Sernova Corp. (SVA.TO)
Rating: Buy

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Phase 1/2 T1D Cell Pouch Study Gets Green Light to Enroll Second Cohort; Interim Data Expected in 2023

Stock Data	11/03/2022
Price	C$0.86
Exchange	TSX
Price Target	C$6.00
52-Week High	C$2.22
52-Week Low	C$0.69
Enterprise Value (M)	C$225
Market Cap (M)	C$252
Public Market Float (M)	256.1
Shares Outstanding (M)	293.1
3 Month Avg Volume	111,758
Short Interest (M)	0.31
Balance Sheet Metrics	
Cash (M)	C$27.20
Total Debt (M)	C$0.00
Total Cash/Share	C$0.09

EPS (C$) Diluted			
Full Year - Oct	2021A	2022E	2023E
1Q	(0.01)	(0.02)A	--
2Q	(0.01)	(0.02)	--
3Q	(0.01)	(0.02)	--
4Q	(0.01)	(0.02)	--
FY	(0.03)	(0.08)	(0.08)

Revenue (C$M)			
Full Year - Oct	2021A	2022E	2023E
1Q	C$0.0	C$0.0A	--
2Q	C$0.0	C$0.0	--
3Q	C$0.0	C$0.0	--
4Q	C$0.0	C$0.0	--
FY	C$0.0	C$0.0	C$0.0

Second cohort of Phase 1/2 T1D Cell Pouch study to begin enrollment by YE22; data anticipated 2023. Yesterday, Sernova announced it had received authorization to begin enrollment of the second patient cohort as part of the Phase 1/2 study with Cell Pouch in Type 1 Diabetes (T1D) patients with hypoglycemia unawareness. In conjunction, the company only also announced the approval of a protocol amendment by the University of Chicago IRB and no objections from the FDA, to proceed with a strategically optimized protocol designed to expedite patient treatment time while accelerating potential secondary endpoint efficacy achievement with more optimal dosing.The authorization to advance patient enrollment was informed by positive interim results from the first six patients in the first cohort of the T1D study (described further below). The second cohort will begin enrolling up to seven patients by YE22 and will evaluate the company's optimized 10-channel Cell Pouch, which is designed to provide 50% more islet capacity compared to the 8-channel Cell Pouch used to date in the study. Together, the results from both cohorts will help inform the design of Sernova's pivotal study and support regulatory advancements including an anticipated BLA submission to the FDA. The company expects to report interim data in 2023.

T1D is first on the menu for Cell Pouch; reaching insulin independence is a big win for the platform. Sernova's most advanced clinical progress is in patients diagnosed with type 1 diabetes (T1D). A Phase 1/2 trial is ongoing, assessing a donor islet cell containing Cell Pouch in T1D patients. We remind investors, T1D is estimated to affect 50 million individuals globally. Due to the significant market size, as well as the Cell Pouch's MoA, we believe the T1D addressable population represents low-hanging fruit on the way to even broader potential market opportunities. In the meantime, the company's diabetes trial intends to enroll seven insulin dependent T1D patients with hypoglycemia unawareness. To date, six patients have been successfully administered the Cell Pouch and subsequently, islet cells. In recent data disclosures, Sernova has detailed that the device is well-tolerated, effective, and has demonstrated impressive durability (functional activity of the pouch has been recorded for up to 32 months). Moreover, we believe the implant's preliminary efficacy is particularly encouraging. Clinical benefits in T1D patients worth highlighting, in our opinion, include: 1) sustained blood levels of C-peptide; 2) a reduction of HbA1c; 3) overall improvement in glucose control, including reduction/ elimination in hypoglycemia unaware events; and 4) reduction or an elimination of the need for daily insulin injections. Critically, the first three patients are now considered to have reached complete and sustained insulin independence for over 2 years, 6 months, and 3 months, respectively. While insulin independence is not yet a primary objective of current or future studies, reliably achieving this result would represent a significant improvement to patient quality of life, and could make Cell Pouch the preferred method of treatment for T1D patients upon approval. A more complete data readout from this Phase 1/2 trial is expected at the end of 2022 or in early 2023. Subsequent any positive results, Sernova intends to meet with the FDA to discuss next steps, including the design, initiation, and timeline of a Phase 3 study.

Vertex acquired ViaCyte for T1D-based pipeline. Recently, Vertex (VRTX; Buy; Fein) announced it has entered into a definitive agreement to acquire ViaCyte (private), which is focused on developing stem-cell derived cell replacement therapies as a functional cure for T1D, for $320 million in cash. Vertex is currently developing VX-880, a stem cell-derived, fully differentiated, insulin producing islet cell replacement therapy for people with T1D, in an ongoing Phase 1/2 clinical trial, which recently had its clinical hold lifted (details below). Alternatively, ViaCyte has developed its T1D pipeline by utilizing pluripotent stem cell (PSC) derived pancreatic progenitor cells. Both companies have potentially complementary approaches, with the larger Vertex taking notice and resulting in a consolidation within the T1D space, particularly of those with stem cell-based platforms. We remind investors, Sernova is also developing an iPSC-based technology (below) to expand its current proprietary Cell Pouch's reach within T1D, and beyond. We believe today's announcement underscores the continued interest in the overall technology, with Sernova's approach remaining differentiated, in our belief, with its compelling clinical data thus far, signaling insulin independence in ongoing Phase 1/2 studies. Additionally, with this consolidation, interest not only appears to remain high in the space, but as Pharma looks to expand pipelines, Sernova remains the most advanced, in our belief, that has shown early yet quite significant clinical data in haven driven three patients, thus far, to insulin independence. Further details on Sernova and competitor pipelines can be found in our recent initiation Maybe Buh Bye to Insulin in T1D Patients? Initiating at Buy and $CDN 6 PT.

Clinical hold on Vertex' T1D trial lifted. Recently, Vertex (VRTX; Buy; Fein) announced that the FDA has lifted the clinical hold placed on the company's Phase 1/2 clinical trial of VX-880. Earlier this year, the FDA had placed a clinical hold on the ongoing trial citing there wasn't enough evidence to support increasing the treatment dose as planned. We note that while on hold in the U.S., the Canadian site continued with the trial. With the hold now lifted, the Phase 1/2 trial will be reopened for screening, enrollment and dosing at multiple sites in the U.S. Per company management, to date, three patients have been dosed in the Phase 1/2 study with VX-880. Two patients received half the target dose of cells in Part A of the study. A third patient has received the full target dose in Part B of the study. Part B will evaluate safety and efficacy in five patients at the target dose before expanding to additional patients in Part C. Recall, Sernova has an ongoing Phase 1/2 trial assessing a donor islet cell containing Cell Pouch in T1D patients. Beyond on this trial, the company is also developing an iPSC-based technology to expand the Cell Pouch's reach, which we think would be most directly impacted by today's regulatory update from Vertex. Further details on the Sernova pipeline, VX-880, and competitors in the T1D therapeutic space can be found in our recent initiation Maybe Buh Bye to Insulin in T1D Patients? Initiating at Buy and $CDN 6 PT. While we believe that Sernova's platforms differentiate it from competitors, a positive development in the news flow for competitors boosts confidence in the broad technology approach and supports the reigning hypothesis that islet replacement might be the answer to T1D.

A differentiated regenerative medicine play. We recently initiated coverage of Sernova with a Buy rating and C$6 price target based on the initial promise of the Cell Pouch system in Type 1 diabetes (T1D) patients in driving insulin independence. Sernova is a company developing a proprietary implantable device designed and engineered for the long-term transplantation of therapeutic cells into a subcutaneous device. This device, also called the Cell Pouch, is made with a medical grade, porous polymer exterior that permits local vascularization, shields from immune surveillance, and simulates an organ-like environment for donor cells to engraft and function normally. With these properties, the Cell Pouch platform is predicted to have the capacity to treat a wide variety of chronic illnesses and potentially provide curative therapy for patients that have limited, or no other, options. Examples of therapeutic cells that can be incorporated into the Cell Pouch system include pancreatic islet cells, thyroid tissue, and genetically altered endothelial cells that produce proteins necessary for blood clotting in those diagnosed with hemophilia. In this way, Cell Pouch is an example of a pipeline in a product. Its inherent modulatory and capacity to engraft varied types of therapeutic cells is predicted to grant access to significant markets across a spectrum of indications.

T1D is first on the menu for Cell Pouch; reaching insulin independence is a big win for the platform. Sernova's most advanced clinical progress is in patients diagnosed with type 1 diabetes (T1D). A Phase 1/2 trial is ongoing, assessing a donor islet cell containing Cell Pouch in T1D patients. We remind investors, T1D is estimated to affect 50 million individuals globally. Due to the significant market size, as well as the Cell Pouch's MoA, we believe the T1D addressable population represents low-hanging fruit on the way to even broader potential market opportunities. In the meantime, the company's diabetes trial intends to enroll seven insulin dependent T1D patients with hypoglycemia unawareness. To date, six patients have been successfully administered the Cell Pouch and subsequently, islet cells. In recent data disclosures, Sernova has detailed that the device is well-tolerated, effective, and has demonstrated impressive durability (functional activity of the pouch has been recorded for up to 32 months). Moreover, we believe the implant's preliminary efficacy is particularly encouraging. Clinical benefits in T1D patients worth highlighting, in our opinion, include: 1) sustained blood levels of C-peptide; 2) a reduction of HbA1c; 3) overall improvement in glucose control, including reduction/elimination in hypoglycemia unaware events; and 4) reduction or an elimination of the need for daily insulin injections. Critically, the first three patients are now considered to have reached complete and sustained insulin independence for over 2 years, 6 months, and 3 months, respectively. While insulin independence is not yet a primary objective of current or future studies, reliably achieving this result would represent a significant improvement to patient quality of life, and could make Cell Pouch the preferred method of treatment for T1D patients upon approval. A more complete data readout from this Phase 1/2 trial is expected at the end of 2022 or in early 2023. Subsequent any positive results, Sernova intends to meet with the FDA to discuss next steps, including the design, initiation, and timeline of a Phase 3 study.

Next generation iPSC technology looks to expand the Cell Pouch's reach. While the initial T1D Cell Pouch clinical program utilizing donor islet cells is a key focus, investors should also focus on the long-term promise of the system with next generation technologies, led by the recently announced partnership announced with Evotec (EVO; not rated). More specifically, the company has recently acquired an option for an exclusive license to Evotec's autologous, Induced Pluripotent Stem Cell (iPSC)-based human beta cells for use with its Cell Pouch system. This agreement, in our opinion, removes current supply chain constraints from solely using donor human islets and now provides an otherwise unlimited supply of iPSC-based islet cells with potential to treat a significantly larger patient population with an 'off the shelf' approach.

Pipeline defines the future beyond quite large T1D opportunity, in our belief. As previously described, we believe a differentiating feature of the Cell Pouch platform is the ability to transplant and engraft a variety of different cells and tissues to become as a satellite, pseudo-organ replacement. Beyond T1D, numerous indications exist in which critical biological molecules, proteins, or other factors are no longer produced over the natural history of the disease and can be corrected by applying Sernova's strategy. Additional indications the company is considering pursuing are hypothyroidism and hemophilia A. With aggregate treatment costs for hemophilia A patients coming in at approximately US$10 billion per year, and an estimated US$2.2 billion market for hypothyroidism in the U.S. alone, a clear unmet clinical need and significant market opportunity exists for the Cell Pouch platform. On top of the aforementioned repertoire of differentiated cell types that are options for transplantation, Sernova is also pursuing technology that reduces the requirement of immunosuppressive drugs following device implantation. In addition to autologous iPSC, which are inheritably more immuno-privileged, the company has a world-wide exclusive license to a Conformal Coating Technology. The Conformal Coating Technology consists of a thin biocompatible cross-linked polymer hydrogel coating that surrounds therapeutic cells (i.e. donors islets or stem cell-derived islets). The unique barrier permits the exchange of molecules between transplanted cells in the device and the local stroma but prevents infiltration and activation of immune cells. Eventual adoption of the Conformal Coating into the Cell Pouch platform would, in our opinion, expand the therapeutic possibilities, make it an even more attractive therapeutic option for patients and physicians, and further differentiate the pouch's predicted exceptional safety and tolerability profile.

Pipeline for the future starting with hemophilia and hypothyroidism; preclinical data pointing the way forward. As previously outlined, beyond T1D, numerous chronic illnesses persist with significant unmet clinical demand and pathology that is addressable by the Cell Pouch system. In fact, Sernova has disclosed encouraging preclinical data suggesting Cell Pouch is a potentially effective means of treating both hemophilia A and hypothyroidism. In hemophilia, the company has demonstrated that cells modified using a lentiviral vector-mediated gene transfer to induce expression of FVIII (the missing clotting factor in hemophilia patients), and subsequently transplanted within Sernova's vascularized Cell Pouch into a mouse model of hemophilia A. Data suggest the engrafted Cell Pouch provides a continuous release of factor VIII into the bloodstream. Restoration of FVIII was both durable and effective at reducing bleeding in these mice. Towards efforts of adapting the Cell Pouch platform for hypothyroidism, thyroid tissue successfully engrafted, and human thyroid hormone (thyroglobulin) was produced by the xenografted device, while also being detected at appreciable levels in the circulation. While still preliminary, we are encouraged by these preclinical data and believe they nicely prepare the groundwork for future clinical studies following or in parallel to current diabetes endeavors.

Valuation and risks to price target achievement. We reiterate our Buy rating and C$6 price target; we also believe visibility for the company should increase around its opportunities around its Cell Pouch system across multiple indications starting with T1D in driving insulin independence in patients. To this end, we currently value Sernova on the proverbial low-hanging fruit addressing hypoglycemic unawareness patients being monitored by their physicians. We currently project that the Cell Pouch system could reach the market in the U.S. in 2027, and currently assign a 25% chance of success on sales of $2.3 billion; importantly these peak sales are based on a very low approximate 2.1% market penetration in the hypoglycemic unawares population. We believe the market could be significantly larger with the broader T1D population and the continuing dramas surrounding insulin supply and its costs. Currently, the data support, at the minimum, a two-year, cell implant impact on insulin independence, which we believe has a significant impact on the broader healthcare costs of T1D patients. Our price target is based on our clinical net present value (NPV) model, which allows us to flex multiple assumptions affecting a drug's potential commercial profile. Factors that could impede reaching our PT include failed or inconclusive clinical trials, the inability of the company to secure adequate funding to progress its drugs through the development pathway or the occurrence of dilutive capital raises.

(CDN$ in millions except per share data) - October fiscal year

Profit & Loss	2019A	2020A	2021A	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Licensing and R&D revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Milestone revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Product and Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	151.2	600.1
Other revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Revenues	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**151.2**	**600.1**
CoGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	18.1	72.0
Gross Profit	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**133.1**	**528.1**
Gross margin	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*88%*	*88%*
G&A	2.0	2.5	2.3	9.2	9.7	11.4	13.9	16.4	18.4	21.2
R&D	2.0	2.8	4.6	13.4	15.0	19.9	23.5	27.0	33.7	45.5
Other op ex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	**(4.0)**	**(5.3)**	**(6.9)**	**(22.6)**	**(24.6)**	**(31.3)**	**(37.4)**	**(43.4)**	**80.9**	**461.4**
EBIT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*54%*	*77%*
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Amortization Intangibles	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA	**(4.0)**	**(5.3)**	**(6.9)**	**(22.6)**	**(24.6)**	**(31.3)**	**(37.4)**	**(43.4)**	**80.9**	**461.4**
EBITDA margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*54%*	*77%*
Non operating expenses	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Interest Income/Other	0.0	(0.1)	(0.0)	0.0	0.0	0.0	0.1	0.3	0.3	0.3
Interest expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBT	**(4.0)**	**(5.3)**	**(7.0)**	**(22.5)**	**(24.6)**	**(31.3)**	**(37.3)**	**(43.1)**	**81.2**	**461.7**
EBT margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*54%*	*77%*
Provision for taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	20.3	115.4
Net Income	**(4.0)**	**(5.3)**	**(7.0)**	**(22.5)**	**(24.6)**	**(31.3)**	**(37.3)**	**(43.1)**	**81.2**	**461.7**
Participation of preferred stock	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income to common	**(4.0)**	**(5.3)**	**(7.0)**	**(22.5)**	**(24.6)**	**(31.3)**	**(37.3)**	**(43.1)**	**60.9**	**346.3**
net margin	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*nm*	*40%*	*58%*
Number of shares - basic	175.9	197.3	245.5	266.4	292.0	301.5	309.3	350.0	355.4	368.0
Number of shares - diluted	175.9	197.3	245.5	266.4	292.0	301.5	309.3	350.0	362.0	385.0
EPS - basic	**(0.02)**	**(0.03)**	**(0.03)**	**(0.08)**	**(0.08)**	**(0.10)**	**(0.12)**	**(0.12)**	**0.17**	**0.94**
EPS - diluted	**(0.02)**	**(0.04)**	**(0.03)**	**(0.08)**	**(0.08)**	**(0.10)**	**(0.12)**	**(0.12)**	**0.17**	**0.90**

Source: SEC filings and H.C. Wainwright estimates.

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Quarterly P&L	Jan	Apr		Jul			Oct	Jan	Apr		Jul			Oct
October fiscal year - CDN$	Q1'21A	Q2'21A	H1'21A	Q3'21A	9M'21A	Q4'21A	FY'21A	Q1'22A	Q2'22E	H1'22E	Q3'22E	9M'22E	Q4'22E	FY'22E
Licensing and R&D revenue	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Milestone revenue	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Product and Royalties	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Other revenues	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Revenues	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.0**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.0**
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Gross Profit	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.0**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.0**
Gross margin	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
G&A	0.49	0.57	1.05	0.68	1.73	0.57	2.3	2.29	2.30	4.59	2.31	6.90	2.31	9.2
R&D	0.68	1.11	1.79	0.96	2.75	1.89	4.6	3.17	3.23	6.40	3.41	9.81	3.54	13.4
Other op ex	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBITDA	**(1.2)**	**(1.7)**	**(2.8)**	**(1.6)**	**(4.5)**	**(2.5)**	**(6.9)**	**(5.5)**	**(5.5)**	**(11.0)**	**(5.7)**	**(16.7)**	**(5.9)**	**(22.6)**
EBITDA margin							*nm*							*nm*
Non operating expenses	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
Net Interest Income/Other	(0.33)	0.01	(0.32)	0.01	(0.31)	0.28	(0.0)	(0.00)	0.01	0.01	0.01	0.02	0.01	0.0
Interest expense	0.00	0.00	0.00	0.00	0.00	0.00	0.0	0.00	0.00	0.00	0.00	0.00	0.00	0.0
EBT	**(1.5)**	**(1.7)**	**(3.2)**	**(1.6)**	**(4.8)**	**(2.2)**	**(7.0)**	**(5.5)**	**(5.5)**	**(11.0)**	**(5.7)**	**(16.7)**	**(5.8)**	**(22.5)**
EBT margin							*nm*							*nm*
Provision for taxes	0.00	0.01	0.01	0.00	0.01	(0.01)	0.0	0.00	0.00	0.00	0.00	0.00	(0.00)	0.0
Participation of preferred stock							0.0							0.0
Net Income to common	**(1.5)**	**(1.7)**	**(3.2)**	**(1.6)**	**(4.8)**	**(2.2)**	**(7.0)**	**(5.5)**	**(5.5)**	**(11.0)**	**(5.7)**	**(16.7)**	**(5.8)**	**(22.5)**
net margin							*nm*							*nm*
NoSH	211.9	236.7	224.27	239.77	229.44	260.00	245.52	261.5	264.8	263.13	268.20	264.82	271.30	266.44
NoSH	211.9	236.7	224.27	239.77	229.44	260.00	245.52	261.5	264.8	263.13	268.20	264.82	271.30	266.44
EPS - basic	**(0.01)**	**(0.01)**	**(0.01)**	**(0.01)**	**(0.02)**	**(0.01)**	**(0.03)**	**(0.02)**	**(0.02)**	**(0.04)**	**(0.02)**	**(0.06)**	**(0.02)**	**(0.08)**
EPS - diluted	**(0.01)**	**(0.01)**	**(0.01)**	**(0.01)**	**(0.02)**	**(0.01)**	**(0.03)**	**(0.02)**	**(0.02)**	**(0.04)**	**(0.02)**	**(0.06)**	**(0.02)**	**(0.08)**

Source: SEC filings and H.C. Wainwright estimates.

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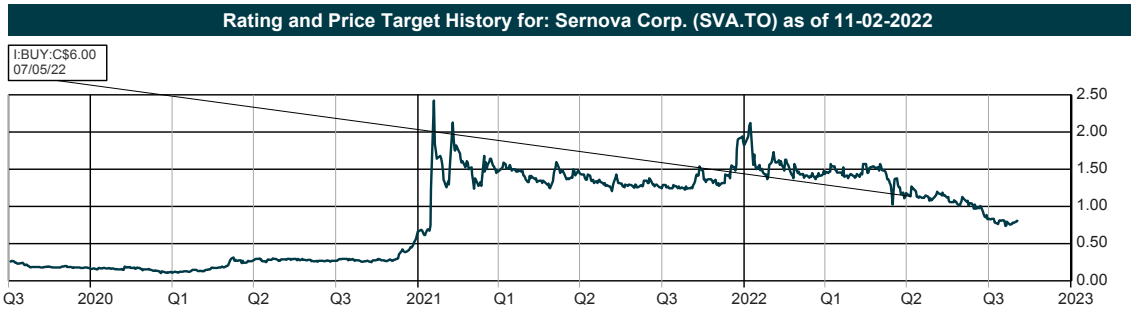
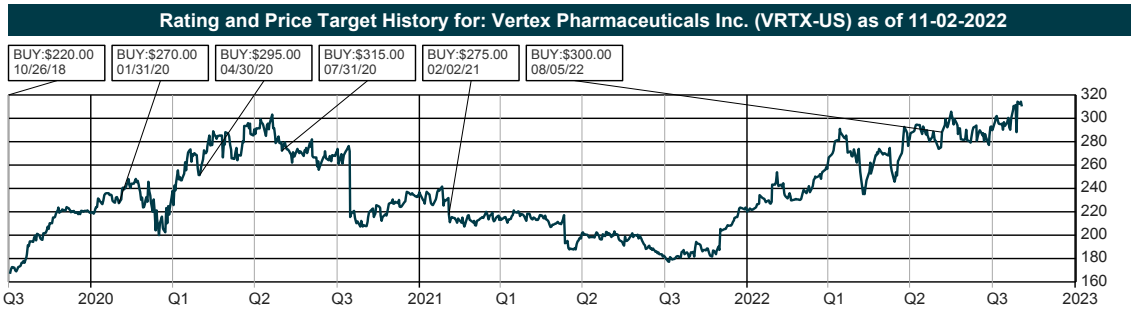
RETURN ASSESSMENT

Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

Market Perform (Neutral): The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

Market Underperform (Sell): The common stock of the company is expected to underperform a passive index comprised of all the common stock of companies within the same sector.





Related Companies Mentioned in this Report as of Nov/03/2022

Company	Ticker	H.C. Wainwright Rating	12 Month Price Target	Price	Market Cap
Vertex Pharmaceuticals Inc.	VRTX	Buy	$300.00	$310.01	$79908

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Distribution of Ratings Table as of November 2, 2022				
			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	576	88.07%	127	22.05%
Neutral	64	9.79%	7	10.94%
Sell	0	0.00%	0	0.00%
Under Review	14	2.14%	3	21.43%

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