

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 1.90
Return Potential	783.7%
Risk Rating	High

IND SUBMISSION TO THE FDA FOR HYPOTHYROIDISM COMPLETED

Sernova Biotherapeutics Inc has submitted an Investigational New Drug (IND) application to the FDA to test its Cell Pouch in patients with hypothyroidism following total thyroidectomy, a surgical procedure to remove the thyroid gland when nodules are present. The company anticipates that following treatment each patient's own thyroid tissue will regain its natural ability to release thyroid hormones in the Cell Pouch without the need for lifelong hormone replacement or immunosuppression, thereby curing the patient. We note that preclinical data showed successful restoration of thyroid hormone levels and functional thyroid tissue within the device. Subject to IND approval by the FDA and, in particular, the necessary funding, we expect Sernova to initiate a first-in-human clinical trial in H2 2025 or H1 2026 to investigate the safety and efficacy of this approach. This is positive news as the company is one step closer to potentially advancing a second product into clinical trials. With regard to the ongoing lead phase 1/2 clinical trial of the Cell Pouch for the treatment of type 1 diabetes (T1D), we expect final results for cohort B for all of the up to four planned last patients (patients #7 to #10) by mid-2025. Based on unchanged pipeline estimates, we confirm our CAD1.90 price target and our Buy rating.

IND for the Cell Pouch for the treatment of hypothyroidism following total thyroidectomy submitted to the FDA on 3 February 2025 Hypothyroidism is a medical condition characterised by the underproduction of thyroid hormones (mainly thyroxine, or T4, and triiodothyronine, or T3) by the thyroid gland. These hormones play a critical role in regulating the body's metabolism, and thyroid malfunction affects all critical body functions, including heart rate, energy levels, and the rate at which energy is produced from nutrients. The company's strategy is to harvest healthy tissue from each patient's thyroid gland following removal through thyroidectomy and transplant this tissue into the preimplanted vascularised Cell Pouch. The company anticipates that following treatment...
 (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 10 Feb 2025

Closing Price	CAD 0.22
Shares outstanding	325.32m
Market Capitalisation	CAD 69.94m
52-week Range	CAD 0.19 / 0.70
Avg. Volume (12 Months)	295,990

Multiples	2023/24	2024/25E	2025/26E
P/E	n.a.	n.a.	n.a.
EV/Sales	n.a.	n.a.	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 Oct 2024

Liquid Assets	CAD 6.01m
Current Assets	CAD 6.47m
Intangible Assets	CAD 0.00m
Total Assets	CAD 7.53m
Current Liabilities	CAD 20.02m
Shareholders' Equity	CAD -12.96m

SHAREHOLDERS

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



...each patient's own thyroid tissue will regain the natural ability to release thyroid hormones in the Cell Pouch without the need for lifelong hormone replacement or immunosuppression, thereby curing the patient. As the treatment uses the patient's own tissue, there is no risk of immune rejection. This suggests that this programme could develop at a faster pace than the T1D programme. Provided that the IND is approved by the FDA and, in particular, the necessary funding is obtained, we expect that Sernova will start a first-in-human clinical trial in H2 2025 or H1 2026 to investigate the safety and efficacy of this approach. This is positive news as the company is one step closer to potentially advancing a second product into clinical trials. In our view, getting a second indication into the clinic will establish Sernova's Cell Pouch as a platform technology.

We anticipate final data from the ongoing phase 1/2 clinical trial of the Cell Pouch for cohort B for the treatment of T1D in mid-2025 We recall that the company reported positive data at the September 2024 European Association for the Study of Diabetes (EASD) Annual Meeting in Madrid, Spain. All six patients in Cohort A using the small 8-channel Cell Pouch following islet transplantation achieved sustained insulin independence following a top-up via the portal vein. Unfortunately, there were delays in Cohort B using the larger 10-channel Cell Pouch which intends to eliminate the need for top-up via the portal vein. In an attempt to explore a friendlier immunosuppression regimen, the first six patients received a lower immunosuppression dose and the islets died (see more details in our update from September 2024). Subsequently, the FDA granted approval to expand this cohort by up to three additional patients to up to 10 patients to study and demonstrate an optimised immunosuppression regimen. We expect the company to release final data on the last up to four patients in Cohort B (patients #7 to #10) by mid-2025. We view the update after the second implantation in mid-2025 as a key milestone and catalyst for the share. Subject to funding, we expect the company to launch a further confirmatory phase 1/2 clinical trial for cohort B with the optimised regimen in H2 2025.

Four important recent additions to the leadership team In October 2024, Sernova appointed (1) Mr James Parsons as CFO. He brings over 20 years of financial management experience, with a comprehensive track record in biotech corporate finance, governance, and strategic planning. We believe he is an important addition to support the CEO, Mr Jonathan Rigby in raising the required funding. Sernova also appointed (2) Marylyn Rigby as Chief Communications Officer (CCO). Ms Rigby is an accomplished professional with a rich history in branding, corporate communications, and biotech and health tech marketing. Her fingerprint can already be recognised at the upgraded homepage. In December 2024, (3) Dr Robert Gabbay, former Chief Scientific and Medical Officer at the American Diabetes Association, joined Sernova as a clinical advisor. Dr Gabbay brings extensive expertise in diabetes care and research, which will be instrumental as Sernova advances its clinical trial development with the Cell Pouch in T1D. On 30 January 2025, Sernova appointed (4) Ross Haghghat as Chair of the Board. Mr Haghghat has over three decades of experience in founding, funding, and scaling technology ventures in healthcare, with a proven track record in driving successful innovations, strategic growth, and mergers and acquisitions in the biotechnology and life sciences sectors. His extensive financing and deal experience is expected to support Sernova's strategic direction and financing objectives.

Results of the AGM held on 10 January 2025 and renaming of the company to Sernova Biotherapeutics Inc (formerly Sernova Corp) On 10 January Sernova held its Annual and Special General Meeting of Shareholders (AGM). At the AGM, shareholders elected six directors: Tanya Lewis, Bernd Muehlenweg, David Paterson, Jonathan Rigby, Steven Sangha, and Ross Haghghat and reappointed KPMG LLP as the company's auditor for the ensuing year. Additionally, shareholders approved the continuance of Sernova as a British Columbia corporation and the alteration of the company's authorised share structure to allow an unlimited number of preferred shares. We believe allowing an unlimited number of preferred shares is a significant step providing the company with greater financial and



strategic flexibility as it can now raise capital, close strategic partnerships, and or structure mergers and acquisitions without immediately diluting control of common shareholders or founders (preferred shares usually do not come with voting rights). On 30 January 2025, Sernova Corp. announced its rebranding to Sernova Biotherapeutics Inc. This name change reflects the company's focus on developing regenerative medicine solutions, particularly its Cell Pouch bio-hybrid organ aimed at providing a functional cure for T1D.

P&L KPI OVERVIEW OF 23/24 RESULTS

FY 2023/24 financial results better than expected chiefly do due to lower R&D spending Sernova reported EBIT of CAD-31.7m (FBe: CAD-37.3m; 22/23: CAD-40.5m). The substantial OPEX decline YoY chiefly reflects lower R&D expenses of CAD22.7m (FBe: CAD28.0m; 22/23: CAD32.0m) due to the company's cost-saving measures, which include focusing spending on the ongoing 1G Cell Pouch phase 1/2 study and the preclinical hypothyroidism programme, as well as discontinuing spending on the conformal coating technology for the 3G Cell Pouch programme following disappointing performance. G&A rose slightly to CAD9.0m (FBe: CAD9.3m; 22/23: CAD8.5m). The net financial result came in at CAD-0.5m (FBe: CAD-0.3m) vs CAD1.5m in 22/23. The net result amounted to CAD-32.2m (FBe: CAD-37.6m; 22/23: CAD-39.0m).

Table 1: P&L 2023/24 reported figures vs FB estimates and 2022/23 (KPIs)

in CAD'000	2023/24	2023/24E	Delta	2022/23	Delta
Revenue	0	0	-	0	-
General & Administrative	-8,973	-9,300	-	-8,459	-
Research & Development	-22,691	-28,000	-	-32,043	-
OPEX	-31,664	-37,300	-	-40,502	-
EBIT	-31,664	-37,300	-	-40,502	-
<i>margin</i>	-	-	-	-	-
Net financial result	-521	-330	-	1,504	-
Net income / loss	-32,192	-37,630	-	-38,998	-

Source: First Berlin Equity Research, Sernova Biotherapeutics Corp

Balance sheet and Cash Flow 2023/24 – Cash & ST investments down to CAD6.0m; cash runway until ~end of Q1/25, indicating needed upcoming financing measures

Sernova's cash position including short-term investments declined to CAD6.0m at YE 23/24 (FB: CAD2.2m; YE 22/23: CAD19.8m), due to funding of ongoing operations. Operating cash flow totalled only CAD-18.9m (FY 22/23: CAD-30.3m), chiefly attributable to lower OPEX and a cash flow increase in accounts payable & accrued liabilities to CAD10.6m (FY 22/23: CAD4.8m). Financing cash flow increased to CAD5.1m (FY 22/23: CAD0.5m) due to an oversubscribed, non-brokered private placement that Mr Rigby completed in September 2024 shortly after taking over as the new CEO. Based on the company's cash burn, the cash funds can finance operations until ~end of Q1 2025 or early Q2 2025.

Funding efforts are underway and we expect results soon In December 2024, Sernova signed a non-binding letter of intent with HealthGena (a Riyadh-based business accelerator focused on biotechnology innovation) and GOLDTRACK Ventures (a German VC firm focused on life science) under "Project REEM Ventures" to explore financing and commercialisation opportunities in Saudi Arabia, particularly with a focus on T1D solutions. Given the company's short cash runway, we expect first results soon. We note that the company has made significant strategic and corporate progress since October 2024 which may support ongoing financing efforts.



VALUATION MODEL

Buy rating and price target confirmed Despite the pipeline delays for T1D over the past year, Sernova's Cell Pouch is the only and most advanced device in the industry which provides a proven, well-vascularised environment and is capable of housing functioning islets producing insulin, glucagon, and somatostatin across all chambers (e.g. patient #1 in cohort A from phase 1/2 T1D clinical trial). Regarding the ongoing lead phase 1/2 clinical trial of the Cell Pouch for the treatment of T1D, we expect positive final data for the last up to four planned patients in mid-2025. The recent submission of the IND to the FDA for the treatment of hypothyroidism is good news and represents a significant milestone for Sernova. It brings the company one step closer to potentially advancing a second product into clinical trials, which would establish Sernova's Cell Pouch as a platform technology. Assuming funding is secured, we expect Sernova to initiate a first-in-human clinical trial in H2 2025 or H1 2026 to evaluate the safety and efficacy of this approach. We expect that Sernova will succeed in raising further funding in the coming months. Based on unchanged pipeline estimates, we confirm our CAD1.90 price target and our Buy rating.

Table 2: "Sum-of-the-parts" valuation model

Cell Pouch-Based Compound	Project ¹⁾	Present Value	Patient Pop (K)	Treatment Cost (USD)	Market Size (USDMM)	Market Share (%)	Peak Sales (USDMM)	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 69.3M								
NPV		USD 534.2M								
Milestones PV		USD 22.9M								
Net cash (proforma)		USD 30.9M								
Fair Value		USD 588.0M								
Share Count (proforma)		432,203K								
Price Target		USD 1.40								
Price Target		CAD 1.90	(based on CAD-USD exchange rate of 0.70)							
Price Target		EUR 1.30	(based on EUR-USD exchange rate of 1.04)							

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

4) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project



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 working 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 financing 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 VALUATION SYSTEM

First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

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	Today	CAD0.22	Buy	CAD1.90

INVESTMENT HORIZON

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.

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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

can be accessed through the following internet link: <https://firstberlin.com/disclaimer-english-link/>

SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Marie-Curie-Straße 24-28, 60439 Frankfurt am Main

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