Sernova Corp.

Initiating Coverage – Transplant Sernova into Your Portfolio: Cell Pouch Tech Could Provide Functional Cure for Diabetes & Other Chronic Diseases

SVA-TSXV: $1.56
Speculative Buy
$3.25 Target

Event – We are initiating coverage of Sernova with a Speculative Buy rating and $3.25 price target, representing 108% upside. Sernova is an early clinical-stage biotechnology company developing a regenerative medicine platform to provide functional cures for chronic diseases such as diabetes, hypothyroidism, and hemophilia A. Its lead technology platform, the Cell Pouch System (CPS) is a complete solution consisting of a novel implantable and scalable medical device that forms a natural vascularized environment for the long-term housing and function of therapeutic cells that release proteins or factors to treat chronic diseases.

- **Cell Pouch System is a Potential 'Functional Cure' for Diabetes and Other Chronic Diseases –** In Type 1 Diabetes (T1D), its most advanced indication, the CPS has demonstrated that it is a safe, organ-like environment for implanted pancreatic islet cells to produce healthy levels of insulin and reduce/eliminate insulin dependence, positioning it as a potential functional cure for the most difficult to manage diabetes patients.
- **Active US Phase I/II T1D Clinical Trial Showing Very Promising Safety and Efficacy Results to Date –** While the trial is small (n=7) and ongoing, the first two patients treated have achieved sustained insulin independence and freedom from severe hypoglycemic events for over 22 and 3 months, respectively, with no serious Cell Pouch-related safety issues.
- **Clear Advantages Over Competing Technologies –** The CPS appears to be safer than competing clinical-stage devices while better controlling T1D symptoms and pathology, according to recent updates from key competitors, ViaCyte and Beta-O2 (both private).
- **Diabetes is a Blockbuster Initial Opportunity; Hypothyroidism and Hemophilia A are Analogous Markets –** While the CPS technology will first target only the highest-risk T1D patients, the potential transformative impact of reducing or eliminating the need for insulin injections or pumps will garner pricing in the US$100-200K range per course of treatment per patient, resulting in a multi-billion-dollar market opportunity in the context of a ~US$50B+ global diabetes drug market. Analogous blockbuster opportunities could follow with thyroid disorders and hemophilia A.
- **Upcoming Clinical and Business Development Milestones are Catalysts for the Stock –** Sernova will provide preclinical and clinical updates on its technology including on its ongoing T1D trial and the initiation of a Phase I/II trial for its hypothyroidism product. In the coming year, we expect the Company to announce formal med-tech/pharma partnerships for Cell Pouch distribution and scalable supply of stem cell-derived therapeutic cells to address supply constraints of donor cells for diabetic patients.

Valuation – We value Sernova at a $3.25/share target price using a probability-adjusted DCF (14% discount rate, 20% probability of approval for lead T1D program, 5% residual growth). Given the significant upside to our target, we are initiating with a Speculative Buy rating while noting the inherent clinical trial risks. This is in line with T1D and hemophilia A focussed cell therapy comparables Semma Therapeutics, which was purchased for ~US$950M by Vertex in 2019, Sigilon Therapeutics, which achieved a valuation of ~US$1.5B in 2020 prior to clinical setbacks, and ViaCyte, which has an estimated private valuation of ~US$0.5-1B.

Projected Return: 108%
Discount Rate: 14%

Sernova Corp.

Market Cap.	Basic (C$M)	407
	FD (C$M)	498
Pro-forma Net Debt	(C$M)	-26
Enterprise Value	FD (C$M)	472
Basic Shares O/S	(M)	261
FD Shares O/S	(M)	319
Avg. Daily Volume	(M)	382
52 Week Range		$1.16 - $2.22

Financial Metrics

FYE - October 31	F2022E	F2023E	F2024E
Revenue ($M)	-	-	-
Gross Profit ($M)	-	-	-
EBITDA ($M)	(14.0)	(26.0)	(33.0)
EPS	($0.06)	($0.10)	($0.11)

Valuation Data

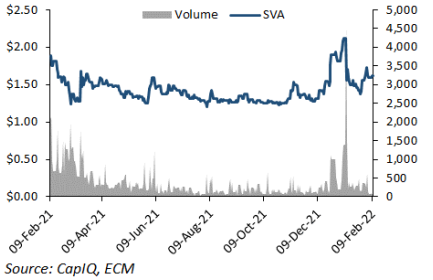
		F2022E	F2023E	F2024E
EV / Sales	SVA	NA	NA	NA
	Peers	16.7x	10.4x	9.3x
EV / EBITDA	SVA	NMF	NMF	NMF
	Peers	84.5x	66.7x	49.8x

Quarterly Data

		FQ1	FQ2	FQ3	FQ4
Revenue ($M)	2020A	0.0	0.0	0.0	0.0
	2021E	0.0	0.0	0.0	0.0
	2022E	0.0	0.0	0.0	0.0
EBITDA ($M)	2020A	(1.1)	(1.5)	(1.0)	(0.8)
	2021E	(1.0)	(1.7)	(1.5)	(1.8)
	2022E	(2.2)	(2.8)	(3.9)	(5.1)
EPS	2020A	($0.01)	($0.01)	($0.01)	($0.01)
	2021E	($0.01)	($0.01)	($0.01)	($0.01)
	2022E	($0.01)	($0.01)	($0.02)	($0.02)

Company Description

Sernova Corp. is a clinical-stage regenerative medicine company focused on the development and commercialization of its proprietary Cell Pouch System and associated technologies, including Conformal Coating for local immune protection of therapeutic cells. Its Cell Pouch system is a medical device thta creates a vascularized tissue environment for the transplantation of therapeutic cells or tissues to treat chronic diseases, such as diabetes, hemophilia, and hypothyroid disease. Sernova Corp. was incorporated in 1998 and is headquartered in London, Canada.



Source: CapIQ, ECM

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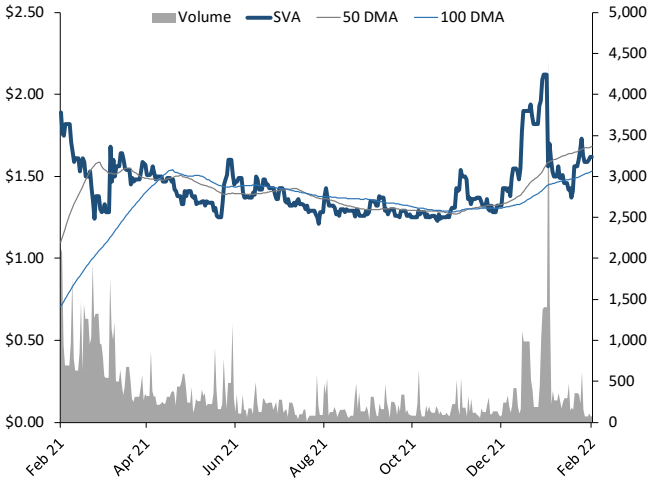
Sernova Corp (TSXV: SVA, $1.56) - Data Sheet

Speculative Buy | PT: $3.25



Company Description

Sernova Corp., a clinical-stage regenerative medicine therapeutics company, focuses on the development and commercializing of its proprietary Cell Pouch System and associated technologies, including the cell pouch and systemic and/or locally immune protected therapeutic cells and tissues. Its Cell Pouch system is a medical device designed to create a vascularized tissue environment for the transplantation and engraftment of therapeutic cells or tissues for the treatment of chronic diseases, such as diabetes, hemophilia, and hypothyroid disease. The company has a research collaboration with AgeX Therapeutics, Inc. to generate immune-protected universal therapeutic cells; and a research agreement with the University of Miami to advance the development of Cell Pouch cell therapy platform. Sernova Corp. was incorporated in 1998 and is headquartered in London, Canada.

Consensus Ratings	3M Ago	Current	Return
Rating:	Outperform	Outperform	
Target:	$2.50	$2.75	76%
Median:	$2.50	$2.75	76%
High:	$2.50	$3.00	92%
Low:	$2.50	$2.50	60%

Consensus Distribution	
Outperform/Buy	2
Perform/Hold	0
Underperform/Sell	0
# Est	2

Key Statistics		
52-Week High	$2.22	42%
52-Week Low	$1.16	(26%)
Avg Vol (3-Mo)	382	
Shares Outstanding	319	
Market Cap (FD)	498	
Net Debt	-26	
Enterprise Value	472	
Div Yield	0.0%	
FYE	Oct	

Key Financial Metrics

Sernova Corp.	F2020A	F2021E	F2022E	F2023E	F2024E	F2025E	F2026E	F2027E	F2028E	F2029E	F2030E	F2031E	F2032E
Revenue	-	-	-	-	-	-	-	**148.4**	**428.7**	**649.5**	**848.1**	**1,022.8**	**1,162.7**
Growth y/y	-	-	-	-	-	-	-	*NA*	*189.0%*	*51.5%*	*30.6%*	*20.6%*	*13.7%*
Consensus Revenue			-	-	-	-	0.3	135.8	345.5	577.5	766.0	-	-
Gross Profit	-	-	-	-	-	-	-	**96.4**	**278.7**	**428.6**	**559.7**	**685.2**	**779.0**
Gross Margin	-	-	-	-	-	-	-	*65%*	*65%*	*66%*	*66%*	*67%*	*67%*
Consensus Gross Margin			-	-	-	-	-	*65%*	*66%*	*67%*	*68%*	-	-
EBITDA	(4.4)	(5.9)	(14.0)	(26.0)	(33.0)	(40.0)	(47.0)	(3.3)	154.8	291.1	404.5	517.7	599.9
EBITDA Margin	-	-	-	-	-	-	-	*-2%*	*36%*	*45%*	*48%*	*51%*	*52%*
EBITDA Margin Growth y/y								*-2 bps*	*38 bps*	*9 bps*	*3 bps*	*3 bps*	*1 bps*
Consensus EBITDA			(6.2)	(13.9)	(20.9)	(24.0)	(25.4)	117.3	291.4	487.9	643.0	-	-
EPS	$ (0.03)	$ (0.03)	$ (0.06)	$ (0.10)	$ (0.11)	$ (0.12)	$ (0.14)	$ (0.02)	$ 0.29	$ 0.56	$ 0.78	$ 0.99	$ 1.15
Consensus EPS			*$ (0.01)*	*$ -*	*$ (0.03)*	*$ (0.02)*	*$ (0.01)*	*$ 0.10*	*$ 0.36*	*$ 0.56*	*$ 0.81*	*$ -*	*$ -*

Comparables

Name	Ticker	Last Price US$	Market Cap FD	EV (US$M) FD	Returns 1 Month	3 Month	YTD	1 Year	EV/Sales F2021	F2022	F2023	EV/EBITDA F2020	F2021	F2022
Sernova	**SVA**	**$1.56**	**407**	**472**	**-24%**	**13%**	**-11%**	**-24%**	**NA**	**NA**	**NA**	**NMF**	**NMF**	**NMF**
Type 1 Diabetes Comps														
DexCom	DXCM	$566.36	52,444	51,408	-10%	-33%	-21%	6%	16.7x	13.7x	11.4x	84.5x	66.7x	49.8x
Insulet	PODD	$323.01	21,722	22,267	-1%	-21%	-7%	-12%	16.3x	13.8x	11.4x	104.3x	84.5x	65.2x
Tandem Diabetes Care	TNDM	$154.68	9,530	9,176	-10%	-13%	-22%	16%	10.6x	8.8x	7.2x	176.5x	85.4x	51.5x
Average					**-7%**	**-22%**	**-16%**	**3%**	**14.5x**	**12.1x**	**10.0x**	**121.8x**	**78.9x**	**55.5x**
Median					**-10%**	**-21%**	**-21%**	**6%**	**16.3x**	**13.7x**	**11.4x**	**104.3x**	**84.5x**	**51.5x**
Cell Therapy/Regenerative Medicine Comps														
Sangamo Therapeutics	SGMO	$7.54	1,043	430	-17%	-47%	-25%	-63%	3.1x	2.8x	2.7x	NMF	NMF	NMF
uniQure	QURE	$22.78	1,019	420	-11%	-51%	-16%	-55%	0.7x	2.5x	2.5x	1.1x	NMF	NMF
VistaGen Therapeutics	VTGN	$2.05	396	291	-11%	-33%	-20%	-17%	250.5x	190.7x	190.7x	NA	NA	NA
Athersys	ATHX	$1.22	281	230	8%	-29%	4%	-66%	24.5x	7.1x	7.1x	NMF	NMF	NA
Brainstorm Cell Therapeutics	BCLI	$4.08	147	119	-15%	5%	-20%	-56%	NA	NA	NA	NA	NA	NA
Pluristem Therapeutics	PSTI	$2.29	73	39	22%	-37%	23%	-77%	NA	NA	NA	NMF	0.4x	0.1x
Lineage Cell Therapeutics	LCTX	$1.93	311	230	-27%	-42%	-41%	-49%	48.9x	12.1x	12.1x	NMF	NMF	NMF
Sigilon	SGTX	$2.29	70	-64	-31%	-67%	-38%	-96%	NMF	NMF	NMF	0.7x	0.7x	0.7x
SanBio	4592	$12.05	624	584	-7%	-7%	9%	-36%	115.1x	NA	NA	NMF	NMF	NMF
Average					**-10%**	**-34%**	**-14%**	**-57%**	**73.8x**	**43.1x**	**43.0x**	**0.9x**	**0.6x**	**0.4x**
Median					**-11%**	**-37%**	**-20%**	**-56%**	**36.7x**	**7.1x**	**7.1x**	**0.9x**	**0.6x**	**0.4x**

Source: Consensus Data, Chart - CapIQ, Historical Data – Company Filings, Forecasts / Estimates – Echelon Capital Markets

Company Overview and Milestones

Functional Cures for Chronic Diseases

Headquartered in London, Ontario, Sernova is a clinical-stage biotechnology company using a regenerative medicine platform to deliver long-lasting cell therapies that eliminate the need for chronic medication in debilitating diseases such as T1D, hemophilia A, and postoperative hypothyroidism. The common underlying driver of these three conditions is that at least one protein or hormone critical to bodily function is not being produced properly by the patient's cells. The missing hormone in T1D patients is insulin and ancillary hormones, in hemophilia A patients it is the blood-clotting protein Factor VIII (FVIII), and postoperative hypothyroidism patients are missing triiodothyronine and thyroxine which are produced by the thyroid gland after it is partially or wholly removed.

Exhibit 1 – Overview of Sernova's Therapeutic Pipeline

Indication	Product Candidate	Therapeutic Cell Source	Immune Protection	Preclinical	Phase I/II	Phase III	Submission	Approval
Type 1 Diabetes	Cell Pouch	Human donor islets	Immuno-suppressives					
	2nd Gen	Human donor islets	Local Immune Protection					
	3rd Gen	Stem cells	Local Immune Protection					
Hemophilia A - Severe	Cell Pouch	Corrected patient cells	Autogenic Cells					
Hemophilia A - All Patients	2nd Gen	Allograft immune-protected stem cells	Local Immune Protection					
Post-operative Hypothyroidism	Cell Pouch	Thyroid cells	Autogenic Cells					
Hypothyroidism - All Patients	2nd Gen	Allograft immune-protected stem cells	Local Immune Protection					

Source: Company Presentation, ECM

Multiple Clinical and Business Development Catalysts on the Horizon

With the seventh and final patient recently identified for the flagship Phase I/II T1D study, we anticipate top-line clinical data to be released by the Company in late C2022 or early C2023, followed by the commencement of the Phase III Pivotal study which we expect to follow into C2025/2026 with marketing of the first generation of the CPS expected in C2027. We anticipate the commencement of Phase I/II trials to explore the use of the patient's own healthy thyroid tissue to correct post-operative hypothyroidism in C2022, and the use of stem cell-derived islets with proprietary local immune protection for the broader, lower-risk T1D population in C2023.

Exhibit 2 – Key Upcoming Clinical Milestones

Indication	Product Candidate	Therapeutic Cell Source	Immune Protection	Milestone	Est. Timing (CY)	Est. Approval (CY)
Type 1 Diabetes	Cell Pouch	Human donor islets	Immuno-suppressives	Clinical Updates	2022/2023	
				Full Phase I/II Results	2022/2023	2027
				Phase III Initiation	2023	
	2nd Gen	Human donor islets	Local Immune Protection	Phase I/II Initiation	2023	2028
	3rd Gen	Stem cells	Local Immune Protection	Phase I/II Initiation	2023	2028
Hypothyroidism	Cell Pouch	Patient cells	None	Phase I/II Initiation	2022	2027
	2nd Gen	Stem cells	Local Immune Protection	Phase I/II Initiation	TBD	TBD
Hemophilia A	Cell Pouch	Corrected patient cells	None	Phase I/II Initiation	2023	2027
	2nd Gen	Stem cells	Local Immune Protection	Phase I/II Initiation	TBD	TBD

Source: Company Presentation, ECM

In addition to clinical milestone updates, we expect business development updates to come in the form of:

- Med-tech partnership for took kit development and potential marketing and distribution of the CPS,
- Pharma collaboration and supply agreements to provide Sernova with stem cell-derived therapeutic cells,
- Non-dilutive funding and grants for clinical development and collaborations, and
- Up-listing from the TSXV to the TSX and NASDAQ exchanges.

Innovative life sciences companies such as Sernova typically lack the internal resources to commercialize products on their own and often opt to collaborate with a larger partner to bring their products to market. We expect Sernova to enter into a distribution partnership with a larger med-tech whereby Sernova develops the CPS while the partner receives payment for distribution of the CPS as well as a surgical tool kit used for quick implantation in an outpatient setting. Similarly, we expect Sernova to enter into an agreement with a pharmaceutical partner for stem cell-derived islet cell supply whereby Sernova licenses the cell technology to be transplanted into the Cell Pouch and pays royalties to the partner on a per use basis once the CPS is approved and marketed.

The Company also intends to up-list from the TSXV to the TSX and NASDAQ exchanges in 2022 – a move that is expected to improve the stock's liquidity and visibility, thus raising its investor profile, and generating interest among institutional investors.

Strong Cash Position as R&D Spend Ramps in F2023 and Beyond

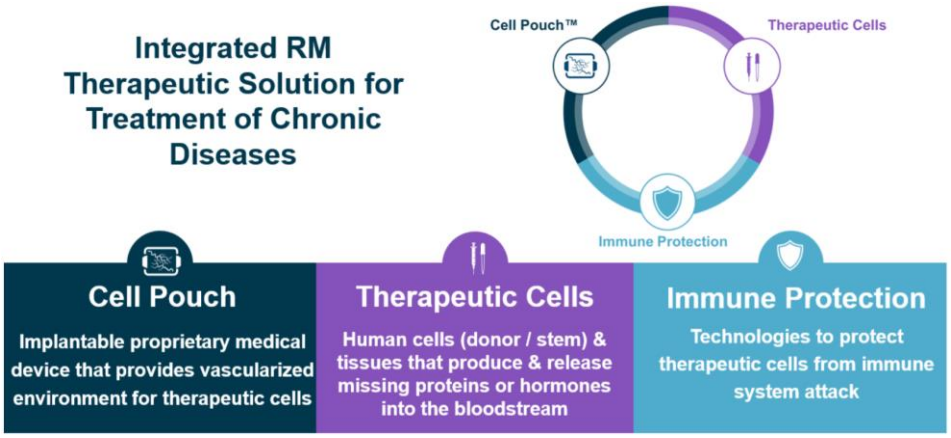
Sernova burned $3.1M and $4.4M in R&D and G&A in F2019 and F2020, respectively, and an estimated ~$5.9M in F2021. We expect the R&D component of this burn to meaningfully accelerate over the coming years as the Company's various technologies progress to successive clinical development stages. With the Company expecting to move its hypothyroidism product to the clinical stage in C2022 and initiate a Phase III study of its Cell Pouch product for T1D in early C2023, we expect cash burn to be ~$14M in F2022, ~$26M in F2023, and climbing meaningfully over the subsequent years. The Company currently has ~$27M in cash as well as a potential ~$45M available from warrants expected to be exercised in the coming 15 months.

Platform Approach – A Trifecta of Promising Functional Cure Technologies

As outlined in Exhibit 3 below, the Company's platform approach to regenerative medicine, collectively named CPS, has three main elements that work in conjunction to provide functional cures for patients.

Sernova's clinical efforts to date have focused on T1D, a chronic condition in which the pancreas produces little or no insulin – the hormone that triggers the body's cells to allow entry of sugar (glucose) for use as an energy source. Despite years of active research, there is no approved cure for T1D, and treatment remains focused on managing blood sugar levels with insulin, diet, and lifestyle to prevent complications.

Exhibit 3 – Overview of Sernova's Platform Approach to Regenerative Medicine



Source: Company Presentation

We believe that Sernova's Cell Pouch provides unique advantages over other cell macroencapsulation devices currently pursuing regulatory approval, and that the Company's conformal coating technology appears superior to immune protection technologies attempted by competitors in past and ongoing clinical and preclinical trials (see pages 19 and 24, respectively).

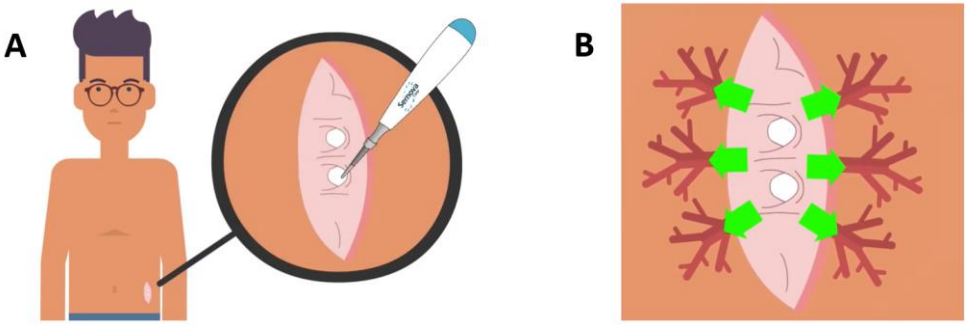
The Cell Pouch – An Organ-like Environment that Allows for Vascularization Without Fibrosis

Sernova's proprietary Cell Pouch, around which the Company's regenerative medicine platform is built, is designed to ameliorate many of the issues that have hindered successful islet transplantation over the last two decades. It is a scalable, implantable, cell therapy device that houses therapeutic cells that release biomolecules for the long-term, hands-off treatment of chronic disease. The Cell Pouch has small cylindrical chambers made from non-degradable polymers with removable plugs. When placed between the superficial and deep fascia, beneath the subcutaneous space, it incorporates with patient's tissue and allows micro blood vessels to penetrate throughout within three weeks, creating an organ-like environment. This vascularization allows for the supply of oxygen and nutrients to the therapeutic cells so that they survive for years and provide a continuous supply of the therapeutic proteins or hormones as needed. This reduces or eliminates the patients' reliance on prescribed medications. The vascularization of the Cell Pouch and its incorporation into tissue also prevents fibrosis (i.e., thickening and scarring of connective tissue), which has plagued competitors' implantable cell therapy devices (see Exhibit 15).

Therapeutic Cells Produce Biomolecules to Treat the Disease

The therapeutic cells in Sernova's first-generation product will be human donor islet cells, which were proven in the late 1990s to produce insulin in response to circulating blood glucose when transplanted directly into the portal vein of diabetic patients' livers. For hypothyroid patients, Sernova's first-generation product will use healthy thyroid tissue salvaged during the removal of the same patient's thyroid gland. For the treatment of hemophilia A, the first generation of therapeutic cells will be the patient's own endothelial cells, isolated from a blood sample, that are then genetically corrected to produce Factor VIII and scaled up for transplantation into the Cell Pouch. The second-generation hypothyroidism and hemophilia A products will use stem cell-derived therapeutic cells with local immune protection, using the Company's proprietary conformal coating (see next section).

Exhibit 4 – Infusion of Therapeutic Cells into the Cell Pouch (A) and Release of Therapeutic Proteins or Hormones (B)



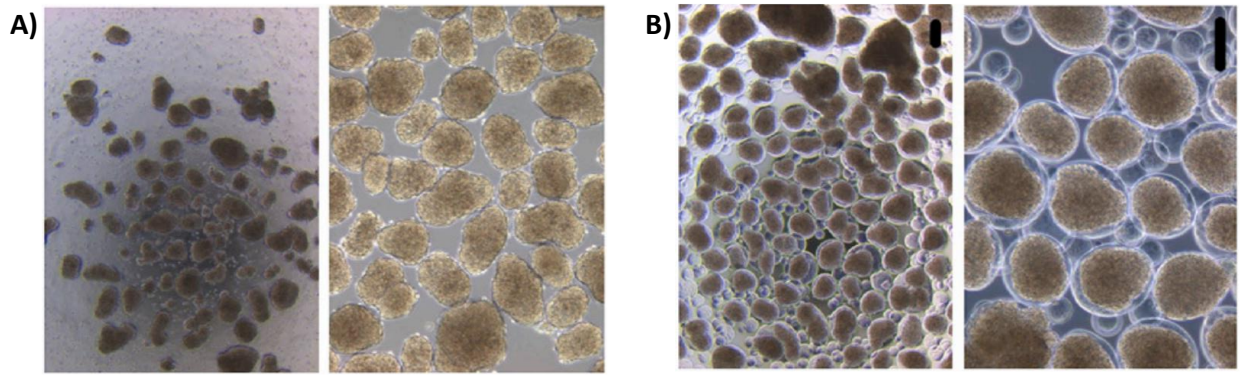
Source: Company Website

Protecting the Therapeutic Cells from the Patient's Immune System

As is the case with any cell therapy using non-self therapeutic cells, concomitant, life-long use of costly immunosuppressive drugs (US$10-14K annually) is required to prevent rejection of the cells by the patient's immune system. As such, high-risk T1D patients using the first generation of the Cell Pouch will be treated with standard of care immunosuppression (typically, Thymoglobulin induction followed by maintenance MMF (Mycophenolic Mofetil) and tacrolimus (Prograf)) as they would be following a portal vein transplant. To avoid the use of these drugs alongside future products, Sernova acquired all IP for a conformal coating technology from Converge Biotech Inc. (private) and the University of Miami in 2020. This conformal coating effectively "shrink-wraps" individual therapeutic cells with a thin crosslinked polymer coating to protect them from being identified by the patient's immune cells, while allowing for efficient transfer of nutrients and other biomolecules and thus full cellular function and survival.

Sernova's second generation T1D product will use conformal coated human donor islet cells, while the third generation T1D product will use highly uniform and scalable stem cell-derived islets also protected by the conformal coating. The company also aims to use this coating to protect stem cell-derived therapeutic cells to treat Hemophilia A and Hypothyroidism patients.

Exhibit 5 – Naked Stem Cells (A) and Conformal Coated Stem Cells (B)



Source: Stock, A.A. Stem Cell Reports, 2019

Multiple Peer Firms Reflect Favourably on Sernova's Cell Therapy Opportunity

Rare disease stalwart, Vertex Pharma (VRTX-NASDAQ, NR), acquired Semma Therapeutics in late 2019 for US$950M in cash with the aim of bringing its cell and device combination to market. Semma's device remains in the preclinical stage while its stem cell-derived islets have shown promise in Phase I/II clinical trials when transplanted directly into the patient's portal vein alongside the standard immunosuppressive drugs.

Privately held ViaCyte has raised US$290M to date, most recently in a US$54M Series D in April 2021, according to Crunchbase data implying a valuation likely in the US$0.5-1B range. ViaCyte has partnered with J&J (JNJ-NYSE, NR) to bring its proprietary macroencapsulation devices and stem cell-derived islets to market. Despite a positive tone from the company, clinical results reported in December 2021 from the Phase I/II study of its flagship embryonic stem cell derived progenitor therapeutic cells and vascularizing device showed that diabetes was not well controlled in the subjects while 5/15 subjects were withdrawn after nine months due to failed risk-benefit assessment.

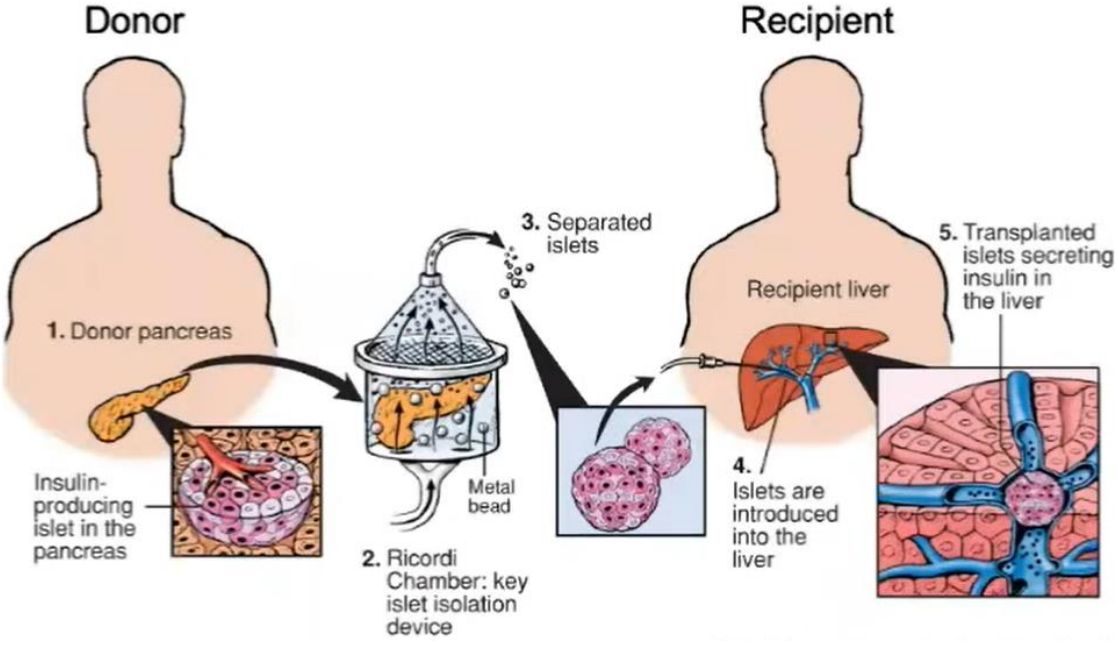
Sigilon Therapeutics (NASDAQ-SGTX) is a biopharmaceutical company that IPO'd in December 2020 at a US$1.05B valuation and reached a peak market cap of US$1.5B in the same month. Prior to this, it announced a strategic collaboration with Eli Lily (LLY-NYSE, NR) to use its cell encapsulation technology alongside Eli Lily's stem cell-derived therapeutic cells for the treatment of T1D. The deal included US$63M upfront, an undisclosed equity investment, US$410M in development and commercialization milestone payments, and single to double-digit royalties on any future product sales. Sigilon's only clinical-stage study, however, a Phase I/II trial of its technology to functionally cure hemophilia A, was put on clinical hold by the FDA in July 2021 due to a severe adverse event stemming from the fibrosis of the encapsulated cells in human subjects. Current valuation of ~US$60M aside, we believe that Sigilon's earlier valuation and partnership with Eli Lily reflected the value of a technology with genuine promise in providing functional cures for chronic diseases.

Portal Vein Transplantation

Trail-Blazing Early Attempts at Functional Cure Leave Significant Room for Improvement

The only cell therapy treatment currently available to hypoglycemia unaware diabetics is direct transplantation of donor islet cells into the portal vein of the liver, where they then lodge in the organ's microvasculature and produce insulin. While successful portal vein delivery demonstrates that transplanted islets do not need to be located in the pancreas to have a therapeutic effect, the longevity of the procedure leaves substantial room for improvement. Between 2007 and 2010, 44% of patients registered with the Clinical Islet Transplant Registry achieved insulin independence at three years, however, 75% of patients required exogenous insulin injections after five years.

Exhibit 6 – Islet Isolation and Portal Vein Transplant Procedure



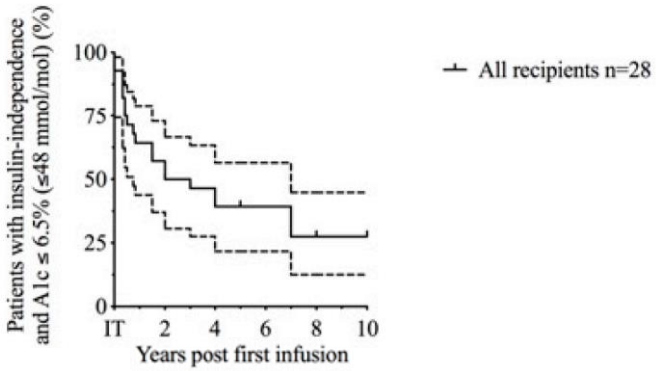
Source: Diabetes Research Institute, University of Miami

Transplanted Cells are Vulnerable to Inflammation-Induced Cell Death in the Portal Vein

Following islet infusion into the portal vein, an immediate blood-mediated inflammatory reaction (IBMIR) often kills off of a substantial proportion of the islets, causing the therapeutic effect to be transient and any insulin independence to be short-lived. Furthermore, the procedure can cause portal vein hypertension, thrombosis, and liver steatosis (fatty liver), limiting the number of times it can be done.

Systemic immunosuppressive drugs are prescribed on a chronic basis to prevent rejection of the transplanted cells, and two or more donors per patient are typically needed due to the cells' low survival rate of 30-50%. For these reasons, along with the paucity of islets from deceased donors, portal vein islet transplantation has been restricted almost exclusively to the highest-risk patients. Only human donor islet cells are currently being used for this use under research protocols as naked stem cell-derived and animal donor cells are not retrievable from the liver if complications occur. The only rectification for such complications would be a total liver transplant.

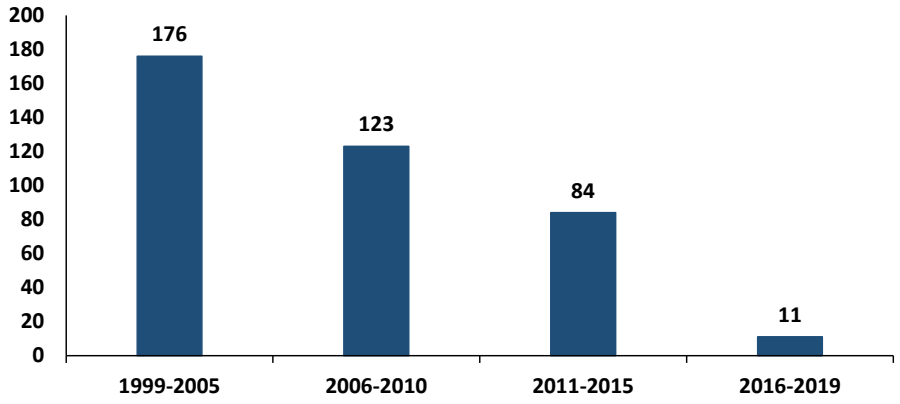
Exhibit 7 – Percentage of Insulin Independent Patients After Portal Vein Islet Transplantation



Source: Vantyghem et. al. Diabetes Care, 2019

Despite early promises, the transient therapeutic effect, paucity of islet donors, and inherent risks have caused interest in portal vein transplantations to dwindle over the last two decades, as shown in Exhibit 8.

Exhibit 8 – Islet Transplant Clinical Trials Funded by the NIH and JDRF



Source: Islets4US, ECM

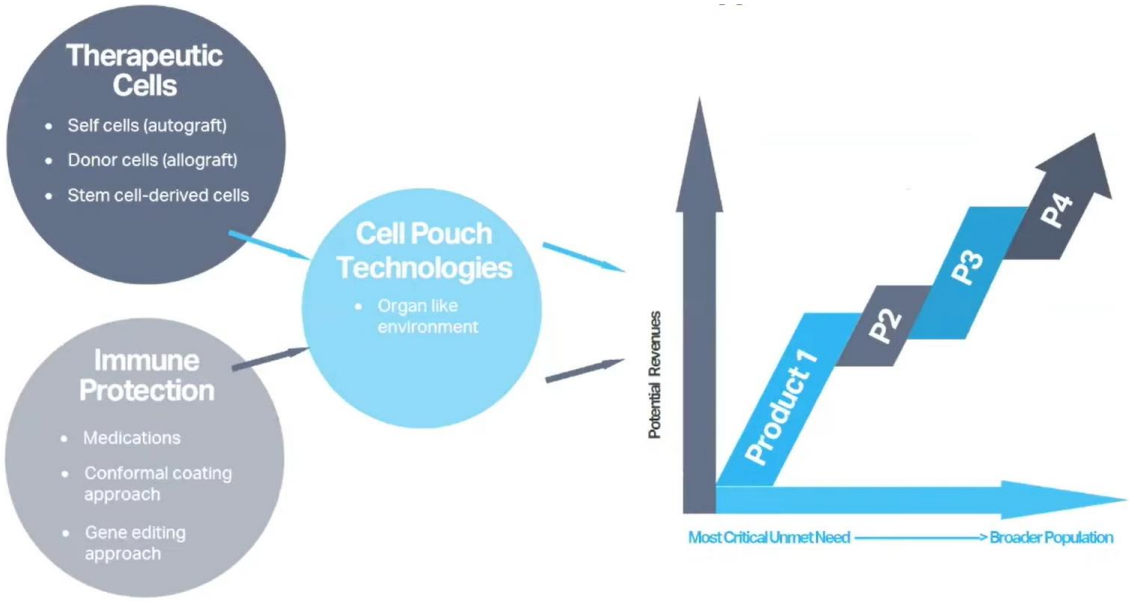
Functional Cures Meaningfully More Palatable Than Traditional Disease Management

T1D, hemophilia, and hypothyroid patients are significantly burdened by the near-constant monitoring and cognisance of certain blood protein levels as well as the injectable, infusion, or oral medications they currently require at least daily. Indeed, improvements in quality of life have been demonstrated in the 6-12 months post portal vein transplantation. As shown in Exhibit 7, however, the insulin independence endowed by portal vein procedures is not long-lived. The CPS, which requires only a handful of minimally invasive, outpatient procedures, has the potential to allow for lifelong insulin independence.

Platform Approach Provides Multiple Revenue Streams

The Company aims to take a multi-stage commercialization approach (see Exhibit 9), with each new approved product increasing the target market and adding a revenue stream. Due to the drawbacks of immunosuppressive therapies, Sernova aims to first prove the safety and efficacy of its Cell Pouch technology on the highest-risk T1D patients – those with the most critical unmet need. Once proven, the technology will be de-risked by replacing the immunosuppressive medications with the conformal coating and any bottlenecks in the therapeutic cell supply will be ameliorated by the use of stem cell-derived islets. As such, the Company will look to expand the clinical studies over time to include much larger, lower-risk populations including all T1D, hemophilia A, and hypothyroidism patients.

Exhibit 9 – Multi-Stage Commercialization Approach



Source: Company Presentation

Clinical Progress to Date – Early Days But Very Promising

Of the CPS-based studies listed in Exhibit 1, the most advanced is the Phase I/II study of T1D treatment using human donor islet cells and immunosuppressive medication. The study's principal investigator, Dr. Piotr Witkowski, MD, Ph.D., is an Associate Professor of Surgery at the University of Chicago as well as the Director of its Pancreatic and Islet Transplant program. Dr. Witkowski regularly attends conferences and meetings to provide updates on the trial, the preliminary results of which are very encouraging and validate the first-generation Cell Pouch product. The next high-profile event of this kind is the American Diabetes Association conference in June 3-7, 2022.

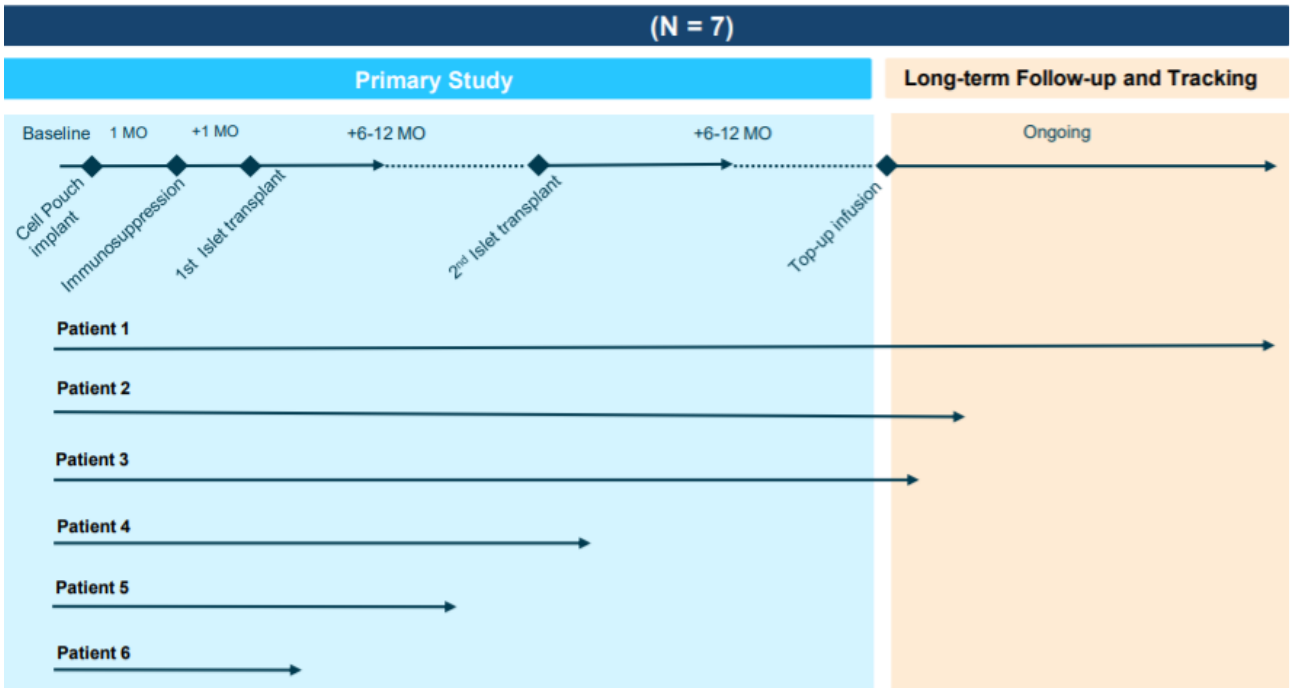
Phase I/II Safety, Tolerability and Efficacy Study of the Cell Pouch

The Phase I/II study of the first-generation Cell Pouch in T1D patients is an open-label, single-arm study involving 7 patients with hypoglycemia unawareness and a history of severe hypoglycemic events. As outlined in Exhibit 10, the patients first undergo Cell Pouch implantation and, a minimum of three weeks later, begin standard of care immunosuppression. Once optimized, a marginal islet mass of approximately 3,000 islet equivalents per kg of patient body weight (IEQ/kg) of purified islet cells is transplanted into half of the Cell Pouch chambers. Six to twelve months later, the patient receives their second marginal islet mass of approximately 3,000 IEQ/kg islet transplant into the second half of the Cell Pouch chambers and, six to twelve months after that, the patient may receive a supplemental marginal dose infusion of islet cells into the portal vein of the liver (see page 6 for an explanation of portal vein infusion). A small sentinel pouch, transplanted alongside the first Cell Pouch, is removed at ~90 days following transplant for an early assessment of islet function within the Cell Pouch. If the cells have not perished in the first 90 days post transplant, it is highly unlikely that they will over a longer duration.

Safety Findings Continue to Meet Primary Endpoints

The primary outcome of the clinical trial is a safety assessment as measured by the incidence and severity of any resultant adverse events within a year of the procedure. At the time of writing, 6 patients have been enrolled and the first 6 have had at least their first islet cell transplant into the Cell Pouch. The 7th patient has been identified. Both the Cell Pouch and islet cells continue to be well-tolerated in patients, having been implanted in the first two patients for 32+ and 30+ months, respectively, with no adverse events traceable back to the Cell Pouches.

Exhibit 10 – Phase I/II Study Design



As of January 2022

Source: Company Presentation

Sustained Efficacy Seen So Far: The Most Advanced Subjects Remain Insulin Independent

The secondary outcomes of the clinical trial include survival of the cells in the Cell Pouch, proportion of participants with a reduction in severe hypoglycemic events, and proportion of participants with a reduction in HbA1c, all at defined intervals of 90 days, 180 days, and 365 days post-implantation.

Early findings from a preliminary analysis of the first patient enrolled in the trial show that, in addition to meeting the safety criteria, purified islets were successfully transplanted. The analysis showed that hypoglycemic events were reduced by 87.5% and that blood levels of insulin and C-peptide, a marker of islet function that is produced alongside insulin, were stimulated as measured by patient-blinded continuous glucose monitoring (CGM) and a mixed meal tolerance test at 90 days post-transplant.

New data were presented in June 2021 wherein six patients had been enrolled in the study and five had been transplanted with at least one dose of the therapeutic islet cells. The longest treated study patients continued to show defined clinical benefit as measured by reduction/elimination of the need for daily injectable insulin, continued reduction/elimination of severe hypoglycemic events, persistent detection of fasting and stimulated C-peptide in the bloodstream, reduction in HbA1c, and improved blood sugar control as determined through patient-blinded CGM.

As previously mentioned, the two most advanced patients in the study currently remain insulin independent with no need to take any injectable insulin for 22 and 3 months, respectively, and ongoing.

Larger Cell Pouch Expected to Negate the Need for Supplemental Portal Vein Infusion

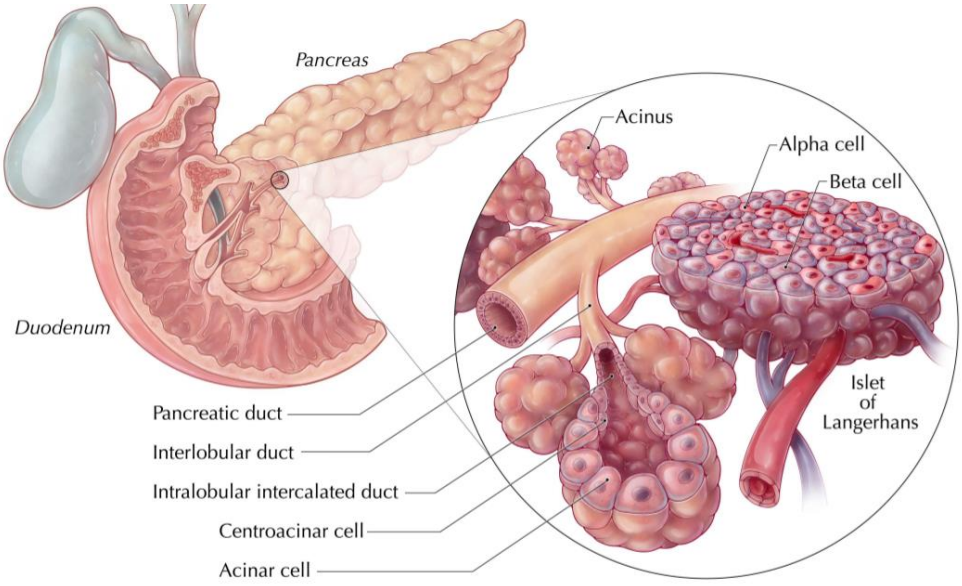
The first six patients enrolled and dosed in the Phase I/II T1D clinical trial were implanted with the eight-chambered, medium-sized Cell Pouch. For the seventh participant, Sernova and the clinical trial principal investigator have opted to use an upsized, ten-chambered Cell Pouch with ~50% additional capacity. Use of the larger pouch is expected to negate the supplemental portal vein infusions by allowing for a larger total dose of cells to be stored in the Cell Pouch while maintaining a density that maximizes the cellular surface area that is in contact with the microvasculature.

Diabetes Market Overview

Diabetes Pathology Arises from Malfunctioning or Fragile Beta Cells

Diabetes occurs when the patient's body either doesn't make enough insulin (Type 1) or doesn't use it properly (Type 2). Insulin, which is produced by beta cells in the pancreatic islets, is required to maintain safe levels of glucose in the blood. Pancreatic islets continuously detect circulating glucose and secrete insulin accordingly. Increased insulin causes the body's cells to absorb glucose present in the bloodstream for use as an energy source. In diabetics, this signal is diminished by the lack of insulin and the circulating sugar levels remain elevated at toxic levels. This chronic hyperglycemia damages blood vessels and nerves, leading to an accumulation of ill-health effects that result in death if left untreated. As the glucose is not absorbed and used by the cells, diabetic patients first experience tiredness and a lack of energy, along with constant hunger, abnormal thirst, and blurred vision. Other symptoms include sudden weight loss, frequent urination, and tingling in the hands and feet.

Exhibit 11 – Anatomy of the Pancreas, Islet, and Beta Cell



Source: Company Presentation, ECM

Type 1 Diabetes

Type 1 Diabetes (T1D), which accounts for ~10% of the total diabetes prevalence, is caused by an autoimmune reaction in which the body's own immune system attacks and kills the body's insulin-producing islet cells in the pancreas. This results in a build-up of sugar in the bloodstream as little to no insulin is transported to other cells. The exact root cause of the underlying pathology is unclear but appears to be due to a combination of genetic susceptibility and environmental factors. T1D tends to develop in children or young adults who then must constantly attempt to control their blood sugar levels and minimize both the acute effects of hyper- and hypoglycemia as well as the long-term effects of diabetes, which include heart and kidney disease, blindness, and amputations. Subsequent to diagnosis, T1D patients take insulin via regular injections or a wearable infusion pump.

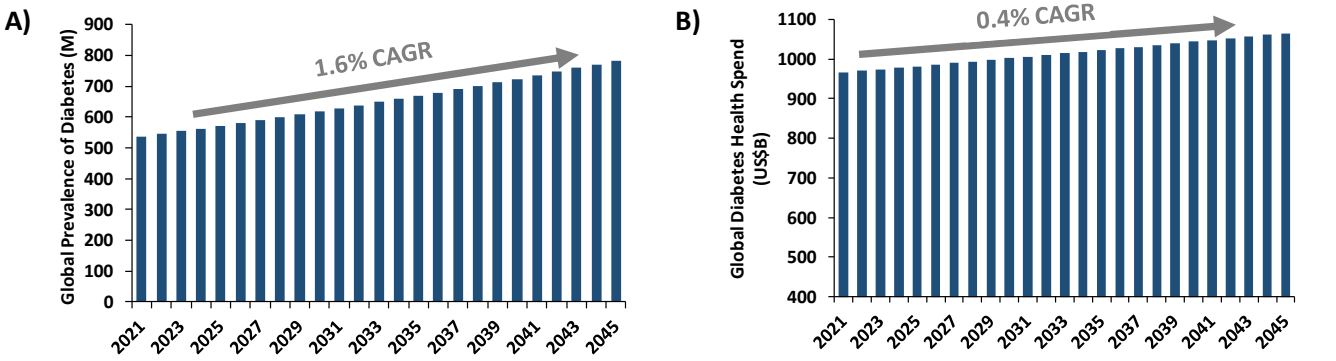
Type 2 Diabetes

Type 2 Diabetes (T2D), which accounts for ~90% of the total diabetes prevalence, occurs when the patient's cells acquire resistance to insulin due to genetic factors, obesity, and chronic high-sugar diets. Because of the cells' resistance to insulin, blood glucose levels keep rising as they are not absorbed, and the body releases more insulin in response. In some T2D patients, this can eventually exhaust the pancreas, resulting in even lower insulin production and even higher blood sugar levels. The initial symptoms are similar to those exhibited by T1D patients, only no amount of additional insulin can correct the effects of the disease. Instead, patients are prescribed Metformin, which increases the body's response to insulin and decreases the amount of glucose absorbed from food and released into the bloodstream by the liver. T2D is more commonly diagnosed in adults, but is increasingly seen in children, adolescents, and younger adults due to increasing physical inactivity and poor diet leading to rising obesity.

Global Disease, Global and Growing Market

According to the International Diabetes Foundation, there are ~537M people living with diabetes, including ~240M undiagnosed, in 2021. This led to ~US$966B of health expenditures (10% of total spending on adults) along with ~6.7M deaths. The global prevalence is expected to grow at an ~1.6% CAGR to ~783M by 2045, while the healthcare system expenses related to the disease are expected to rise to ~US$1,065B. With the root cause of T1D yet to be elucidated, its global prevalence is expected to grow largely in line with population growth whereas the prevalence of T2D, which is characterized by acquired resistance to insulin, is expected to outpace general population growth due to current diet and lifestyle trends.

Exhibit 12 – Projections for Global Diabetes Prevalence (A) & Health Spend (B)



Source: Company Presentation, ECM

Rapidly Rising Insulin Prices Boost Growth of the ~US$24B Insulin Market

The global insulin market is estimated to be ~US$24B in 2021 and is expected to grow at a 3.4% CAGR to ~US$28B through 2026, with the US accounting for ~32% of insulin consumption and ~84% of sales, due to its relatively high insulin prices and higher than average diabetes prevalence. According to a RAND Corp. study, insulin costs are eight times higher in the US than in 32 comparable high-income nations. In 2018, the average US manufacturer price per standard unit across all insulins was $98.70, compared to $6.94 in Australia, $12.00 in Canada, and $7.52 in the UK.

Insulin list prices in the US have increased dramatically over the past decade, as noted in a CMS report stating that the average wholesale acquisition price for rapid-acting, long-acting, and short-acting insulin increased by 15-17% per year from 2012 to 2016. Indeed, a 2019 analysis also found that insulin spending per person doubled between 2012 and 2016 while the average out-of-pocket costs increased by 10% per year for insulin-using Medicare Part D enrollees.

Multiple Insulin Types Optimize but Complicate Treatment

Insulin products come in two forms: analog and human. The analog form, which accounts for ~85% of global sales and volume, is made synthetically and modified to change the speed at which it is absorbed by the body. The human form, which accounts for the remaining ~15% of US sales and volume, is manufactured by bacteria with the human insulin gene inserted into its DNA. As outlined in Exhibit 13, insulin can be further differentiated into four subtypes based on the rapidity of its absorption. Diabetics typically use multiple types of insulin throughout the day as needed. During and immediately after mealtimes, for example, blood sugar spikes and the patient requires a quicker-acting but shorter-acting form of insulin than the steadier slow-release form that is typically used between meals or overnight. As such, diabetic patients typically require various forms of insulin to be in their proximity throughout the day and need to keep close tabs on their supplies in order to not run out unexpectedly.

Exhibit 13 – Insulin Treatment Options

Insulin Action	Time to Peak	Duration	Product Names	Comments
Rapid	3-5 minutes	2-3 hours	Asparat, Glulisine, Lispro	Taken with or just before a meal. It is essential to avoid overdosage to minimize the risk of low blood sugar
Short	30 minutes	3-6 hours	Actrapid, Humulin R, Insuman Rapid	Taken before meals. Also called regular or neutral insulins
Intermediate	0.5-1 hours	up to 18 hours	Humulin NPH, Protaphane, Insulatard	Often taken together with a short-acting insulin
Long	1-2 hours	up to 24 hours	Detemir, Glargine	Steadily released, commonly taken in the morning or before bed

Source: IDF, WebMD, ECM

Diagnosis of T1D and Monitoring its Effects in the Blood

Diagnosis of diabetes typically includes glycated hemoglobin (HbA1c) and oral glucose tolerance tests along with blood sugar tests. The HbA1c test indicates the patient's average blood sugar level for the past two to three months whereas the oral glucose tolerance test measures the body's response to glucose after fasting. For this test, the patient's blood sugar is tested after fasting overnight and then periodically again over two hours after they consume a sugary liquid. Higher readings indicate insufficient insulin production. In addition to diagnosis, these tests are typically used to monitor the efficacy of cell therapies in clinical trials.

Hyperglycemia and Hypoglycemia – A Delicate Balance for Diabetics

Hyperglycemia is the technical term for high blood sugar which, if left unmonitored and untreated, can lead to ketoacidosis (a diabetic coma). Without insulin, cells cannot use glucose for fuel and instead uses fats. In this process, the liver breaks down the fats to ketones which eventually cause the blood to become toxically acidic, which can lead to fluid buildup in the brain, kidney failure, and/or cardiac arrest.

Hypoglycemia, conversely, is the technical term for low blood sugar, which mostly occurs as a result of the administration of too large a dose of insulin, as a side-effect of certain medications, excessive alcohol consumption, or as a result of certain other critical illnesses. When hypoglycemic, T1D patients consume sugar to raise their blood sugar. Hypoglycemia typically presents with shakiness and an irregular heartbeat and, if left untreated, can lead to seizures and loss of consciousness, which can be particularly perilous if the person is alone, falls over, or is operating heavy machinery at the time.

Sernova's Initial Target Market – Hypoglycemia-Unaware Diabetes Patients

For ~15% of T1D patients, and ~240,000 diabetics in the US, repeated hypoglycemic episodes lead to hypoglycemia unawareness (also known as 'brittle diabetes'), which occurs when the body and brain no longer produce the signs and symptoms that warn of low blood sugar. When this happens, the risk of severe, life-threatening hypoglycemia massively increases. Due to its high-risk status and a lack of proven therapies, this is the initial target population for virtually all companies attempting to provide a cell therapy-based functional cure, including Sernova.

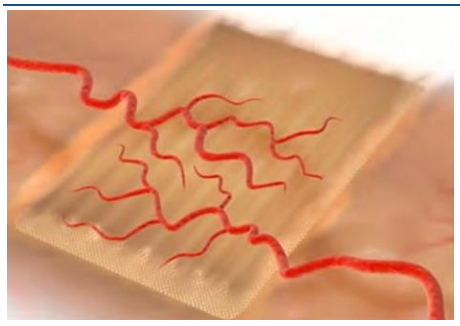
The Cell Pouch System™ – A Biologically Compatible Delivery Process

Cell Therapy and Regenerative Medicine for Insulin Independence

Cell therapy is the transplantation of live human cells into a patient to replace damaged cells/tissue and effectuate a medicinal effect. The cells may originate from the same patient (autologous cells) or a human donor (allogenic cells), which are vulnerable to immune system rejection. Often, when the patient's own dysfunctional cells are used, they are first harvested and genetically modified or corrected before being transplanted back into the patient.

For people with diabetes, insulin independence generally requires an average meal-stimulated C-peptide level of 1,000–1,500 pM, although early studies suggest that as low as 20% of this level may be sufficient for some patients to achieve near insulin independence, implying that low engrafted islet mass may offer substantial physiological benefit.

Exhibit 14 – The Cell Pouch – A Discreet Organ-Like Environment to House Therapeutic Cells

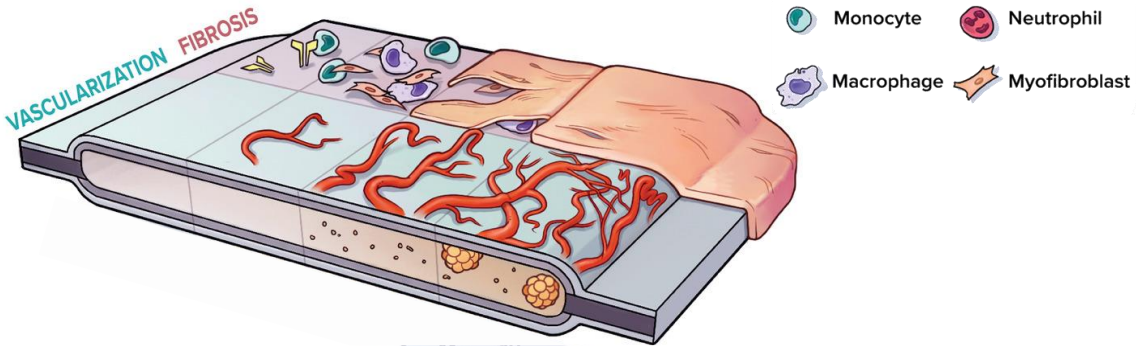


Source: Company Presentation

Implantation and Vascularization of the Cell Pouch

Four Cell Pouches are first implanted deep under the patient's skin, between the superficial and deep fascia beneath the subcutaneous space, via a quick keyhole surgery performed in an out-patient setting. Once implanted, they become fully vascularized without the body recognizing it as a foreign object, preventing it from being encased in thick, fibrous tissue. This process of fibrosis (see Exhibit 15) has been the downfall of previous competitors' devices. With the Cell Pouch effectively incorporated into the body's circulatory system after ~3 weeks, the delivery of oxygen and nutrients into the chambers is unencumbered. Once this is achieved, therapeutic cells are transplanted into the vascularized tissue chambers where, following engraftment, they release the missing proteins or hormones into the bloodstream to treat disease.

Exhibit 15 – Vascularization (Positive) and Fibrosis (Negative) of a Generic Implanted Device

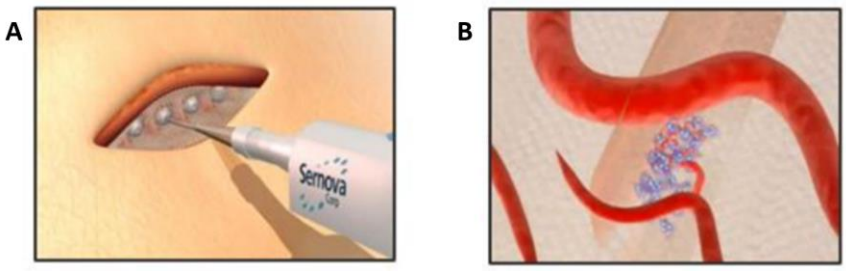


Source: Goswani D et. al. Design Considerations for Macroencapsulation Devices for Stem Cell Derived Islets for the Treatment of Type 1 Diabetes; Advanced Science (2021), doi: 10.1002/advs.202100820

Quick and Easy Transplantation of Therapeutic Cells into the Chambers

Once the Cell Pouch has been vascularized, live therapeutic cells are transplanted into the chamber of the pouch. The Company's preclinical studies have shown that human donor pancreatic islets transplanted into the Cell Pouch react to the patient's circulating blood sugar levels to release insulin as needed. In addition to insulin release for the treatment of T1D, encouraging preclinical results have been observed with other cells in other potentially therapeutic applications. For example, genetically edited or corrected patient cells that produce Factor VIII may be used to treat hemophilia A, a rare clotting disorder, and transplanted thyroid tissue may be used to replace the function of the removed thyroid gland with the goal to recover the natural feedback loop of thyroid hormone production.

Exhibit 16 – Transplantation of Therapeutic Cells into the CPS (A) and Diffusion of Therapeutic Proteins or Hormones from the Vascularized CPS to the Circulatory System (B)

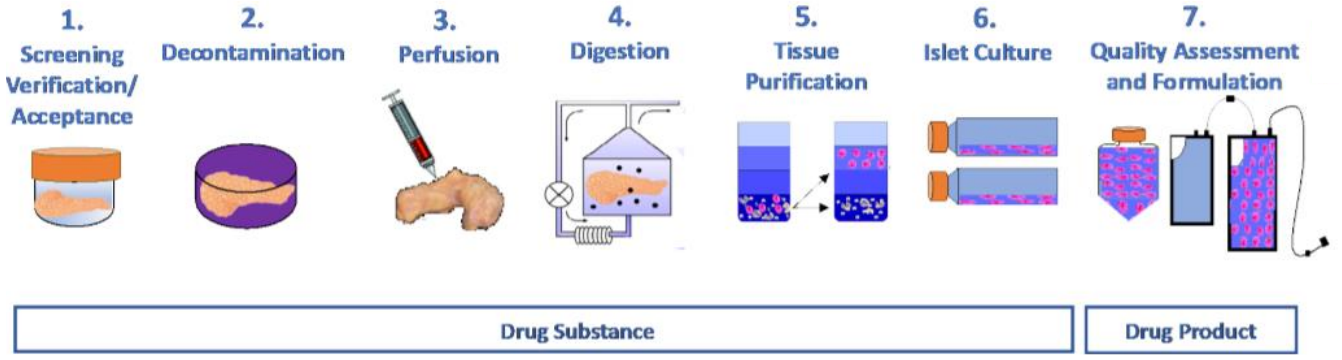


Source: Company Filings

Human Donor Islets Show Promise but are Difficult to Harvest and are in Limited Supply

So far only human donor islet cells have been used for cell therapy outside of clinical trials, exclusively in portal vein transplants. Multiple donors are often needed in order to yield enough insulin-producing cells to treat a single patient, however, due to the procedure's high cell attrition rate. Despite their vulnerability, donor islets have been shown to produce insulin in response to elevated blood glucose. Compared to other organs for transplant, human donor islet removal and isolation are much more laborious and time-consuming, as outlined in Exhibit 17 below.

Exhibit 17 – CellTrans' Human Donor Islet Purification and Quality Assessment Method



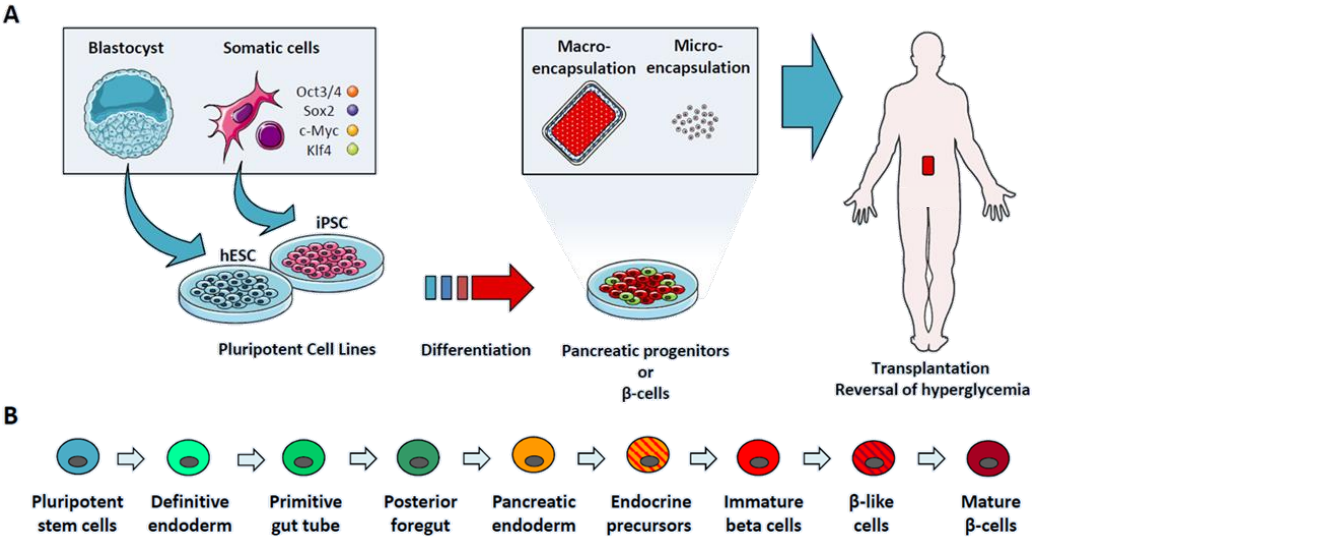
Source: N. Quiskamp et. al., Differentiation of human pluripotent stem cells into ß-cells: Potential and challenges (2015), doi: 10.1016/j.beem.2015.10.011

Stem Cell-Derived Islets Expected to Alleviate Donor Islet Supply Bottlenecks

Sernova expects to initiate a Phase I/II Cell Pouch clinical trial in 2023 with immune protected, stem cell-derived islets. Pluripotent stem cells (PSCs) are a potentially unlimited source of various cell types and, with the potential to be differentiated to produce any cell or tissue the body needs, they have advanced as a treatment option for a number of diseases including cardiovascular, autoimmune, and various cancers. Despite islet transplantation's potential to reverse T1D, insufficient supply of donor islets has led to increasing efforts to use stem cells to generate functional, insulin-producing beta-like cells. Several protocols have been developed to systematically guide the differentiation of stem cells into pancreatic endoderm cells, which have been shown to mature into functional beta cells. The differentiation process takes approximately one month and has eight steps, as outlined in Exhibit 18.

In its third-generation product, Sernova is looking to transplant mature stem cell-derived islet cells into the fully vascularized implanted Cell Pouch. This is a meaningful point of differentiation versus ViaCyte, arguably Sernova's closest competitor. While Sernova's cells are placed into a pre-vascularized environment, ViaCyte's PEC-01 cells are pre-loaded into the device prior to implantation. Without full vascularization upon transplantation, cells are unlikely to obtain sufficient nutrients and oxygen for survival. Furthermore, the cells are transplanted at an early development stage and are thus unable to produce insulin prior to development in the body. These progenitor cells require months of further development inside the body prior to the being able to produce insulin. With this technology, physicians cannot immediately assess the success of the transplant as any potential therapeutic benefit of the stem cells to the patients comes with a lag.

Exhibit 18 – Overview of Generation (A) and Differentiation (B) of PSCs for the treatment of T1D



Source: N. Quiskamp, J. E. Bruin, T. J. Kieffer, Differentiation of human pluripotent stem cells into ß-cells: Potential and challenges (2015), doi: 10.1016/j.beem.2015.10.011

Immune Protection of Therapeutic Cells

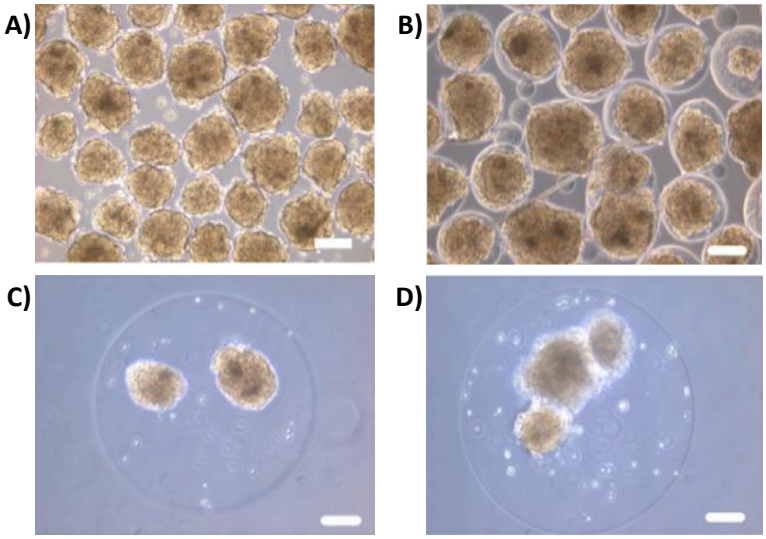
As previously discussed, Sernova's first-generation T1D product will be used alongside immunosuppressive medications that reduce the strength of the patient's immune system, which is not ideal as it leaves the patient susceptible to other opportunistic infections. Use of these drugs will be averted in the second- and third-generation products as the Company will look to instead use local protection in the form of its conformal coating technology.

Conformal Coating Averts the Need for Immunosuppression Without Compromising Cellular Function

In June 2020, Sernova acquired a cellular local immune protection technology from Converge Biotech and the University of Miami. This technology is expected to be a highly complementary addition to the Company's cell therapy platform as it has the potential to eliminate the need for chronic immunosuppression, thus significantly de-risking the product and expanding the number of treatable patients to include all type 1 diabetics.

Developed by Dr. Alice Tomei at the University of Miami's Diabetes Research Institute, the proprietary conformal coating technology consists of a thin crosslinked polymer layer that effectively "shrink-wraps" individual islets to protect them from recognition and attack by the patient's immune system. It also enables close contact of the transplanted cells with the vascularized tissue matrix within the Cell Pouch to enable quick and unencumbered diffusion of nutrients and biomolecules (i.e., glucose, insulin, and other proteins or hormones). This allows for a physiological, glucose-stimulated insulin response without delay that occurs with other cell encapsulation materials, such as PEG-alginate, that have been used in competitors' protocols. In addition, the improved diffusion of biomolecules allows for the use of fewer therapeutic cells than PEG-alginate encapsulation to achieve the desired therapeutic effect as there is virtually no "empty space" between the cell surface and the coating.

Exhibit 19 – Naked Stem Cells (A) and Stem Cells Coated in Proprietary Conformal Coating (B), Alginate (C) and PEG-Alginate (D)



Source: Stock, A.A. Stem Cell Reports, 2019

PEG-Alginate – One-Size-Fits-All Doesn't Work for All

Alginate is a one-size-fits-all cell microencapsulation strategy that has been employed by a handful of clinical- and preclinical-stage companies with mixed success. The coating is made from a natural polysaccharide purified from algae or bacteria with a sound safety record and, while the microcapsules do not fibrose when directly implanted into immunocompetent mice, any impurities or endotoxins can trigger fibrosis and lead to therapeutic cell death.

Pancreatic islets have an inherently high metabolic activity and are prone to hypoxia and death if oxygen diffusion is insufficient. Indeed, islets receive ~10% of the pancreatic blood flow despite only comprising ~2% of the mass. The islets are also not uniform in size or shape, as shown in Exhibit 19, however alginate forms uniform capsules often around multiple islets. As can be seen in Exhibit 19, the distance between the islet surface and the wall of the alginate

microcapsule is generally much larger than that of Sernova's conformal coating. The excess empty space in the alginate microcapsules causes the volume transplanted to be much larger than naked or conformal coated islets, and the size of the device required to be much larger and less discreet. It also means that oxygen is likely to reach the islets much slower in alginate than via the conformal coating.

AgeX Collaboration – Potential for Edited Therapeutic Stem Cells to Evade the Immune System

Sernova may also look to use stem cell-derived therapeutic cells that have been genetically edited to mask them from immune detection and attack. In May 2020, the Company entered into a research collaboration with AgeX Therapeutics (AGE-NYSE, NR) to investigate its UniverCyte gene-editing technology to generate transplantable, universally immune-protected therapeutic cells for use in the Cell Pouch. The UniverCyte process involves the insertion of the HLA-G gene to the patient's stem cells. The HLA-G gene is expressed on fetal-derived placental cells with its primary role being prevention of immune rejection of a baby by the mother.

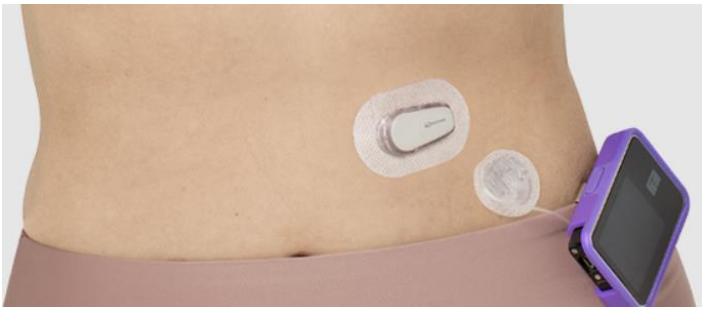
Insulin Pumps – Improvement over Injectables, Inferior to Functional Cure

Insulin pumps are wearable, computerized devices that deliver either smaller doses of short-acting insulin continuously (basal rate) and/or larger amounts of insulin when a meal is eaten (bolus). The global market for this technology is projected to grow at a CAGR of 16%, from US$4.1B to US$11.9B between 2021 and 2028, as the technology improves and adoption increases. According to Insulet, a leading patch pump provider, ~95% of diabetics opt for injectable insulin over wearable insulin pumps. Nevertheless, this delivery method has been gaining traction as the devices have become easier to use and more discreet.

Traditional insulin pumps attach to and integrate with the body via tubing and have an insulin reservoir and pumping mechanism (Exhibit 20A). The pump has buttons to program insulin delivery for meals, adjust basal rates, or suspend the insulin infusion, if necessary. Insulin patch pumps are worn directly on the body, are controlled wirelessly by a separate device, and have a reservoir, pumping mechanism, and infusion set inside a small case (Exhibit 20B). If the patient decides to eat or exercise more than initially planned, the patient can direct the pump to administer more or less insulin as needed. Blood sugar levels can remain much steadier as the pump's continuous background drip of insulin more closely mimics the action of a healthy pancreas than insulin injections.

Exhibit 20 – Tandem tSlim Insulin Pump (A) and Insulet Omnipod Pump Patch (B)

A)



B)

Source: MRI Questions, Insulet

Glucose Tracking Errors and High Out-of-Pocket Costs Could Limit Adoption

A healthy pancreas, however, secretes varying levels of insulin in response to the patient's blood glucose levels, not at a constant basal rate or in boluses. To address this, insulin pumps increasingly feature continuous glucose monitors (CGMs), together known as a "closed loop system", for more automated glucose monitoring and reactive insulin dosing. While more convenient than fingerstick testing, CGM devices are considered to be less reliable as the sensor glucose readings are taken from the patient's interstitial fluid, rather than the blood. Glucose levels generally rise (or fall) first in the blood and then in the interstitial fluid with a lag of 15-20 minutes. Also, the interstitial glucose profile is more complex than that of the blood and, as such, CGM has an overall percentage of error of ~15%, with particularly poor correlation during the more crucial periods of hypoglycemia and times of rapid change.

While insulin pumps have advantages and disadvantages when compared to injectables, they also cost ~44% more per year (2005-2013). Furthermore, patients using insulin pumps would have experienced the same doubling of the input insulin prices from 2012-2016, as discussed earlier.

Insulet & Tandem Show Where Sernova's Later-Stage Products Could Go with Scale

Insulet (PODD-NASDAQ, NR) and Tandem Diabetes Care (TNDM-NASDAQ, NR) are the two market leaders in pure-play diabetes management and the provision of closed loop pump systems. With market capitalizations of ~US$16B and ~US$8B, and NTM EV/Sales valuations of ~14x and ~13x, respectively, Insulet and Tandem show the value of de-risked diabetes management products once produced at scale and offered to the broader T1D population (compared to Sernova's market capitalization of ~C$500M). Sernova's later-stage Cell Pouch products with locally protected, stem cell-derived islets prove safe and efficacious in clinical trials, we believe that similar valuations could be warranted.

Diabetes and Minimally Invasive Surgery Tech Make Medtronic a Potential Partner

While not a diabetes management pure play, Medtronic (MDT-NYSE, NR) achieves ~US$2.4B per year in diabetes segment sales via its insulin pumps, CGM systems, and the InPen smart insulin pen system, which combines a reusable Bluetooth-enabled insulin pen with a mobile app that helps users administer the appropriate insulin dose. In addition to its diabetes management expertise, Medtronic is a world leader in minimally invasive surgery, making it a potential partner for Sernova in the coming years for distribution and co-commercialization of the Cell Pouch as well as a surgical kit for minimally invasive laparoscopic (keyhole) insertion of the Cell Pouch and therapeutic cells. We note that the two companies have an existing relationship, with Medtronic providing Sernova with the CGMs used in its clinical trials. Similarly, Abbot Laboratories (ABT-NYSE, NR) is another potential partner with both surgical equipment and diabetes offerings, while medical device and surgical equipment giants Stryker (SKY-NYSE, NR) and Zimmer Biomet (ZBH-NYSE, NR) could also look to Sernova to tap the diabetes, hypothyroid and hemophilia A markets.

Clinical-Stage Competition

Interest in hands-off cell therapy has led to a highly competitive market in recent years, with various large players such as J&J, Eli Lilly, and Vertex Pharmaceuticals looking to build on the early successes of portal vein transplantation to bring a more robust solution to market. As highlighted in Exhibit 21, various players have made progress in the clinic, although many have shown poor data thus far and/or have design flaws that we believe make Sernova's Cell Pouch the preeminent vehicle for delivery of a functional cure for T1D.

Exhibit 21 – Type 1 Diabetes Cell Therapy Competitive Landscape – Clinical Stage

Sponsor	Product	Indication	Therapeutic Cells	Device	Immune Protection	Notes
Submitted						
CellTrans	Donislecel	High-risk T1D	Human donor islets	None *	Immuno-suppressives	Submitted BLA to FDA for manufacturing process, waived all exclusivity rights.
Phase II						
Diatranz Otsuka	Diabecell	High-risk T1D	Porcine islets	None **	Alginate Micro-encapsulation	Preparing for Phase III clinical trial. No timeline given.
Phase I/II						
Sernova	**Cell Pouch System**	**High-risk T1D**	**Human donor islets**	**Vascularizing device**	**Immuno-suppressives**	**Sernova's flagship study, 7/7 patients enrolled. First two patients showing insulin independence, more data to come in over the next year. No fibrosis of the pouch.**
ViaCyte / J&J	PEC-Direct (VC-02)	High-risk T1D	Stem cells	Vascularizing device	Immuno-suppressives	Reduction in HbA1c not significant at 52 weeks post implantation. 5/15 patients withdrawn after 9 months due to failed risk-benefit assessment, based primarily on undetected C-peptide.
ViaCyte / J&J	PEC-Encap (VC-01)	All T1D	Stem cells	Immunoprotective Encaptra device	Device	Clinical trial currently enrolling. Earlier versions of the device fibrosed in human subjects.
Vertex	VX-880	High-risk T1D	Stem cells	None *	Immuno-suppressives	Restoration of insulin production in first patient at Day 90. Generally well tolerated, improved glucose control. Portal vein transplants typically show poor longevity.
Beta-O2	βAir	All T1D	Human donor islets	Artificial Pancreas	Alginate Micro-encapsulation	Only minute levels of circulating C-peptide were observed with no impact on metabolic control.

** Portal vein transplant*
*** Intraperitoneal transplant*

Source: ECM

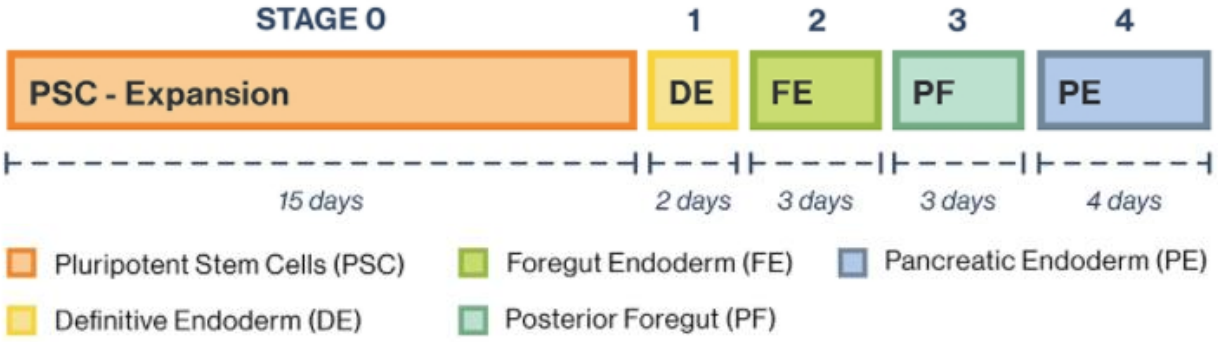
ViaCyte – Studies so Far Show Underwhelming Risk/Benefit Profile

San Diego-based ViaCyte is a privately funded regenerative medicine company focused on stem cell-derived islet cell replacement for T1D and is arguably Sernova's main competitor in the race to commercialize an implantable functional cure. In 2014, Johnson & Johnson (JNJ-NYSE, NR) invested US$20M into ViaCyte with an option to acquire its lead T1D therapy as it commenced human testing. In 2016, however, ViaCyte merged with BetaLogics, a New Jersey-based JNJ subsidiary, to form a single, clinical-stage company with the goal of developing a stem cell-based cure for diabetes.

PEC-01 Cells

ViaCyte has two clinical stage encapsulation device products, PEC-Direct and PEC-Encap, that use the same therapeutic PEC-01 cells. The PEC-01 cells are a type of pancreatic endoderm cell (also known as pancreatic precursor cells) created by inducing differentiation of pluripotent stem cells (PSCs) in a multi-step process that mimics the natural development of the human pancreas. Over a ~30-day period, different types and amounts of growth factors, growth media, and supplements direct PSCs along the differentiation pathway until they become PEC-01 cells. The PEC-01 cells are placed in a device that is then implanted under the skin of a patient where the cells are supposed to mature and become functional, insulin-producing islet cells that control blood glucose levels.

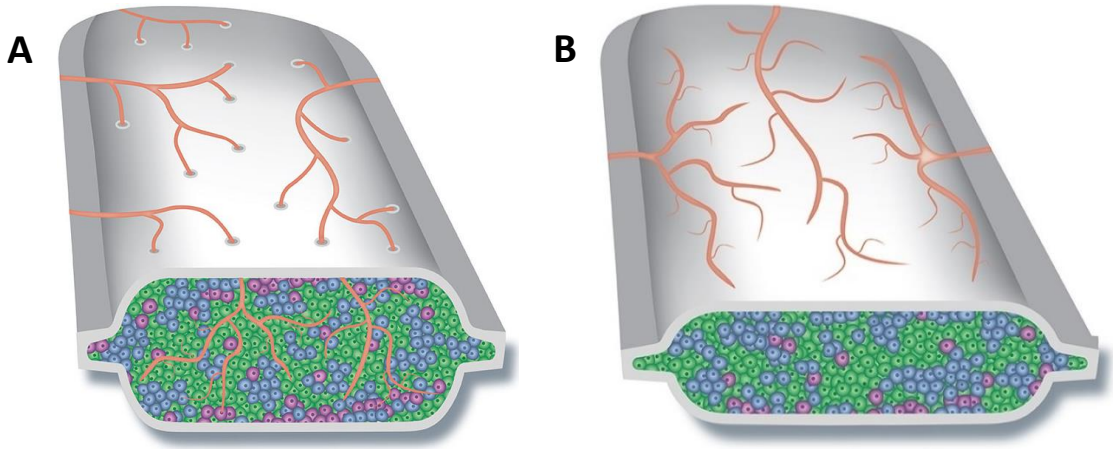
Exhibit 22 – ViaCyte's PEC-01 Manufacturing Process



Source: ViaCyte Website

The PEC-Direct device allows for direct vascularization and requires concomitant immune suppression, whereas the PEC-Encap device protects the therapeutic cells from immune rejection while allowing for the passive transfer of nutrients and therapeutic proteins/hormones, as shown in the schematic in Exhibit 23.

Exhibit 23 – ViaCyte's PEC-Direct (A) and PEC-Encap (B) Devices



Source: ViaCyte Website

PEC-Direct (VC-02) – Failed Risk-Benefit Assessment in 33% of Subjects at 9-Month Checkpoint

The PEC-Direct, ViaCyte's most clinically advanced product, uses PEC-01 cells pre-transplanted into a device that allows for direct vascularization for the treatment of diabetics with hypoglycemia unawareness. Similar to the donor islets in the first-generation CPS, the PEC-01 cells are not protected from rejection by the host's immune system and, as such, immunosuppressive medications are required. As is the case with Sernova's first-generation CPS, this product would be limited to the diabetics at highest risk – those with hypoglycemia unawareness. In contrast to the first-generation CPS, however, the device is not vascularized before transplantation of the cells, leaving them vulnerable to starvation and cell death while the blood vessels form and penetrate the device.

The ongoing Phase I/II study is an open-label, first-in-human study to evaluate the product's safety, tolerability, and efficacy in two cohorts of 15 and 60 participants. The primary outcome measures for the first and second cohorts will be the incidence of adverse events and the change in C-peptide from baseline at six months post-implant, respectively.

An interim analysis of one year of data from 15 patients enrolled in the PEC-Direct Phase I/II study showed that implanting a mass of 5,300 IEQ cells per kg of patient body weight (~50% of the dose used in portal vein transplantation) led to C-peptide levels reaching only 10% of the level associated with insulin independence. Indeed, 5/15 patients were withdrawn from the study by the clinical trial coordinators after 9 months due to a failed risk-benefit assessment. Given that survival of transplanted islets is highly dependent upon oxygen and nutrient transfer

immediately following transplantation, and that hypoxia is known to be a major contributor to islet death in portal vein transplants, we suspect that device vascularization is not occurring quickly enough to keep enough of the pre-encased PEC-01 cells alive and functioning. The Company would likely need to increase the cell dosage or improve cell survival for insulin independence and a functional cure for T1D. Indeed, this first cohort of patients in the study had up to six device implants, whereas the next, larger cohort will have up to twelve devices implanted.

PEC-Encap (VC-01) – Therapeutic Cells Could Suffer the Same Fate as in PEC-Direct Device

ViaCyte's second product is the PEC-Encap. Here, the PEC-01 cells are placed in a device designed to protect them from direct contact and attack by immune cells, while also allowing passive movement of proteins, hormones, oxygen, and glucose between the cells and the blood vessels, which grow along the outside of the device.

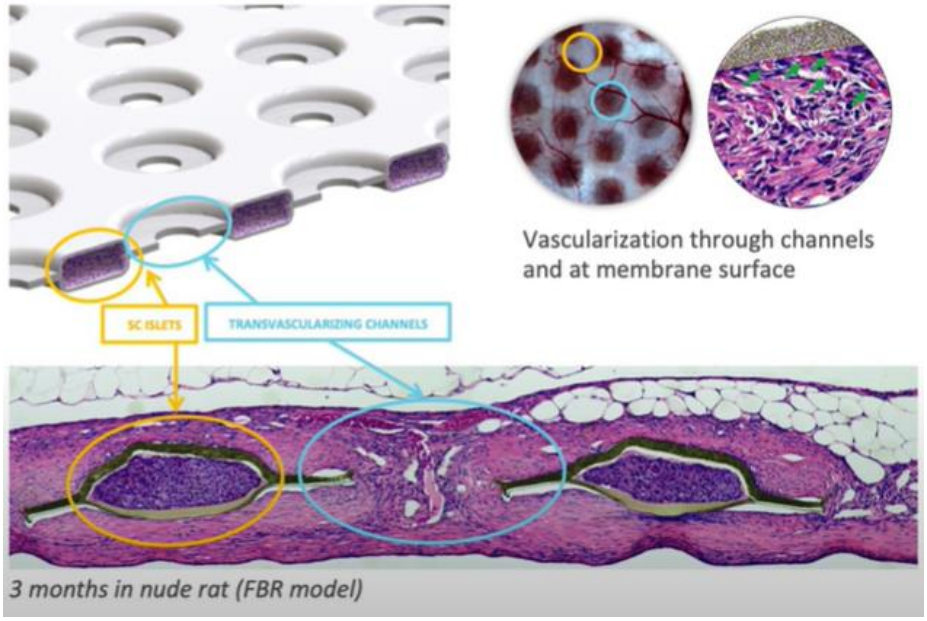
ViaCyte is currently enrolling for a Phase I/II trial to assess the safety, engraftment, and efficacy of the PEC-Encap in 70 diabetic participants, regardless of hypoglycemia awareness. The first cohort of 30 participants will receive up to 10 implanted devices, while the second cohort of 40 participants will receive up to 12. The primary outcome measures for the first and second cohorts will be the percentage of graft cells present relative to preclinical models at six months post-implant, and the change in C-peptide from baseline at six months post-implant, respectively.

Given that hypoxia-induced cell death in the more vascularized PEC-Direct device likely led to an unfavourable risk-reward profile for at least 5 of 15 clinical trial subjects, and that human patients' immune responses to earlier versions of the PEC-Encap resembled the more aggressive responses seen in animals, we are sceptical that the PEC-Encap device will ultimately provide a functional cure for T1D.

Vertex VX-880 – US$950M Acquisition of Semma's Stem Cells and Device

Vertex Pharmaceuticals acquired privately held Semma Therapeutics in September 2019 for US$950M in an all-cash deal. Semma's two major advances at the time were its scalable, stem cell-derived, human pancreatic beta cells (VX-880 cells, formerly STx-02), which had been proven to restore glucose responsiveness in animal models, and an implantable macroencapsulation device that protects the cells from the immune system and enables durable implantation without the need for chronic immunosuppressive medications. Vertex is currently conducting a Phase I/II study of the VX-880 cells using the traditional portal vein transplantation approach (as described below), while the implantation of VX-880 cells macroencapsulated in the immuno-protective device is currently in preclinical studies (see Exhibit 28). The timeline to begin clinical trials for this device is not yet clear.

Exhibit 24 – Vertex Pharmaceuticals VX-880 Cell Encapsulation Device



Source: Semma Therapeutics Presentation

Vertex – VX-880: Promising Initial Data, Longevity of Portal Vein Transplants Typically Disappoints

In March 2021, Vertex Pharmaceuticals announced that the FDA had granted Fast Track Designation for VX-880 and that the company had initiated a Phase I/II safety and efficacy study in T1D patients with severe hypoglycemia and impaired hypoglycemia unawareness (n = 17). The procedure involves an infusion of stem cell-derived islets into the portal vein with chronic administration of concomitant immunosuppressive therapy.

In October 2021, Vertex announced positive Day 90 data from the study's first patient enrolled, who received half the target dose of VX-880 through a hepatic portal vein infusion. While promising, the trial is ongoing with the results from the remaining 16 patients yet to be collected. As shown in Exhibit 7, patients that receive a donor islet portal vein transplant show promising glucose control soon after the procedure, however, this control declines over the medium- and longer term. While it is not yet clear whether the VX-880 cells will be more robust than donor islets, the 17 patients will be followed for five years post-procedure to determine the longevity of the procedure.

Exhibit 25 – Baseline and Day 90 Measures of Islet Cell Function for VX-880 Patient 1

	Baseline before VX-880 infusion	Day 90 after VX-880 infusion
Fasting C-peptide (pmol/L)	Undetectable*	280
Peak Stimulated C-peptide with MMTT (pmol/L)	Undetectable*	560
HbA1c (%)	8.6	7.2
Daily insulin dose (units/day)**	34	2.9

** The lower limit of quantitation of the C-peptide assay is 13 pmol/L.*
*** Daily insulin dose for baseline was measured on Day 3 prior to VX-880 infusion. For Day 90 post-infusion, it was calculated over a 7-day period*

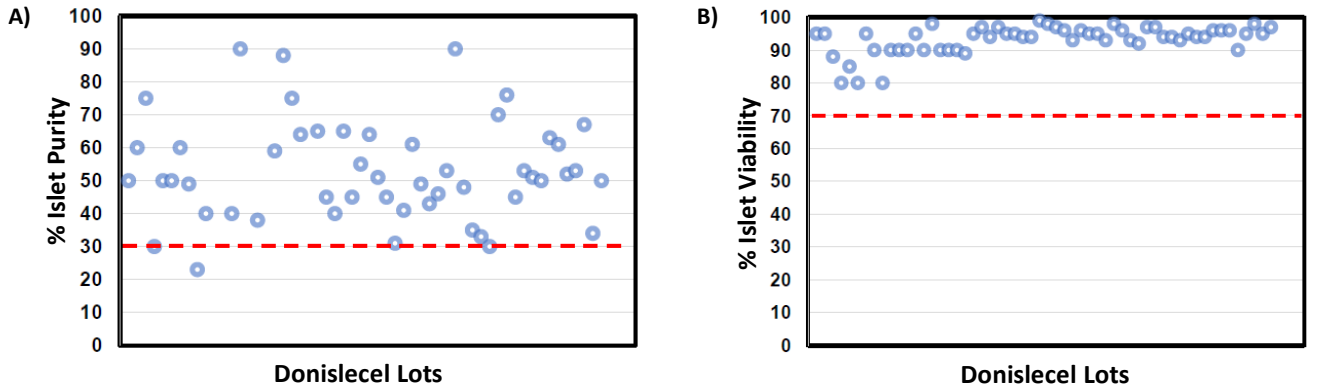
Source: Vertex Pharmaceuticals

CellTrans: Donislecel – Appears Dead in the Water After Physicians Oppose Approval

CellTrans (private) has filed a biological license application (BLA) with the FDA for the approval of its Donislecel procedure, which involves human donor islet isolation and portal vein transplant. While CellTrans has shown that it can extract viable islet cells somewhat reliably using its Donislecel workflow, as shown in Exhibit 26, one FDA Advisory Committee member noted that the critical purity and potency of the islets did not sufficiently correlate with clinical effectiveness. According to the Islets4US Collaborative, a group of physicians opposing the approval of CellTrans' BLA, these data show that the number of islets required to reliably yield the desired outcome cannot be confirmed prior to transplantation and thus the procedure as a whole is likely unreliable. Approval of the BLA could, therefore, provide a misleading level of assurance and allow for islet transplantation without the appropriate clinical oversight.

This BLA has been a source of controversy among key opinion leaders in the diabetes cell therapy and islet transplant space. At the heart of the controversy is the FDA's regulation of donor islet cells as a drug/biologic, rather than an organ for transplant, as is the case in Canada, Europe, Australia, and Japan. Some argue that if the FDA were to approve the Donislecel BLA, physicians would have to buy islets from CellTrans and transplant them with little assurance of efficacy. If the FDA were to reject the BLA, however, the procedure will continue to see little use outside of clinical trials as insurance companies continue to not pay for islet transplantation, which they deem to be unproven.

Exhibit 26 – Donislecel Isolated Islet Lot Purity (A) and Transplant Viability (B)

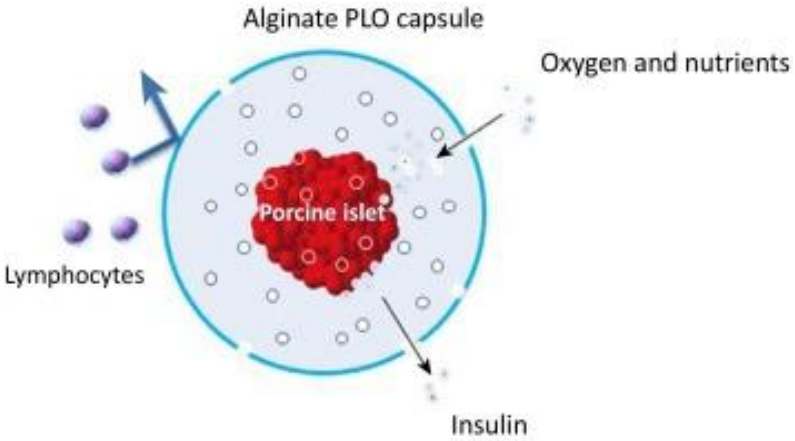


Source: CellTrans: Cellular Tissue and Gene Therapies Advisory Committee Presentation – April 15, 2021

Diatranz Otsuka – Studies Completed Years Ago, No Efficacy Data Reported

Diatranz Otsuka has conducted three Phase I/II clinical trials to date and, in 2017, reported positive safety findings for its DiabeCell procedure in which porcine islets microencapsulated in alginate/poly-L-ornithine are transplanted into the patient's intraperitoneal space. Although the results on safety are encouraging, with no observed transmission of porcine endogenous retroviruses at 113 weeks post-transplant, efficacy results of the trial have not been published. Nevertheless, Diatranz Otsuka's parent company, Otsuka Pharmaceutical Factory (TSE-4578, NR), purports to be preparing for a larger Phase III study in the US to elucidate the product's efficacy.

Exhibit 27 – Diatranz Otsuka's DiabeCell: Porcine Islets Microencapsulated in Alginate/PLO



Source: G. Orive, D. Emerich, A. Khademhosseini, S. Matsumoto, R.M. Hernandez, J.L. Pedraz, T. Desai, R. Calafiore, P. de Voz, Cell Trends in Biotechnology: Engineering a Clinically Translatable Bioartificial Pancreas to Treat Type I Diabetes. (2018), doi: 10.1016/j.tibtech.2018.01.007

Preclinical Competition for Sernova's 2nd and 3rd Generation Products

In addition to the clinical-stage competition, there is a litany of early-stage companies and products yet to reach the clinical stage, as shown in Exhibit 28. These programs consist primarily of potential functional cures that aim to avert the donor cell supply bottleneck using stem cell-derived therapeutic cells and/or the need for chronic immunosuppression via the use of immune-protected devices, cell coatings, or genetically edited stem cells. With similar aims and clinical timelines, these programs primarily present as competition for Sernova's second- and third-generation Cell Pouch products, which use the conformal coating and stem cell-derived cells. We expect the Company to move the products to the clinical stage in 2023.

Exhibit 28 – Type 1 Diabetes Cell Therapy Competitive Landscape – Preclinical Stage

Sponsor	Product	Indication	Therapeutic Cells	Device	Immune Protection	Notes
Preclinical						
Sernova	**2nd Gen System**	**All T1D**	**Human donor islets**	**Vascularizing device**	**Conformal coating**	**Clinical trial to begin enrolling in 2023.**
Sernova	**3rd Gen System**	**All T1D**	**Stem cells**	**Vascularizing device**	**Conformal coating**	**Clinical trial to begin enrolling in 2023.**
ViaCyte / CRISPR	PEC-QT / VCTX210	All T1D	Immune-evasive stem cells	Vascularizing device	None	Clinical trial to begin enrolling in 2022. Uses the PEC-Direct device, which shows poor control of T1D with donor cells despite immunosuppression.
Sigilon / Eli Lilly	SIG-002	All T1D	Stem cells	None **	Afibromer Micro-encapsulation	Microencapsulation material causes fibrosis. Hemophilia A study, which uses the same coating, was placed on clinical hold July 2021.
Novo Nordisk / Procyon	TBD	All T1D	Stem cells	Immunoprotective device	Oxygenated Device	Preclinical, no timeline for clinical trial enrollment.
Novo Nordisk / Cornell	TBD	All T1D	Stem cells	Immunoprotective device	Nanofibrous device	Preclinical, no timeline for clinical trial enrollment.
Encellin	CED	High-risk T1D	Human donor islets	Pouch	Device	Preclinical, no timeline for clinical trial enrollment.
Seraxis / Eli Lilly	SR-01	All T1D	Stem cells	SeraGraft	Device	Preclinical, no timeline for clinical trial enrollment.
Beta-O2	βAir	All T1D	Stem cells	Articifial Pancreas	Alginate Micro-encapsulation	Preclinical, no timeline for clinical trial enrollment. Alginate microencapsulation.
Vertex	Cells in Device	All T1D	Stem cells	Immunoprotective device	Device	Preclinical, no timeline for clinical trial enrollment.
Betalin	Micropancreas + Donor Cells	High-risk T1D	Human donor islets	Micropancreas	Immuno-suppressives	Preclinical, no timeline for clinical trial enrollment.
Betalin	Micropancreas + Stem Cells	All T1D	Stem cells	Micropancreas	Immuno-suppressives	Preclinical, no timeline for clinical trial enrollment.

** Portal vein transplant*
*** Intraperitoneal transplant*

Source: ECM

Novo Nordisk – Early Days but Diabetes Giant's Clinical Prowess a Threat (or Potential Opportunity)

With its significant diabetes expertise and clinical prowess, Denmark-based Novo Nordisk (NOVO-CPSE, NR) is a noteworthy competitor for Sernova despite its relatively recent move to explore cell therapies for T1D. Novo Nordisk is a global leader in the treatment of T1D with 19 medications approved, mostly injectable insulin, and 11 at the clinical stage. In its search for a functional cure, Novo Nordisk has established a stem cell manufacturing site in California and claims to have been making major progress on developing stem cell-derived, insulin-producing beta cells. In addition, it has partnered with Procyon Technologies (Private) and Cornell University to develop immune-protective macroencapsulation devices. Neither partner's device nor the therapeutic cells have entered human clinical trials, and there is no clear timeline for them to do so. As such, we expect any resultant cell and device combination to enter the clinical stage much later than Sernova's second- and third-generation Cell Pouch products. Novo Nordisk's vast clinical network, and ability to recruit patients do, however, make it a player worth monitoring closely as it provides updates with regard to preclinical data and timelines to move to the clinic. Conversely, given its stem cell-derived therapeutic cell manufacturing capabilities, as well as its hemophilia franchise, Novo Nordisk could potentially benefit from a collaboration with Sernova should its preclinical-stage device partners yield disappointing results.

ViaCyte's PEC-QT – Alleviates Donor Supply Bottleneck but has the Same Fatal Flaw as PEC-Direct

Of the competing programs listed in Exhibit 28 above, we highlight ViaCyte as Sernova's main competition in the near term, with ambitions to initiate clinical trials in 2022 using gene-edited, immune-evasive stem cells from CRISPR in its vascularizing PEC-Direct (VC-02) device. As previously discussed, however, the cells are pre-enclosed in the device prior to implantation, leaving the cells vulnerable to hypoxia and cell death while they vascularize. As a result, recently presented PEC-Direct clinical data have shown poor efficacy in reversing T1D pathology.

Sigilon Therapeutics – Blockbuster IPO Reflected Early Promise, Fibrosis Scarred Clinical Prospects

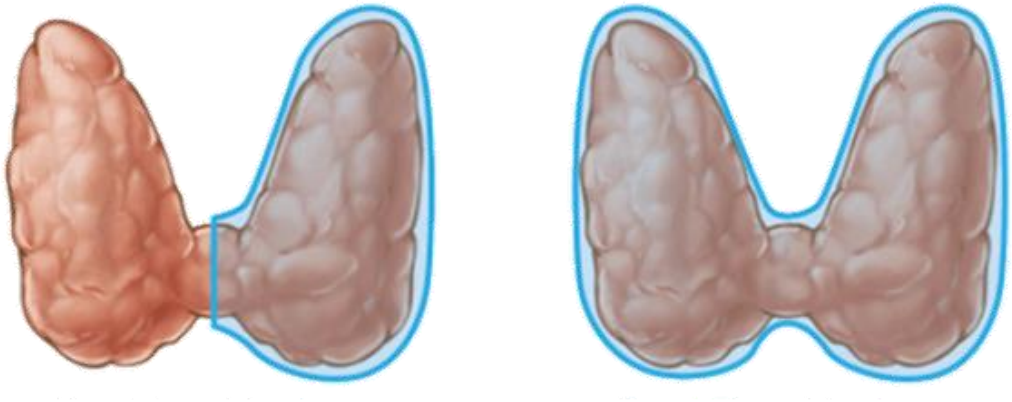
Sigilon Therapeutics is an early-stage biotechnology company pursuing functional cures for chronic diseases, such as hemophilia A and T1D. After announcing a strategic collaboration with Eli Lily to use its immune protective encapsulation technology alongside Eli Lily's stem cell-derived therapeutic cells for the treatment of T1D, it IPO'd in December 2020 at a US$1.05B valuation and reached a peak market cap of US$1.5B in the same month. Its Shielded Living Therapeutics (SLTx) Platform uses its proprietary, immune protective Afibromer material to encapsulate a large number of cells in "capsules" that are then transplanted into the patient's peritoneal cavity (between the abdominal wall and internal organs). Its only clinical-stage study, a Phase I/II trial of its technology to functionally cure hemophilia A, was put on clinical hold by the FDA in July 2021 due to a severe adverse event stemming from the fibrosis of the beads in patients. Sigilon has since reprioritized to focus its efforts on T1D and Mucopolysaccharidosis type I (MPS-I), a rare disease in which the body does not produce enough of an enzyme needed to break down long chains of sugar molecules. Given that fibrosis was likely triggered by the Afibromer capsules, not the therapeutic cells, we view these trials as having a low probability of success.

Hypothyroidism – A Large Market Underserved by Generic Medications

Hypothyroidism is a common endocrine disorder where the thyroid gland doesn't create and release enough thyroid hormones triiodothyronine (T3) and thyroxine (T4) into the bloodstream, impairing the body's ability to use energy, stay warm, and keep the brain, heart, muscles, and other organs working as they should. According to the American Academy of Family Physicians, approximately 1.1M (1 in 300) Americans have hypothyroidism, with the common causes being autoimmune disease (such as Hashimoto's thyroiditis), radiation treatment, and surgical removal of part or all of the thyroid gland. Up to 60% of people with hypothyroidism go undiagnosed and unaware of their condition as clinical symptoms are nonspecific and may be subtle, especially in the elderly. The prevalence increases with age, is higher in females than in males and can cause obesity, joint pain, infertility, heart disease, and death, if left untreated.

It is estimated that ~150K total thyroidectomy and hemithyroidectomy (partial removal) procedures are performed annually in the US. Thyroidectomies are conducted to treat several thyroid disorders including cancer, noncancerous enlargement of the thyroid (goiter), and overactive thyroid (hyperthyroidism). All patients that undergo total thyroidectomy, and 15-20% of patients that undergo hemithyroidectomy, require lifelong daily thyroid hormone replacement therapy using oral, synthetic T4 (levothyroxine (LT4)).

Exhibit 29 – Types of Thyroidectomies



Hemithyroidectomy	Total Thyroidectomy
15-20% require lifelong daily thyroid hormone replacement therapy	100% require lifelong daily thyroid hormone replacement therapy

Source: thancguide.org – Thyroidectomy Overview

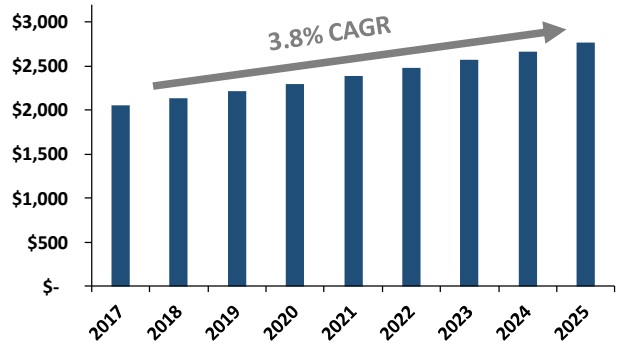
Standard Therapy Remains Inadequate for 30-50% of Patients

While a healthy thyroid produces both T3 and T4, synthetic T4 alone is the mainstay therapy for hypothyroidism due to its long half-life and its conversion to the bioactive T3 hormone in the peripheral tissues. Combination therapy using synthetic versions of both T3 and T4 has been shown to lead to symptoms that mimic hyperthyroidism or overactive thyroid. Overmedication with LT4 can lead to side effects that include headache, vomiting, diarrhea, changes in appetite, and fever, while undermedication can lead to hypothyroidism symptoms such as fatigue, constipation, dry skin, weight gain, hoarseness, and muscle weakness. Meanwhile, 30-50% of standard LT4 therapy users do not achieve adequate hormone levels and T3/T4 ratios in the blood, and some remain symptomatic despite achieving levels within the laboratory reference interval. This may be due to one or more factors, including but not limited to medication compliance, lab monitoring consistency, contraindication with other medications, food intake, and malabsorption in the gastrointestinal system. Even when these other factors appear to be optimized, the 'normal' laboratory reference interval for the hormones may be misleading due to differences in individuals' metabolisms and thyroid homeostasis systems. In addition, patients that have undergone hemithyroidectomy often see diminished production of T3 by the otherwise healthy portion of the gland, leading to lower circulating T3/T4 ratios.

Thyroid Disease Market – Cost of Imperfect Generics Accumulate Over a Lifetime

According to Allied Market Research, the global thyroid disorder treatment market was US$2.1B in 2017 and is expected to grow at a CAGR of 3.8% and reach US$2.7B in 2025. The major factors driving the growth of the market include increased thyroid disorder incidence and a rise in the number of disease awareness programs, especially in developing countries, leading to higher rates of diagnosis. The market is dominated by generic, oral, and synthetic hormone replacement treatments for hypothyroidism, which typically cost insurance companies or the patient US$15-100 per month, or US$180-1,200 per year, depending on the dose. While this cost appears relatively bearable on a per-dose basis, the costs accumulate over a lifetime of use. In addition, hypothyroid patients tend to require a higher-than-average number physician visits per annum to keep up with their changing medication/dosage needs. As such, we estimate that a regenerative medicine approach that eliminates the need for chronic daily administration and reduces physician visits could command a price of between US$50-60K per procedure.

Exhibit 30 – Thyroid Gland Disorder Treatment Market (US$M)

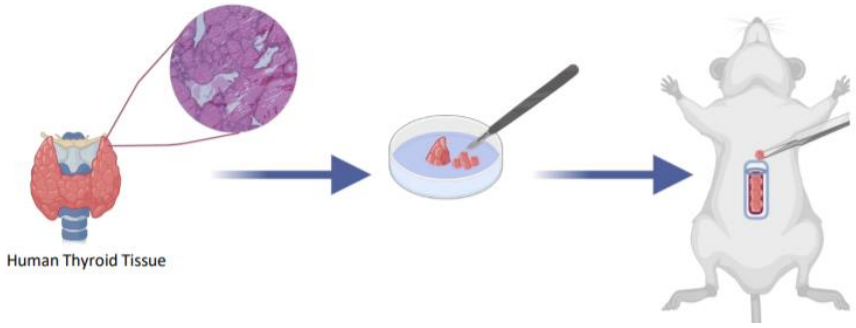


Source: Allied Market Research

Cell Pouch System – Positive Preclinical Study Findings Warrant Move to Clinical Studies

To explore an alternative to lifelong use of thyroid hormone replacement therapy, especially for patients that do not achieve adequate resolution of symptoms, Sernova has conducted a preclinical study to evaluate the transplantation of fresh healthy human thyroid tissue into the Cell Pouch in a mouse model, as outlined in Exhibit 31.

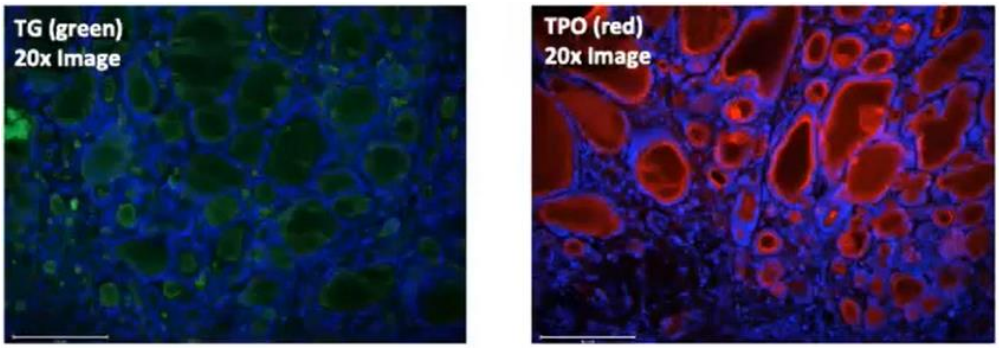
Exhibit 31 – Preclinical Mouse Model Procedure



Source: Company Presentation

Three months after transplant, the tissue was removed from the Cell Pouch in the mouse and, as can be seen in the histological sections displayed in Exhibit 32, the thyroid tissue remains viable and the thyroid enzymes and molecules that contribute to the production of thyroid hormones remain active. Thyroperoxidase (TPO, stained red in Exhibit 32) converts Thyroglobulin (TG, stained green) to the T3 and T4 hormones in the thyroid before secretion into the bloodstream. The preclinical data demonstrated promising blood levels of Thyroglobulin, the precursor to thyroid hormone production, and were recently published in a peer reviewed article.

Exhibit 32 – Transplanted Human Tissue in Cell Pouch Expressing Thyroglobulin (TG, Green) and Thyroperoxidase (TPO, Red)



Source: Wiseman et al. (2022) Subcutaneous transplantation of human thyroid tissue into a pre-vascularized Cell Pouch™ device in a Mus musculus model: Evidence of viability and function for thyroid transplantation. PLoS ONE 17(1): e0262345. https://doi.org/10.1371/journal.pone.0262345

Key Next Steps – Phase I/II Clinical Trial in Post-Surgical Hypothyroid Patients

While the presence and activity of TPO and TG molecules three months post-transplant indicate that the thyroid tissue remains viable and active, Sernova will look to prove the restoration of thyroid function in human patients in upcoming human clinical trials. The Company has completed the proof-of-concept study and is in the process of preparing and submitting regulatory documents in order to initiate a company-sponsored clinical trial. Upon regulatory and clinical site clearance, the Company will initiate a Phase I/II clinical study in human patients with postoperative hypothyroidism. Prior to thyroidectomy, the patient will have a Cell Pouch implanted beneath the abdominal subcutaneous space and, once it has vascularized, their thyroid will be surgically removed from their upper throat. From here, the gross and microscopic characteristics of the removed thyroid will be evaluated and the healthy portion of it will be transplanted into the vascularized Cell Pouch, where it is expected to resume normal function, including the natural feedback loop of thyroid hormone production. Importantly, the risk of developing hypothyroidism after hemithyroidectomy is somewhat predictable based on the patient's preoperative thyroid stimulating hormone (TSH) level. This should afford Sernova the ability to appropriately select clinical trial patients that have the best chance of showing an improved outcome with the CPS.

Potential for Stem Cell-Derived Cell Therapy for Hypothyroidism

In addition to using the healthy portion of the patient's own recovered thyroid tissue, Sernova will be exploring the use of T3- and T4-producing thyroid cells derived from stem cells in conjunction with the Cell Pouch as a way to restore the production of the thyroid hormone in all patients, regardless of what portion of their thyroid remains functional. In addition, this may negate the need for retrieval of healthy thyroid tissue following the thyroidectomy. Similar to the stem cell-derived islet cells for use in diabetes, the Company will look to use the conformal coating to protect the cells from the patient's immune cells.

Early Days but Meaningful Market Potential for Lower-Risk, Lasting Treatment

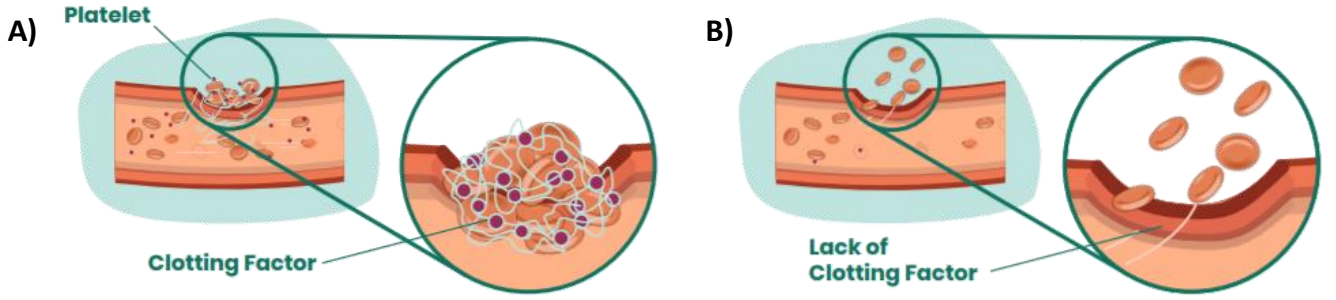
While the development of a product for the postoperative hypothyroid market is in the earlier stages, we believe that a truly curative regenerative medicine that allows for sustained normal endocrine function, elimination of daily lifelong thyroid medication use, and resolution of clinical symptoms in post-thyroidectomy hypothyroidism patients would be readily adopted in medical markets if proven in human studies and approved by regulators.

Assuming a Cell Pouch procedure price of US$50-60K, Sernova's initial target market of the ~150K US thyroidectomy patients per year represents a US$7.5-9.0B opportunity. With the same pricing assumption, the ~40% of the 1.1M Americans that do not respond adequately to traditional hormone replacement therapy (0.44M patients) represents a total addressable market of ~US$22-26B.

Hemophilia A – An Orphan Market with Huge Potential

Hemophilia A is an inherited bleeding disorder that arises due to a gene mutation in the X chromosome that causes the partial or total deficiency of coagulation Factor VIII (FVIII) protein. Without enough FVIII, the blood cannot clot properly to control bleeding. Even in circumstances where small blood vessels naturally break and heal, such as in joints or during exercise, excessive bleeding can in damage joints and cause inflammatory arthritic symptoms.

Exhibit 33 – Healthy Blood Clotting (A) and Lack of Clotting in Hemophilia A Patients (B)



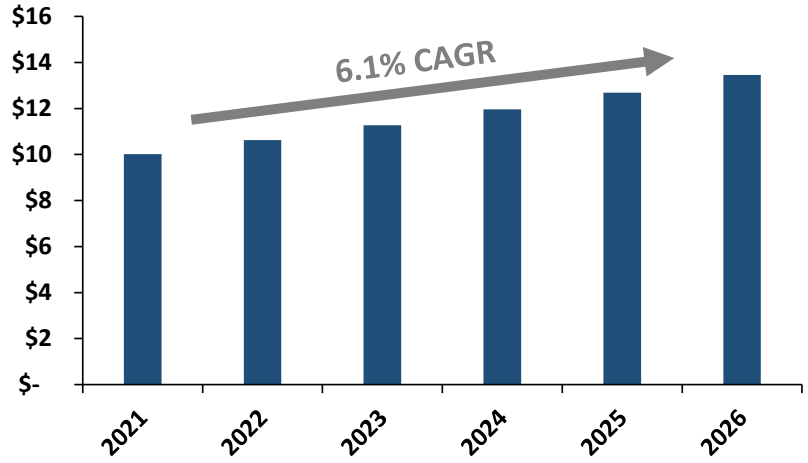
Source: American Society of Gene and Cell Therapy

Given that males only have one X chromosome, a mutated or missing FVIII gene will cause hemophilia A. Females have two copies of the X chromosome, so if the FVIII gene on one chromosome does not work, the gene on the other can make enough to compensate. For this reason, the disease is more prevalent in males, occurring ~1 in 5,600 live male births, with the severe form accounting for roughly half of all diagnoses. Females comprise nearly 20% of the diagnoses of mild hemophilia A, but account for less than 1% of the severe cases.

Global Hemophilia A Market – Expensive Treatments Driving Growth

While there are only ~33K hemophilia A patients in the US according to the CDC, the high treatment costs translate to an ~US$10B global orphan indication that is growing at a 6.1% CAGR and is expected to reach ~US$13B by 2026. The major factors driving the growth of the market include increased awareness and more timely and accurate diagnosis, allowing people to live longer with the disease.

Exhibit 34 – Global Hemophilia A Market (US$M)



Source: Fortune Business Insights

Clotting Factor Replacement Therapy – Expensive and Carries Significant Risks

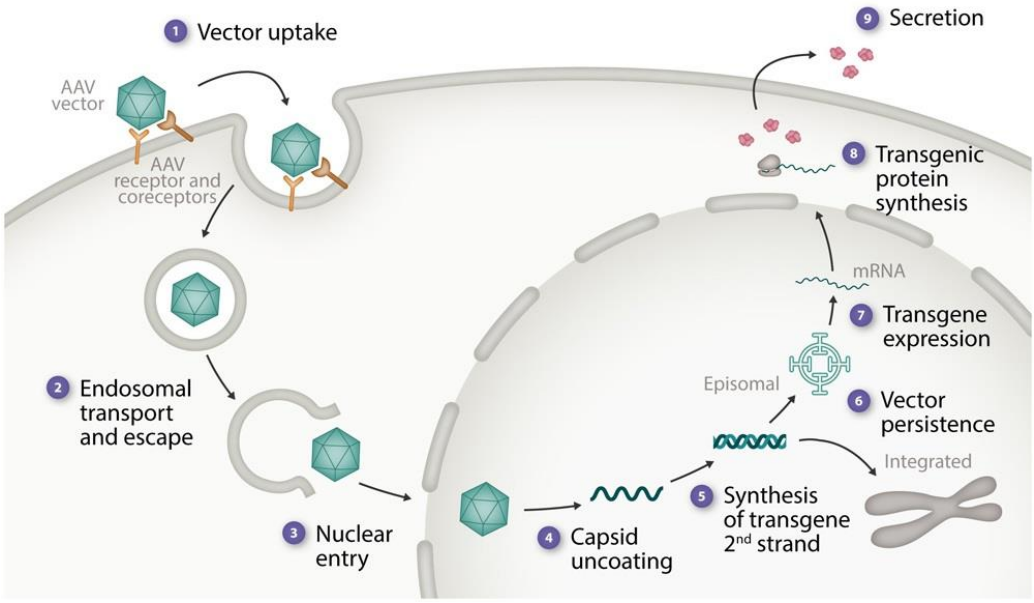
According to the National Hemophilia Foundation, the average annual cost of replacement therapy for a person with severe hemophilia is ~US$300,000. This is the most common treatment for hemophilia and entails slowly dripping or injecting concentrates of FVIII into a patient's vein. Clotting factor concentrates can be sourced from human blood that is treated to prevent the spread of blood-borne diseases such as HIV and hepatitis. Alternatively, patients can take recombinant clotting factors that are produced and isolated from animal cells in a lab. Replacement therapy can be taken on a regular basis to prevent bleeding (prophylactic therapy) or on an as-needed basis to stop bleeding when it occurs (demand therapy). Demand therapy is less expensive and intensive than prophylactic therapy, however, there's a risk that bleeding will cause damage before the demand therapy is administered.

There are numerous complications associated with clotting factor replacement therapy. First, the patient can develop antibodies that can recognize and destroy the clotting factor before it has a chance to work. These antibodies develop in 20-30% of patients with severe hemophilia A. Doctors may use larger doses of clotting factor or try different clotting factor sources when antibodies develop. Sometimes the presence of antibodies is transient. Second, despite best efforts, clotting factors isolated from human blood can carry the viruses that cause HIV/AIDS and hepatitis. Third, delays in treatment can cause damage such as bleeding into a joint, which can lead to a wide array of joint problems.

Gene Therapies – Higher Risk, High Reward

Gene therapy aims to be a one-time administration that delivers working genes into the patient's liver cells that should be producing clotting factors. This offers the possibility of enhancing hemophilia patients' quality of life by eliminating the burden of repeated administration of replacement therapy. This effect has been seen in hemophilia patients who have undergone a liver transplant for other reasons (e.g., HCV-related liver failure). Gene therapy involves delivery of functional FVIII genes to the liver cells using a viral vector with all viral genes removed. This allows the liver cells to secrete functional clotting factors into the bloodstream, resulting in better control of hemophilia A and fewer bleeds.

Exhibit 35 – Adeno-Associated Virus (AAV) Delivery of Functional FVIII Genes in Gene Therapy



Source: Batty, P., Lillicrap, D. Hemophilia Gene Therapy: Approaching the First Licensed Product, HemaSphere: Mar 2021 - Vol 5 - Iss 3 - p e540

Various other gene delivery mechanisms have been explored, including non-viral techniques such as chemical, electroporation, and polymer-based procedures; however, r-adeno-associated virus (rAAV) mediated delivery has been most commonly used (see Exhibit 36).

Exhibit 36 – Current Ongoing Hemophilia A Gene Therapy Clinical Trials

Sponsor	Product	Gene Delivery	Est. Completion	Clinical Trial Number	Notes
Phase III					
Spark Therapeutics	SPK-8011	rAAV	Dec-22	NCT03432520	Observational long-term safety follow-up study
BioMarin	BMN-270	rAAV	May-23	NCT03392974	Open-label, single-arm safety and efficacy study
BioMarin	BMN-270	rAAV	Nov-24	NCT03370913	Open-label, single-arm safety and efficacy study
BioMarin	BMN-270	rAAV	Sep-26	NCT04323098	Safety and efficacy study in combination with prophylactic corticosteroids
Pfizer	SB-525	rAAV	Jan-27	NCT04370054	Open-label, single-arm safety and efficacy study
Phase II					
Pfizer	SB-525	rAAV	Jul-24	NCT03061201	Open-label, adaptive, dose-ranging safety and tolerability study
Phase I/II					
Spark Therapeutics	SPK-8011	rAAV	Dec-22	NCT03003533	Dose-finding safety, tolerability, and efficacy study
Spark Therapeutics	SPK-8016	rAAV	Dec-22	NCT03734588	Dose-finding study in patients with FVIII inhibitors
BioMarin	BMN-270	rAAV	Mar-24	NCT02576795	Dose-escalation, safety, tolerability and efficacy study
Shire / Takeda	BAX-888	rAAV	Sep-26	NCT03370172	Open-label, dose escalation and safety study
BioMarin	BMN-270	rAAV	Nov-26	NCT03520712	Safety, tolerability, and efficacy study in patients with anti-AAV5 antibodies
Bayer / Ultragenyx	DTX-201	rAAV	Jun-27	NCT03588299	Safety and dose-finding study
Phase I					
Shenzhen Medical Institute	YUVA-GT-F801	Lentivirus	Jun-22	NCT03217032	Safety and efficacy study
Wisconsin Medical College	Patient's cells, edited *ex vivo*	Stem Cells	May-23	NCT03818763	Safety and feasibility study
Expression Therapeutics	Patient's cells, edited *ex vivo*	Stem Cells	Apr-25	NCT04418414	First-in-human, open label, safety and efficacy study
UCL	AAV2/8-HLP-FVIII-V3	rAAV	Jun-25	NCT03001830	Open-label, dose-finding safety and efficacy study

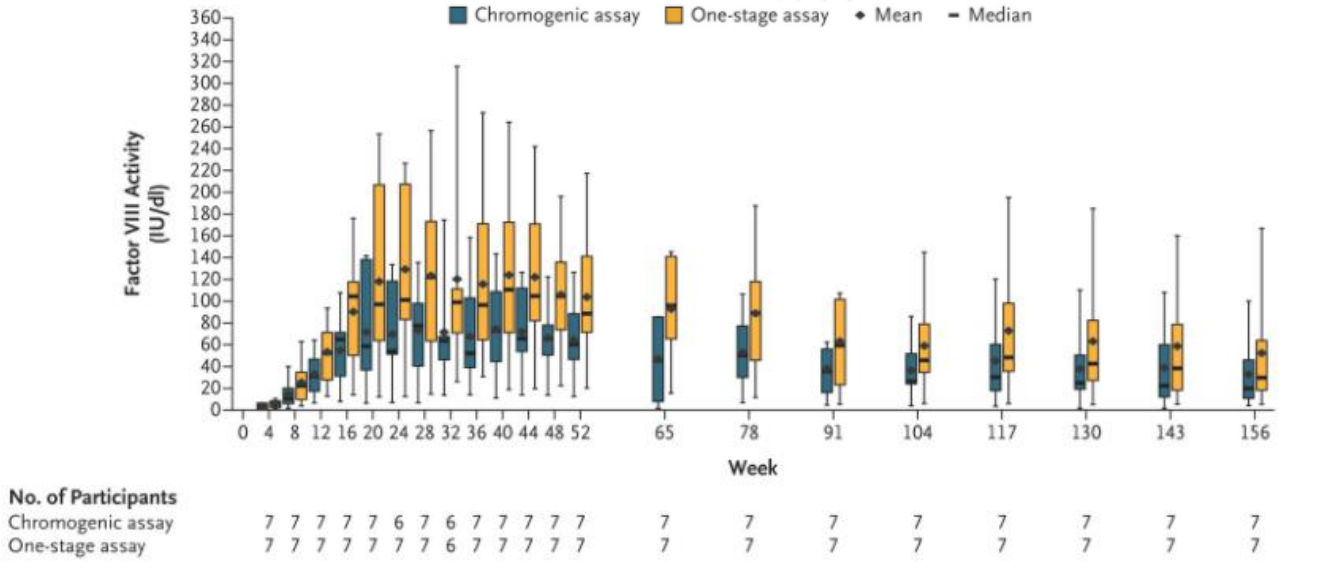
Source: Marchesini E., Morfini M., Valentino L. Recent Advances in the Treatment of Hemophilia: A Review. BTT.2021;15:221–235, ECM

Questions Remain Around Gene Therapies' Long-Term Safety and Efficacy

In terms of safety, open questions remain regarding the cause and long-term implications of liver toxicity, which occurs in ~60% of patients 4-12 weeks after delivery of hemophilia A gene therapies, along with questions around the risks of insertional mutagenesis. Furthermore, patients' pre-existing antibodies to adeno-associated viruses represent a significant hurdle to overcome in ~50% of patients. Dosing in children and the need for repeat dosing are also open questions.

While the longer-term data for FVIII gene therapy for hemophilia A is still being collected, human factor IX (FIX) gene therapy studies in adult hemophilia B patients are now out to eight years post-administration. These studies have shown only minimal evidence of a decline in plasma FIX levels over this period. The FVIII gene, however, is ~6x longer than the FIX gene and has a longstanding reputation for being problematic in molecular studies. A three-year follow-up study by BioMarin (BMRN-NASDAQ, NR) published in early 2020 showed that the FVIII activity spiked in year 1 and peaked 20-40 weeks post-administration before declining over 40% over year 2 and 8% over year 3 (see Exhibit 37). Despite the decrease in circulating FVIII levels over the study period, the mean annualized rate of bleeding events per year decreased by 96%, from a mean of 16.3 at baseline to 0.7 events at the end of year 3.

Exhibit 37 – FVIII Activity Over Three-Year Follow Up After Gene Therapy



Source: Pasi, J. K. et. al. Multiyear Follow-up of AAV5-hFVIII-SQ Gene Therapy for Hemophilia A, N Engl J Med 2020; 382:29-40

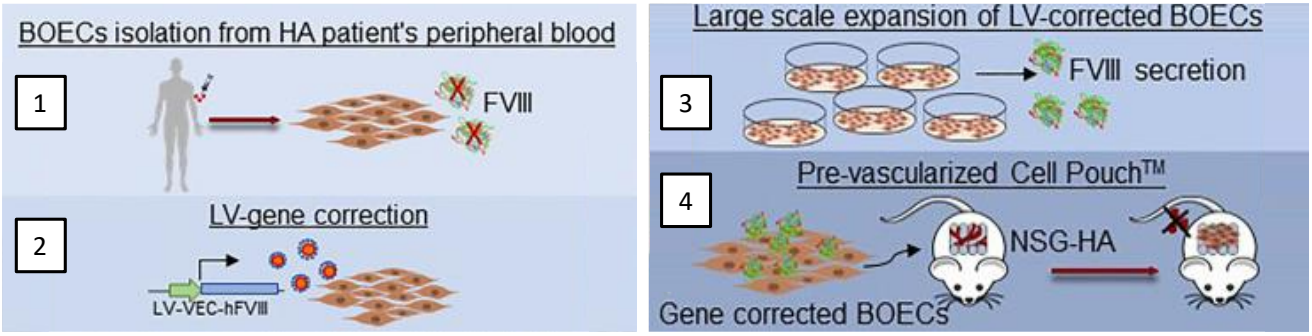
Annualized Bleed Rate, Not FVIII Activity, as the Primary Endpoint for Hemophilia A Clinical Trials

Notably, BioMarin was expected to win FDA approval for its hemophilia A gene therapy in 2020 on the back of its FVIII activity data. However, the FDA pivoted and asked the company to use the two-year annualized bleeding rate (ABR) as the primary endpoint in its Phase III clinical trial. While the FVIII activity of BioMarin's gene therapy will remain a focal point for stakeholders as it appears relatively short-lived, management anticipates that its ABR data will be sufficient to warrant regulatory filing and approval.

Cell Pouch System – A Potentially Lower-Risk Alternative to Factor Replacement

Unlike Sernova's Cell Pouch, gene therapy is irreversible, and patients incur the risk of off-target effects that could lead to cancer. Sernova's first-generation cell therapy approach for hemophilia A will look to use a small sample of the patient's blood, isolating the blood outgrowth endothelial cells (BOECs) and inserting a genetically corrected version of the FVIII gene into the cells. Once the cells are producing functional FVIII protein, they will be multiplied and quality-assessed in the lab before being transplanted back into the patient via the Cell Pouch as a potential functional cure. For its second-generation cell therapy, the Company will look to use a stem cell approach similar to the prospective second-generation hypothyroidism product, with stem cell-derived FVIII-producing cells protected from the patient's immune system using Sernova's Conformal Coating technology.

Exhibit 38 – Sernova and HemaCure's Preclinical Mouse Model Protocol

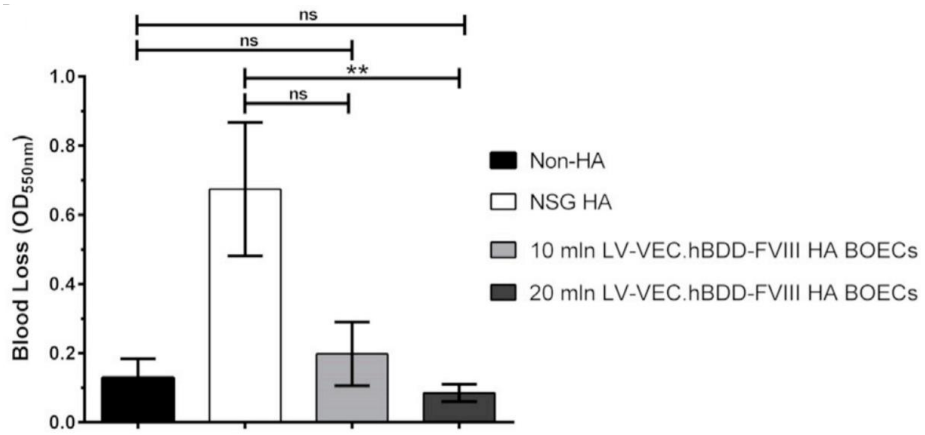


Source: Olgasi C. et. al. Efficient and safe correction of hemophilia A by lentiviral vector-transduced BOECs in an implantable device, Cell 2021; 23:551-566

Completed Proof-of-Concept Preclinical Studies Validate Progression to Clinical Studies

In 2016, a three-year proof-of-concept study funded by a European Commission grant was initiated by Sernova and the HemaCure Consortium, a European team of experts, to generate genetically corrected BOECs and develop the Cell Pouch for use in hemophilia A patients. This completed project involved a mouse model protocol (see Exhibit 38) that demonstrated that the corrected BOECs maintained functionality after transplant and safely increased the level of FVIII over 5x (from 4.5ng/mL to 24 ng/mL) to reach a therapeutic level. FVIII was detectable in peripheral blood up to four months post-transplantation and the level showed a dose-dependent relationship. As can be seen in Exhibit 39, the higher dose of 20M BOECs significantly reduced blood loss in hemophilia A mice compared to the control (NSG HA) and brought it in line with that of healthy mice. This provides a solid scientific rationale for progression to human clinical studies.

Exhibit 39 – Improvement in Clotting with FVIII-Producing Cells in the Cell Pouch



Source: Olgasi C. et. al. Efficient and safe correction of hemophilia A by lentiviral vector-transduced BOECs in an implantable device, Cell 2021; 23:551-566

Lucrative Orphan Market Leads to High Valuations and Large Deals

While hemophilia A and B (individually and in aggregate) are considered orphan indications, the reimbursement value of the therapies makes them lucrative markets. As such, there have been a handful of high-profile deals conducted in the space in recent years as big pharma names look to take a lower-risk approach to gaining entry to the market by acquiring clinical-stage or marketed products.

Sanofi Acquisition of Bioverativ for US$11.6B (2018)

In January 2018, French pharmaceutical giant Sanofi (SAN-NEXT, NR) acquired Bioverativ for US$11.6B (10.7x TTM sales). Bioverativ, a US-based biopharma that was spun out of Biogen (BIIB-NASDAQ, NR) had two hemophilia A replacement therapies, Alprolix and Eloctate, which generated combined revenues of US$1.1B in 2017. Beyond its two marketed products, its pipeline included an agglutinin disease product in Phase III trials, and early-stage programs in other rare blood disorders including sickle cell disease and beta thalassemia.

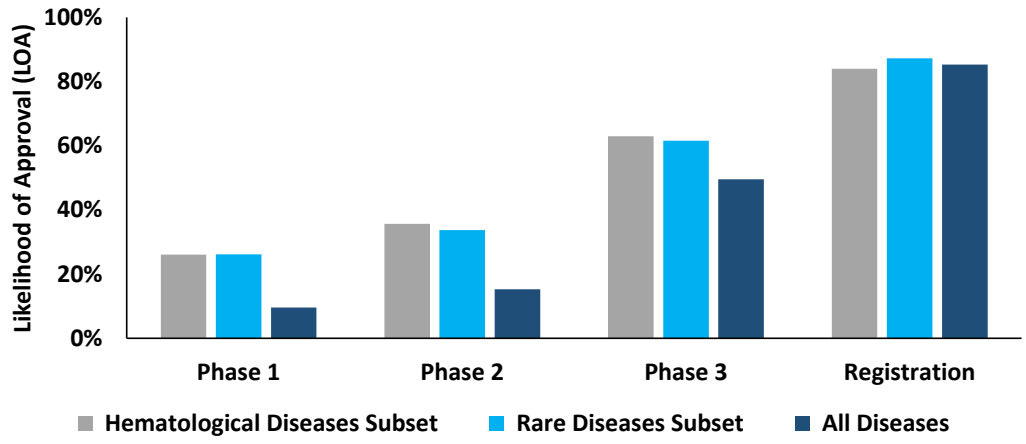
CSL Multi-Billion Dollar with uniQure for Hemophilia B Gene Therapy

In May 2021, Australian/German biopharma with over US$1B in hemophilia-related sales in 2020, CSL Behring (CSL-ASX, NR), announced a commercialization and license agreement with uniQure for its investigational hemophilia B gene therapy. Per the agreement, uniQure received a US$450M upfront payment, is eligible to receive up to US$1.6B in milestone payments and will be eligible to receive tiered double-digit royalties on net product sales. We note that the hemophilia B market is only ~20% the size of the hemophilia A market, and that gene therapy could be considered riskier than the Cell Pouch given the therapy's irreversible nature and the potential for off-target genetic alterations that could lead to tumour formation and cancer.

Hematological and Rare Diseases Typically Have Greater Clinical Success Rates

While noting that historical, industry-wide data may not reflect future outcomes, especially for any individual therapeutic candidate, hematological and rare diseases such as hemophilia A have seen higher chances of progression through the clinical pipeline and higher approval rates from the FDA than those in the broader biopharma space (see Exhibit 40 below).

Exhibit 40 – Likelihoods of FDA Approval for Hematological, Rare and All Disease Treatments at Various Clinical Development Stages



Source: Clinical Development Success Rates 2006-2015 – Biomedtracker

Key Patents Protect All Elements of the Regenerative Medicine Platform

Sernova has an international patent portfolio consisting of issued and pending patents that cover the Cell Pouch and other technologies that comprise its regenerative medicine platform in North and South America, Europe, and Asia. The key patent protecting the Cell Pouch (US10034963B2) was issued in 2015 and includes claims covering implantable polymer devices, surgical tools for cell transplantation, and methods of use including the use of a wide array of therapeutic cell types. This provides protection of the Cell Pouch System™ through to 2030. In 2015, the Patent Offices in China, Israel, Singapore, and New Zealand also issued similar patents to the Company, protecting the technology through to 2030. In addition, Sernova owns patents relating to its stem cell-derived therapeutic cells and conformal coating technology that provide protection through 2032 and 2033, respectively. The Company has more recently filed several patent applications that are expected to provide additional patent protection.

Exhibit 41 – Key Patents Protecting Sernova's Regenerative Medicine Technologies

US Patent Office Number	Patent Title	Patent Expiration
US10034963B2	Methods and devices for cellular transplantation	2030
US20140147483A1	Conformal coating of cells for immunoisolation	2032
CA2871795A1	Methods and compositions for generating pancreatic progenitors and functional beta cells from hPSCs	2033

Source: Google Patents, ECM

If the FDA and EMA grant orphan product designation to Sernova's technology, the patents' lives may be extended another 7 years in the US and 10 years in Europe.

Capital Structure

Balance Sheet is Healthy After Most Recent Raise

Sernova closed a bought deal of 19.2M units for $23M in March 2021, including full exercise of the over-allotment option of 2.5M units. Each unit included one SVA common share and one warrant with an exercise price of $1.70 until March 1, 2023. The warrants' expiry date may be accelerated by the Company if the daily volume weighted average trading price of the common shares exceeds $3.10 for the preceding 10 consecutive trading days.

Additional Financing Likely Required for Later Stage Clinical Development

With ~$30M in cash and no debt as of the last reporting date, along with a projected burn rate of $14M, $26M and $33M over the next three years, we expect the Company to raise ~$150M in the coming years in order to fund ongoing clinical trials and bring its products to market.

Sernova has access to multiple sources of capital, including from equity financing and non-dilutive sources such as debt, grants or even via an upfront payment from a putative collaboration agreement. While the Company has a history of successfully securing capital from non-dilutive grants, any such funding will be incorporated into the model as it is secured. For now, future capital needs are assumed to be met with equity financing in our model.

Given that the Company's valuation is driven in large part by the likelihood of the Cell Pouch products being approved by regulators, its market capitalization ought to increase with each de-risking event (publication of positive safety and/or efficacy data, advancement to successive clinical development stages). This creates a virtuous cycle in which each de-risking event raises the valuation, which in turn enables the financing of the next stage of development.

Exhibit 42 – Sernova Capital Structure

Based on a Share Price of $1.56	Basic	Effect of Dilutive Securities	Diluted
Shares (M)	260.8	58.5	319.3
Market Value of Equity ($M)	$ 406.9	$ 91.2	$ 498.1
Debt (Principal Amount) ($M)	$ -		$ -
Leases ($M)	$ -		$ -
Cash ($M)	$ 29.9	$ 44.8	$ 74.6
Enterprise Value ($)	**$ 377.0**	**$ 46.4**	**$ 423.5**
Equity as a % of Capital	*93%*		*87%*
Debt as a % of Capital	*7%*		*13%*
Cash as a % of MV of Equity	*7%*		*15%*
Cash per Share	*$ 0.11*		*$ 0.23*

Warrants Outstanding (M)	Exercise Price	Expiry Date
7.2	$ 0.30	Aug 16, 2022
7.3	$ 0.30	Aug 31, 2022
0.2	$ 0.30	Sep 9, 2022
11.1	$ 0.35	Sep 22, 2022
19.6	$ 1.70	Mar 1, 2023
1.2	$ 1.20	Mar 1, 2023
46.7	**$ 0.92**	

Type of Shares	Outstanding	Common Share Equivalents	Exercise/Conversion Proceeds	Notes
Basic Share Count	260,838,258	260,838,258		
Options	7,655,863	7,655,863	$1,837,407	Weighted average exercise price of $0.24
Warrants	46,656,892	46,656,892	$42,924,341	Weighted average exercise price of $0.92
DSUs	4,150,001	4,150,001		
Convertible Debt (C$)	-	-	-	
Fully Dil. Shares Outstanding		**319,301,014**	**$44,761,748**	

Source: Company Filings, ECM

Insider Ownership

Sernova has a majority retail shareholder base, with plenty of room for adoption by institutional investors. Management owns ~6.8M shares, primarily through long-time President and CEO, Dr. Philip Toleikis, who owns ~5.2M shares.

Exhibit 43 – Insider Ownership

Holder	Occupation/Notes	Common Stock Equivalent Held		Position Date
Philip Toleikis	President, CEO	5,228,596	2.00%	12/09/2021
Jeff Bacha	Director	598,314	0.23%	12/09/2021
Frank Holler	Director, Chairman	533,333	0.20%	12/09/2021
James Parsons	Director	274,728	0.11%	12/09/2021
Deborah Brown	Director	100,000	0.04%	12/09/2021
David Swetlow	CFO	65,000	0.02%	12/09/2021
Insider Total		**6,799,971**	**2.61%**	
Total FD Shares Outstanding		**260,838,258**		

Source: Company Filings, ECM

Forecast

Development Timelines

We anticipate that the top line results of the Company's Phase I/II T1D clinical trial will be available in C2023 and that a pivotal Phase III trial will be conducted over two to three years (n≈50), bringing the projected timeline for approval and marketing to C2027. Assuming regulatory approval on the back of preclinical studies of the second- and third-generation T1D products, we anticipate Phase I/II clinical studies (including conformal coating and stem cell-derived islets) in human subjects to commence in C2023 with potential advancement to pivotal Phase III trials in C2025 and approval in C2028.

We also anticipate Phase I/II clinical trials for postoperative hypothyroidism and hemophilia A to begin in C2022 and C2023, respectively, following regulatory approval. While these earlier-stage products are more prospective and do not drive our valuation, we estimate that they could reach the market in C2027.

Sernova's products could quite feasibly be granted breakthrough therapy designation and/or fast track by the FDA given their transformational potential, resulting in dramatically accelerated development and approval timelines.

High Prices Warranted by Transformative Technology & Small, High-Risk Target Population

A 2016 analysis showed that the cost of organ procurement for islet transplantation from a single donor was ~US$38K, with an additional ~US$$31K for isolation costs and ~US$30K in other medication and hospital costs. With an islet isolation success rate of ~50% and multiple donors needed for portal vein transplantation, the cost is generally US$140K+ per patient. This excludes the US$10-14K per year cost of immunosuppressive medications. This is, however, considerably more palatable than the ~US$400K cost associated with a total pancreas transplant, as estimated by Vertex Pharma on its Q321 earnings call, which was previously the only potential remedy for high-risk, hypoglycemia unaware T1D patients. For context, Spark Therapeutics (private) launched Luxturna®, a potentially curative gene therapy for the treatment of vision loss due to inherited retinal dystrophy, in 2017 at a cost of US$425K per eye for a single dose. Similarly, gene therapies to functionally cure Duchenne Muscular Dystrophy (DMD) launched by Sarepta (NASDAQ-SRPT, NR) cost ~US$750K per treatment.

Meaningful Cost Savings Lead to CPS Pricing of ~US$130K per Procedure per Patient

A physician and payor survey conducted by LifeSci Partners and commissioned by the Company indicated that the market could support potential pricing ~US$100-200K per patient would be justifiable for the first-generation Cell Pouch product given that it would serve as a functional cure for T1D. Where in this range the pricing ultimately falls will depend on the degree of insulin dependence afforded to patients by the CPS in the clinical trial, the durability of this insulin independence, and the CPS safety profile. With fewer donor islets required in the Cell Pouch than in a

portal vein transplant, our model assumes that Sernova would receive ~US$100K per course of treatment per patient, with Sernova keeping 70% of the economics and receiving ~US$30K for the implanted Cell Pouches, on which it will earn a 75% margin. This results in Sernova receiving ~US$130K course of treatment per patient with a 65% gross margin after accounting for the cost of the donor cells and shared economics with a prospective med-tech distribution partner. Given that the Cell Pouch can be quickly implanted via keyhole surgery in an outpatient setting, ancillary hospital costs are likely to be meaningfully reduced compared to portal vein transplant or whole pancreas transplant.

Later-Generation CPS Products Likely Priced Similarly to the First

Our model assumes that the pricing and margins of the second- and third-generation CPS products will be similar to those of the first-generation product in our model until further details regarding the cell source, estimated pricing and related microeconomics of the product are released by the Company. While the Company would likely be able to command a higher price for this product at first, it would likely have a lower gross margin. We expect the Company to in-license the technology to produce the stem-cell derived therapeutic cells for use in the CPS and, depending on its cash balance at the time, would most likely opt to pay for it with a higher royalty rate and lower upfront fee versus a larger upfront payment and lower royalties.

High-Risk Population with Significant Unmet Needs Allows for Swift Initial Adoption

There are currently ~60,000 severely hypoglycemia unaware T1D patients in the US and Europe that are immediate, obvious candidates for cell therapy given their risk status and high unmet need, according to market research by Vertex. While we expect rapid adoption among this population, Sernova's Cell Pouch clinical trial subjects include lower-risk subjects with less severe hypoglycemia unawareness and, as such, it will likely be indicated for use in the broader hypoglycemia unaware T1D population. With a particularly high-risk sub-population already present, we expect adoption to be swift. After anticipated approval in F2027, we expect that the Company will acquire 1.5% of the market in the first year, with marketing being led by its distribution partner, 4% in the second year, and another 2% per year in subsequent years to reach 8% by F2030.

Strong Cash Position as R&D Spend Ramps in F2023 and Beyond

With the Company expecting to move its hypothyroidism product to the clinical stage in C2022 and initiate a Phase III study of its Cell Pouch product for T1D in early C2023, we expect cash burn to be ~$14M in F2022, ~$25M in F2023, and climbing meaningfully over the subsequent years. The Company currently has ~$27M in cash as well as a potential ~$45M available from warrants expected to be exercised in the coming 15 months.

Financial Forecasts

~C$850M in Probability-Adjusted Revenues in F2030

With multiple indications and a multi-stage launch approach, we estimate that Sernova will achieve ~$850M in probability-adjusted sales in F2030. We estimate that the Company could acquire ~8.0% of the relatively small, high-risk, hypoglycemia unaware diabetic market, along with ~0.9% of the low-risk diabetes market and ~2.5% of the postoperative hypothyroidism market in this timeframe. As the Company is yet to begin the regulatory submission process to commence hemophilia A clinical trials in humans, our model and valuation solely rely on the probability-adjusted T1D and hypothyroidism indications for now. We will update our model to include this indication upon provision of additional clarity on the clinical timeline and possible pricing.

High-Risk Type 1 Diabetes – Smaller Population with More Critical Unmet Need

Given our anticipated clinical timeline, we expect F2027 to be the first year of Cell Pouch sales in the US and Canada with its first indication being high-risk/hypoglycemia unaware diabetic patients, as shown in Exhibit 44 below. Our estimated probability of approval of 20% is broadly consistent but at a slight premium to the recent historical rate of ultimate approval of potential endocrine treatments in Phase II clinical trials. We view this probability of approval as appropriate given the safety and efficacy shown in the Phase I/II trials to date.

Exhibit 44 – Cell Pouch Launch Curve: High-Risk Type 1 Diabetics

Revenues - High-Risk Type 1 Diabetes			F2025	F2026	F2027	F2028	F2029	F2030
US & Canada High-Risk Type 1 Diabetes Patients, #			281,306	285,807	286,093	279,226	266,940	249,856
High-Risk Type 1 Diabetes Market Penetration, %					1.5%	4.0%	6.0%	8.0%
High-Risk Type 1 Diabetes Procedures, #					4,287	11,444	16,754	21,355
High-Risk Type 1 Diabetes Revenue/Procedure, US$					$ 130,000	$ 130,000	$ 130,000	$ 130,000
High-Risk Type 1 Diabetes Revenues, US$M					557.3	1,487.7	2,178.0	2,776.2
High-Risk Type 1 Diabetes Revenues (probability-adjusted), US$M	Prob. Approv.	20%			111.5	297.5	435.6	555.2
High-Risk Type 1 Diabetes Revenues (probability-adjusted), C$M	**USD/CAD:**	**1.27**			**141.4**	**377.5**	**552.7**	**704.5**
High-Risk Type 1 Diabetes Revenue Growth, %						*167%*	*46%*	*27%*

Source: ECM

Low-Risk Type 1 Diabetes – Larger Blue-Sky Opportunity

In F2028, following a successful roll-out to high-risk diabetics, we expect the second- and third-generation Cell Pouch products using donor islets then stem cell-derived therapeutic cells, respectively, each protected by conformal coating, to generate sales among the lower-risk diabetic population. Given that the Cell Pouch itself has been proven in preclinical as well as clinical studies to safely vascularize after implantation, our model assumes that it is largely de-risked and that any clinical risk now lies in proving the safety and efficacy and longevity of the therapeutic cells. As such, the probability of approval of later-stage products are not conditional on the approval of the first.

Assuming the commencement of Phase I/II clinical trials for each product in C2023, our probability of approval of 5% for these two products combined is lower than the recent historical approval rate of potential endocrine treatments in Phase I clinical trials as the final product is contingent on the success of two separate technologies – the stem cell-derived therapeutic cells and conformal coating. We expect that, once approved, these technologies will also be used to treat high-risk diabetics.

Exhibit 45 – Cell Pouch Launch Curve: Low-Risk Type 1 Diabetics

Revenues - Low-Risk Type 1 Diabetes			F2025	F2026	F2027	F2028	F2029	F2030
US & Canada Low-Risk Type 1 Diabetes Patients, #			1,594,066	1,619,572	1,645,485	1,671,364	1,697,196	1,722,974
Low-Risk Type 1 Diabetes Market Penetration, %						0.3%	0.6%	0.9%
Low-Risk Type 1 Diabetes Procedures, #						4,936	10,028	15,275
Low-Risk Type 1 Diabetes Revenue/Procedure, US$						$ 130,000	$ 130,000	$ 130,000
Low-Risk Type 1 Diabetes Revenues, US$M						641.7	1,303.7	1,985.7
Low-Risk Type 1 Diabetes Revenues (probability-adjusted), US$M	Prob. Approv.	5%				32.1	65.2	99.3
Low-Risk Type 1 Diabetes Revenues (probability-adjusted), C$M	**USD/CAD:**	**1.27**				**40.7**	**82.7**	**126.0**
Low-Risk Type 1 Diabetes Revenue Growth, %							*103%*	*52%*

Source: ECM

Post-Thyroidectomy Hypothyroidism

The regulatory submission process has begun for Sernova to advance the post-thyroidectomy hypothyroidism indication to the clinic by the end of 2022. While this advancement is not yet certain, we believe that the low risk profile of such a study and the preclinical results generated to date provide favourable odds that Phase I/II will go ahead as scheduled. We use a conservative probability of approval of 5% in our model for this indication, which is conservatively below the historical average of 15.5% for Phase I metabolic treatment clinical trials. A price of ~US$50-60K is likely warranted for the hypothyroidism product as it is a lower-risk condition, and the therapeutic tissue is taken from the patient's own thyroid.

Exhibit 46 – Cell Pouch Launch Curve: Postoperative Hypothyroidism

Revenues - Postoperative Hypothyroidism		F2025	F2026	F2027	F2028	F2029	F2030
US & Canada Post-Operative Hypothyroid Patients, #		178,348	181,851	183,605	184,457	184,392	183,405
Thyroid Market Penetration, %				1.0%	1.5%	2.0%	2.5%
Thyroid Procedures, #				1,819	2,754	3,689	4,610
Thyroid Revenue/Procedure, US$				$ 60,000	$ 60,000	$ 60,000	$ 60,000
Thyroid Revenues, US$M				109.1	165.2	221.3	276.6
Thyroid Revenues (probability-adjusted), US$M	Prob. Approv. 5%			5.5	8.3	11.1	13.8
Thyroid Revenues (probability-adjusted), C$M	**USD/CAD: 1.27**			**6.9**	**10.5**	**14.0**	**17.5**
Thyroid Revenue Growth, %					*51%*	*34%*	*25%*

Source: ECM

Preclinical Hemophilia A Timeline TBD, Not Currently Included in our Model

Sernova has completed preclinical, proof-of-concept studies of its Cell Pouch to treat hemophilia A in mice, however, it has not yet commenced the regulatory submission process to advance to the clinical stage. As such, we do not include any revenues in our model derived from the treatment of hemophilia A. The Company intends on using therapeutic cells harvested from the patient and genetically corrected to produce FVIII and anticipates commencing a Phase I/II clinical trial in 2023.

Exhibit 47 – Financial Summary and Forecast Estimates

Financial Summary (C$M)	F2020 Act.	F2021 Est.	F2022 Est.	F2023 Est.	F2024 Est.	F2025 Est.	F2026 Est.	F2027 Est.	F2028 Est.	F2029 Est.	F2030 Est.
High-Risk Type 1 Diabetes Revenues (probability-adjusted, 20%)	-	-	-	-	-	-	-	141.4	377.5	552.7	704.5
Low-Risk Type 1 Diabetes Revenues (probability-adjusted, 5%)	-	-	-	-	-	-	-	-	40.7	82.7	126.0
Thyroid Revenues (probability-adjusted, 5%)	-	-	-	-	-	-	-	6.9	10.5	14.0	17.5
Revenue	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**148.4**	**428.7**	**649.5**	**848.1**
Growth	-	-	-	-	-	-	-	*NA*	*189.0%*	*51.5%*	*30.6%*
Consensus Revenue		-	-	-	-	-	0.3	135.8	345.5	577.5	766.0
Consensus Revenue Growth		-	-	-	-	-	-	*NMF*	*154.4%*	*67.1%*	*32.6%*
Cost of Revenue	-	-	-	-	-	-	-	51.9	150.1	220.8	288.3
Gross Profit	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**96.4**	**278.7**	**428.6**	**559.7**
Gross Profit Margin	-	-	-	-	-	-	-	*65.0%*	*65.0%*	*66.0%*	*66.0%*
Consensus Gross Profit Margin		-	-	-	-	-	-	*65.0%*	*66.0%*	*67.0%*	*68.0%*
Sales & Marketing	-	-	-	-	-	-	-	37.1	42.9	39.0	42.4
General & Administrative	1.6	2.0	3.5	6.0	8.0	10.0	12.0	18.2	38.2	53.2	61.9
Research & Development	2.8	3.9	10.5	20.0	25.0	30.0	35.0	44.5	42.9	45.5	50.9
EBITDA	**(4.4)**	**(5.9)**	**(14.0)**	**(26.0)**	**(33.0)**	**(40.0)**	**(47.0)**	**(3.3)**	**154.8**	**291.1**	**404.5**
EBITDA Margin	-	-	-	-	-	-	-	*-2.2%*	*36.1%*	*44.8%*	*47.7%*
Consensus EBITDA		(4.3)	(6.2)	(13.9)	(20.9)	(24.0)	(25.4)	117.3	291.4	487.9	643.0
Consensus EBITDA Margin		-	-	-	-	-	*NMF*	*86.4%*	*84.4%*	*84.5%*	*83.9%*
Net Income	**(5.3)**	**(6.8)**	**(14.8)**	**(28.9)**	**(35.5)**	**(43.0)**	**(50.6)**	**(7.4)**	**111.0**	**211.5**	**295.0**
EPS - WAD	**$ (0.03)**	**$ (0.03)**	**$ (0.06)**	**$ (0.10)**	**$ (0.11)**	**$ (0.12)**	**$ (0.14)**	**$ (0.02)**	**$ 0.29**	**$ 0.56**	**$ 0.78**
Consensus EPS		$ -	$ (0.01)	$ -	$ (0.03)	$ (0.02)	$ (0.01)	$ 0.10	$ 0.36	$ 0.56	$ 0.81

Source: ECM

Valuation

We are initiating coverage of Sernova with a Speculative Buy rating and $3.25/shr target price that is derived from a probability-adjusted DCF (14% discount rate and 5% residual growth). Our $3.25/shr target price represents 108% of upside from the current price of $1.56 (see Exhibit 48, below for DCF inputs and sensitivities). Our target price implies an equity value of C$1B, which is in line with T1D and hemophilia A focussed cell therapy comparables Semma Therapeutics, which was purchased for ~US$950M by Vertex in 2019, Sigilon Therapeutics, which achieved a valuation of ~US$1.5B in 2020 prior to clinical setbacks, and ViaCyte with an estimated private valuation of ~US$0.5-1B.

Exhibit 48 – DCF Assumptions (A), Discounted Cashflows (B), and Sensitivity Analysis (C)

A

Assumptions	
Current Stock Price	***$1.56***
WACC (%)	14.0%
Residual Growth Rate (%)	5.0%
Tax Rate	26.0%
PV of CF	45.4
PV of Terminal Value	976.9
Enterprise Value	**1,022.2**
Pro forma Cash (F2022)	21.9
Debt & Leases	-
Net Cash (Debt)	**21.9**
Equity Value	**1,044.1**
Diluted Shares Outstanding (F2022)	320.4
DCF Target Price	**$3.25**
DCF Target Price % Upside	*108%*

B

Discounted Cashflows	F2022	F2023	F2024	F2025	F2026	F2027	F2028	F2029	F2030
Operating Profit (EBIT)	**(14.8)**	**(28.9)**	**(35.5)**	**(43.0)**	**(50.6)**	**(7.4)**	**150.1**	**285.8**	**398.6**
LESS: Income Tax	-	-	-	-	-	-	39.0	74.3	103.6
Net Operating CF (NOPAT)	**(14.8)**	**(28.9)**	**(35.5)**	**(43.0)**	**(50.6)**	**(7.4)**	**111.0**	**211.5**	**295.0**
D&A	0.4	0.4	0.5	0.5	0.6	0.6	0.7	0.8	0.9
Net Change in WC	-	-	-	-	-	(23.8)	(43.9)	(34.4)	(31.0)
Capex	(0.4)	(0.5)	(0.7)	(0.7)	(0.9)	(0.9)	(1.1)	(1.1)	(1.3)
FCF	**(14.8)**	**(29.0)**	**(35.7)**	**(43.2)**	**(50.9)**	**(31.6)**	**66.7**	**176.8**	**263.5**
Tax Rate %	-	-	-	-	-	-	*26%*	*26%*	*26%*
PV of Annual CF	**(13.4)**	**(23.1)**	**(24.9)**	**(26.4)**	**(27.3)**	**(14.9)**	**27.6**	**64.0**	**83.7**
Terminal Value									**3074.3**

C

Residual Growth \ Discount Rate	13%	14%	15%
7%	$5.25	**$4.20**	$3.40
6%	$4.50	**$3.65**	$3.05
5%	**$3.95**	$3.25	**$2.75**
4%	$3.50	**$2.95**	$2.45
3%	$3.15	**$2.65**	$2.25

All in C$M, except per share amounts

Source: ECM

For context, we consider the valuations of two subsets of companies: pure-play T1D companies, and other cell therapy/regenerative medicine companies. While the valuations of the high-risk, high-reward cell therapy/regenerative medicine companies have a high degree of dispersion among their valuations, the diabetes-oriented companies allude to the valuations attributable to treatments/technologies that gain mass appeal among the large diabetic population. We also note that the most directly comparable peers, Vertex/Semma and ViaCyte, are highly diversified and not publicly traded, respectively. See page 6 for full descriptions.

Exhibit 49 – Comparables Analysis

Entity Name	Ticker	Mkt Cap - B (C$M)	EV - FD (C$M)	Returns 1M	3M	YTD	1Y	EV/Sales F2021	F2022	F2023
Type 1 Diabetes Comps										
DexCom	DXCM	52,444.1	51,408.5	-10%	-33%	-21%	6%	16.7 x	13.7 x	11.4 x
Insulet	PODD	21,721.8	22,267.0	-1%	-21%	-7%	-12%	16.3 x	13.8 x	11.4 x
Tandem Diabetes Care	TNDM	9,530.4	9,175.6	-10%	-13%	-22%	16%	10.6 x	8.8 x	7.2 x
Average		**27,898.8**	**27,617.1**	**-7%**	**-22%**	**-16%**	**3%**	**14.5 x**	**12.1 x**	**10.0 x**
Median		**21,721.8**	**22,267.0**	**-10%**	**-21%**	**-21%**	**6%**	**16.3 x**	**13.7 x**	**11.4 x**
Sernova	**SVA**	**406.9**	**472.4**	**-24%**	**13%**	**-11%**	**-24%**	**NA**	**NA**	**NA**
Cell Therapy/Regenerative Medicine Comps										
Sangamo Therapeutics	SGMO	1,042.9	430.3	-17%	-47%	-25%	-63%	3.1 x	2.8 x	2.7 x
uniQure	QURE	1,019.0	419.5	-11%	-51%	-16%	-55%	0.7 x	2.5 x	2.5 x
VistaGen Therapeutics	VTGN	396.1	290.5	-11%	-33%	-20%	-17%	250.5 x	190.7 x	190.7 x
Athersys	ATHX	281.2	230.2	8%	-29%	4%	-66%	24.5 x	7.1 x	7.1 x
Brainstorm Cell Therapeutics	BCLI	147.2	118.8	-15%	5%	-20%	-56%	NA	NA	NA
Pluristem Therapeutics	PSTI	73.3	39.3	22%	-37%	23%	-77%	NA	NA	NA
Lineage Cell Therapeutics	LCTX	310.8	230.0	-27%	-42%	-41%	-49%	48.9 x	12.1 x	12.1 x
Sigilon	SGTX	69.8	(64.0)	-31%	-67%	-38%	-96%	NMF	NMF	NMF
SanBio	4592	624.2	584.0	-7%	-7%	9%	-36%	115.1 x	NA	NA
Average		**440.5**	**253.2**	**-10%**	**-34%**	**-14%**	**-57%**	**73.8 x**	**43.1 x**	**43.0 x**
Median		**310.8**	**230.2**	**-11%**	**-37%**	**-20%**	**-56%**	**36.7 x**	**7.1 x**	**7.1 x**
Sernova	**SVA**	**406.9**	**472.4**	**-24%**	**13%**	**-11%**	**-24%**	**NA**	**NA**	**NA**

Source: ECM

Appendix I: Management, Board of Directors, and Advisory Teams

Management

Dr. Philip M. Toleikis, Ph.D. – President and CEO

Dr. Toleikis is President and Chief Executive Officer of Sernova Corp since April 2009. From 2006 until 2009, Dr. Toleikis consulted for multiple device, combination product and pharmaceutical companies. From 1996 to 2006 he held multiple roles at Angiotech Pharmaceuticals, Inc. including Vice President, Research and Development – Pharmacology and Drug Screening where he built a product development team of over 50 scientists and was responsible for multiple corporate and academic product development collaborations. While at Sernova, Dr. Toleikis has secured over $60 million in various forms of financings, including equity raises and multiple non-dilutive grants and has been responsible for negotiating a worldwide exclusive license with UHN for its stem cell derived technologies and the University of Miami for its conformal coating immune protection technologies as well as developing business relationships and or collaborations with multiple pharmaceutical and academic institutions involving its Cell Pouch System™ technologies.

Dr. Toleikis is an author on over 100 patent applications and issued patents, and multiple scientific publications involving transplantation, metabolic, cardiovascular, oncology, and autoimmune disease. He obtained his Ph.D. in Medicine, Pharmacology and Therapeutics from the University of British Columbia, his M.Sc. at the University of Michigan and B.A. at the University of Vermont.

Frank Shannon – VP Clinical and Regulatory Affairs

Mr. Shannon has a track record of more than 25 years of proven experience in clinical development and regulatory affairs. He has served in senior level positions within the international medical device, pharmaceutical, and biologic industries where he achieved commercial goals through innovative risk management and execution strategies, to obtain marketing approval of products. Mr. Shannon most recently served as VP Clinical Development, Regulatory Affairs and Quality at Ripple Therapeutics, a spin-out of Interface Biologics where he served in the same capacity since 2016. Prior to these appointments, he held various senior clinical/regulatory positions at Baxter International, St. Jude Medical, Boehringer-Ingelheim, Hoffmann-La Roche/Roche Laboratories, Inc., Genentech Canada, Inc., and Ciba-Geigy Canada, Ltd.

David Swetlow, CA – CFO

Mr. Swetlow is a high-tech and life sciences/biotech veteran with over 20 years in various senior management, board & advisory roles predominantly for start-up, acceleration, and high-growth stage companies, including multiple companies listed on the TSX and NASDAQ such as QLT Inc., Protox Therapeutics Inc., and Xillix Technologies. His life sciences/biotech experience includes biopharmaceutical, medical device, and drug/device combination technologies and products. Mr. Swetlow has a Bachelor of Business Administration degree from Simon Fraser University (SFU) and earned his CA designation while at Deloitte. He was previously a co-founding Director of TSXV company OMNItech Capital Corp. and served as Director and Audit Committee Chairman for successor companies One Person Health Sciences and HealthPricer Interactive.

Christopher Barnes – VP Investor Relations

Chris has worked in financial services for 23 years, first as an investor relations consultant, then as the investor relations officer for Extendicare Inc., a large North American nursing home company listed on both the TSX and NYSE. Subsequently Chris moved directly into capital markets as an IIROC registered institutional salesperson with three Toronto based investment boutiques, including Fraser Mackenzie, Octagon Capital and Pace Securities covering accounts in Canada, the United States and Europe. Chris holds a bachelor's degree in English and Political Science from Laurentian University plus he completed the Richard Ivey School of Business at University of Western Ontario, Strategic Investor Relations diploma.

Board of Directors

Dr. Philip M. Toleikis, Ph.D. (see above)

Frank Holler – Director and Chairman

Mr. Holler is currently President & CEO of Ponderosa Capital Inc. He previously served as Chairman & CEO of BC Advantage Funds (VCC), a venture capital firm investing in emerging technology companies in BC from 2004 to 2016; President and CEO of Xenon Pharmaceuticals, a NASDAQ-listed, genomics-based drug development company, from 1999 to 2003; President and CEO of ID Biomedical, a TSX/NASDAQ vaccine development company, from 1991 to 1998; and a founding director of Angiotech Pharmaceuticals, a TSX/NASDAQ-listed biotechnology company, from 1992 to 1997. Prior to working in biotechnology and healthcare, Mr. Holler was a VP of Investment Banking with Merrill Lynch Canada and Wood Gundy. He was previously a Director of the BC Biotechnology Association from 1992 to 1998, and in 2003 received the BC Biotech Award for Vision and Leadership. Mr. Holler has an MBA and BA (Economics) from the University of British Columbia.

James Parsons – Director

Mr. Parsons is the CFO of Trillium Therapeutics since August 2011. From 2010 to May 2013, he was VP Finance and Corporate Secretary at DiaMedica Therapeutics. He has a broad background in the life sciences industry across therapeutics, diagnostics and device companies and 25+ years of financial management experience. He has secured over $300M of various forms of financing during his career and has advised and assisted on over $200M of product licensing deals. Mr. Parsons serves on the board of directors of DiaMedica Therapeutics and has extensive experience in public company governance and compliance. Mr. Parsons received his Master of Accounting degree from the University of Waterloo and is a CPA and CA.

Jeffrey Bacha – Director

Mr. Bacha currently serves as executive chairman of Rakovina Therapeutics, a biopharmaceutical company focused on novel DNA-damage response inhibitors for the treatment of cancer. He is the CEO of Edison Oncology Holding Corp., a company he co-founded in 2018 to develop and commercialize new cancer treatments. From 2010 to 2017, Mr. Bacha served as CEO and chairman of Kintara Therapeutics, a company he co-founded in 2010. From 2002 through 2005, Mr. Bacha served as President and Founding CEO of Inimex Pharmaceuticals and raised more than $35M to support the company's research programs. He served as senior manager and director of KPMG Health Ventures. Mr. Bacha has an MBA from Emory University and a degree in BioPhysics from UCSD.

Deborah Brown – Director

Ms. Brown is currently a Partner at Accelera Canada Ltd. She has extensive leadership experience with 20+ years in senior management roles. She served as President of EMD Serono, a division of Merck KGaA, EVP at Serono US, GM, Director of Marketing, and Business Unit Director at Serono Canada and Manager, and International Regulatory at Pasteur Merieux Connaught. She is a former Board Chair and Director of Rx&D and former Board Director of BIOTECanada. Ms. Brown earned an MBA from the Ivey School of Business and completed the ICD.D designation in 2019. She sits on the board of several corporate and not-for-profit organizations.

Dr. Mohammed Azab – Director

Dr. Azab is President and CMO of Astex Pharmaceuticals, Inc., a pharmaceutical company focused on the discovery and development of drugs in oncology. As of November 2020, upon retirement from his management role, he has served as the Chair of the Board of Directors for Astex Pharmaceuticals. Previously, he served as President and CEO of Intradigm Corporation, a developer of siRNA cancer therapeutics. Prior to this, he served as EVP of R&D and CMO of QLT Inc., and in several leadership positions at AstraZeneca in the UK and Sanofi in France. Dr. Azab has a medical degree from Cairo University and an MBA from Western University, Ontario. He has 30+ years of experience in clinical research and business management and led the global development of several drugs currently approved in oncology and other therapeutic areas. Currently, he also serves on the board of directors of NASDAQ-listed companies Xenon Pharmaceuticals and Durect Corporation.

Appendix II: Investment Risks

Share Dilution Risk

It is highly likely that the Company will sell additional equity securities in future offerings, including through the sale of securities that are convertible to equity, to finance its operations, acquisitions, or projects, and issue additional common shares if outstanding warrants, stock options, and/or convertible debenture conversion rights are exercised, which may result in dilution of current investors.

Reliance on Third Parties for Supply and Manufacture of Products

Sernova does not currently have manufacturing facilities to independently manufacture its product candidates and, as such, may not have total or any control over the availability of its product candidates, their quality, or cost. If Sernova were unable to obtain third-party manufacturers on commercially acceptable terms, it may not be able to distribute its product candidates.

Early-stage Development and Scientific Uncertainty

Sernova's products are at an early stage of development and significant additional investment in R&D, product validation, production scale-up, manufacturing, and regulatory submissions will be required prior to commercialization. There can be no assurance that any such products will be developed. The development and regulatory processes may require access to raw materials and inputs that may not be available in sufficient amounts or in a timely fashion to allow completion of development or receipt of regulatory approval of any product or process. Furthermore, it is not known whether any of Sernova's product candidates will meet applicable health regulatory standards and obtain regulatory approvals required for commercialization and distribution.

Heavy Reliance on the Cell Pouch

All of Sernova's current product candidates involve the use of its CPS and are still in preclinical or clinical development. If the Company is unable to commercialize its product or experiences significant delays in doing so, the business may be materially harmed. The Company's conformal coating and other related technologies currently rely entirely on the Cell Pouch for their use.

Patent and IP Risk

Sernova's success will depend in part on its ability to obtain, maintain, and enforce patent rights, maintain trade secret protection, and operate without infringing the proprietary rights of third parties. There can be no assurance that pending patent applications will be allowed, that issued patents will provide it with any competitive advantage or will not be challenged by any third parties, or that patents of others will not have an adverse effect on its ability to conduct its business. Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of Sernova's patented products.

Dependence on Collaborative Partners and Licensors

Sernova currently utilizes licensed technology alongside its own. Specifically, it depends upon its license to use certain technology provided under sublicense agreement with UHN (dated September 9, 2015) for the development of stem cell product candidates. In addition, it is dependent upon its license to use the conformal coating technology provided under sublicense agreement with UMiami (dated July 28, 2020). While the Company's licenses are in good standing, a breach of the agreements could lead to termination by the licensor.

Product Liability Claims

Although Sernova currently carries what it believes to be adequate product liability and clinical trial insurance, there can be no assurance that it will be able to maintain its current insurance, or obtain other insurance as required, on acceptable terms, with adequate coverage in the future against potential liabilities or at all. If the Company's clinical trial and product liability insurance prove inadequate; product liability claims may harm its business.

Rapid Technological Change

The biotechnology and pharmaceutical industries are characterized by rapid and substantial technological change and there can be no assurance that developments by others will not render Sernova's proposed products or technologies non-competitive, or that it will keep pace with technological developments.

Government Regulations

Biotechnology and pharmaceutical companies operate in a high-risk regulatory environment where the manufacture and sale of therapeutic products are governed by numerous statutes and regulations in the countries where Sernova intends to market its products. Such legislation affects the approval of manufacturing facilities, controlled research, and testing procedures, review, and approval of manufacturing, preclinical and clinical data prior to marketing approval, as well as regulation of marketing activities, notably advertising and labelling.

Healthcare Reimbursement

Sernova's ability to successfully market its products may depend in part on the extent to which reimbursement will be available from government health administration authorities, private health insurers, and other organizations. Uncertainty exists as to whether newly approved healthcare products will qualify for reimbursement and challenges to the price of medical products are becoming more frequent. There can be no assurance that adequate third-party coverage will be available at price levels that would allow the Company to meet our forecasts.

Important Information and Legal Disclaimers

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ANALYST CERTIFICATION

Company: Sernova Corp.| TSXV:SVA

I, Stefan Quenneville, hereby certify that the views expressed in this report accurately reflect my personal views about the subject securities or issuers. I also certify that I have not, am not, and will not receive, directly or indirectly, compensation in exchange for expressing the specific recommendations or views in this report.

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Is Echelon Wealth Partners Inc. a market maker in the issuer's securities at the date of this report?	No

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Buy	The security represents attractive relative value and is expected to appreciate significantly from the current price over the next 12-month time horizon.
Speculative Buy	The security is considered a BUY but in the analyst's opinion possesses certain operational and/or financial risks that are higher than average.
Hold	The security represents fair value, and no material appreciation is expected over the next 12-18 month time horizon.
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Number of recommendations	33	39	1	0	4	2	0
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% of Total (excluding Restricted)	35%	63%	0%	0%	2%		

PRICE CHART, RATING & PRICE TARGET HISTORY

Date	Target ($)	Rating
Feb 9, 2022	$3.25	Speculative Buy

Coverage Initiated: Feb 9, 2022

Data Source: CapIQ

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