

Quantum Genomics

Development update

All set for an eventful 2019

Pharma & biotech

1 April 2019

Price €4.96

Market cap €81m

Net cash (€m) at 31 December 2018 14.8

Shares in issue 16.4m

Free float 75%

Code ALQGC

Primary exchange Euronext Paris

Secondary exchange OTCQX

Quantum Genomics recently reported its 2018 annual results and updated development timelines. Results from the pharmacokinetic study of sustained-release (once per day) firibastat as well as the initiation of the 294-patient Phase IIb QUORUM study in heart failure are both expected in Q219. The company is also planning to initiate its Phase III trial hypertension in H219. In addition, it is currently in discussions with a number of potential partners for the firibastat programme following the strong NEW-HOPE data.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/17	0.0	(10.3)	(0.93)	0.0	N/A	N/A
12/18	0.0	(13.6)	(0.94)	0.0	N/A	N/A
12/19e	0.0	(17.6)	(0.88)	0.0	N/A	N/A
12/20e	0.0	(23.1)	(1.12)	0.0	N/A	N/A

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

Controlled-release formulation data in Q219

Quantum is developing a controlled-release formulation of firibastat that would allow it to be administered once a day (currently twice a day). A trial in 12 healthy volunteers to evaluate pharmacokinetics (PK) in prototype formulations has been fully enrolled and is expected to produce results in Q219.

QUORUM study in heart failure patients coming

The QUORUM study will enrol 294 subjects from 40 centres in the US and Europe within 24 hours of suffering acute myocardial infarction (AMI), commonly referred to as a heart attack. The primary endpoint will be the change from baseline in the left ventricular ejection fraction (LVEF) after a three-month treatment. Patient recruitment is expected to start in Q219, with results in H220.

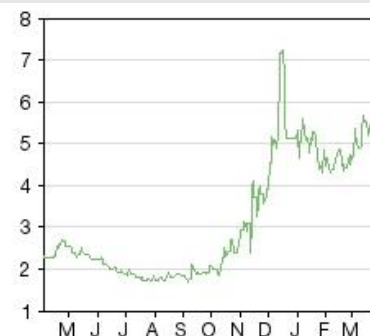
Phase III hypertension study to begin in H219

The company is preparing to follow up the positive NEW-HOPE data of firibastat in patients with hypertension with a Phase III trial, which is expected to begin in H219. As a reminder, in the 256-patient NEW-HOPE trial, patients saw a statistically significant reduction from baseline ($p < 0.0001$) in systolic automated office blood pressure (AOBP) of 9.7mmHg.

Valuation: €860m or €52.43 per share

We have adjusted our valuation of Quantum Genomics to €860m or €52.43 per share from €803m or €66.91 per share. The total valuation has increased due to rolling forward our NPVs and a higher net cash level, while the valuation per share has decreased due to a higher share count as the company utilised an equity line with Kepler Cheuvreux. Quantum had €14.8m in cash at end 2018 and has utilised an additional €2.6m of its equity line since then, which should fund the company's trials to the end of 2019.

Share price performance



%	1m	3m	12m
Abs	10.0	(5.5)	115.2
Rel (local)	9.4	(16.2)	112.1
52-week high/low		€7.2	€1.7

Business description

Quantum Genomics is a biopharmaceutical company developing firibastat, a brain aminopeptidase A inhibitor for the treatment of hypertension and heart failure. Its mechanism is implicated in the 25% of patients resistant to treatment. The Phase IIb study in hypertension was recently very positive and the Phase IIb in heart failure should start in Q219.

Next events

Sustained-release firibastat PK data	Q219
Phase IIb heart failure study initiation	Q219
Start of Phase III in hypertension	H219

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A busy year ahead

The company recently reported its full year results for 2018 and provided an update on development timelines. It is developing a controlled-release formulation of firibastat that would allow it to be administered once a day (compared to twice a day with the current formulation). A trial in 12 healthy volunteers to evaluate PK in prototype formulations has been fully enrolled and is expected to have results in Q219.

Quantum Genomics is also moving forward with the Phase IIb trial in heart failure. The QUORUM study will assess the safety and efficacy of Quantum's drug firibastat compared to ramipril, an angiotensin-converting enzyme (ACE) inhibitor, in 294 subjects enrolled within 24 hours of suffering AMI, who were treated with primary percutaneous coronary intervention and have reduced LVEF. The primary endpoint will be the change from baseline in LVEF after a three-month treatment. Secondary endpoints will include cardiac events, functional status and change in heart failure biomarkers. The subjects will be recruited from 40 centres in the US and Europe, and the trial is expected to launch in Q219 with results expected in H220. Originally, we had expected the study to begin by the end of 2018, but despite the delayed initiation, the company did not change guidance on the timing of the results.

The company is also preparing to follow up the positive NEW-HOPE data of firibastat in patients with hypertension with a Phase III trial, which is expected to begin in H219. As a reminder, the NEW-HOPE trial completed enrolment faster than expected, enrolling 256 patients (254 included in the intent-to-treat analysis) in just 10 months. NEW-HOPE focused enrolment on hypertensive overweight (BMI 25–45kg/m²) patients (65% of patients were obese), with a primary endpoint of change from baseline in systolic AOBP at week eight. Patients saw a statistically significant reduction from baseline ($p < 0.0001$) in AOBP of 9.7mmHg.

The results are in the vicinity of many of the standards of care (see Exhibit 1), but with a differentiated mechanism, which could be especially helpful in treating those currently not well controlled. Needless to say, there are a number of potential partners interested in this programme and discussions with them are ongoing, according to the company.

Exhibit 1: Competitor efficacy table

Drug	Class	Company (originator)	Peak sales (all indications)	Duration	Reduction in systolic blood pressure (mmHg)
Firibastat	BAPAI	Quantum Genomics	N/A	8 weeks	9.7
Diovan (valsartan)	ARB	Novartis	\$6.0bn (2010)	8 weeks	5.6–9
Vasotec (enalapril)	ACE inhibitor	Merck	\$2.5bn (1996)	4 weeks	10–14
Norvasc (amlodipine)	Calcium channel blocker	Pfizer	\$4.9bn (2006)	8 weeks	12.1–16

Source: Quantum Genomics, FDA, company filings, Liu et al, (2010) Tolerability and effectiveness of (S)-amlodipine compared with racemic amlodipine in hypertension; *Current therapeutic research, clinical and experimental* 71, 1-29; Ruilope et al. (2010) Blood-pressure reduction with LCZ696, a novel dual-acting inhibitor of the angiotensin II receptor and neprilysin, *Lancet*, 375: 1255-66.

Valuation

We have adjusted our valuation of Quantum Genomics to €860m or €52.43 per share from €803m or €66.91 per share. The total valuation has increased due to rolling forward our NPVs and a higher net cash level, while the valuation per share has decreased due to a higher share count as the company utilised an equity line with Kepler Cheuvreux. Note that the probability of success in hypertension remains at a discount to where it would normally be (for a Phase III asset we usually use a 60–70% probability of success) as the company will require a partner to advance firibastat to approval. A partnership with a major pharmaceutical company would likely increase that probability.

Exhibit 2: Quantum Genomics valuation

Product	Main indication	Local	Status	Prob. of success	Launch year	Peak sales (\$m)	Patent protection	rNPV
Firibastat (QGC001)	Hypertension	US	Phase II	50%	2023	\$1,110	2031	€441.40
Firibastat (QGC001)	Hypertension	Europe	Phase II	50%	2023	\$959	2031	€374.49
Firibastat (QGC001)	Development costs							(€140.35)
Firibastat (QGC001)	Heart failure	US	Phase IIb	20%	2023	\$574	2031	€112.71
Firibastat (QGC001)	Heart failure	Europe	Phase IIb	20%	2023	\$687	2031	€133.73
Firibastat (QGC001)	Development costs							(€76.53)
Total								€845.44
Net cash (31 December 2018) (€m)								€14.78
Total firm value (€m)								€860.22
Total shares (28 February 2019) (m)								16.41
Value per basic share (€m)								€52.43

Source: Edison Investment Research

Financials

Quantum Genomics reported an operational loss of €13.6m in 2018 compared to €10.3m in 2017, with the increase primarily driven by additional spending on R&D. We have increased our operating loss estimates for 2019 by around €2m to €16.8m due to a greater than expected spending in 2018. We also have introduced estimates for 2020, in which we expect spending to increase to €20.9m.

Quantum ended 2018 with €14.8m in cash and investments. In March 2018, it announced an equity line of credit with Kepler Cheuvreux, and has approximately €6.5m of the original €24m line remaining after drawing down an additional €2.6m after the end of the quarter. The company has stated that it believes the equity line will fund its clinical trials through to the end of 2019, although we expect it to raise €10m in additional capital (either through a partnership or equity raise) by the end of the year (but far more if through a partnership).

Exhibit 3: Financial summary

	€000s	2017	2018	2019e	2020e
Year end 31 December		PCG	PCG	PCG	PCG
PROFIT & LOSS					
Revenue		0	0	0	0
Cost of Sales		0	0	0	0
Gross Profit		0	0	0	0
EBITDA		(10,292)	(13,598)	(16,792)	(20,879)
Operating Profit (before amort. and except.)		(10,292)	(13,598)	(16,792)	(20,879)
Intangible Amortisation		0	0	0	0
Other		0	0	0	0
Exceptionals		0	0	0	0
Operating Profit		(10,292)	(13,598)	(16,792)	(20,879)
Net Interest		0	0	(801)	(2,201)
Other		(239)	150	0	0
Profit Before Tax (norm)		(10,292)	(13,598)	(17,593)	(23,080)
Profit Before Tax (FRS 3)		(10,531)	(13,448)	(17,593)	(23,080)
Tax		1,150	1,458	2,287	3,000
Deferred tax		0	0	0	0
Profit After Tax (norm)		(9,142)	(12,140)	(15,306)	(20,080)
Profit After Tax (FRS 3)		(9,381)	(11,990)	(15,306)	(20,080)
Average Number of Shares Outstanding (m)		9.9	12.8	17.3	18.0
EPS - normalised (c)		(93.45)	(93.94)	(88.49)	(111.62)
EPS - FRS 3 (€)		(0.95)	(0.94)	(0.88)	(1.12)
Dividend per share (c)		0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets		439	626	636	644
Intangible Assets		91	0	0	0
Tangible Assets		52	24	34	42
Other		296	602	602	602
Current Assets		13,478	17,855	15,139	12,551
Stocks		189	422	422	422
Debtors		2,197	2,636	2,636	2,636
Cash		11,089	14,797	12,081	9,494
Other		3	0	0	0
Current Liabilities		(4,572)	(5,764)	(5,764)	(5,764)
Creditors		(4,571)	(5,762)	(5,762)	(5,762)
Short term borrowings		(1)	(2)	(2)	(2)
Long Term Liabilities		(474)	(849)	(10,849)	(28,349)
Long term borrowings		(19)	(12)	(10,012)	(27,512)
Other long term liabilities		(454)	(837)	(837)	(837)
Net Assets		8,871	11,868	(838)	(20,918)
CASH FLOW					
Operating Cash Flow		(7,977)	(10,901)	(15,300)	(20,071)
Net Interest		0	0	0	0
Tax		0	0	0	0
Capex		32	(16)	(16)	(16)
Acquisitions/disposals		0	0	0	0
Financing		7,733	15,071	2,600	0
Dividends		0	0	0	0
Other		104	(446)	0	0
Net Cash Flow		(108)	3,708	(12,716)	(20,087)
Opening net debt/(cash)		(11,179)	(11,069)	(14,783)	(2,067)
HP finance leases initiated		0	0	0	0
Exchange rate movements		0	0	0	0
Other		-2	6	0	0
Closing net debt/(cash)		(11,069)	(14,783)	(2,067)	18,021

Source: Quantum Genomics accounts, Edison Investment Research.

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