)	0.28	(0.0)	(0.00)	0.01	0.01	0.01	0.02	0.01	0.0
Interest expense	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBT	(1.5)	(1.7)	(3.2)	(1.6)	(4.8)	(2.2)	(7.0)	(5.5)	(5.5)	(11.0)	(5.7)	(16.7)	(5.8)	(22.5)
EBT margin							nm							nm
Provision for taxes	0.00	0.01	0.01	0.00	0.01	(0.01)	0.0	0.00	0.00	0.00	0.00	0.00	(0.00)	0.0
Participation of preferred stock							0.0							0.0
Net Income to common	(1.5)	(1.7)	(3.2)	(1.6)	(4.8)	(2.2)	(7.0)	(5.5)	(5.5)	(11.0)	(5.7)	(16.7)	(5.8)	(22.5)
net margin							nm							nm
NoSH	211.9	236.7	224.27	239.77	229.44	260.00	245.52	261.5	264.8	263.13	268.20	264.82	271.30	266.44
NoSH	211.9	236.7	224.27	239.77	229.44	260.00	245.52	261.5	264.8	263.13	268.20	264.82	271.30	266.44
EPS - basic	(0.01)	(0.01)	(0.01)	(0.01)	(0.02)	(0.01)	(0.03)	(0.02)	(0.02)	(0.04)	(0.02)	(0.06)	(0.02)	(80.0)
EPS - diluted	(0.01)	(0.01)	(0.01)	(0.01)	(0.02)	(0.01)	(0.03)	(0.02)	(0.02)	(0.04)	(0.02)	(0.06)	(0.02)	(80.0)

Source: SEC filings and H.C. Wainwright estimates.

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Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

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Distribution of Ratings Table as of October 27, 2023									
			IB Se	IB Service/Past 12 Months					
Ratings	Count	Percent	Count	Percent					
Buy	565	89.40%	142	25.13%					
Neutral	58	9.18%	10	17.24%					
Sell	0	0.00%	0	0.00%					
Under Review	9	1.42%	3	33.33%					

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