Sernova Corporation

Further Corroboration of Cell Pouch's Islet Function-Preserving Activity In Ongoing Phase I Type I Diabetes Trial – Spec BUY

SVA-TSXV: $0.25
Speculative BUY
$1.00 Target

Event: Sernova provided another interim update from another initially enrolled subject in the firm's ongoing University of Chicago-based Juvenile Diabetes Research Foundation (JDRF)-supported seven-patient type I diabetes (T1D) trial testing the firm's lead implantable cellular therapy reservoir technology Cell Pouch as a pancreatic islet-preserving platform. Herein the firm again demonstrated that Cell Pouch-incorporated pancreatic islets were able to support C-peptide and insulin production at least one month after implantation, an encouraging supplemental finding that is consistent with data from the first enrolled patients as described in our July 3rd note and for which 90-day sustained blood glucose control, along with C-peptide and insulin release, were also documented by University of Chicago collaborators.

Bottom line: device indicative of restoring insulin function, though function is exogenously rather than endogenously produced. The key takeaway in our view is that Cell Pouch continues to perform to our expectations as an immune surveillance-avoiding, function-preserving cell reservoir for pancreatic islet cells in vivo, and we expect future enrolled subjects in this and future trials to perform similarly. Our model assumes that enrollment continues and that final 90-day follow-up data from all seven subjects (assuming that full enrollment would be necessary to justify concluding the trial) could be available during F2020.

C-peptide detection is a widely-accepted measure of islet function and insulin release, and thus is a reasonable biomarker for assessing Cell Pouch function: Returning to the press release, the patient evaluated was observed to have fasting C-peptide (a 31-amino acid peptide that is a precursor of insulin but does not influence blood glucose levels on its own until biochemically processed in the body) in the patient's bloodstream at follow-up, but was specifically enrolled because of an inability of endogenous islets to produce insulin, meaning that any C-peptide detected in Cell Pouch-implanted patients must be derived from islets contained within Cell Pouch and not from the patient's disease pancreas itself. Moreover, quantifying C-peptide as a secondary measure of islet function avoids the challenges associated with quantifying endogenously-produced insulin in patients requiring insulin pharmaceutical supplementation.

Enrolment criteria for the trial specifically states that patients are not producing C-peptide (C-peptide negative), and thus the detection of C-peptide in the bloodstream is a significant finding. In this patient's case, the C-peptide was identified while the patient was undergoing an overnight fast (the other method of measuring levels of C-peptide is via a glucose tolerance test). The presence of C-peptide even in the absence of food indicates normalizing response in T1D patients, wherein patients are often subject to fluctuating blood sugar levels which can predispose patients to hypoglycemic unaware events and for which could have life-threatening implications.

Multiple milestones on the horizon and not just in type I diabetes: On milestones from this seven patient trial, we still anticipate that the firm could provide additional interim updates from the trial. Since the primary endpoint for the trial is Cell Pouch-based adverse event rate out to one-year, we continue to be somewhere in the midpoint of the trial and thus anticipate further case data to come out until formal conclusion of T1D testing by end-F2020 (primary endpoint of the trial is expected to conclude by H220).

Projected Return: 308%
Valuation: NPV (40% disc rate), 20x EPS, 12.5x EV/EBITDA (F2024)

Market Data

Market value (C$M)	$53.7
Total debt (C$M, most recent Q)	$0.0
Proforma Cash (C$M, most recent Q)	$6.1
Ent Value (C$M)	$47.5
Shares out. (M; basic)	219.1
Shares out. (M; fd)	281.7
Avg. Daily Volume (000)	354.5
52 Week Range	0.145-0.285
Fiscal year-end	Oct-31
52 Week High	0.285
52 Week Low	0.145

Milestone Forecasts (calendar year)

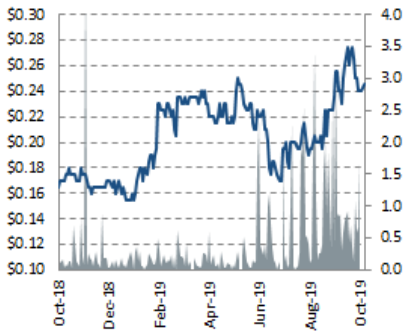
Update US-based Phase I/II Cell Pouch testing, islet transplantation (Jul/19)	Q3-19
Update on hemophilia A/thyroid programs	H2-19

Financial Metrics

In C$000	F2021E	F2022E	F2023E
Cell Pouch rev, TI/IID	0	380	10,297
Cell Pouch rev, hemo A	0	0	923
Cell Pouch rev, thyroid	0	0	0
Islet replace rev, T2D	0	0	23,170
Total product rev	0	380	34,390
EBITDA	(2,365)	(1,864)	2,500
Net income (fully-taxed)	(2,750)	(2,244)	1,381
EPS (fd, fully-taxed)	($0.01)	($0.01)	$0.01
P/E	NA	NA	24.7x
EV/EBITDA	NA	NA	15.5x

Company Description

Sernova is an ON-based medical technology & cell therapy developer, with lead implantable cell reservoir platform Cell Pouch in early development for targeting type I/II diabetes, hemophilia A, and hypothyroidism



Source: Consensus Data - Capital IQ; Forecasts/Estimates - Echelon Wealth Partners

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On other milestones, we remind readers again that T1D is one of at least three regenerative medicine markets for which Cell Pouch could be successfully developed in. The other two markets includes hemophilia A/Factor VIII deficiency and thyroid deficiency post-thyroidectomy. On hemophilia A, the firm has been relatively silent on recent updates, but we anticipate that data from the firm's collaboration with the EU-based HemAcure Consortium in regards to demonstrating sustainable production of Factor VIII in hemophilia A animal models could be published in peer-reviewed format imminently. On thyroid deficiency, we anticipate that Sernova's R&D collaboration with University of British Columbia-affiliated, St. Paul's Hospital-based surgical oncologist Sam Wiseman could transition from preclinical testing to formal clinical testing in clinical hypothyroidism by H220 or H121. In both Indications, we expect that the solid demonstration of Cell Pouch vascularization without immunologic attack positions the device well to support other regenerative therapies, and not constrained to purely the T1D indication.

Exhibit 1 – Income Statement & Financial Forecast Data for Sernova

(C$000, exc per share data)	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Capital sales, Cell Pouch, T1D	0	0	0	380	10,297	35,967	55,885	52,167	47,989	49,185
Capital sales, Cell Pouch, hemophilia A	0	0	0	0	923	4,664	7,207	9,899	12,747	15,759
Capital sales, Cell Pouch, hyperthyroidemia	0	0	0	0	0	1,445	3,007	5,474	10,171	12,698
Cell therapy, T1D	0	0	0	0	23,170	105,885	234,454	368,875	509,326	663,895
Cell therapy, hemophilia A	0	0	0	0	1,319	7,981	18,075	31,667	48,827	69,626
Cell therapy, hyperthyroidism	0	0	0	0	0	2,064	6,276	13,793	27,484	44,243
Total revenue	**0**	**0**	**0**	**380**	**35,709**	**158,007**	**324,902**	**481,875**	**656,544**	**855,405**
Revenue growth (%, y/y)	*NA*	*NA*	*NA*	*NA*	*9,296%*	*342%*	*106%*	*48%*	*36%*	*30%*
Gross margin	**0**	**0**	**0**	**133**	**16,069**	**84,800**	**191,637**	**306,465**	**448,945**	**587,137**
Gross margin (%)	*NA*	*NA*	*NA*	*NA*	*45%*	*54%*	*59%*	*64%*	*68%*	*69%*
Milestone revenue	(5,000)	(7,500)	(7,500)	(7,500)	(7,500)	(7,500)	(7,500)	(7,500)	(7,500)	(7,500)
R&D expense	7,500	7,500	7,500	7,500	5,000	4,000	4,000	4,000	4,000	4,000
Other operating costs	1,055	1,310	2,365	1,997	16,069	28,441	42,237	57,825	72,220	89,817
EBITDA	**(3,555)**	**(1,310)**	**(2,365)**	**(1,864)**	**2,500**	**59,859**	**152,899**	**252,140**	**380,225**	**500,819**
EBITDA margin (%)	*NA*	*NA*	*NA*	*NA*	*7.0%*	*37.9%*	*47.1%*	*52.3%*	*57.9%*	*58.5%*
EBITDA growth (%, y/y)	*NA*	*NA*	*NA*	*NA*	*NA*	*NA*	*155.4%*	*64.9%*	*50.8%*	*31.7%*
Non-oper expenses (income)	395	390	385	380	375	370	365	360	355	350
Tax expense	0	0	0	0	744	20,821	53,387	88,123	132,955	175,164
Less: tax loss carryforwards	0	0	0	0	(744)	(16,401)	0	0	0	0
Net Income (loss)	**(3,950)**	**(1,700)**	**(2,750)**	**(2,244)**	**2,125**	**55,069**	**99,147**	**163,657**	**246,916**	**325,305**
Net income (loss) (fully-taxed)	(3,950)	(1,700)	(2,750)	(2,244)	1,381	38,668	99,147	163,657	246,916	325,305
EPS (basic)	($0.02)	($0.01)	($0.01)	($0.01)	$0.01	$0.25	$0.45	$0.75	$1.13	$1.48
EPS (fully-diluted, fully-taxed)	**($0.01)**	**($0.01)**	**($0.01)**	**($0.01)**	**$0.01**	**$0.22**	**$0.39**	**$0.64**	**$0.97**	**$1.27**
Shares outstanding (basic)	*219,083*	*219,083*	*219,083*	*219,083*	*219,083*	*219,083*	*219,083*	*219,083*	*219,083*	*219,083*
Shares outstanding (fd)	*281,692*	*255,742*	*255,742*	*255,742*	*255,742*	*255,742*	*255,742*	*255,742*	*255,742*	*255,742*
P/E	*NA*	*NA*	*NA*	*NA*	*24.7x*	*1.0x*	*0.5x*	*0.3x*	*0.2x*	*0.2x*
EV/EBITDA	*NA*	*NA*	*NA*	*NA*	*15.5x*	*0.6x*	*0.3x*	*0.2x*	*0.1x*	*0.1x*

Source: Historicals – Company Information, Forecasts/estimates - Echelon Wealth Partners

On other non-clinical developments, collaborations signed with corporate partners could certainly provide additional upside to our existing Sernova forecasts. While we have not explicitly adjusted our model to reflect the potential of the addition of partners, future potential partnership economics (both cash contributing and share ownership enhancing) will be viewed as a positive for the firm as the firm seeks to expand into larger trials following the conclusion of its main T1D trial. For context, ViaCyte has in place partnerships with CRISPR Therapeutics (CRSP-Q, NR; US$25M deal announced in Sep/18 for the development and commercialization of gene-edited allogeneic stem cell therapies for the treatment of diabetes; deal consists of US$15M in either cash or CRISPR stock as well as US$10M in a convertible promissory note) and Gore (Private; announced in 2017 for the development of implantable cell therapy delivery device that provides protection from immune rejection).

Peer firm ViaCyte recently released clinical data suggesting C-peptide detection as well, showing us that cell therapies can engender strong clinical outcomes when paired with effective Cell Pouch-like technologies: While we are on the topic of ViaCyte, we continue to track activities of the firm, since this is one of Sernova's closest private peers. On that, the firm most recently provided an update at the Cell & Gene Meeting on preliminary data from the firm's PEC-Direct Clinical Trial (55-patient Phase I/II trial in T1D patients with hypoglycemia, and with primary endpoint completion anticipated in Sep/20) as announced in early October. The firm uses a different approach from Sernova, in that the cells used in ViaCyte's VC-02 device are pancreatic precursor cells derived from ViaCyte's proprietary stem cell line; Sernova uses transplanted islet cells. Enrolment criteria is similar to that of Sernova, with patients enrolled only if they are C-peptide negative. Data from that trial showed the initial detection of C-peptide via histological and biochemical measurements in several patients, though it is not clear whether C-peptide was likewise measured via overnight fasting or via other methods. As a reminder, in both Sernova and ViaCyte's case, both sets of patients are under immune suppression medication.

Summary & valuation: We are also taking the opportunity to provide an update on our capital structure assumptions and balance sheet considerations, now that FQ319 financial data are in the public domain and after giving consideration to the firm's recent equity offering. Our model now incorporates fully-diluted S/O of 281.7M, which includes adjusted basic S/O of 219.1M (including 23.4M shares from the recent offering) and 58.8M in pro forma warrants, most of which with an exercise price that is below our one-year PT and thus assumed by us to be eventually converted into basic shares during our forecast period. Cash at quarter end was $1.5M, so which we add $4.6M in new equity capital to bring pro forma cash of $6.1M. The firm has no LT debt, as before.

Exhibit 2 – Valuation Scenarios for Sernova

NPV, discount rate		20%	30%	35%	40%	50%	60%
Implied value per share		$5.89	$2.78	$1.95	**$1.13**	$0.73	$0.40
Price/earnings multiple, F2024	**P/E**	**20%**	**30%**	**35%**	**40%**	**50%**	**60%**
Implied share price[1]	**10**	$0.83	$0.60	$0.52	$0.45	$0.34	$0.26
	20	$1.66	$1.20	$1.04	**$0.79**	$0.68	$0.52
	30	$2.49	$1.80	$1.56	$1.35	$1.02	$0.78
EV/EBITDA multiple, F2024		**5x**	**7.5x**	**10x**	**12.5x**	**15x**	**20.0x**
Implied share price[1]		$0.28	$0.42	$0.56	**$0.70**	$0.84	$1.11
One-year Sernova target price [1]				**$0.87**			

[1] *F2024 EPS (fd) forecast $0.22; EBITDA $59.9M; NPV discounted at 40%; basic S/O 219.1M, fd S/O 281.7M; Proforma cash of $6.1M (FQ319 cash of $1.5M and $4.7M raised from recent financings in Aug/Sep), no LT debt*

Source: Forecasts/estimates - Echelon Wealth Partners

With FQ319 financial data now firmly embedded within our model, **we are maintaining our Speculative BUY rating and one year PT of $1.00 on SVA**, with our valuation still based on NPV (40% discount rate) and multiples of our F2024 EBITDA/EPS forecasts ($59.9M/$0.22, respectively), with our EV calculation incorporating proforma cash of $6.1M and no LT debt, as stated above. We continue to recommend SVA as a Speculative BUY, not because of our lack of conviction in Cell Pouch's medical prospects in endocrinologic cellular/regenerative therapy development (this has been well-documented in published pre-clinical studies independent of new clinical data just described) but just because of its early-stage clinical development. At current levels, our PT corresponds to a one-year return of 308%.

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Company: Sernova Corporation | SVA:TSXV

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Number of recommendations	50	42	15	1	7	1	2
% of Total (excluding Restricted)	43%	37%	13%	1%	6%		
Number of investment banking relationships	13	16	4	0	2	0	0
% of Total (excluding Restricted)	37%	46%	11%	0%	6%		

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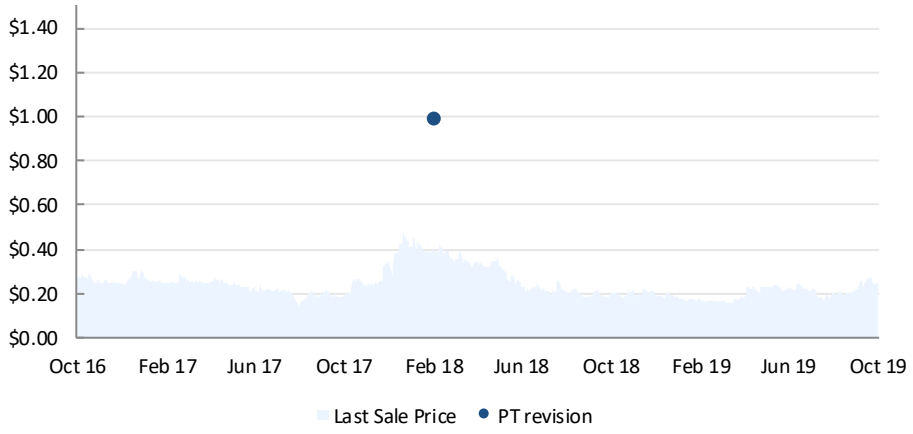

Date	Target ($)	Rating
12 Feb 2018	C$1.00	Spec Buy

Coverage Initiated: Feb 12, 2018

Data sourced from: FactSet

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