Trinity Delta

Serodus

Setting the scene for a significant shift

22 March 2017

Serodus is approaching a major inflection point in its relatively short life. Although it has four programmes in its portfolio, the focus is on SER150 as it progresses through clinical development for diabetic nephropathy. Promising Phase IIa data has spurred interest from several industry parties to collaborate in taking SER150 further. Much will hinge on whether the FDA grants Breakthrough Therapy Designation, which would shorten and facilitate the route to market. We value Serodus at between $134m and $308m.

Year-end: December	2013	2014	2015	2016
Sales (€m)	0.0	0.0	0.0	0.0
Adj. PBT (€m)	(1.3)	(2.0)	(3.6)	(2.7)
Net Income (€m)	(1.3)	(2.0)	(3.6)	(2.7)
Adj. EPS (€)	(0.11)	(0.09)	(0.13)	(0.06)
Cash (€m)	0.6	2.4	2.0	0.6
EBITDA (€m)	(1.3)	(2.0)	(3.6)	(2.7)

Source: Serodus accounts Note: Adjusted numbers exclude share-based payments and exceptionals.

Price (NOK)	N/A
Market Cap (NOKm)	N/A
Enterprise Value	N/A
Shares in issue	44.5m
12 month range (NOK)	N/A
Free float	N/A
Primary exchange	N/A
Other exchanges	N/A
Sector	Healthcare
Company Code	N/A
NOK/EUR	9.0
Corporate client	Yes

- **Lead candidate SER150 offers promise in diabetic nephropathy** Serodus has a very experienced management team that has created a promising development portfolio. The lead programme, SER150, has recently reported encouraging data from a Phase IIa study in diabetic nephropathy. The strength of the results has sparked interest from potential industry partners and could result in the FDA granting Breakthrough Therapy Designation.
- **SER150 was wrongly discarded for toxicity** Serodus acquired SER150 from Evolva after a very high dose of the drug (300mg twice daily) was shown to be effective in a Phase IIa study, but with signals of liver toxicity. The new Phase IIa study, using only 15mg and 30mg BID, showed encouraging signs of efficacy and, importantly, was well tolerated with no safety signals at all. If the positive outcomes are replicated in larger clinical trials then SER150 could become a widely used add-on treatment to the current standard regimes.
- **Rest of the portfolio also shows promise** Serodus has two drugs in clinical development and two others that could enter Phase I in the next 18 months. The other programmes are SER140, which, based on pre-clinical studies, has the potential to stop progression of Type 2 diabetes; SER130, which is ready to enter the clinic for the reduction of scarring in patients with myocardial infarction; and SER100, which has Orphan Drug status for PAH.
- **Additional funding required to progress SER150** Serodus delisted from the Oslo Axess Stock Exchange on 16 February and is now looking to raise sufficient capital to advance its portfolio. Using an rNPV model based solely on the potential for SER150, we value Serodus at $308m if Breakthrough Therapy Designation is granted. In the absence of this designation, our valuation is $134m or $147m depending on when SER150 is partnered.

Company description:
Serodus is a Scandinavian drug development company focused on the complications of diabetes. Its lead asset is SER150, which is in Phase II for diabetic nephropathy.

Analysts

Mick Cooper PhD
mcooper@trinitydelta.org
+44 20 3637 5042

Franc Gregori
fgregori@trinitydelta.org
+44 20 3637 5041

Investment case

An attractive portfolio of assets, with an opportunity that could address diabetic nephropathy

Serodus is a Scandinavian drug development company that has built, through acquisition and in-licensing, an attractive portfolio of pre-clinical and clinical assets. The focus has been on the treatment of diabetes and its co-morbidities; targeting indications with clear unmet clinical needs. The pipeline consists of four programmes; two of which are in clinical development and two are at the pre-clinical stages. SER150 is the most advanced and addresses diabetic nephropathy. Serodus operates a lean structure, out-sourcing the required functions through a network of contract research organizations (CROs) and contract manufacturers. The strategy centres on taking programmes through to the "proof of concept" stage (typically Phase II) and then seeking to out-licence or partner ahead of the later clinical stages. The management is experienced and credible, with a proven track record of bringing new compounds to the market and concluding major deals. The company was listed on the Oslo Axess exchange in April 2013 and delisted in February 2017.

Valuation

Our valuation of Serodus ranges from $134m to $308m, with the higher valuation being dependent upon Breakthrough Therapy Designation

We value Serodus using an rNPV model. We have employed conservative assumptions throughout; for example, erring on the cautious side for factors such as the timing of various developmental phases, market launches, adoption curves, and patient penetration. Similarly, we do not include the implicit value of the earlier pre-clinical programmes. Despite this, our valuation suggests that the potential of SER150 is such that, even when discounting aggressively, the value of Serodus ranges from $134m to $308m, with the higher valuation being dependent on the FDA granting Breakthrough Therapy Designation to SER150.

Financials

Funding required to progress main asset through key inflection point and beyond

Serodus has recently de-listed from the Oslo Axess (February 2017). This followed feedback from its major investors that the valuation consistently failed to reflect the progress being achieved and its underlying asset strength, together with indications from a number of potential new investors who were not willing to invest in such a public company. Whilst their support will provide near-term funding, it is clear that substantial sums will be required to progress SER150 through the key Phase II/III studies and beyond. This stage would typically be partnered with a major pharmaceutical player and, given SER150's profile, we would expect no shortage of potential collaborators.

Sensitivities

Serodus is exposed to the usual risks associated with drug development

Serodus is subject to the sensitivities commonly associated with drug discovery and development. These include clinical trial failure, IP protection and litigation, and regulatory, execution and commercial risks. Specific sensitivities include reliance on third parties (eg CROs, contract manufacturers, etc) to progress development; the financial terms of potential licensing deals and collaborations; the strength of the patent estate and other barriers to entry; and the earlier pipeline requiring further clinical validation.

Serodus: on the cusp of a golden opportunity

Through a combination of acquisition and licensing, Serodus has created an interesting pipeline of clinical and pre-clinical programmes. The most advanced, and commercially appealing, is SER150; which was in-licensed from Evolva. It addresses diabetic nephropathy, a large and growing clinical need, where its novel anti-inflammatory profile (inhibiting thromboxane synthase as well as blocking the thromboxane receptor) offers the prospect of disease modification. Extensive, and costly, clinical trials are required to assess its potential; however the next value inflection point will arise if the FDA grants SER150 a Breakthrough Therapy Designation. Serodus is actively seeking a partner to advance SER150. Our rNPV-based valuation, based on conservative assumptions, values Serodus at between $134m and £308m.

Serodus has built a promising pipeline but the potential star is SER150 for diabetic nephropathy

Serodus has a strong and well-respected management team that has sought out attractive product candidates from external sources. The team has a proven track record of taking products to market and executing licensing deals. The initial therapeutic focus was on cardiovascular diseases and, taking advantage of previous personal experience, the first drug that was brought in was SER100 from Zealand Pharma for pulmonary hypertension. In 2013, again exploiting previous knowledge, SER130 and SER140 were acquired through the acquisition of Phlogo and widened the focus onto diabetes and its co-morbidities. In 2014, exploiting a poorly understood set-back in a key early stage clinical trial, SER150 (previously known as EV-077) was in-licensed from Evolva on favourable terms.

The strategy is to maintain a lean structure, using an established network of specialists such as contract research organizations (CROs), universities, and contract manufacturers to progress the programmes to "proof of concept" stages before either out-licensing or partnering with established larger pharmaceutical players for the later, and more expensive, clinical trials. The pipeline (see Exhibit 1 overleaf) currently consists of two programmes in clinical development and two that could enter Phase I in the next 18 months. Three are being developed for diabetes-related indications and the fourth has orphan drug designation for pulmonary arterial hypertension (PAH). All address clear medical needs; however, in our view, it is SER150 that offers most potential.

SER150 has an attractive profile in a large market

SER150 targets a large, growing, and poorly treated market segment

SER150 is an oral small molecule anti-inflammatory with a novel mode of action that both inhibits thromboxane synthase (TS) and blocks the thromboxane receptor (TXA_2). SER150 is believed to specifically inhibit the inflammatory processes in the arterioles and glomeruli of the kidney and so reduce the progression of renal impairment typically seen in diabetic nephropathy. Currently the standard of care involves treatment with an ACE inhibitor or angiotensin II receptor blockers (ARB) antihypertensive but these, whilst effective, do not address the underlying causes of the renal damage.

The pathogenesis behind the progression of diabetic nephropathy is still not fully understood, with complex signalling between many classes of cells believed to result in abnormal inflammatory responses. Thromboxane is known to be an important mediator but prior studies with a variety of blockers and antagonists failed to demonstrate significant benefit. It is thought that combined blockade of the two pathways may overcome these limitations, which underpins the rationale for SER150 being examined in such nephropathies.

Exhibit 1: Details on the Serodus pipeline

Product	Indication (Target)	Development stage (Next steps)	Notes
SER150	Diabetic nephropathy (TXA_2 antagonist and TS inhibitor)	Phase IIa completed (The next study design will depend on the Breakthrough Treatment Designation status)	Phase IIa data (placebo, 15mg and 30mg BID; n=72): Strong trend towards reduced proteinuria compared to placebo (statistically significant reductions in proteinuria compared to baseline in both SER150 arms) AE evenly distributed between placebo and SER150 arms. Phase IIa data (300mg BID; n=32) conducted by Evolva in diabetic patients with no albuminuria. Improvements in peripheral blood flow, reduced platelet aggregation and reduced exercise induced proteinuria; however signs indicative of liver toxicity detected. Examination of the pre-clinical data (including PK/PD studies) suggests SER150 should be efficacious at 30mg; pre-clinical studies indicate that the dose could be not more than 5mg/kg/day and show no toxicity signals.
SER140	Diabetes and co-morbidities (IL-1β receptor antagonist)	Pre-clinical studies ongoing (Phase IIa to start in H118)	Pre-clinical data in non-obese diabetic (NOD) mouse model indicate that SER140 is able to reduce the number of NOD mice that develop diabetes and preserve beta cell mass. It has no effect on HbA1c in db/db mice with a single dose. SER140 is a peptide that reduces low-grade inflammation.
SER130	AMI in diabetics (IL-4 receptor agonist)	Pre-clinical studies completed (Phase I/IIa to start in H217)	SER130 is a peptide that activates the anti-inflammatory IL-4 receptor, that reduces the inflammatory response to an AMI (diabetics have elevated baseline levels of pro-inflammatory cytokines). By reducing the inflammatory response, SER130 is expected to reduce heart scarring after an AMI.
SER100	Pulmonary arterial hypertension (ORL-1 receptor partial agonist)	Phase I completed (Phase IIa H118)	Phase I data (10mg BID for 2 consecutive days; n=17; placebo-controlled with crossover design). Average reduction in systolic blood pressure was 7.0mm Hg (p=0.0032); and average reduction in diastolic blood pressure was 3.8mm Hg (p=0.0011). SER100 was well tolerated, with mild AEs at injection site. Granted Orphan Drug status by the FDA in October 2016.

Source: Serodus Note TXA2: thromboxane receptor; TS: thromboxane synthase; BID: twice daily; PK/PD: pharmacokinetic/pharmacodynamic; db/db mice have the leptin receptor mutated and spontaneously develop diabetes; AMI: acute myocardial infarction; AE: adverse event

SER150 was first evaluated in a Phase IIa trial performed by Evolva (as EV-077) in diabetic patients who had no known diabetic nephropathy. But, for what are now uncertain reasons, the dose was selected as 300mg twice daily. The results were encouraging, with positive outcomes against both primary and secondary measures, but signals indicative of possible liver toxicity were detected and the programme was halted. Serodus examined the data and an evaluation of the pre-clinical data package suggested that the desired efficacy could be achieved at doses an order of magnitude lower. Animal models indicated that at such doses the potential liver issues would not arise.

Phase IIa study shows positive results for both primary and secondary end-points

Serodus performed a Phase IIa study evaluating two dose strengths (15mg and 30mg twice daily) for one month in 72 patients with known diabetic nephropathy across ten centres in Germany. Top line results were announced in January 2017 that showed no toxicity concerns and confirmed that a strong trend towards reduced protein (albumin) excretion in the urine was seen. No safety issues, biochemical abnormalities or bleeding tendencies were identified and the adverse events were distributed evenly between the active and placebo groups and mild to moderate in intensity. A statistically significant reduction in albumin excretion from baseline was observed in both the high- and low-dose groups and a very strong trend towards reduction was observed compared to the placebo arm.

Exhibit 2: A summary of the benefits of Breakthrough Therapy Designation

Breakthrough Therapy Designation confers many benefits, notably the time and costs savings in getting to market

Breakthrough therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

A breakthrough therapy designation conveys all of the fast track program features, more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review. These will include:

- **holding meetings with the sponsor and the review team throughout the development of the drug;**
- **providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;**
- **taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment;**
- **assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the cross-discipline members of the review team (ie clinical, pharmacology-toxicology, chemistry, manufacturing and control, compliance) for coordinated internal interactions and communications with the sponsor through the review division's Regulatory Health Project Manager;**
- **involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review.**

Source: FDA

Chronic and common conditions typically require larger and costlier trial programmes

Serodus has discussed these results with a number of expert bodies, with the feedback supporting the view that SER150 would be viewed favourably for classification as a Breakthrough Therapy by the FDA. There are multiple benefits of such a designation (summarised in Exhibit 2), including the possibility of a smaller approval study (followed by a more exhaustive Phase IV trial post marketing) and the saving up to 3 to 4 years to the point of commercialisation.

The patient population suffering from diabetic nephropathy is large and growing. The development strategy for SER150 has yet to be clarified but,

typically, the clinical trials required for products that address such chronic and prevalent conditions tend to be large (involving 1,000s of patients) and lengthy (usually one year plus). The trials programme for SER150 would depend firstly on whether Breakthrough Therapy designation were granted and then on the guidance given. We estimate that, assuming it were granted, the expectation would be for a Phase II/III clinical study involving 500-1,000 patients evaluated over a six month to one year period.

Serodus, in our view, needs to strengthen its financial position ahead of partnering discussions

A positive outcome would result in a rapid approval conditional on the results being corroborated by a larger Phase III/IV study that would complete within a year or so post-marketing. The costs of such a programme are difficult to gauge with any accuracy, but we estimate it to be around $100m to $150m. Clearly, Serodus would seek to partner SER150 ahead of embarking on such a programme but, in our view, would need to raise capital to enable the required preparatory work (such as ensuring sufficient active material to conclude the trials is available and finishing the pre-clinical dossiers) to be undertaken.

The market opportunity is significant. WHO estimates the number of people globally with diabetes has increased from 100m in 1980 to 442m in 2014 and that the prevalence among adults has risen from 4.7% to 8.5% during the same period. Diabetic nephropathy is one of the more important complications and whilst its understanding may have changed in recent years, it is still expected to affect around a third of diabetic patients. Global Data estimates that there will be circa 20m patients with diabetic nephropathy by 2022 in the seven major markets alone.

Even a modest success would result in a sizeable commercial opportunity

Since the inflammation is a progressive process causing loss of the renal function, SER150 could potentially become a material element of any treatment plan. Assuming the results seen in the Phase IIa study are replicated in the confirmatory trials, then SER150 would likely be employed as add-on therapy to existing treatments (ACE and ARBs). Even assuming only very modest penetrations, SER150 could be a sizeable commercial success. If the profile were to show that SER150 treatment delays progression or were capable of disease modification then the market potential would be significant.

More than just a one product company

Three other promising programmes in the portfolio

Whilst, understandably, SER150 is the primary focus, Serodus also has three other programmes. The other diabetes related drugs are SER140, which has the potential to stop progression of Type 2 diabetes, and SER130, which is ready to enter the clinic for the reduction of scarring in patients with myocardial infarction. Its final programme is SER100 for Pulmonary Arterial Hypertension (PAH), which is ready to enter a Phase IIa trial.

SER140 in pre-clinical testing for the prevention of diabetic progession and complications

SER140 is a small (a tetramer of 14 amino acids) peptide that is a potent antagonist of the IL-1β receptor. In animal models it has been shown to protect pancreatic β-cells from cytokine-induced (L-1β mediated) apoptosis and to reduce the fundamental low-grade inflammation associated with diabetes

progression. Pre-clinical studies are continuing in two animal models to establish the maximum tolerated does. A clinical study, most likely a Phase I/IIa trial, to examine safety and tolerability in diabetic patients could start in H118. Successful outcomes would mean that SER140 could offer a disease modifying treatment option.

SER130 aims to reduce the scarring of cardiac infarcts in diabetics

SER130 is a small (16 amino acid) peptide that is an anti-inflammatory IL-4 receptor agonist. It mimics the response of endogenous human IL-4 and so inhibits a cascade of pro-inflammatory responses. It is being developed as a treatment for AMI (acute myocardial infarction) scar reduction in diabetic patients. Diabetics are believed to have chronic hyperactive low-grade inflammation that exacerbates the pro-inflammatory responses seen following an AMI. SER130 would act by restoring the balance and so, hopefully, reducing the infarct damage. The pre-clinical work is nearing completion and a Phase I/IIa study could start in H217.

SER100 in early clinical phases for pulmonary arterial hypertension

SER100 is a small molecule targeting the ORL-1 (Opiate Receptor-Like) receptor, where its competitive activity (it is a partial agonist) is thought to result in potent but selective vasodilation. A promising pre-clinical programme has shown its value in Pulmonary Arterial Hypertension and a Phase I study demonstrated good safety and tolerability. A Phase IIa trial could start in H118. In October 2016 the FDA granted SER100 Orphan Drug status.

Sensitivities

Serodus is exposed to all of the risks associated with a small drug development business

In common with other companies undertaking drug development, Serodus is subject to a number of important sensitivities. These notably include the risk of a pivotal clinical trial failing to demonstrate the expected result; the strength of the patent estate and having the ability to protect against litigation; the failure to obtain timely regulatory clearances; as well as the usual execution and commercial risks associated with smaller pharmaceutical companies.

Specific sensitivities include an explicit reliance on third parties to progress development, which, despite the ensuring the use of high quality Contract Research Organisations (CRO) and third-party manufacturers, remains largely outside of their control.

Similarly, future commercial outcomes depend highly on the financial terms of potential licensing deals and collaborations, particularly for SER150.

The strength of the patent estate, and other barriers to entry, is also critical and to a degree untested. For instance, SER150 appears to have composition of matter patents lasting through to 2027. However, the degree and utility of any likely supplemental protection is as yet unknown.

Elsewhere within the portfolio, the earlier pipeline carries a higher risk as it still requires further clinical development and validation.

Valuation

Serodus is well suited to being valued using an rNPV approach

Serodus can be viewed as a classic drug development company and is well suited being valued using an rNPV methodology. Typically the rNPV of the individual clinical projects (adjusted for the success probabilities) are summed and netted against the costs of running the operation. However, for Serodus we have only modelled SER150 (see Exhibit 3).

The success probabilities of each project are based on standard industry criteria for each stage of the clinical development process but are flexed to reflect the inherent risks of the individual programme, the indication targeted, and the trial design. Understandably, it follows that it is the later stage products that have a higher current value, with the step change occurring typically at Phase II when the proof of concept is usually established.

Exhibit 3: Summary of valuation with different development and partnering scenarios

Scenario	Details	Unrisk-adjusted valuation ($m)	Risk-adjusted Valuation ($m)
Scenario 1	Breakthrough Therapy Designation awarded Licensing deal in Q417 (Upfront: $50m; Development milestones: $210m; Royalties: 18%) Peak sales: $4,154m Launch year: 2021 Likelihood of success: 30%	1,026.3	307.9
Scenario 2	No Breakthrough Therapy Designation awarded Licensing deal in Q417 (Upfront: $20m; Development milestones: $150m; Royalties: 15%) Peak sales: $4,154m Launch year: 2024 Likelihood of success: 30%	448.1	134.4
Scenario 3	No Breakthrough Therapy Designation awarded Licensing deal in 2020 (Upfront: $50m; Development milestones: $130m; Royalties: 18%) Peak sales: $4,154m Launch year: 2024 Likelihood of success: 30%	490.4	147.1

Source: Trinity Delta; Note: Valuations are based on cashflows until 2032, with forecast product revenues declining by 20% pa from the earlier of five years after launch or 2028.

We use a 12.5% discount rate, which is our standard rate for such early stage companies. We also employ conservative assumptions in terms of the commercial potential for the clinical programmes; including likely reimbursement, market penetration, licensing and royalty rates, and market adoption. Maintaining our conservative stance, we have attributed no value to the pre-clinical programmes; similarly we only model SER150 potential in diabetic nephropathy, although Evolva showed that the drug could be used to treat other complications of diabetes.

We value Serodus at between $134m and $308m, with Breakthrough Therapy Designation significantly enhancing the value of SER150

We value Serodus at between $134m and $308m depending on whether Breakthrough Therapy designation is granted and the timing of a potential partnering deal (Exhibit 3). Our peak sales estimate are based on 35% of diabetics in the US and Western Europe suffering from diabetic nephropathy and 10% penetration of this market, with the drug priced at $4,000 pa in the US and 50% of this price in Europe. It also takes into account that up to 30% of the total licensing income will be paid to Evolva. Our valuations indicate how much the potential Breakthrough Therapy Designation is worth to Serodus, as it would provide a faster route to market for SER150 and should result in the drug being partnered on more favourable terms.

Exhibit 4: Sensitivity analysis for peak sales potential with different price/ and market penetration assumptions

Peak Sales ($m)		Price per patient per annum ($)				
		3,000	3,500	4,000	4,500	5,000
Market penetration	5%	1,322	1,543	1,763	1,983	2,204
	10%	3,115	3,634	4,154	4,673	5,192
	15%	5,379	6,276	7,172	8,069	8,965
	20%	8,114	9,466	10,818	12,171	13,523
	25%	11,319	13,206	15,092	16,979	18,865

Source: Trinity Delta

Exhibit 5: Sensitivity analysis for rNPV of Serodus with Breakthrough Therapy designation with different price/market penetration assumptions

rNPV of Serodus ($m)		Price per patient per annum ($)				
		3,000	3,500	4,000	4,500	5,000
Market penetration	5%	114	129	144	159	174
	10%	237	272	308	343	379
	15%	392	453	515	576	638
	20%	579	672	765	858	950
	25%	799	929	1,058	1,187	1,317

Source: Trinity Delta

Exhibit 6: Sensitivity analysis of rNPV of Serodus with Breakthrough Therapy designation with various peak sales/discount rate assumptions

rNPV of Serodus ($m)		Peak sales ($)				
		2,000	3,000	4,000	5,000	6,000
Discount rate	12.5%	160	229	297	366	435
	15.0%	133	189	246	302	358
	17.5%	112	158	204	251	297
	20.0%	95	133	171	210	248
	25.0%	69	96	123	150	177

Source: Trinity Delta

At this stage, there is considerable uncertainty about the eventual pricing of SER150 and its potential market penetration, and these assumptions together with the discount rate have a significant effect on the peak sales calculation and valuation of Serodus. A sensitivity analysis of these factors is shown in Exhibits 4, 5 and 6.

Even a relatively modest success with SER150 could see a material uplift in our rNPV model. It is also worth noting that any progress with the other portfolio products represents upside too.

Financials

Serodus requires further funding to advance SER150 and the rest of its pipeline...

Serodus had a cash position of NOK5.6m (€0.6m) at FY16. Its operating costs in FY16 were only NOK24.5m (€2.7m), 19% less that in FY15, thanks to Serodus' very lean operating structure. However, its operating costs will have to increase significantly in FY17 and beyond to fund the next clinical trial with SER150, including the manufacturing of the drug substance, and to advance the other products in its portfolio.

The company has not communicated the amounts that it needs to raise in order to advance the products in its pipeline through to value inflection points. This is understandable given the various scenarios and uncertainties. However it is clear that priority will be given to the development of SER150 and SER140, both of which have blockbuster potential. We estimate that such a comprehensive clinical programme would cost between $100m and $150m.

...regardless of a potential licensing deal

Serodus could sign a licensing deal for SER150 in FY17 with a significant upfront payment, and have its partner bear all subsequent costs. However, in our view, the earliest that a deal is likely to be concluded is in Q417. Hence, it would be prudent for Serodus to raise sufficient capital to complete the Phase II/III trial, assuming Breakthrough Therapy Designation is granted, (or the Phase IIb study should it be required) ahead of serious partnering discussions to strengthen its negotiating position.

Company information

Contact details

Serodus,
Oslo Research Park,
Gaustadalleen 21
N-0349 Oslo, Norway

Tel: +47 959 34 199
www.serodus.com
post@serodus.com

Key personnel

Person	Position	Biography
Svein S. Jacobsen	Non-Executive Chairman	Elected Chairman in 2012. He also serves as Chairman of Strongpoint, Fluid Control, Presentasjonsdata, Ericsen & Horgen, and Falkenberg. Previously, he was CFO and VP of Finance of Tomra Systems ASA, from 1984 and CEO and President from 1988 to 1996.
Eva Steiness MD	CEO	Joined Serodus in 2010. From 1989 to 1998 she was Exec SVP for R&D at Lundbeck and was responsible for the development of Cipramil (citalopram), the blockbuster antidepressant drug. In 1998 she founded Zealand Pharma and was CEO until 2007 and led the development of lixisenatide (Lyxumia) for Type 2 diabetes (launced by Sanofi). She was also Chairman of Genmab, a Director of several Lundbeck affiliates, and Chairman of the Danish Governmental Advisory Board on Research Politics.
Tore Kvam	CFO	Joined in 2014. Tore Kvam has worked for over 15 years as CFO in both early stage and established companies, including CellCura, Rubik Solution Group, and Factor Insurance Group.
Dr Jurgen Langharig	VP Business Development	Joined in 2015. Jurgen Langharig has over 30 years of experience in international marketing/business development having worked at Sandoz (now Novartis), Nycomed (now Takeda), Novo Nordisk, Zealand Pharma and most recently was VP Business Development at Bavarian Nordic. .

Top 5 shareholdings

	No. of shares (m)	% holding
Viggo Harboe Holding 2006	12.6	28.3
Danske Bank	5.1	11.5
Bjorns Invest	3.8	8.5
Eva Steiness	2.3	5.1
MP Pensjon PK	1.8	4.0

Source: Serodus

Mick Cooper PhD CFA mcooper@trinitydelta.org
+44 20 3637 5042

Franc Gregori fgregori@trinitydelta.org
+44 20 3637 5041

Disclaimer

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