EDISON

Quantum Genomics

Development update

Firibastat Phase III to start by end of the year

Pharma & biotech

The company recently reported positive feedback from the FDA for its Phase III programme design for firibastat. There will be two studies required for approval: one focused on efficacy and one on safety. The efficacy study, QGC001/3QG1, will be a three-month 500-patient study comparing firibastat to placebo in difficult-to-treat or resistant hypertension patients who are already on treatments from two or three anti-hypertensive classes. Enrolment is expected to begin by the end of this year with data in H221. The safety study will enrol 750 patients, with 650 staying on the drug for six months and 100 staying on it for a year.

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	(17.0)	(0.87)	0.0	N/A	N/A
12/20e	0.0	(22.6)	(1.11)	0.0	N/A	N/A

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

Advanced partnership discussions ongoing

The company has stated it is in advanced discussions with several pharmaceutical companies to partner firibastat and recently announced exclusive negotiations with a potential partner to commercialise firibastat for hypertension in Latin American markets. If these negotiations prove successful, they will enable Quantum Genomics to fund development through non-dilutive financing (we currently model €23.3m in additional financing through the end of 2020.).

QUORUM study in heart failure enrolling patients

The Phase IIb QUORUM study is enrolling 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. Results are expected in H220.

Trial in patients with renal failure launched

Based on analysis of the NEW-HOPE study, firibastat appears to not have any impact on renal function, which is a problem with many popular treatments such as Diovan. To confirm this finding, the company has initiated a small study investigating one 500mg dose of firibastat in 14 healthy volunteers and 14 patients with severe renal failure. Results are expected in April 2020. If confirmed, this finding would help expand the market and provide a marketing edge for firibastat.

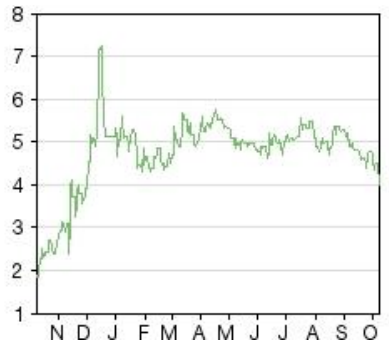
Valuation: €909m or €53.01 per share

We have increased our valuation from €860m or €51.76 per share to €909m or €53.01 per share mainly due to rolling forward our NPV. It was partially offset by a lower net cash balance and a slightly higher number of shares outstanding. Quantum had €11.6m in cash and investments at the end of H119. It has an additional €5.8m available through its equity line of credit with Kepler Cheuvreux.

8 October 2019

Price	**€4.00**
Market cap	**€68m**
Net cash (€m) at 30 June 2019	11.6
Shares in issue	17.1m
Free float	89.4%
Code	ALQGC
Primary exchange	Euronext Paris
Secondary exchange	OTCQX

Share price performance



%	1m	3m	12m
Abs	(18.5)	(21.6)	100.0
Rel (local)	(17.3)	(20.6)	97.0
52-week high/low		€7.25	€1.85

Business description

Quantum Genomics is a biopharmaceutical company developing firibastat, a brain aminopeptidase A inhibitor for treating 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 study in heart failure was recently initiated.

Next events

Phase III hypertension study initiation	YE19
QUORUM heart failure study data	H220

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Progress on the clinical front

In September Quantum Genomics reported that it received positive feedback from the FDA for its Phase III programme design for firibastat. There will be two studies required for approval: one focused on efficacy and one on safety. The efficacy study, QGC001/3QG1, will be a three-month 500-patient study comparing firibastat to placebo in difficult-to-treat or resistant hypertension patients who are already on treatments from two or three anti-hypertensive classes (firibastat and placebo will be added on top of the current treatment) yet still have systolic automated office blood pressure (AOBP) above 140mmHg. The primary endpoint will be a change from baseline in systolic AOBP. Enrolment is expected to begin by the end of the year with data in H221. The safety study will enrol 750 patients, with 650 staying on the drug for six months and 100 staying on it for a year.

The company's most recent trial in hypertensive patients, NEW-HOPE, 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/m^2) 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.

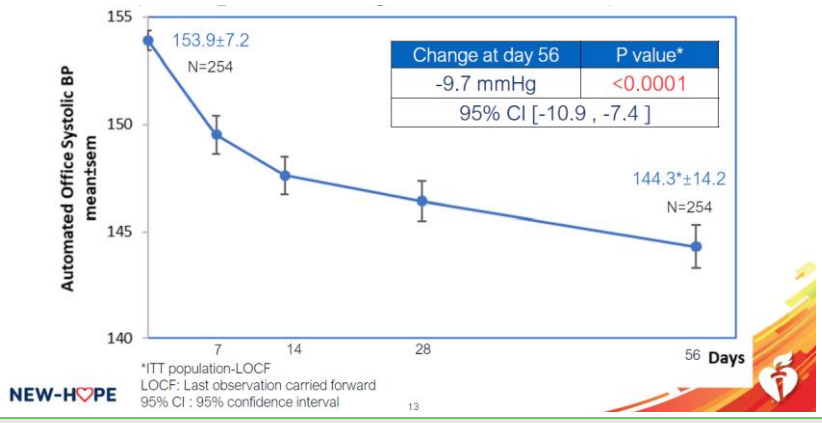
Exhibit 1: Competitor efficacy table

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.

The design of Phase III will be somewhat different than NEW-HOPE with one of the major differences being that patients in NEW-HOPE were taken off their prior treatment (if any) before receiving firibastat, whereas in the upcoming Phase III it will be used on top of the patients' current treatment regimen. This may make it more difficult to see the degree of treatment effect that was seen in NEW-HOPE. However, another design change that may benefit firibastat is that the QGC001/3QG1 trial will be somewhat longer than NEW-HOPE (90 days versus 56 days) and data from NEW-HOPE indicated a greater efficacy the longer patients were on firibastat (see Exhibit 2).

Exhibit 2: Change in systolic AOBP at week eight in NEW-HOPE trial



Source: Quantum Genomics

Importantly, the company has stated it is in advanced discussions with several pharmaceutical companies to partner firibastat and announced in October it is in exclusive negotiations with a potential partner to commercialise firibastat for hypertension in Latin American markets. This potential partner has a portfolio of over 100 products and has signed over 50 international partnerships. Quantum Genomics has also stated it will be moving forward with a regional partnership strategy in hypertension rather than one global partner. This should mean shorter timelines for partnership agreements and an increased commercial focus on firibastat by those smaller regional partners as it would be more strategic for it than for a giant pharmaceutical company.

In terms of the heart failure programme, Quantum Genomics is continuing to enrol the QUORUM study, which will assess the safety and efficacy of Quantum's drug firibastat compared to ramipril, an angiotensin-converting enzyme inhibitor, in 294 subjects enrolled within 72 hours of suffering AMI, who were treated with primary percutaneous coronary intervention and have reduced LVEF. There are three arms in this randomised, 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 is 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. We expect potential partnership discussions for firibastat in heart failure to intensify once the QUORUM study results are out. We do not believe that licensing agreements for hypertension will necessarily preclude separate agreements for heart failure as the product may have different formulations and dosages in the two indications.

Valuation

We have increased our valuation of Quantum Genomics from €860m or €51.76 per share to €909m or €53.01 per share mainly due to rolling forward our NPV. It was partially offset by a lower net cash balance and slightly higher shares outstanding.

Exhibit 3: Quantum Genomics valuation

Product	Main indication	Local	Status	Prob. of success	Launch year	Peak sales ($m)	Patent protection	rNPV (€m)
Firibastat (QGC001)	Hypertension	US	Phase II	50%	2023	1,110	2031	468.17
Firibastat (QGC001)	Hypertension	Europe	Phase II	50%	2023	959	2031	397.21
Firibastat (QGC001)	Development costs							-148.70
Firibastat (QGC001)	Heart failure	US	Phase IIb	20%	2023	574	2031	119.54
Firibastat (QGC001)	Heart failure	Europe	Phase IIb	20%	2023	687	2031	141.84
Firibastat (QGC001)	Development costs							-80.82
Total								897.25
Net cash (30 June 2019) (€m)								11.57
Total firm value (€m)								908.82
Total shares (30 September 2019) (m)								17.15
Value per basic share (€m)								53.01

Source: Edison Investment Research

Financials

The company reported an operational loss of €5.3m in H119 compared to €6.8m in H118, with the decrease primarily driven by the completion of the NEW-HOPE study. We have decreased our operating loss estimates for 2019 by around €0.3m to €16.5m due to lower than expected spending in the first half. We have also lowered operating loss estimates for 2020 by €0.2m to €20.7m.

Quantum had €11.6m in cash and investments at the end of H119. In March 2018, it announced an equity line of credit with Kepler Cheuvreux and has approximately €5.8m of the original €24m line remaining after drawing down an additional €3.4m during the first half of the year. The company has stated it believes its available cash and equity line will be enough to fund the company for the next 12 months. We model (as illustrative long-term debt) that the company will use the remainder of the available credit line by the end of 2019 and will raise an additional €17.5m in 2020, assuming no partnerships are signed. These financing needs could be significantly reduced or eliminated through successful partnership discussions and upfront/milestone payments.

Exhibit 4: 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)	(16,507)	(20,704)
Operating Profit (before amort. and except.)	(10,292)	(13,598)	(16,507)	(20,704)
Intangible Amortisation	0	0	0	0
Other	0	0	6	0
Exceptionals	0	0	0	0
Operating Profit	(10,292)	(13,598)	(16,507)	(20,704)
Net Interest	0	0	(468)	(1,868)
Other	(239)	150	310	0
Profit Before Tax (norm)	(10,292)	(13,598)	(16,976)	(22,572)
Profit Before Tax (FRS 3)	(10,531)	(13,448)	(16,666)	(22,572)
Tax	1,150	1,458	2,167	2,934
Deferred tax	0	0	0	0
Profit After Tax (norm)	(9,142)	(12,140)	(14,809)	(19,638)
Profit After Tax (FRS 3)	(9,381)	(11,990)	(14,499)	(19,638)
Average Number of Shares Outstanding (m)	9.9	12.8	17.0	17.7
EPS - normalised (c)	(93.45)	(93.94)	(87.03)	(111.02)
EPS - FRS 3 (€)	(0.95)	(0.94)	(0.85)	(1.11)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	439	626	940	961
Intangible Assets	91	0	260	260
Tangible Assets	52	24	34	55
Other	296	602	646	646
Current Assets	13,478	17,855	11,070	8,912
Stocks	189	422	422	422
Debtors	2,197	2,636	3,461	3,461
Cash	11,089	14,797	7,055	4,897
Other	3	0	132	132
Current Liabilities	(4,572)	(5,764)	(4,577)	(4,577)
Creditors	(4,571)	(5,762)	(4,576)	(4,576)
Short term borrowings	(1)	(2)	(1)	(1)
Long Term Liabilities	(474)	(849)	(6,705)	(24,205)
Long term borrowings	(19)	(12)	(5,853)	(23,353)
Other long term liabilities	(454)	(837)	(852)	(852)
Net Assets	8,871	11,868	729	(18,909)
CASH FLOW				
Operating Cash Flow	(7,977)	(10,901)	(16,774)	(19,630)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	32	(16)	(29)	(29)
Acquisitions/disposals	0	0	0	0
Financing	7,733	15,071	3,360	0
Dividends	0	0	0	0
Other	104	(446)	(99)	0
Net Cash Flow	(108)	3,708	(13,542)	(19,659)
Opening net debt/(cash)	(11,179)	(11,069)	(14,783)	(1,201)
HP finance leases initiated	0	0	0	0
Exchange rate movements	0	0	0	0
Other	-2	6	-40	0
Closing net debt/(cash)	(11,069)	(14,783)	(1,201)	18,457

Source: Quantum Genomics accounts, Edison Investment Research

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