

# Sequana Medical

Guidance maintained for key programmes

Financial update

Pharma & biotech

27 April 2022

**Price** €6.66

**Market cap** €158m

\$1.09/€

Net cash (€m) at 31 December 2021  
(excluding €0.8m lease liabilities) 2.3

Shares in issue 23.75m

Free float 45%

Code SEQUA

Primary exchange Euronext

Secondary exchange N/A

## Share price performance



% 1m 3m 12m

Abs 8.6 7.9 (23.9)

Rel (local) 8.8 7.1 (25.0)

52-week high/low €9.68 €5.50

## Business description

Based in Belgium, Sequana Medical develops devices based on its alfapump platform for the treatment of diuretic-resistant fluid overload in liver disease, malignant ascites and heart failure. Alfapump is CE marked for refractory ascites and is in a pivotal North American study for this indication.

## Next events

Top-line results of SAHARA DESERT study H222

Top-line results of POSEIDON study Q422

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Sequana reported its FY21 results on 12 April and confirmed its operating guidance for the coming months. The company continues to expect to report top-line data for its North American POSEIDON study of alfapump in recurrent and refractory ascites (RRA) in Q422 and submit a US premarket approval (PMA) application in mid-2023. It plans to report top-line data for its SAHARA DESERT alfapump DSR study in patients with decompensated heart failure (HF) in H222. The company plans to begin its first human study (MOJAVE DESERT) of its 'standalone' short-term DSR treatment in HF patients in H222. After increasing our R&D cost estimates following the FY21 results and reducing alfapump sales forecasts in Europe (which is not a prioritised RRA market for Sequana), we lower our equity value per basic share slightly to €13.12 (versus €13.55 previously).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/20	1.0	(19.0)	(1.25)	0.0	N/A	N/A
12/21	0.4	(24.4)	(1.36)	0.0	N/A	N/A
12/22e	0.6	(23.3)	(0.98)	0.0	N/A	N/A
12/23e	0.7	(22.8)	(0.96)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

## European alfapump sales remain tepid

FY21 revenue, generally consisting of alfapump sales in France and Germany, was €0.37m (down 61% y-o-y), below our forecast of €0.53m. The product's uptake in Europe has been limited and, as the region is not a core priority for Sequana in RRA, we have reduced our RRA alfapump sales estimates for the area but maintain our US market forecasts. We expect the opportunity for alfapump in North America to be substantially more robust given the rising prevalence of non-alcoholic steatohepatitis (NASH) in this region. NASH-related cirrhosis is expected to account for a larger proportion of RRA cases in the US and Canada and these patients are generally older, insured and well-integrated into the healthcare system.

## FY21 R&D costs mildly above expectations

FY21 R&D costs were €16.9m (+43% y-o-y), higher than our forecast of €15.6m. The year-on-year increase was largely due to costs associated with the ongoing clinical trials and for the planned alfapump regulatory submissions in North America. The FY21 operating loss was €22.6m (+27% y-o-y), and we have raised our R&D cost forecasts for FY22e and subsequent years. The company continues to expect its funds on hand to support its operating cash runway into Q223, and we maintain our future total financing expectations of €100m (until H127).

## Valuation: Nudge down in pipeline rNPV to €288m

Following the adjustments described above, we now obtain a pipeline rNPV valuation of €287.8m versus €296.4m, previously. After adding Q122e net cash of €23.7m (excluding lease liabilities), we obtain an equity valuation of €311.5m or €13.12 per share (€12.19 fully diluted), versus €13.55 previously (€12.59 fully diluted).

## FY21 update confirms current expectations

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Sequana reported its [FY21 results](#) on 12 April 2022, and confirmed its operating guidance for the coming months. Having recently [completed all the alfapump implantations](#) required for its [North American POSEIDON pivotal study](#) for the treatment of RRA due to liver cirrhosis, the company continues to expect to report top-line efficacy data in Q422 and plans to submit a US PMA application in mid-2023. As it relates to the company's direct sodium removal (DSR) programmes in HF, it expects to complete enrolment for its [SAHARA DESERT](#) alfapump DSR study in patients with decompensated HF in Q222 and report top-line data in H222. The company reported continued progress with the development of its proprietary DSR Infusate 2.0, a sodium-free dextrose/icodextrin solution that it expects to provide superior therapeutic and safety profiles (to the simple 10% dextrose solution used in prior DSR clinical studies). Preclinical studies on DSR Infusate 2.0 are underway, with the company maintaining its guidance for starting a US study for short-term DSR therapy (MOJAVE DESERT) in HF patients before year-end 2022.

## Review of DSR heart failure programmes

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Our [prior note](#) reviewed the key upcoming catalysts for the alfapump system in RRA due to cirrhosis, which is Sequana's earliest revenue opportunity, given its current CE mark (and ongoing commercialisation in France and Germany), and our forecast for potential US launch in mid-2024 provided there is positive top-line data from the POSEIDON study.

As explained in our [initiation report](#), HF could be a larger commercial opportunity for Sequana than RRA although the company's programmes (alfapump DSR, and short-term 'standalone' DSR) in this indication are at earlier development stages and we do not expect them to reach commercialisation until H226 at the earliest. HF can often lead to sodium retention and resulting fluid retention and accumulation (congestion). Congestion in HF patients is generally treated with diuretics in the first line, most commonly loop diuretics (eg furosemide, bumetanide and torsemide), but these drugs become less effective with disease progression. Consequently, there are over one million hospitalisations for HF per year in the United States<sup>1</sup> and in Europe, and of such admissions, c 90% are due to fluid overload.<sup>2</sup> Sequana's DSR approach aims to resolve persistent congestion through the periodic and controlled introduction of a zero-sodium infusate solution, which is designed to remove excess sodium in patients and would then be expected to lead to more regular fluid release into the kidneys and excretion. The company's first HF programme is based on the alfapump DSR system, which consists of three elements: the alfapump system, DSR infusate solution and a surgically implanted port (whereby controlled quantities of DSR infusate are administered externally and reach the peritoneal cavity).

The SAHARA DESERT [interim results](#) suggest that alfapump DSR can effectively and rapidly eliminate persistent congestion and restore euolemia (normal bodily fluid volume) in diuretic-resistant HF patients. The study also suggests that DSR therapy can result in improvements in cardio-renal parameters (such as NT-proBNP) and lead to material sustained improvements in diuretic responsiveness (DR). As stated earlier, top-line data are expected in H222. [In May 2021](#) the company reported positive results from the [RED DESERT](#) study (in chronic HF patients taking high doses of oral diuretics), showing that a controlled DSR administration using alfapump over a six-

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<sup>1</sup> Jackson SL, Tong X, King RJ et al. *Circ Heart Fail*. 2018 Dec;11(12):e004873. doi: 10.1161/CIRCHEARTFAILURE.117.004873. PMID: 30562099

<sup>2</sup> Costanzo MR, Ronco C, Abraham WT et al. *J Am Coll Cardiol*. 2017 May 16; 69(19): 2428–2445. doi: 10.1016/j.jacc.2017.03.528

week period led to persistent reduction in the needed oral diuretic dose over nearly a year, on average.

In parallel to the alfapump DSR system, Sequana is advancing a short-term ('standalone') DSR treatment approach, which does not require the implantation of an alfapump device. Short-term DSR therapy will involve repeated DSR treatment for about two weeks, using DSR Infusate 2.0 in combination with a peritoneal catheter (instead of requiring alfapump implantation). Similar to alfapump DSR, the goal of short-term DSR therapy would be to treat fluid overload by allowing the renal system to itself excrete excess sodium more effectively with diuretics (improving the patient's DR) and improve cardio-renal parameters. The short-term DSR approach would require insertion or usage of a peritoneal catheter each time DSR therapy is applied, whereas the implantation of the alfapump ('alfapump DSR', also referred to as 'long-term DSR approach') avoids the need for repeated catheter insertion.

We believe that the company's primary rationale for advancing short-term DSR (without alfapump) therapy is primarily to provide clinicians with the option of a 'gateway' or one-off treatment for HF patients with persistent congestion, with the goal of transitioning them to alfapump DSR as the DSR interventions become required more often. Adding a short-term DSR approach (ie as a 'gateway product') may not necessarily increase the potential market for HF patients suffering from congestion, in our view, but could help accelerate DSR product adoption among clinicians by providing them with one-off DSR treatment options. However, we also note that the sustained improvements in DR shown in the RED DESERT and SAHARA DESERT (interim data) provide some optimism that a short-term DSR therapy approach could similarly also provide durable meaningful improvements in DR. The MOJAVE DESERT study will be very helpful in determining the durability and extent of DR improvement possible with 'standalone' DSR therapy. The results and DR shown in this study may help guide the future development path and the company may even prioritise the advancement of short-term DSR ahead of the alfapump DSR platform. The regulatory approval pathway for short-term DSR (based on DSR Infusate 2.0) could be simpler than alfapump DSR since it would be regulated as a drug by the FDA's Center for Drug Evaluation and Research division, whereas alfapump DSR would need to be regulated as a drug-device combination.

As stated above, Sequana's next planned study is the US-based MOJAVE DESERT trial assessing short-term DSR therapy in chronic HF patients with persistent congestion and it remains on track to start before the end of 2022. The company continues to guide that it will start the first US-based alfapump DSR trial, SONORAN (not a registration study), in H223, after the completion of long-term good laboratory practice (GLP) animal safety studies (expected in early 2023). We expect the completion of SONORAN in H224. For alfapump DSR and short-term DSR, we expect Sequana to enter into a sales and distribution partnership or agreement with an established medical device marketer with experience in the cardiovascular markets.<sup>3</sup> We expect the company to enter into such discussions while the SONORAN study is ongoing.

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<sup>3</sup> We believe Sequana Medical may also consider partnering the alfapump DSR and short-term DSR programmes with a pharmaceutical company, but we believe an arrangement with a medical devices company is more likely.

**Exhibit 1: DSR therapy and alfapump DSR for fluid overload in heart failure milestones and timelines**

Event	Start date	Approximate completion
Start SAHARA feasibility study in decompensated HF patients	Q221	H222
Formulation and manufacturing of DSR Infusate 2.0	Ongoing	Mid-2022
GLP animal study for short-term DSR (w/o alfapump)	Mid-2022	H222
MOJAVE Phase Ib/Phase IIa proof-of-concept short-term DSR US study	H222	Mid-2023
Phase IIb study for short-term DSR	Mid-2023	Mid-2024
GLP animal study for alfapump DSR	Mid-2022	Mid-2023
SONORAN alfapump DSR US study	H223	H224
Registration-enabling alfapump DSR and short-term DSR studies	Late 2024 (*)	H126 (*)
Partnership negotiations for alfapump DSR and short-term DSR	Mid-2023 (*)	Mid-2026 (*)
Potential US launch	H226 (*)	
Potential European launch	2028 (*)	

Source: Sequana Medical guidance, \*Edison Investment Research estimates

As a reminder, DSR Infusate 2.0 is a proprietary formulation of the sugars dextrose and icodextrin, and is intended to deliver a superior therapeutic profile (ie potentially reducing the amount of infusate that needs to be administered to render an equivalent therapeutic response) and better safety (with longer and slower dwells) while providing the potential for a higher-margin recurring revenue stream. The infusate solution is a vital part of the DSR treatment approach since it will need to be administered repeatedly (providing revenue per infusion), and a simple 10% dextrose solution (ie the DSR formulation used in SAHARA DESERT and RED DESERT) would not carry the premium pricing potential of a more specialised formulation (eg DSR Infusate 2.0). We expect all human DSR studies after SAHARA DESERT will employ DSR Infusate 2.0 (as will the commercial products assuming eventual approval), starting with the MOJAVE DESERT study.

## Financials

Sequana's FY21 results showed a larger loss than expected, primarily due to higher than anticipated R&D costs. FY21 revenue, generally consisting of alfapump sales in France and Germany, were €0.37m (down 61% y-o-y), lower than our forecast of €0.53m. Sales were affected by COVID-19 health restrictions and by the company's prioritisation of alfapump supply towards the POSEIDON and RED DESERT clinical trials. The company's sales and marketing expenses decreased 10% y-o-y to €2.1m, primarily due to a reduction in European commercial activities.

As highlighted in prior notes, product uptake in Europe has been relatively limited since alfapump's launch in the region in 2013 and is likely to remain so in the near to medium term, as most of the refractory ascites in these regions is being attributed to alcoholism or hepatitis, the treatment of which may not be as effectively integrated into the healthcare systems. As a reminder, we expect the opportunity for alfapump in North America to be much more robust given the rising prevalence of NASH in this region. NASH-related cirrhosis is expected to account for a larger proportion of RRA cases in the US and Canada, and these patients are generally older (and thus more likely to be contraindicated for transjugular intrahepatic portosystemic shunt, an alternative treatment for RRA), insured (those aged over 65 have government-run Medicare insurance in the United States) and well-integrated into the healthcare system.

Total SG&A costs (including sales and marketing expenses described above) came in at €7.2m, slightly above our €7.1m estimate. R&D costs (which include clinical expenses, quality and regulatory costs, supply chain and engineering costs) were €16.9m (+43% y-o-y), above our forecast of €15.6m, with the increase largely due to the costs associated with the trials underway during the period (POSEIDON, RED DESERT, SAHARA DESERT) and development work on DSR Infusate 2.0. In addition, regulatory, supply chain and engineering costs rose due to preparation

work conducted for the planned regulatory submissions for alfapump in the United States and Canada.

Overall, the reported FY21 operating loss increased to €22.6m in FY21, up from €17.8m in FY20 and above our forecast loss of €22.3m. FY21 net operating cash burn was €23.6m, above our estimate of €22.6m.

Following FY21 results, we have increased our R&D cost forecasts to reflect the increased expense run-rate shown in FY21. FY22 R&D costs will also include costs for GLP (preclinical) work required for the DSR programmes and costs associated with the ramp up of the MOJAVE DESERT study. We now expect FY22 R&D costs of €16.5m, up from €15.5m previously. While we have raised our FY23 R&D costs to €13.5m (from €12m previously), we expect R&D costs to decline year-on-year in FY23 given our expectation that relative savings following the conclusion of POSEIDON will likely offset the start-up costs for the SONORAN study.

Altogether we now expect net operating cash burn rates of €23.4m and €22.0m in FY22e and FY23e, respectively, from our prior forecasts of €23.0m and €20.5m, respectively.

Sequana reported €9.6m gross cash at 31 December and €7.3m in long-term debt, resulting in a net cash position of €2.3m, excluding €0.76m in lease liabilities. The company strengthened its balance sheet through an equity issue in [early March](#), raising €28.4m (gross) through the issue of 5.167m shares at €5.50 per share.

The company continues to expect its funds on hand to support its operating cash runway into Q223. Importantly, it has sufficient funds to fund the company well through the POSEIDON study's primary endpoint data readout and the SAHARA DESERT top-line results, both expected before the end of 2022. We believe the POSEIDON primary endpoint readout in particular is very critical and, if positive, could trigger a re-rating of the stock as it would signal an improved likelihood of success for advancing the alfapump system in RRA for the all-important US market, which is the largest driver of our valuation for the product in this indication.

We maintain our future total financing expectations of €100m, which we model that Sequana will raise over the next few years until it starts to generate sustained positive operating cash flows (which we continue to expect in H127). We have reduced our alfapump (in RRA) sales forecasts for Europe given recent trends but have not adjusted our forecasts for North American markets, nor have we modified any of our short-term DSR or alfapump DSR forecasts.

Based on our assumptions described above and the Q122 financing, we currently estimate 31 March 2022 net cash of c €23.7m (vs our previous estimate of €25.4m).

## Valuation

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We continue to value Sequana Medical using a risk-adjusted NPV model with a 12.5% cost of capital for alfapump in North America and alfapump DSR (and short-term DSR), and a 10% rate for alfapump in ex-North American markets (where it is commercialised).

**Exhibit 2: Sequana Medical rNPV assumptions**

Product contribution	Indication	Stage	NPV (€m)	Probability of success	rNPV (€m)	rNPV/ basic share (€)	Launch year	Sales (€m) in 2032
Alfapump in North America (net of R&D and SG&A costs)	Refractory and recurrent ascites and malignant ascites	Pivotal studying ongoing	249.6	55%	134.4	5.66	Mid-2024	191.7
Alfapump in Europe and ex-NA regions (net of SG&A costs)	Refractory and recurrent ascites and malignant ascites	Commercial/ marketed	(2.3)	100%	(2.3)	(0.10)	2013	1.7
Alfapump DSR and short-term DSR	Fluid overload in heart failure	Human feasibility studies	889.4	25%	211.5	8.91	H226 in US	473.8*
Corporate costs			(55.9)	100%	(55.9)	(2.35)		
Total			1,080.8		287.8	12.12		
Net cash (Q122e) excluding lease liabilities			23.7		23.7	1.00		
<b>Total equity value</b>			<b>1,104.6</b>		<b>311.5</b>	<b>13.12</b>		
Basic shares outstanding (000) (10 March 2022)			23,747					
Outstanding warrants and share options (000)			1,812					
FD shares outstanding (000) (10 March 2022)			25,559					

Source: Edison Investment Research. Note: \*Reflects estimate of projected transfer pricing revenue to Sequana Medical rather than end-market commercial sales.

Following the adjustments described above, we now obtain a pipeline rNPV valuation of €287.8m versus €296.4m, previously. After adding Q122e net cash of €23.7m (excluding lease liabilities), we obtain an equity valuation of €311.5m or €13.12 per share (€12.19 fully diluted), versus €13.55 previously (€12.59 fully diluted). While we note that the valuation for alfapump in Europe and ex-North America regions is now negative given our reduced European market estimates, we view the overall effect of alfapump commercialisation in these regions as positive, as they help provide support (ie clinical data, quality, manufacturing and regulatory expertise) to the projected commercialisation in the core North American markets.

**Exhibit 3: Financial summary**

	€000	2018	2019	2020	2021	2022e	2023e	2024e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>								
Revenue		1,029	971	963	371	600	690	2,981
Cost of Sales		(158)	(198)	(202)	(77)	(120)	(138)	(596)
Gross Profit		871	773	761	294	480	552	2,385
General & Administrative		(8,206)	(7,102)	(6,738)	(7,177)	(6,956)	(8,461)	(13,978)
Net Research & Development		(5,816)	(7,652)	(11,835)	(16,935)	(16,500)	(13,500)	(13,000)
Operating profit before exceptionals		(13,150)	(13,981)	(17,813)	(23,818)	(22,976)	(21,409)	(24,594)
EBITDA		(13,070)	(13,737)	(17,506)	(23,409)	(22,539)	(21,033)	(24,247)
Depreciation & other		(81)	(244)	(307)	(409)	(437)	(376)	(347)
Operating Profit (before amort. and except.)		(13,150)	(13,981)	(17,813)	(23,818)	(22,976)	(21,409)	(24,594)
Exceptionals including asset impairment		74	18	41	1,205	0	0	0
Operating Profit		(13,077)	(13,964)	(17,771)	(22,613)	(22,976)	(21,409)	(24,594)
Net Interest		(883)	(878)	(1,178)	(608)	(364)	(1,375)	(3,473)
Profit Before Tax (norm)		(14,033)	(14,859)	(18,991)	(24,426)	(23,340)	(22,784)	(28,067)
Profit Before Tax (FRS 3)		(13,960)	(14,841)	(18,949)	(23,221)	(23,340)	(22,784)	(28,067)
Tax		(24)	(136)	(157)	(393)	0	0	0
Profit After Tax and minority interests (norm)		(14,057)	(14,995)	(19,148)	(24,819)	(23,340)	(22,784)	(28,067)
Profit After Tax and minority interests (FRS 3)		(13,983)	(14,977)	(19,106)	(23,614)	(23,340)	(22,784)	(28,067)
Average Number of Shares Outstanding (m)		10.0	12.3	15.3	18.2	23.8	23.8	23.9
EPS - normalised (€)		(1.41)	(1.22)	(1.25)	(1.36)	(0.98)	(0.96)	(1.17)
EPS - normalised and fully diluted (€)		(1.41)	(1.22)	(1.25)	(1.36)	(0.98)	(0.96)	(1.17)
EPS - (IFRS) (€)		(1.40)	(1.22)	(1.25)	(1.30)	(0.98)	(0.96)	(1.17)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>								
Fixed Assets		242	829	772	1,814	1,617	1,517	1,846
Tangible Assets		184	765	705	1,732	1,535	1,435	1,764
Investments in long-term financial assets		58	63	67	82	82	82	82
Current Assets		3,099	8,522	13,441	12,890	14,229	16,597	14,185
Short-term investments		0	0	0	0	0	0	0
Cash		1,318	5,586	11,016	9,600	13,568	16,290	12,597
Other		1,782	2,935	2,425	3,290	661	307	1,588
Current Liabilities		(18,727)	(5,315)	(5,966)	(7,180)	(3,546)	(3,039)	(3,454)
Creditors		(6,654)	(4,855)	(5,966)	(7,180)	(3,546)	(3,039)	(3,454)
Short term borrowings		(12,073)	(459)	0	0	0	0	0
Long Term Liabilities		(3,374)	(3,110)	(8,135)	(8,312)	(8,312)	(33,312)	(58,312)
Long term borrowings		(2,582)	(2,261)	(7,473)	(7,325)	(7,325)	(32,325)	(57,325)
Other long term liabilities		(792)	(849)	(662)	(987)	(987)	(987)	(987)
Net Assets		(18,760)	926	113	(788)	3,989	(18,237)	(45,736)
<b>CASH FLOW</b>								
Operating Cash Flow		(8,987)	(17,596)	(15,791)	(22,786)	(22,998)	(20,627)	(24,545)
Net interest and financing income (expense)		(883)	(878)	(1,178)	(608)	(364)	(1,375)	(3,473)
Tax		(5)	(9)	(36)	(222)	0	0	0
Net Operating Cash Flow		(9,875)	(18,482)	(17,005)	(23,616)	(23,362)	(22,002)	(28,018)
Capex		(39)	(106)	(138)	(326)	(240)	(276)	(676)
Acquisitions/disposals		0	0	0	0	0	0	0
Financing (net of costs)		2	26,165	19,000	22,771	27,567	0	0
Dividends		0	0	0	0	0	0	0
Other		0	0	0	0	0	0	0
Net Cash Flow		(9,912)	7,576	1,857	(1,171)	3,966	(22,278)	(28,694)
Opening net debt/(cash)		0	13,337	(2,866)	(3,543)	(2,275)	(6,243)	16,035
HP finance leases initiated		0	0	0	0	0	0	0
Other		(3,425)	8,627	(1,179)	(97)	0	0	(0)
Closing net debt/(cash)		13,337	(2,866)	(3,543)	(2,275)	(6,243)	16,035	44,728
Lease debt		na	504	387	760	760	760	760
Closing net debt/(cash) inclusive of IFRS16 lease debt		13,337	(2,362)	(3,157)	(1,515)	(5,483)	16,795	45,488

Source: Company data, Edison Investment Research

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