

Quantum Genomics

Progress in heart failure and controlled release

Quantum Genomics recently announced that it has enrolled the first patient in the 294-patient Phase IIb QUORUM study of firibastat in heart failure. Separately, following a successful pharmacokinetic study, it has have selected a controlled release version of firibastat that will allow for once-a-day dosing (though the QUORUM study will still use the twice-a-day formulation). Successfully developing a once daily formulation should make the program more attractive to partners. As a reminder, the company 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 normalized, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

QUORUM study in heart failure initiated

The QUORUM study will enrol 294 subjects from 40 centres in the US and Europe within 72 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 has now initiated, with results in H220.

Controlled-release formulation successful

Quantum has developed a controlled-release formulation of firibastat that would allow it to be administered once a day (currently twice a day). In a 12-subject pharmacokinetic study, the once daily controlled release formulation had similar drug exposure levels to the twice daily version. Besides being more convenient for patients, the once daily formulation is more attractive to partners.

Phase III hypertension study coming 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 €51.76 per share

We have slightly adjusted our valuation of Quantum Genomics. While our total valuation of the company of €860m has not changed, our per-share valuation has declined from €52.43 per share to €51.76 per share, due to an increase in total shares outstanding. Quantum had €14.8m in cash at end 2018 and has utilized an additional €2.6m of its equity line since then (as of the most recent disclosure from 30 April 2019).

Development update

Pharma & biotech

13 June 2019

Price €4.70

Market cap €78m

Net cash (€m) at 31 December 2018 14.8

Shares in issue 16.6m

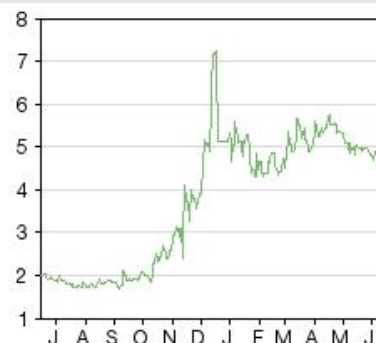
Free float 75%

Code ALQGX

Primary exchange Euronext Paris

Secondary exchange OTCQX

Share price performance



% 1m 3m 12m

Abs (5.1) (11.2) 125.4

Rel (local) (5.7) (12.6) 131.8

52-week high/low €7.25 €1.70

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 very positive and a Phase IIb in heart failure was recently initiated.

Next events

Start of Phase III in hypertension H219

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Progressing on schedule

Quantum Genomics announced that it has enrolled the first patient in its 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 72 hours of suffering AML, who were treated with primary percutaneous coronary intervention and have reduced LVEF. There will be three arms in this randomized, double-blind, active-controlled study with patients receiving either 100mg of firibastat twice a day, 500mg of firibastat twice a day or 5mg of ramipril twice a day. 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 trial results are expected in H220.

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 slightly adjusted our valuation of Quantum Genomics. While our total valuation of the company of €860m has not changed, our per-share valuation has declined from €52.43 per share to €51.76 per share, due to an increase in total shares outstanding.

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 (30 April 2019) (m)								16.62
Value per basic share (€m)								€51.76
Source: Edison Investment Research								

Financials

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 year (as of 30 April). 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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