EDISON

Sequana Medical

H121 and timeline update

Pushing back alfapump PMA to mid-2023

Pharma & biotech

Sequana Medical indicated that due to a worldwide shortage of electronic components, it now anticipates its US premarket approval (PMA) application for the alfapump will now be submitted in mid-2023, compared to prior guidance of Q422. We have pushed back our potential North American alfapump launch estimate in recurrent and refractory ascites (RRA) to mid-2024 (from H223 previously), while our projections for the Direct Sodium Removal (DSR) programmes in heart failure are unchanged. We now obtain a new pipeline rNPV of €219.8m (vs €248.2m, previously).

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/19	1.0	(14.9)	(1.22)	0.0	N/A	N/A
12/20	1.0	(19.0)	(1.25)	0.0	N/A	N/A
12/21e	0.5	(22.7)	(1.25)	0.0	N/A	N/A
12/22e	1.2	(22.8)	(1.22)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

Awaiting FDA clearance to expand POSEIDON

Sequana previously announced it is seeking to expand POSEIDON study enrolment by c 10 patients to address higher attrition rates to meet its target of 50 implantations for the primary efficacy analysis. It has submitted a protocol amendment to the FDA and communicated with the agency, but has not yet received approval for the expansion. It has withdrawn its prior timeline guidance for enrolment completion and the primary efficacy readout, and plans to provide an update once it receives clarity from the FDA. Sequana remains very optimistic that the request will be accepted and we remain confident in alfapump's efficacy profile to date as trends shown in recent interim analyses appear to significantly exceed the primary endpoints as defined for the pivotal cohort.

H121 expenses ahead of forecasts

The H121 net operating cash burn was €11.9m, above our €8.9m forecast, primarily due to higher than anticipated R&D costs. We have increased our future R&D and SG&A forecasts going forward. While we continue to expect Sequana's funds on hand should be sufficient to maintain operations into Q222, we now model the company will need to raise a total of €125m to reach profitability, up from our prior estimate of €85m, including an estimated €20m in 2022.

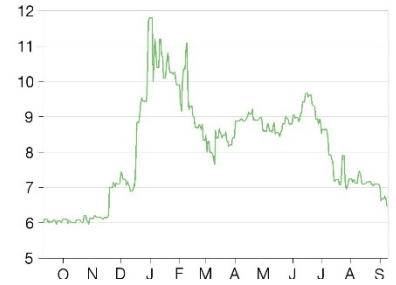
Valuation: Adjusting for new alfapump timeline

We now obtain a pipeline rNPV valuation of €219.8m versus €248.2m previously. This revision is attributable to the revised North American alfapump success probability estimate (55% vs 60% previously), the increase in our operating expense forecasts and the pushing back of the forecast North American alfapump launch date in RRA, offset by rolling forward our estimates and the slight revision in our forex assumptions. After adding H121 net cash of €14.7m (excluding lease liabilities), we obtain an equity valuation of €234.5m or €12.62 per share (€11.54 fully diluted).

10 September 2021

Price	**€6.46**
Market cap	**€120m**
	$1.19/€
Net cash (€m) at 31 June 2021 (excluding €0.3m lease liabilities)	14.7
Shares in issue	18.58m
Free float	50%
Code	SEQUA
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(12.0)	(29.0)	5.9
Rel (local)	(9.9)	(30.1)	15.5
52-week high/low		€11.8	€6.0

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

Interim data for SAHARA DESERT alfapump DSR study	Q421

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Edison profile page

Subcomponent shortages push back alfapump PMA

Sequana Medical recently provided a H121 update, with the primary takeaway being that the planned submission of a US PMA application for the alfapump is now anticipated for mid-2023, compared to prior guidance of Q422. This delay is primarily attributed to the worldwide shortage of electronic components. As part of the PMA submission, the company will be required to conduct verification and validation activities (VVA) using the many components and subcomponents to be deployed in the prototype model designed for US commercial use. The alfapump is a complex electronic medical device with more than 1300 components in total, including over 600 electronic components from over 200 suppliers. Following recent planning discussions with its suppliers, Sequana learned the lead time for obtaining some of the (sub)components needed for VVA is much longer than usual given the global shortage, and consequently it now estimates the completion of VVA would push the PMA submission timing to mid-2023.

Awaiting FDA clearance for expanding POSEIDON enrolment

Regarding the POSEIDON pivotal study in patients with RRA due to liver cirrhosis, Sequana reported positive data in July from the second interim analysis in patients in the roll-in cohort.[1] At the time Sequana announced that, based on an analysis of attrition rates between study enrolment and alfapump implantation, it anticipated c 10 additional patients will need to be enrolled in the pivotal cohort (above the pre-specified study size of 60 for the pivotal cohort approved by the FDA) to meet its target of 40 evaluable implantations for the primary efficacy analysis. Initially the company planned to enrol 60 patients in the pivotal cohort, to implant at least 50 of these patients with the alfapump (following the three-month pre-implant observation period and eligibility reassessment) and have at least 40 of the implanted patients evaluable for the primary endpoint analysis at six months after implantation. Due to the higher attrition rate between initial enrolment and implantation, Sequana is seeking to enrol 10 additional patients to still have 50 patients for alfapump implantation and 40 for the primary endpoint analysis (as originally planned).

Sequana had submitted a protocol amendment to the FDA to extend the patient enrolment and has had discussions with the agency on the topic, but has not yet received approval for the requested enrolment expansion. As a result, the company has withdrawn its prior guidance for POSEIDON enrolment completion (previously Q321) and the attainment of the primary endpoint readout (previously Q322). The company plans to provide an update once it receives clarity from the FDA on study expansion. Company management remains very optimistic the agency will approve its request, but the process is taking longer than the company had originally envisioned.

In the unlikely event that the FDA does not agree to the expansion of enrolment, Sequana would still proceed with its pivotal efficacy analysis as intended, but we estimate the study's evaluable pivotal cohort would then consist of c 35 patients, thereby dampening the statistical power compared to the planned target of c 40 in that cohort. As a reminder, the primary effectiveness outcomes of POSEIDON include:

- the proportion of patients with a 50% reduction in the overall average frequency of therapeutic paracentesis (TP) per month in the post-implant observation period (reflecting month four to month six after implantation) as compared to the pre-implant observation period; and

[1] The POSEIDON study allows for up to 30 patients to be enrolled in a training (or 'roll in') cohort (which will be excluded from primary efficacy analysis), to ensure centres are experienced with the alfapump before the actual study (pivotal) cohort is enrolled.

- whether at least 50% of patients receive a 50% reduction in their monthly frequency of required TP post-implantation compared to the average monthly number of TP required pre-implantation.

As outlined in our recent note, the second interim analysis of the study roll-in cohort showed that subjects had a greater than 90% reduction in mean frequency of TP versus baseline, and all patients experienced at least 50% reduction in mean TP frequency per month versus baseline. As these trends substantially exceed the primary endpoints as defined for the pivotal cohort, it appears there could be a sufficient efficacy buffer or margin (assuming the pivotal cohort data would be similar to the roll-in cohort data to date) for the pivotal cohort to still potentially meet the primary endpoint targets despite the lower number of patients. Nonetheless, allowing the study to reach the company's intended target for pivotal cohort implantations would provide it with the desired (pre-planned) statistical power and thus the highest likelihood, in our view, of meeting the primary endpoint. We expect Sequana will continue to actively seek FDA clearance for cohort expansion and in any event, we are confident the company will report the completion of enrolment before Q222 and primary endpoint data no later than Q123.

Given the new guidance for the alfapump PMA submission, we have revised our US and Canadian launch expectation to mid-2024, from H223 previously.

Financials

Sequana had a 30 June 2021 net cash position of €14.7m (€21.8m in cash offset by €7.1m in long-term debt) excluding €0.3m in lease liabilities. The H121 normalised operating loss (EBIT) was €11.5m, up from €9.0m in H120. H121 net operating cash burn was €11.9m, coming in higher than our €8.9m assumption. This was primarily due to higher than anticipated R&D-related costs (consisting of clinical, quality and regulatory, supply chain and engineering activities), collectively coming in at €7.9m versus our €6.0m forecast and to a lesser extent on higher than expected SG&A costs (€3.7m versus our €3.2m estimate). Given these trends, we have increased our R&D and SG&A forecasts for H221 and future years, resulting in increased net operating cash burn rates for 2021 and 2022 of €22.6m and €23.9m, versus our prior assumptions of €17.6m and €18.9m, respectively.

We continue to expect Sequana's funds on hand should be sufficient for it to maintain operations into Q222, but the projected higher cash burn rate and the additional c 9 months to our forecast of a North American alfapump launch increases our forecast cash need until the point at which the company would become cash-flow positive (whereby alfapump sales in RRA will exceed R&D and other opex costs). We now anticipate the company will start to generate positive operating cash flows in H127 (from H226 previously). We now also model the company will need to raise a total of €125m up until this milestone, up from our prior estimate of €85m. We now model the company will raise €20m in 2022, €25m in 2023, and additional €80m before FY27. As per our usual policy, we model these financing requirements as illustrative debt.

Valuation

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 a 10% rate for alfapump in ex-North American markets (where it is commercialised). Given the added uncertainty relating to the timing of the POSEIDON study completion and on whether the FDA will eventually accept the company's pivotal cohort expansion request (although we believe it is very likely it will), we have reduced the probability of success for alfapump in the North American market to 55%, from 60% previously. We

continue to remain confident in alfapump's efficacy profile to date (given the interim POSEIDON data cited above) and expect to return the success probability estimate to 60% if the company receives approval to expand POSEIDON enrolment.

Exhibit 1: Sequana Medical rNPV assumptions

Product contribution	Indication	Stage	NPV (€m)	Prob. 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	201.1	55%	104.7	5.63	Mid-2024	175.6
alfapump in Europe and ex-NA regions (net of SG&A costs)	Refractory and recurrent ascites and malignant ascites	Commercial/ marketed	2.1	100%	2.1	0.11	2013	3.4
alfapump DSR and short-term DSR	Fluid overload in heart failure	Human feasibility studies	736.6	25%	169.2	9.11	H226 in US	434*
Corporate costs			(56.2)	100%	(56.2)	(3.02)		
Total			883.7		219.8	11.83		
Net cash (H121) excluding lease liabilities			14.7		14.7	0.79		
Total equity value			898.4		234.5	12.62		
Basic shares outstanding (000) (27 July 2021)			18,577					
Outstanding warrants and share options			1,747					
FD shares outstanding (000) (27 July 2021)			20,324					

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

We now obtain a pipeline rNPV valuation of €219.8m versus €248.2m, previously. Altogether, the reduced rNPV is attributable to the revised North American alfapump success probability estimate, the increase in our operating expense forecasts and the pushing back of the forecast North American alfapump launch date, offset by the rolling forward of our estimates and the slight revision in our forex assumptions ($1.19/€ versus $1.21/€ previously). After adding H121 net cash of €14.7m (excluding lease liabilities), we obtain an equity valuation of €234.5m or €12.62 per share (€11.54 fully diluted).

Exhibit 2: Financial summary

€(000)	2018	2019	2020	2021e	2022e	2023e	2024e
31-December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS							
Revenue	1,029	971	963	525	1,214	1,396	3,609
Cost of Sales	(158)	(198)	(202)	(105)	(243)	(279)	(722)
Gross Profit	871	773	761	420	971	1,117	2,888
General & Administrative	(8,206)	(7,102)	(6,738)	(7,103)	(7,038)	(8,529)	(13,412)
Net Research & Development	(5,816)	(7,652)	(11,835)	(15,606)	(15,500)	(12,000)	(12,500)
Operating profit before exceptionals	(13,150)	(13,981)	(17,813)	(22,289)	(21,567)	(19,412)	(23,025)
EBITDA	(13,070)	(13,737)	(17,506)	(22,117)	(21,380)	(19,275)	(22,921)
Depreciation & other	(81)	(244)	(307)	(172)	(187)	(137)	(104)
Operating Profit (before amort. and except.)	(13,150)	(13,981)	(17,813)	(22,289)	(21,567)	(19,412)	(23,025)
Exceptionals including asset impairment	74	18	41	17	0	0	0
Operating Profit	(13,077)	(13,964)	(17,771)	(22,272)	(21,567)	(19,412)	(23,025)
Net Interest	(883)	(878)	(1,178)	(416)	(1,229)	(3,157)	(5,254)
Profit Before Tax (norm)	(14,033)	(14,859)	(18,991)	(22,705)	(22,795)	(22,569)	(28,279)
Profit Before Tax (FRS 3)	(13,960)	(14,841)	(18,949)	(22,688)	(22,795)	(22,569)	(28,279)
Tax	(24)	(136)	(157)	(129)	0	0	0
Profit After Tax and minority interests (norm)	(14,057)	(14,995)	(19,148)	(22,834)	(22,795)	(22,569)	(28,279)
Profit After Tax and minority interests (FRS 3)	(13,983)	(14,977)	(19,106)	(22,817)	(22,795)	(22,569)	(28,279)
Average Number of Shares Outstanding (m)	10.0	12.3	15.3	18.3	18.7	18.7	18.8
EPS - normalised (€)	(1.41)	(1.22)	(1.25)	(1.25)	(1.22)	(1.20)	(1.50)
EPS - normalised and fully diluted (€)	(1.41)	(1.22)	(1.25)	(1.25)	(1.22)	(1.20)	(1.50)
EPS - (IFRS) (€)	(1.40)	(1.22)	(1.25)	(1.25)	(1.22)	(1.20)	(1.50)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET							
Fixed Assets	242	829	772	640	486	385	371
Tangible Assets	184	765	705	561	407	305	292
Investments in long-term financial assets	58	63	67	79	79	79	79
Current Assets	3,099	8,522	13,441	12,142	8,372	10,295	7,717
Short-term investments	0	0	0	0	0	0	0
Cash	1,318	5,586	11,016	11,035	7,099	9,705	6,017
Other	1,782	2,935	2,425	1,107	1,273	590	1,701
Current Liabilities	(18,727)	(5,315)	(5,966)	(4,950)	(3,464)	(2,490)	(2,805)
Creditors	(6,654)	(4,855)	(5,966)	(4,950)	(3,464)	(2,490)	(2,805)
Short term borrowings	(12,073)	(459)	0	0	0	0	0
Long Term Liabilities	(3,374)	(3,110)	(8,135)	(7,839)	(27,839)	(52,839)	(77,839)
Long term borrowings	(2,582)	(2,261)	(7,473)	(7,089)	(27,089)	(52,089)	(77,089)
Other long term liabilities	(792)	(849)	(662)	(750)	(750)	(750)	(750)
Net Assets	(18,760)	926	113	(8)	(22,445)	(44,650)	(72,556)
CASH FLOW							
Operating Cash Flow	(8,987)	(17,596)	(15,791)	(22,087)	(22,674)	(19,202)	(23,344)
Net interest and financing income (expense)	(883)	(878)	(1,178)	(416)	(1,229)	(3,157)	(5,254)
Tax	(5)	(9)	(36)	(85)	0	0	0
Net Operating Cash Flow	(9,875)	(18,482)	(17,005)	(22,588)	(23,902)	(22,360)	(28,598)
Capex	(39)	(106)	(138)	(71)	(34)	(35)	(90)
Acquisitions/disposals	0	0	0	0	0	0	0
Financing	2	26,165	19,000	22,768	0	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	109	(23,936)	(22,394)	(28,688)
Opening net debt/(cash)	0	13,337	(2,866)	(3,543)	(3,946)	19,990	42,384
HP finance leases initiated	0	0	0	0	0	0	0
Other	(3,425)	8,627	(1,179)	293	(0)	(0)	0
Closing net debt/(cash)	13,337	(2,866)	(3,543)	(3,946)	19,990	42,384	71,073
Lease debt	na	504	387	343	343	343	343
Closing net debt/(cash) inclusive of IFRS16 lease debt	13,337	(2,362)	(3,157)	(3,603)	20,333	42,727	71,415

Source: Company data, Edison Investment Research

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