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Rating:	Speculative BUY
Target:	\$3.30
Price:	\$0.80
Return:	312%
Valuation:	NPV, 25x EPS, 15x EBITDA
	(F2028; 25% disc)

Market Data

Market value (C\$M)	\$220.2
Total debt (C\$M, most rec Q)	\$0.0
Pro forma Cash (C\$M, most rec Q)	\$52.3
Ent Value (C\$M)	\$167.8
Shares out. (M; basic)	275.2
Shares out. (M; fd)	348.3
Avg. Daily Volume (000)	422.3
52 Week Range	\$0.69-\$2.23
Fiscal year-end	Oct-31
52 Week High	\$2.23
52 Week Low	\$0.69

Expected Milestones (calendar year)

Q422 Update, U.Chicago islet transplant trial Update, hemophilia A/thyroid programs Q123

Financial Metrics

In C\$000	2026E	2027E	2028E
Rev, TI/II Diabetes	\$597	\$15,435	\$52,894
Rev, Hemophilia A	\$0	\$1,055	\$5,435
Rev, Hyperthyroidism	\$0	\$0	\$1,752
Islet replace rev, T2D	\$0	\$35,666	\$158,989
Cell rev, hemo A	\$0	\$1,420	\$8,593
Cell rev, hyperthyroidisn	\$0	\$0	\$2,312
Total product rev	\$597	\$53,577	\$229,973
EBITDA	(\$1,904)	\$31,637	\$137,572
Net income (fully-taxed)	(\$2,389)	\$20,249	\$89,106
EPS (fd, fully-taxed)	(\$0.01)	\$0.09	\$0.31
P/E	NA	8.9x	2.6x
EV/EBITDA	NA	5.3x	1.2x

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



Cell Pouch Design Evolution Proceeds in Parallel with Expanding Phase I/II Diabetes Testing - Spec BUY

ON-based regenerative medicine technology developer Sernova provided an update on design innovations for its implantable cell reservoir platform Cell Pouch. In parallel the firm indicated that it will be supplementing its ongoing Phase I/II islet transplantation/hypoglycemia unawareness clinical trial at the University of Chicago in ways that will employ new Cell Pouch geometry with also-new protocols for islet deployment into revised devices. The firm already has permission from the University of Chicago and from the FDA to proceed on this initiative.

Enhancements to the ongoing University of Chicago-based islet transplantation trial should provide supplemental insights into Cell Pouch's ability to preserve islet function in a broader patient population. In today's update, Sernova indicated that it now has permission to incorporate a revised Cell Pouch design into its University of Chicago trial, with the revised device now incorporating ten distinct channels into which islets can be deployed, as compared to eight channels in the original Cell Pouch design. Adding new channels increases the intra-device volume into which pancreatic islets can be incorporated, while allowing for more flexibility on the number of islets that are introduced into each channel, obviously with potential to incorporate higher numbers of islets in larger patients. We assume that Sernova has completed suitable preclinical studies to show that the new ten-channel device becomes as wellvascularized post-implantation as the first-generation eight-channel device is, but that of course will require confirmation in pending human studies.

Most study details in the expanded trial are conventional and focused on measures of blood glucose homeostasis as the original trial design was. On other study details, Sernova will be enrolling an additional seven patients in the active University of Chicago study, presumably with transplantation surgeon Piotr Witkowski still serving as lead investigator in the expanded trial. We assume that initially-enrolled subjects will continue to be supported with the first-generation eight-channel Cell Pouch devices, but it is possible that some later enrollees could be eligible for implantation of the newer larger devices, if patient characteristics justify the procedure. In the new study protocol, patients will be assessed for supplemental islet cell implantation at three-months after the first islet cell instillation, as compared to at six-month followup beforehand, a decision that should accelerate timelines to final data in all enrolled subjects.

Bottom line. Sernova did not specifically provide any new interim data from patients that had already been enrolled in the seven-patient Phase I/II islet transplantation trial indicated above, and we look forward to seeing how initial patients are performing on Cell Pouch support. Recall that at last update in June/22 at the American Diabetes Association annual meeting, there were three patients for which blood glucose homeostasis was achieved without need for supplemental insulin support, one of which achieved this status for at least two years post-islet implantation (three and six-month insulin independence was achieved for the other two patients at this timepoint).

Clearly, we would today have another 4-5 months of follow-up in these patients alone, and we know from the same ADA presentation that another three patients were also randomized into the trial, from which some early insulin independence data could be also available by now. We look forward to an update on the University of Chicago trial before end-of-year. That said, the decision to expand the University of Chicago trial with another seven patients and with a revised Cell Pouch design suggests to us that existing follow-up data from all previously-enrolled subjects is favorable and supportive of trial expansion.

Exhibit 1. Income Statement and Financial Forecasts for Sernova

Year-end October 31									
(C\$000, excl. per share data)	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Revenue									
Cell Pouch, T1D	0	0	597	15,435	52,894	71,714	67,231	62,155	56,422
Cell Pouch, hemophilia A	0	0	0	1,055	5,435	8,398	11,535	17,826	21,425
Cell Pouch, hyperthyroidemia	0	0	0	0	1,752	4,556	7,584	9,863	11,287
Cell therapy, T1D	0	0	0	35,666	158,989	312,607	467,734	623,600	779,360
Cell therapy, hemophilia A	0	0	0	1,420	8,593	19,459	34,092	56,261	82,383
Cell therapy, hyperthyroidism	0	0	0	0	2,312	8,207	17,827	30,093	43,855
Total revenue	0	0	597	53,577	229,973	424,940	606,003	799,796	994,733
Revenue growth (%, y/y)	NA	NA	NA	8,868%	329%	85%	43%	32%	24%
Gross margin	0	0	329	35,030	151,969	284,758	411,250	546,381	682,943
Gross margin (%)	NA	NA	NA	65%	66%	67%	68%	68%	69%
Milestone revenue	(7,500)	(7,500)	(7,500)	(7,500)	(7,500)	(7,500)	(7,500)	(7,500)	(7,500)
R&D expense	12,500	10,000	7,500	5,000	3,500	3,500	3,500	3,500	3,500
Other operating costs	2,000	2,100	2,233	5,893	18,398	27,621	39,390	51,987	64,658
EBITDA	(7,000)	(4,600)	(1,904)	31,637	137,572	261,137	375,860	498,394	622,285
EBITDA margin (%)	NA	NA	NA	59.0%	59.8%	61.5%	62.0%	62.3%	62.6%
EBITDA growth (%, y/y)	NA	NA	NA	NA	334.8%	89.8%	43.9%	32.6%	24.9%
Non-oper exp (income)	535	485	485	485	485	485	485	485	485
Interest expense	50	0	0	0	0	0	0	0	0
Tax expense	0	0	0	10,903	47,980	91,228	131,381	174,268	217,630
Less: tax loss carryforwards	0	0	0	(10,903)	(17,755)	0	0	0	0
Net Income (loss)	(7,535)	(5,085)	(2,389)	31,152	106,861	169,424	243,993	323,641	404,170
Net inc (loss) (fully-taxed)	-7,535	-5,085	-2,389	20,249	89,106	169,424	243,993	323,641	404,170
EPS (basic)	(\$0.03)	(\$0.02)	(\$0.01)	\$0.11	\$0.39	\$0.62	\$0.89	\$1.18	\$1.47
EPS (fd, fully-taxed)	(\$0.02)	(\$0.01)	(\$0.01)	\$0.09	\$0.31	\$0.49	\$0.70	\$0.93	\$1.28
Shares outstanding (basic)	275,207	275,207	275,207	275,207	275,207	275,207	275,207	275,207	275,207
Shares outstanding (fd)	348,300	348,300	348,300	348,300	348,300	348,300	348,300	348,300	316,705
P/E	NA	NA	NA	9.1x	2.6x	1.7x	1.2x	0.9x	0.6x
EV/EBITDA	NA	NA	NA	5.4x	1.2x	0.7x	0.5x	0.3x	0.3x

Source: Historical Data – Sernova; Forecasts/Estimates – Leede Jones Gable

A key SVA value driver for us will continue to be duration of insulin independence for Cell Pouch patients, an efficacy measure by which Cell Pouch has performed well in clinical testing. Our model assumes that interim data from the trial will be periodically provided as before, and we expect an update on patient performance in the expanded larger-device cohort by mid-C2023. Patients will be monitored for up to three years post-randomization, and while we will of course be interested in duration of insulin independence exhibited over this entire timeframe, we believe that Sernova could advance into more substantive Phase II/III islet transplantation testing before three-year follow-up concludes (details on optimal numbers of islets per channel, on which patients would be eligible for which Cell Pouch design, needs for supportive immunosuppression, and other procedural elements, should be apparent before then).

We are encouraged by the involvement of CRO partners who can accelerate patient randomization, and by protocol revisions that will allow for islet cell re-infusion on a more compressed schedule. Though the primary endpoint in the trial is safety, we believe that the safety threshold for Cell Pouch specifically (independent of any cell therapy payload that is deployed into it) has long been established. As such, we are more focused on secondary endpoints specific to diabetes symptoms, such as duration and magnitude of glucose-responsive C-peptide production (C-peptide is an insulin precursor), on average levels of circulating glycosylated hemoglobin (HbA1c) and on frequency of hypoglycemia events, all conventional endpoints for assessing efficacy of any diabetes-targeted pharmaceutical or device. Sernova indicated that it is working with a CRO to facilitate pace of enrollment in the expanded trial.

The CRO was not named but we already knew that Sernova/University of Chicago were already working with KY-based CTI Clinical Trial & Consulting Services (Private) and the Juvenile Diabetes & Research Foundation. We assume that those relationships will continue. Sernova did not provide any guidance on when/if it would be incorporating its University of Miamiderived confocal islet cell coating technology into future clinical studies, but it seems plausible to assume that this technology could be incorporated into the expanded University of Chicago Phase I/II trial as a way to mitigate immunosuppressive therapy burden that transplantation patients endure.

Exhibit 2. Valuation Scenarios for Sernova

NPV, discount rate		10%	15%	20%	25%	30%	35%
Implied value per share		\$11.90	\$8.38	\$5.99	\$4.34	\$3.19	\$2.36
Price/earnings multiple, F20	28	10%	15%	20%	25%	30%	35%
Implied share price ¹	15	\$3.14	\$2.63	\$2.22	\$1.89	\$1.61	\$1.39
	25	\$5.23	\$4.38	\$3.70	\$3.14	\$2.68	\$2.32
	35	\$7.33	\$6.14	\$5.18	\$4.41	\$3.76	\$3.24
EV/EBITDA multiple, F2028		5x	10x	12.5x	15x	17.5x	20x
Implied share price ^{1,2}		\$0.87	\$1.68	\$2.08	\$2.49	\$2.89	\$3.30
One-year Sernova target pr	ice ^{1,2}			\$3.32			

¹ F2028 EPS (fd) forecast \$0.31; EBITDA forecast \$137.6M; NPV discounted at 25%; basic S/O 275.2M, fd S/O 348.3M

Source: Historical Data – Sernova; Forecasts/Estimates – Leede Jones Gable

No major updates on the Evotec alliance but we assume that a stem cell-derived islet-Cell Pouch combination is advancing well in preclinical testing and could be in the clinic in a year or two. Sernova did not provide any new specifics on its cell therapy alliance with German regenerative medicine firm Evotec SE (EVT-EU, NR), other than that development activities are progressing ahead of expectations. We were of course encouraged to see the firm make its supplemental equity investment into Sernova (\$6.8M, purchasing additional SVA shares at \$2.50 per share, well above current price level and close to our one-year PT on the stock) in Aug/22, and to see that Sernova retains high status in Evotec's investor presentations (in the Oct/22 investor deck). In the deck, Cell Pouch and Evotec's first-generation stem cell-derived QRBeta 1.0 cell therapy platform are identified as being in preclinical development, and we believe that formal clinical testing could commence by FH124 (which Sernova and Evotec stated explicitly as a plausible timeline to IND filing when the alliance was announced), pending sustainably favorably performance of Cell Pouch itself in the University of Chicago trial described above.

Our model still assumes that preclinical Cell Pouch testing in hemophilia A and thyroid disorders is progressing in the background, with potential to advance into formal clinical testing in F2023/24. We already knew that Sernova was developing a larger Cell Pouch variation and we are not surprised that the firm is incorporating the device into an ongoing Phase I/II trial as opposed to opening a new trial at a new transplantation center. Accordingly, today's update is more evolutionary than revolutionary in the history of Cell Pouch development, but we are nonetheless highly encouraged by the growing status of Cell Pouch in the islet transplantation market specifically and as a cell reservoir for regenerative medicine markets in general.

Recall that the firm has at least two other active development programs. One targets hemophilia A for which an alliance with HemAcure has long been in place and for which positive preclinical data showing that Factor VIII-producing endothelial cells functioned well in a Cell Pouch environment. Another program targets thyroid disease for which a development alliance with the University of British Columbia is also active. Sernova reported positive preclinical data last year in collaboration with researcher Sam Wiseman, nicely showing that thymocytes deployed into Cell Pouch preserved the ability to secrete thyroxine in a TSH-responsive fashion (thyroid-stimulating hormone, as produced by the anterior pituitary gland). We look for an update on both of these still-preclinical programs also before end-of-year.

Sernova's regenerative medicine peer group continues to be small and limited primarily to Vertex and the peer firms it acquired in recent years. Sernova's main competitor in the regenerative medicine/device universe is still MA-based Vertex Pharmaceuticals (VRTX-Q, NR), which has made substantial investments in this space through its acquisitions of CA-based

² Proforma cash of \$52.3M (FQ322 cash of \$42.0M, \$3.5M in warrant exercise post-quarter-end & \$6.8M in new equity investment by Evotec in Aug/22), no LT debt

private firm ViaCyte (in July/22 for US\$320M in cash) and of MA-based stem cell biology innovator and Harvard University spinout Semma Therapeutics (in Sept/19 for US\$950M). The latter acquisition is relevant to Vertex's clinical activities testing its stem cell-derived islet cell therapy VX-880, for which a 17-patient Phase I/II islet transplantation trial resumed in Jul/22 after being placed on clinical hold earlier in the year. And the Viacyte acquisition is relevant to a ten-patient Phase I/II type I diabetes trial that Vertex is conducting that is testing VCTX210A, a CRISPR-modified allogeneic pancreatic endoderm cell therapy that is incorporated into a removable perforated Cell Pouch like device, for which early safety data could be available in a quarter or two.

Exhibit 3. Development Pipeline for Cell Pouch and Partnered Technologies

					Clinical Sta	ge	
Cell Pouch Product	Collaborators	Indication	Patient Population(s)	Conceptual	Preclinical	Phase I	Phase II
Human Donor Islets, Systemic immune protection	Univ of Chicago/Piotr Witkowski; JDRF; Medtronic (CGM*)	Diabetes	Hypoglycemia unaware	Interim	data: Jan-21,	Phase I/II final data 2023	
Micro-encapsulated islets	TBD	Diabetes	Insulin dependent diabetic		Preclinical		
Micro-encapsulated stem cell derived cells	TBD	Diabetes	Insulin dependent diabetic		Preclinical		
Corrected patient cells, or FVIII- modified endothelial cells	HemAcure	Hemophilia A	Severe Hemophilia A		Preclinical		
Allograft immune protected cells	TBD	Hemophilia A	Hemophilia A	Conceptual			
Autograft thyroid cells	Univ of British Columbia (Dr. Sam Wiseman)	Thyroid disease	Thyroidectomy Hyperthyroidism		Preclinical		

^{*}CGM = Continuous Glucose Monitors; provided to patients by Medtronic to measure efficacy and track function of transplanted cells in Cell Pouch

Source: Company filings, Leede Jones Gable

A larger 40-patient Phase I/II type I diabetes study testing a distinct cell therapy platform called VCTX211 is also enrolling subjects and could generate one-year efficacy data by mid-2025. Two Phase II diabetes studies that Viacyte itself was funding prior to its acquisition (the cell/device combination was then called PEC-Direct/PEC-01) appear to be active but not recruiting new patients and are still on pace to generate next year. Another publicly-traded stem cell development peer Sigilon Therapeutics (SGTX-Q, NR) is on pace to conduct IND-enabling studies for its stem cell-derived islet formulation SIG-002 in type I diabetes next year, according to its FQ222 financial update.

Summary and valuation. In conclusion, we are encouraged by Sernova's ability to sustainably revisit Cell Pouch design elements so that it can be deployed into a broader array of eligible subjects, specifically diabetic subjects in the just-expanded University of Chicago-supported 14-patient Phase I/II islet transplantation trial. We look for another interim update on how legacy Cell Pouch patients are performing in the trial, specifically on duration of blood glucose stabilization without insulin supplementation, but also on pace of patient enrollment in the expanded trial that we expect to accelerate in coming months and for which we expect initial enrollees to be randomized before calendar year-end.

With Sernova's Cell Pouch clinical activities progressing well and to our expectations, we are maintaining our Speculative Buy rating and one-year PT of \$3.30 on the stock. Our valuation as before is based on NPV (25% discount rate) and multiples of our F2028 adjusted EBITDA/EPS forecasts, as shown in Exhibit 2. For our enterprise value calculation, our model assumes that Sernova has pro forma cash of \$52.3M, including FQ322 cash of \$42.0M, \$3.5M in new capital derived from warrant exercise during Sept/22 and \$6.8M in new equity capital from Evotec through its supplemental purchase of SVA shares (at \$2.50 per share) in Aug/22.

Our PT at current price levels corresponds to a one-year return of 312% and we believe that a sizable proportion of that gap can be narrowed through ongoing advances in the Phase I/II diabetes trial alone, independent of other regenerative markets (hemophilia A, thyroid disease) embedded in our model. As an aside, the valuation gap between the acquisition value of ViaCyte (US\$320M) and Semma (US\$950M) as compared to Sernova (enterprise value of C\$171M as of this writing) is unjustified in our view, based solely on pace of clinical development of the respective firms and on the extent to which Sernova has de-risked Cell Pouch's medical prospects through published preclinical studies in diabetes-hemophilia A-thyroid disease and through Phase I/II performance in the University of Chicago study described above.

Exhibit 4. Publicly-traded Diabetes-Focused or Emerging Regenerative Medicine Firms

Shares price Market cap (\$M) Enterprise value (\$M) Company Curr Sym out (M) 3-Nov (curr) (C\$) (curr) (C\$) Status of lead program Type 1 Diabetes focused therapy developers \$57,474.9 \$57,999.3 Dexcom Inc US Dollar **DXCM** 386.8 \$115.95 \$44,849.5 \$44,443.9 Dexcom G4 Platinum-G5 Mobile; continuous glucose monitoring system; Clarity, diabetes management software; T12M rev US\$669M \$24,463.5 Insulet Corp US Dollar PODD 67.7 \$261.70 \$17,716.6 \$22,911.1 \$18,917.0 Omnipod insulin management/delivery system; T12M rev US\$437M Living Cell Australian LCT 875.7 \$0.01 \$12.3 \$12.0 \$13.8 \$13.5 Porcine-drived alginate-encapsulated islet cells [Diabecell], Technologies Ltd Dollar partnered with Otsuka since Q4-11, missed endpoint in Phase I/II Parkinson's disease trial with NTCELL; new focus on retinal degeneration, hearing loss \$2.85 PharmaCyte's Univ of Technology Sydney-licensed Melligen PharmaCyte US Dollar **PMCB** 15.5 \$44.2 \$57.2 (\$23.1)(\$29.9)cells (insulin-producing cells) encapsulated in cellulose-Biotech Inc based 'cell-in-a-box' technology; pre-IND meeting in Q1-17 US Dollar \$492.0 \$636.3 \$466.3 \$603.0 Eversense implantable CGM system/ fluorescence-based Senseonics **SENS** 422.3 \$1.17 sensor; 71-pt PRECISE study [in Diabetes Care] showed Holdings Inc 81% of hypoglycemic events detected within 30 minutes \$16,323.2 \$16,505.0 Average Emerging cell therapy/regenerative medicine firms \$19.1 \$24.7 \$2.51 \$22.5 \$29.1 MultiStem/MAPC, adult-derived stem cell platform, Phase II. Athersys Inc US Dollar **ATHX** 9.0 ischemic stroke data (89/140 pts completed 90d follow-up) showed promise in patients diagnosed < 36 hrs; US\$205M deal with Chugai [Q1-15] US\$111M deal with Pfizer [Q4-09] BioRestorative US Dollar **BRTX** 1.2 \$3.20 \$4.9 (\$6.2)(\$8.1)Bone marrow-derived autologous mesenchymal stem cells \$3.8 (brtxDISC) for treating lumbar disorders; ThermoStem used Therapies Inc brown fat-derived stem cells for treating type II diabetes Brainstorm Cell \$115.8 \$149.8 Nerve growth factor-secreting NurOwn differentiates US Dollar **BCLI** 36.2 \$3.51 \$127.0 \$164.2 mesenchymal stem cells into MSC-NTF cells; based on Therapeutics Inc. discoveries by E Melamed/D Offen; targets CNS CellSeed Inc Japanese 7776 17.2 ¥132 ¥2,270 \$22.7 ¥1,964 \$19.6 Cartilege cell sheet, in preclinical testing Yen Thermogenesis US Dollar THMO 11.8 \$0.10 \$1.1 \$1.5 \$5.7 \$7.4 Encountering challenges with garnering FDA endorsement of study design for proposed 224-patient critical limb Holdings Inc ischemis trial, using SurgWerks (proprietary stem cell pointof-care kit) US Dollar \$49.9 Firm has its Ortho-ATI product already in market, lead \$3.58 \$35.1 \$38.6 Optical Cable OCC 7.6 \$27.2 autologous product targets tendonitis. Corp HiQ Cell approved in 2014 for a case-by-case treatment Regis Corp US Dollar **RGS** 43.6 \$1.33 \$58.0 \$75.0 \$222.9 \$288.3 option for injured players follicle-derived fibroblast regenerative medicine 32.5 Replicel Life Canadian REPCF \$0.07 \$2.3 \$2.3 \$5.6 \$5.6 Sciences Inc Dollar platform; Phase I/II studies in Achilles tendinosis, skin rejuvenation, alopecia are mostly completed. US Dollar Sigilon SGTX 31.9 \$0.48 \$15.3 \$19.8 (\$52.4)(\$67.8)Developed cell-encapsulating tech called Shielded Living Therapeutics Inc Therapeutics (SLTx), targeting rare blood diseases, endocrine & lysosome storage disorders \$1,201.9 \$545.8 \$705.8 Baculovirus/insect cell and adenovirus manufacturing US Dollar QURF \$20.21 \$929.4 Uniqure NV 46.0 facilities; gene therapy platform focused on hemophilia B (AMT-061), Huntington's disease (AMT-130) US Dollar **VRTX** 257.7 \$310.01 \$79.889.6 \$103.313.2 \$70.248.5 \$90,845.4 Acquired MA-based Semma Therapeutics for US\$950M, Vertex Pharmaceuticals iPSC platform, targeting type I diabetes with VX-880/STx-02; 17-pt Phase I trial in Mar/21, final data in 2028 Inc (\$24.1)Previously sublicensed cardiac stem cell platform to VistaGen US Dollar VTGN 198.0 \$0.13 \$25.7 \$33.3 (\$31.1)BlueRock Therapeutics in Dec/16 Therapeutics Inc \$8,741.9 \$7,665.8 Average Canadian \$208.9 \$208.9 \$144.2 Sernova Corp SVA 261.1 \$0.80 \$144.2 Medtech/regenerative medicine. Cell Pouch in Dollar 1/11 hypoglycemia unawareness partnered in hemophilia A & thyroid disease

Source: Refinitiv, Leede Jones Gable

Disclosures 2

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Hold	The security represents fair value and no material appreciation is expected over the next 12 month time horizon.
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Buy	10	45%
Speculative Buy	7	32%
Hold	5	23%
Sell	-	-
Tender	-	-
Under Review	-	-

Historical Target Price



Date	Target (\$)	Rating
1 Dec 2020	C\$1.00	Spec Buy
18 Jan 2021	C\$2.50	Spec Buy
17 May 2022	C\$3.30	Spec Buy

Coverage Initiated: Dec 1, 2020 Data sourced from: Refinitiv