Sernova Biotherapeutics Inc.

Canada, USA, Germany / Biotechnology
TSX, Canada; OTCQX, US; FSE, Germany
Bloomberg: SVA CN
ISIN: CA81732W1041

Pipeline news

RATING	**BUY**
PRICE TARGET	**CAD 1.60**
Return Potential	814.3%
Risk Rating	High

T1D PROGRAMME GAINS STEAM WITH SOLID DATA AND TOP-TIER CLINICAL ADVISORS

Sernova Biotherapeutics has released positive interim results from its ongoing phase 1/2 trial of the Cell Pouch Bio-hybrid Organ in patients with type 1 diabetes (T1D). The data from 12 patients across Cohorts A and B reconfirm the results seen so far, including successful islet engraftment, insulin production (as evidenced by C-peptide levels), and a notable proportion of patients (8 of 12) achieving insulin independence. Importantly, new patient-reported outcomes indicate significant quality of life improvements, which is of great relevance in this debilitating disease. There is no new information on the additional Cohort B patients using the larger 10-channel Cell Pouch who were to have been recruited a few months ago and will be examined for the potential elimination of top-up via the portal vein. The company reaffirmed plans to initiate the Cohort C trial in H2 2025, provided funding is secured. Sernova also aims to begin clinical trials with Evotec's iPSC-derived islet-like clusters in 2026, aiming to enhance the consistency and scalability of islet cell therapy. In addition, Sernova announced the formation of a world-class clinical advisory board to support the clinical development of its Cell Pouch to deliver a functional cure for T1D. The involvement of leading experts from top-tier institutions boosts the credibility and development prospects of the T1D programme, potentially accelerating its path to approval and increasing awareness among potential partners and investors. Based on an updated SOTP valuation model, we arrive at a CAD1.60 price target (previously: CAD1.90). The reduction in our price target stems from higher than previously modelled financing-related dilution due to recent share price weakness. However, we see upside potential of >800% and reiterate our Buy rating.

Encouraging interim data reinforce clinical promise of Sernova's Cell Pouch Bio-hybrid Organ Sernova released positive interim data from its ongoing phase 1/2 trial evaluating the Cell Pouch platform in 12 patients with type 1 diabetes (T1D). The data shows that 8 patients achieved insulin independence following transplantation of donor islet cells. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2020/21	2021/22	2022/23	2023/24	2024/25E	2025/26E
Revenue (CAD m)	0.0	0.0	0.0	0.0	30.0	0.0
Y-o-y growth	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT (CAD m)	-6.9	-24.8	-40.5	-31.7	-4.4	-27.6
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income (CAD m)	-7.0	-24.4	-39.0	-32.2	-4.6	-27.6
EPS (diluted) (CAD)	-0.03	-0.09	-0.13	-0.10	-0.01	-0.96
DPS (CAD)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (CADm)	-6.9	-14.8	-30.4	-18.9	-1.4	-24.6
Net gearing	-99.3%	-7.9%	-69.7%	46.4%	-2194.7%	110.7%
Liquid assets (CAD m)	27.9	49.8	19.8	6.0	19.5	9.8

RISKS

Risks include, but are not limited to development, regulatory, competition and financing risks.

COMPANY PROFILE

Sernova is a Canadian, clinical-stage biotech company focusing on the R&D of cell therapeutics for potential 'functional cures' of chronic debilitating diseases. Sernova's core technology platform is the Cell Pouch™ bio-hybrid organ, an implantable device designed to create a natural environment where therapeutic cells can thrive. The company's lead programme is a phase 1/2 clinical trial in patients with type 1 diabetes, and it also has preclinical programmes for hypothyroidism and haemophilia A.

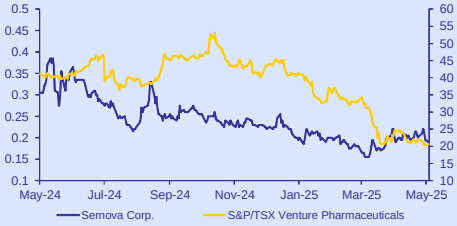
MARKET DATA

As of 30 May 2025

Closing Price	CAD 0.18
Shares outstanding	328.48m
Market Capitalisation	CAD 57.48m
52-week Range	CAD 0.16 / 0.39
Avg. Volume (12 Months)	295,058

Multiples	2023/24	2024/25E	2025/26E
P/E	n.a.	n.a.	n.a.
EV/Sales	n.a.	1.93	n.a.
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Jan 2025

Liquid Assets	CAD 1.21m
Current Assets	CAD 2.07m
Intangible Assets	CAD 0.00m
Total Assets	CAD 3.08m
Current Liabilities	CAD 20.57m
Shareholders' Equity	CAD -17.93m

SHAREHOLDERS

Evotec AG	5.3%
Management and Directors	9.0%
Freefloat and others	85.7%

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Importantly, 7 of 12 patients demonstrated C-peptide levels of 0.3 ng/mL or higher, a well-established biomarker threshold indicating successful islet engraftment and insulin production. The study comprises two patient cohorts: Cohort A with six patients implanted with a smaller Cell Pouch device and Cohort B with six patients utilising an optimised ten-channel high-volume Pouch. The company has not disclosed which data points correspond to which cohort, however all efficacy and patient-reported outcomes reported here pertain to patients who ultimately received islets via the portal vein. As outlined in our September 2024 report, patients #3 through #6 in Cohort B experienced failed islet engraftment due to inadequate immunosuppression, which was reduced as the company adjusted dosing as part of the trial efforts to identify an optimal immunosuppressant regimen. Subsequent analysis attributed islet death in these cases to under-immunosuppression, and the Cell Pouches were removed. These patients were then administered islets via the portal vein, suggesting that a substantial portion of the 8 insulin-independent patients likely achieved this outcome through a hybrid approach.

Glycaemic control achieved in all 12 patients post portal vein implantation All 12 patients reached or maintained HbA1c levels below the ADA-recommended target of <7.0%. Notably, with the Cell Pouch alone (prior to portal vein implantation) one patient reduced HbA1c from 10.3% to 7.8% (a 24% drop), and two maintained normal levels from baseline. This is supported by significant improvements in glycaemic control: 9 patients achieved HbA1c <7.0%, while one showed a 24% decrease to 7.8%. Two additional patients maintained HbA1c <7.0% from baseline. These results underscore the clinical effectiveness of the Cell Pouch system in combination with islet transplantation via the portal vein when required.

Quality of life outcomes strengthen therapeutic case In addition to metabolic outcomes, the company reported first-time data from patient-reported measures. The main improvements recorded in validated patient-reported outcomes were:

- Clarke Hypoglycaemia Awareness Scale: all 12 patients reported improved hypoglycaemia awareness;
- Hypoglycaemia Fear Survey-II: 9 of 12 showed reduced fear of hypoglycaemia;
- Diabetes Distress Scale (DDS): 10 of 12 patients experienced reduced emotional burden from T1D management.

These benefits reflect a meaningful improvement in disease burden and support the Cell Pouch value proposition beyond glycaemic metrics.

No update on the FDA-approved expansion of Cohort B by 3-4 patients According to management, the phase 1/2 trial is on track to meet its primary and secondary endpoints. However, the company gave no update as to whether the up to 4 additional patients approved by the FDA for Cohort B expansion have been enrolled or treated. We currently believe that funding limitations may compel management to consider treating only 1-2 patients and switch immediately to Cohort C which will have the same protocol.

Cohort C remains on track A confirmatory Cohort C, which will further evaluate the optimised 10-channel Cell Pouch with the optimised immune suppression protocol, is expected to initiate in H2 2025, provided the required funding is secured. Confirmation of such stand-alone efficacy remains essential to fully validating the Cell Pouch as a next-generation therapeutic alternative to conventional intrahepatic islet transplantation.

The company confirmed the outlook for the iPSC-based programme in partnership with Evotec The reported findings validate the Cell Pouch's role in islet engraftment and functionality, setting the stage for upcoming trials using induced pluripotent stem cell (iPSC) derived islet-like clusters from Sernova's partner, Evotec. This next-generation study, expected to initiate post-Cohort C in 2026, aims to achieve insulin independence without the need for portal vein implantation.

Setting up a world-class clinical advisory board further validates the Cell Pouch potential and will boost development prospects Sernova announced the formation of a world-class Clinical Advisory Board to support the clinical development of its Cell Pouch Bio-hybrid Organ to deliver a functional cure for T1D. The board will consist of five internationally recognised experts in diabetes, islet transplantation, and regenerative medicine. It will be chaired by Dr Robert Gabbay, a prominent diabetes leader affiliated with Harvard Medical School and the Joslin Diabetes Center. This is good news because it underscores strong scientific and clinical support for Sernova's Cell Pouch as a groundbreaking approach to potentially curing T1D. The full Clinical Advisory Board includes:

- Dr Robert Gabbay (Chair) – *Harvard Medical School & Joslin Diabetes Center*: Former Chief Medical Officer of the American Diabetes Association; expert in diabetes care models and health systems innovation;
- Dr Mark Atkinson – *University of Florida Diabetes Institute*: Director and one of the most cited scientists in T1D research; leads global initiatives in T1D pathogenesis and treatment;
- Dr Melena Bellin – *University of Minnesota*: Professor in paediatric endocrinology and surgery; expert in islet cell transplantation and translational research for T1D;
- Dr Andrew Posselt – *UCSF Medical Center*: Director of the Pancreatic Islet Transplant Programme; a surgeon-scientist focused on transplant immunology and metabolic disease;
- Dr Holger Russ – *University of Florida, Department of Pharmacology and Therapeutics*: Leads research in stem cell-based therapies and the autoimmune mechanisms behind T1D.

Board changes Mr Ross Haghighat resigned as Chairman of Sernova's Board, effective 24 May 2025. His resignation came as a surprise as he had assumed to the role in January during the company's rebranding. The company's Board of Directors has accepted his resignation, but no successor has been named. His short tenure was marked by strategic initiatives aimed at advancing the company's mission in regenerative medicine.

Q1 24/25 RESULTS AND FINANCING

Q1 24/25 financial results – Restructuring yields cost benefits… Sernova reported its financial results for Q1 24/25 (to 31 January 2025). As expected, the company posted no revenue. OpEx declined significantly YoY to CAD 4.8m (Q1 23/24: CAD 10.0m), reflecting the impact of the corporate restructuring initiated in 2024, which included a ~35% workforce reduction, project prioritisation and a change in management. The largest driver of the decline was the sharp contraction in R&D costs, which were more than halved to CAD 2.59m (Q1 23/24: CAD 7.24m), while G&A expenses dropped 21% to CAD 2.21m. Net loss for the quarter narrowed to CAD 5.7m (Q1 23/24: CAD 9.7m).

…but liquidity pressure remains intense Cash flow from operations remained deeply negative at CAD -4.8m, comparable to the prior-year period (Q1 23/24: CAD -4.2m), reinforcing the company's urgent need to raise capital in the near term. The cash position declined sharply to CAD 1.2m at the end of Q1 24/25 (FY 23/24: CAD 6.0m), a level that management acknowledged is insufficient to fund operations beyond Q1 without further financing. As a result, after Q1 24/25, Sernova raised CAD 1.0m in convertible notes from Dr Steven Sangha, a current Sernova shareholder and board member, and CAD 4m through a loan from Navigate Private Yield Fund LP III (matures on 16 April 2026), which provided temporary relief. However, the company will require a more substantial capital injection to initiate Cohort C of its ongoing phase 1/2 trial in T1D and to extend its cash runway into 2026. The shareholders' deficit widened to CAD -17.9m (FY 23/24: CAD -13.0m), underscoring the severity of the liquidity strain.

VALUATION MODEL

Buy rating confirmed at lower price target The interim data reflect the potential of Sernova's Cell Pouch Bio-hybrid Organ to deliver durable glycaemic control and quality-of-life improvements for T1D patients. These early outcomes bolster the likelihood of success in subsequent Cohort C and iPSC-based trials and support our positive outlook on Sernova's equity story. In addition, the involvement of leading experts from top-tier institutions Harvard, UCSF, the University of Florida, and the University of Minnesota on Sernova's Scientific Advisory Board boosts the credibility and development prospects of the programme, potentially speeding its path to approval and creating awareness among potential partners and investors. However, the company's financial standing continues to be challenged by constrained liquidity. Sernova remains dependent on completing financing initiatives in the near term to sustain its operations and continue advancing its Cell Pouch platform and the ongoing phase 1/2 clinical trial in T1D. In light of the recent share price weakness, we have adjusted our SOTP valuation to reflect higher dilution in future financing measures, resulting in a price target of CAD 1.60 (previously: CAD 1.90). Given the upside potential of over 800%, we reiterate our Buy recommendation.

Figure 1: "Sum-of-the-parts" (SOTP) valuation model

Cell Pouch-Based Compound	Project[1)]	Present Value	Patient Pop (K)	Treatment Cost (USD)	Market Size (USDM)	Market Share (%)	Peak Sales (USDM)	PACME Margin[2)] (%)	Discount Factor (%)	Year of market launch
1G product	T1D - US	USD 41.6M	400K	225,000	90,000.0M	0.5%	550.7M	24%	17%	2029
2G product	T1D - US	USD 261.7M	400K	225,000	90,000.0M	3.5%	3,969.7M	24%	17%	2030
3G product	T1D - US	USD 88.7M	1,600K	120,000	192,000.0M	3.5%	7,401.4M	24%	17%	2034
1G product	Hypothyroidism-US	USD 211.4M	50K	225,000	11,250.0M	9.0%	1,401.5M	22%	17%	2030
PACME PV		USD 603.5M			383,250.0M		13,323.3M			
Costs PV[4)]		USD 71.6M								
NPV		USD 531.9M								
Milestones PV		USD 19.8M								
Net cash (proforma)		USD 27.1M								
Fair Value		USD 578.8M								
Share Count (proforma)		486,994K								
Price Target		USD 1.20								
Price Target		CAD 1.60	(based on CAD-USD exchange rate of 0.73)							
Price Target		EUR 0.90	(based on EUR-USD exchange rate of 1.14)							

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues. This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining market exclusivity after the point of approval

Source: First Berlin Equity Research estimates

INCOME STATEMENT

All figures in CAD '000	2020/21	2021/22	2022/23	2023/24	2024/25E	2025/26E
Revenue	**0**	**0**	**0**	**0**	**30,000**	**0**
Cost of goods sold	0	0	0	0	0	0
Gross profit	0	0	0	0	30,000	0
General & Administrative	-2,299	-7,857	-8,459	-8,973	-9,400	-9,600
Research & Development	-4,638	-16,897	-32,043	-22,691	-25,000	-18,000
Total operating expenses (OPEX)	**-6,937**	**-24,754**	**-40,502**	**-31,664**	**-34,400**	**-27,600**
Operating income (EBIT)	**-6,937**	**-24,754**	**-40,502**	**-31,664**	**-4,400**	**-27,600**
Net financial result	-29	333	1,504	-521	-200	-50
Non-operating income/expenses	0	0	0	0	0	0
Pre-tax income (EBT)	**-6,966**	**-24,421**	**-38,998**	**-32,185**	**-4,600**	**-27,650**
Income taxes	0	0	0	-7	0	0
Net income / loss	**-6,966**	**-24,421**	**-38,998**	**-32,192**	**-4,600**	**-27,650**
Diluted EPS (CAD)	**-0.03**	**-0.09**	**-0.13**	**-0.10**	**-0.01**	**-0.96**
Ratios						
EBIT Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBITDA Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Expenses as % of OPEX						
General & Administrative	33.1%	31.7%	20.9%	28.3%	27.3%	34.8%
Research & Development	66.9%	68.3%	79.1%	71.7%	72.7%	65.2%
Y-Y Growth						
Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Operating income	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income/ loss	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

BALANCE SHEET

All figures in CAD '000	2020/21	2021/22	2022/23	2023/24	2024/25E	2025/26E
Assets						
Current Assets, Total	**28,327**	**51,091**	**21,023**	**6,470**	**20,353**	**10,715**
Cash	27,874	3,776	8,722	6,012	19,452	9,771
Short-term investments	0	46,000	11,084	0	0	0
Accounts receivables	449	1,147	1,053	298	750	800
Other current assets	4	168	165	159	151	144
Non-Current Assets, Total	**1,493**	**1,394**	**1,083**	**1,057**	**1,012**	**1,107**
Property plant and equipment	176	402	393	299	370	465
Intangible assets	717	517	317	0	-117	-117
Deposits	212	224	259	224	224	0
Other LT assets	388	251	114	535	535	535
Total Assets	**29,820**	**52,485**	**22,106**	**7,527**	**21,365**	**11,821**
Shareholders' Equity & Debt						
Current Liabilities, Total	**1,476**	**4,740**	**9,592**	**20,015**	**20,103**	**20,309**
Accounts payable	1,358	4,600	9,456	19,914	20,000	20,200
Other current liabilities	117	140	136	101	103	109
Longterm Liabilities, Total	**276**	**136**	**0**	**468**	**375**	**337**
Other liabilities	276	136	0	468	375	337
Shareholders Equity	**28,068**	**47,608**	**12,514**	**-12,957**	**886**	**-8,824**
Total Consolidated Equity and Debt	**29,820**	**52,485**	**22,106**	**7,527**	**21,365**	**11,821**
Ratios						
Current ratio (x)	19.19	10.78	2.19	0.32	1.01	0.53
Quick ratio (x)	19.19	10.78	2.19	0.32	1.01	0.53
Net gearing	-99.3%	-7.9%	-69.7%	46.4%	-2194.7%	110.7%
Book value per share (CAD)	0.11	0.17	0.04	n.a.	0.00	n.a.
Net debt	-27,874	-3,776	-8,722	-6,012	-19,452	-9,771
Equity ratio	94.1%	90.7%	56.6%	-172.1%	4.1%	-74.6%

CASH FLOW STATEMENT

All figures in CAD '000	2020/21	2021/22	2022/23	2023/24	2024/25E	2025/26E
Net income	**-6,966**	**-24,421**	**-38,998**	**-32,192**	**-4,600**	**-27,650**
Interest, net	29	-333	-1,504	521	200	50
Tax provision	0	0	0	7	0	0
Non-operating items	0	0	0	0	0	0
EBIT	**-6,937**	**-24,754**	**-40,502**	**-31,664**	**-4,400**	**-27,600**
Depreciation and amortisation	220	440	446	540	206	85
EBITDA	**-6,716**	**-24,314**	**-40,056**	**-31,123**	**-4,194**	**-27,515**
Derivative liability	0	0	0	0	0	0
Share based payments	218	7,451	3,903	1,746	3,500	3,000
Changes in w orking capital	518	2,947	4,986	11,160	-356	163
Cash interest net	-29	333	1,504	-521	-200	-50
Other adjustments	-835	-839	-676	-157	0	0
Operating cash flow	**-6,844**	**-14,421**	**-30,339**	**-18,896**	**-1,250**	**-24,403**
CapEx	-17	-329	-99	0	-160	-180
Free cash flow	**-6,861**	**-14,750**	**-30,438**	**-18,896**	**-1,410**	**-24,583**
Other investments	-212	-46,012	34,881	11,119	0	0
Cash flow from investing	**-229**	**-46,341**	**34,781**	**11,119**	**-160**	**-180**
Debt Financing, net	0	0	0	0	0	0
Equity Financing, net	31,025	36,510	0	4,960	15,000	15,000
Other financiing activities	1,093	155	503	108	-150	-98
Cash flow from financing	**30,997**	**36,665**	**503**	**5,067**	**14,850**	**14,902**
Net cash flows	**23,925**	**-24,098**	**4,946**	**-2,710**	**13,439**	**-9,681**
Cash, start of the year	3,949	27,874	3,776	8,722	6,012	19,452
Cash, end of the year	**27,874**	**3,776**	**8,722**	**6,012**	**19,452**	**9,771**
Y-Y Growth						
Operating Cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Free cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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ASSET RECOMMENDATION

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy[1]	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

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RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	19 October 2023	CAD0.73	Buy	CAD3.80
2	6 February 2024	CAD0.60	Buy	CAD3.80
3	27 September 2024	CAD0.25	Buy	CAD1.90
4	11 February 2025	CAD0.22	Buy	CAD1.90
5	Today	CAD0.18	Buy	CAD1.60

INVESTMENT HORIZON

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Legally required information regarding

- **key sources of information in the preparation of this research report**
- **valuation methods and principles**
- **sensitivity of valuation parameters**

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