EDISON

# Halozyme Therapeutics

## HyQvia got a favourable vote

Regulatory and quarterly update

Pharma & biotech

**The positive vote (15 to one) by the FDA's Blood Products Advisory Committee (BPAC) for HyQvia should pave the way for its US approval (Q3) and its launch by Baxter, the drug's commercial partner. Potential risk factors raised and extensively discussed by the FDA at the panel meeting could result in some label restrictions, which will be in line with the drug's restricted approval in the EU. An FDA approval would remove one near-term risk for Halozyme. The panel vote, though positive, has only a small impact on Halozyme's valuation, which is now $1,448m, or $11.7 per basic share, vs previously $1,445m, or $11.6 per basic share.**

| Year end | Revenue ($m) | PBT* ($m) | EPS* ($) | DPS ($) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/12 | 42.3 | (53.5) | (0.48) | 0.0 | N/A | N/A |
| 12/13 | 54.8 | (83.5) | (0.74) | 0.0 | N/A | N/A |
| 12/14e | 67.6 | (68.4) | (0.55) | 0.0 | N/A | N/A |
| 12/15e | 88.8 | (55.7) | (0.44) | 0.0 | N/A | N/A |

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

## Favourable vote despite FDA's focus on risks

FDA scientists spent the majority of their time at the panel meeting discussing data of anti-rHuPH20 (recombinant human hyaluronidase) antibodies seen in HyQvia treated patients. Because the nerve systems and sperms of males express high levels of hyaluronidase, raising anti-rHuPH20 antibodies could in theory cause damage to these two tissues. At the end, the panel voted 15 to one recommending the approval of HyQvia based on a favourable risk/benefit profile of the drug. We now project that the FDA will approve the drug in Q3 and as such remove a major near-term overhang of the stock.

## PEGPH20 moving along

Since the restart of the Phase II trial (Study 202) in June, c 75% of the anticipated clinical sites have received independent review board approvals and a number of sites are enrolling new patients of the 200-pt (increased from previously at c 150) pancreatic cancer trial. A new clinical trial for non-small cell lung cancer (NSCLC) will be started before the end of the year.

## Valuation: Small financial impact

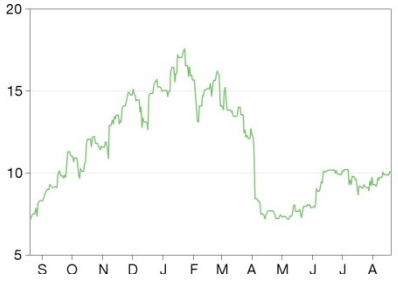
Our valuation of Halozyme has changed slightly to $1,448m, or $11.7 per basic share, after we increased our probability of success of HyQvia from 85% to 100% but slowed down the product's ramp. The change in HyQvia parameters resulted in a change of valuation of $3m, reinforcing our previous assertion that the decision on HyQvia's US approval would have a modest impact on the company's valuation. The bulk of the valuation comes from Herceptin SC, Rituxan SC and PEGPH20 for cancer, and they are not changed at this time. Our valuation suggests there is still upside potential in the stock.

**20 August 2014**

| | |
|---|---|
| **Price** | **US$10.0** |
| **Market cap** | **US$1,247m** |

| | |
|---|---|
| Net cash ($m) at June 2014 | 147.6 |
| Shares in issue | 124.5m |
| Free float | 78.9% |
| Code | HALO |
| Primary exchange | NASDAQ |
| Secondary exchange | N/A |

### Share price performance




| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | 9.2 | 29.0 | 39.2 |
| Rel (local) | 9.0 | 22.7 | 15.6 |
| 52-week high/low | US$17.57 | US$7.10 | |

### Business description

Halozyme Therapeutics focuses on development of extracellular matrix-based drugs. Its rHuPH20-based delivery platform has been used by partners, including Roche, Baxter and Pfizer, to develop SC injection of IV drugs such as Herceptin, Rituxan (Roche) and GAMMAGARD (Baxter). Its pipeline consists of Hylenex, approved for hydration, PEGPH20 in Phase II trials for pancreatic cancer, and HTI-501 in Phase II trials for cellulite.

### Next events

| | |
|---|---|
| Potential HyQvia US approval | Q314 |
| Initiation of second PEGPH20 trial | Q414 |

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## Valuation

We value Halozyme (Exhibit 1) using our discount cash flow method, evaluating its platform and its own pipeline separately. We forecast PEGPH20 and Hylenex (with pump insulin) sales up to 2027. With a 25% probability of success (taking into consideration of the recent protocol modification of the Phase II) for PEGPH20 and 85% (based on success of the late-stage clinical trial) for Hylenex (with pump insulin), and our standard discount rate of 12.5%, we arrived at risk-adjusted, after tax rNPVs of $416m and $336m, respectively. For collaborative products, we focused mainly on Herceptin SC, MabThera SC and HyQvia, as they are either approved or pending approval. Based on our estimates of revenue of these products, 100% probability of success and a 12.5% discount rate, we arrive at an rNPV of $477m. We also arrive at a value of $132m for the remaining collaborative products. Adding $86.3m end of 2014, debt-free cash, we get a total firm value of $1,448m, or $11.7 per basic share ($11.4 per diluted share).

**Exhibit 1: Halozyme valuation model ($m except for per share data)**

| Product | Main Indication | Status | Probability of success | Launch year | Peak sales $m | Patent protection | Royalty | rNPV $m |
|---|---|---|---|---|---|---|---|---|
| PEGPH20 | First-line pancreatic cancer | Phase II | 25% | 2018 | 1,510 | >2027 | Fully own | 416 |
| Hylenex (pump insulin) | Type I diabetes | Late-stage | 85% | 2015 | 295 | >2027 | Fully own | 336 |
| Herceptin SC | Breast cancer | Approved | 100% | 2013 | 1,603 | >2027 | 4% | 218 |
| MabThera SC | NHL | Approved | 100% | 2014 | 1,403 | >2027 | 4% | 181 |
| HyQvia | Primary immune deficiency | Approved/pending | 100% | 2013 | 751 | >2027 | 4% | 36 |
| Future milestone payments (for above three) | | | 100% | N/A | N/A | N/A | 4% | 42 |
| Other collaborative products | | Various | 65% | 2018 | 3,010 | >2027 | 4% | 132 |
| Total | | | | | | | | 1,361 |
| Cash and cash equivalents (YE 14) | | | | | | | | 86.3 |
| Total firm value | | | | | | | | 1,448 |
| Total basic shares (m) | | | | | | | | 124.5 |
| Value per basic share ($) | | | | | | | | 11.7 |
| Stock options (as of 31 December 2013, m) | | | | | | | | 7.4 |
| Cash on exercise | | | | | | | | 51.7 |
| Total firm value inc proceeds from options | | | | | | | | 1,499 |
| Total number of shares (m) | | | | | | | | 131.4 |
| Diluted value per share ($) | | | | | | | | 11.4 |

Source: Edison Investment Research

## Financials

Halozyme reported a net loss of $16.3m, with revenue of $18.4m, SG&A of $8.8m and R&D of $18.6m in Q214. Operating cash burn for the quarter was $15.8m. The company ended the quarter with cash and marketable securities of $147.6m. As of June 2014, the company carried long-term debt of $43.6m and deferred revenue of $48.6m, resulting mainly from milestone payments Halozyme received from its collaborators.

Our forecasts for 2014 and 2015 are not changed materially, including total revenue of $67.6m, R&D expenses of $93m, and SG&A of $32m in 2014. We estimate the company's cash utilisation will be $50.3m in 2014 and it will end the year with cash and cash equivalents of c $135.6m, which is sufficient to support the company's clinical development of PEGPH20 and its operation beyond 2015.

## Exhibit 2: Financial summary

| Year end 31 December $m | 2010 | 2011 | 2012 | 2013 | 2014e | 2015e |
|---|---|---|---|---|---|---|
| | IFRS | IFRS | IFRS | IFRS | IFRS | IFRS |
| **PROFIT & LOSS** | | | | | | |
| Revenue | 13.6 | 56.1 | 42.3 | 54.8 | 67.6 | 88.8 |
| Cost of Sales | (1.0) | (0.3) | (1.1) | (6.2) | (9.5) | (9.6) |
| Gross Profit | 12.6 | 55.8 | 41.2 | 48.6 | 58.1 | 79.1 |
| EBITDA | (60.6) | (26.5) | (63.1) | (91.2) | (81.4) | (65.7) |
| Operating Profit (before amort. and except.) | (54.3) | (19.8) | (53.6) | (80.4) | (66.9) | (53.7) |
| Intangible Amortisation | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Exceptionals | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | 2.0 | 0.1 | 0.1 | (3.3) | (3.0) | (3.0) |
| Operating Profit | (52.3) | (19.8) | (53.5) | (83.7) | (69.9) | (56.7) |
| Net Interest | 0.0 | 0.1 | 0.1 | 0.2 | 1.5 | 1.0 |
| Profit Before Tax (norm) | (54.2) | (19.7) | (53.5) | (83.5) | (68.4) | (55.7) |
| Profit Before Tax (FRS 3) | (52.2) | (19.7) | (53.5) | (83.5) | (68.4) | (55.7) |
| Tax | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Profit After Tax (norm) | (52.2) | (19.7) | (53.5) | (83.5) | (68.4) | (55.7) |
| Profit After Tax (FRS 3) | (52.2) | (19.7) | (53.5) | (83.5) | (68.4) | (55.7) |
| Average Number of Shares Outstanding (m) | 94.36 | 102.57 | 111.08 | 112.81 | 124.00 | 126.50 |
| EPS - normalised ($) | (0.55) | (0.19) | (0.48) | (0.74) | (0.55) | (0.44) |
| EPS - normalised and fully diluted ($) | (0.51) | (0.18) | (0.46) | (0.70) | (0.52) | (0.42) |
| EPS - (IFRS) ($) | (0.06) | (0.19) | (0.48) | (0.74) | (0.55) | (0.44) |
| Dividend per share ($) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Gross Margin (%) | 92.8 | 99.5 | 97.4 | 88.6 | 85.9 | 89.1 |
| EBITDA Margin (%) | N/A | N/A | N/A | N/A | N/A | N/A |
| Operating Margin (before GW and except.) (%) | N/A | N/A | N/A | N/A | N/A | N/A |
| **BALANCE SHEET** | | | | | | |
| Fixed Assets | 1.8 | 1.8 | 3.7 | 6.6 | 5.1 | 5.9 |
| Intangible Assets | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Tangible Assets | 1.8 | 1.8 | 3.7 | 3.4 | 3.0 | 2.5 |
| Investments | 0.0 | 0.0 | 0.0 | 3.2 | 2.1 | 3.4 |
| Current Assets | 89.5 | 64.0 | 131.0 | 95.2 | 161.7 | 131.1 |
| Inventory | 0.2 | 0.6 | 2.7 | 6.2 | 6.5 | 10.0 |
| Accounts receivable, net | 2.3 | 2.3 | 15.7 | 9.1 | 9.5 | 11.4 |
| Cash and cash equivalents | 83.3 | 52.8 | 99.9 | 71.5 | 135.6 | 97.6 |
| Other | 3.7 | 8.3 | 12.8 | 8.4 | 10.1 | 12.1 |
| Current Liabilities | (15.3) | (17.3) | (18.9) | (25.5) | (25.6) | (29.6) |
| Creditors | (15.3) | (17.3) | (18.9) | (25.5) | (25.6) | (29.6) |
| Short term borrowings | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Long Term Liabilities | (55.7) | (37.6) | (66.9) | (96.3) | (100.3) | (98.8) |
| Long term borrowings | 0.0 | 0.0 | (29.7) | (49.8) | (49.3) | (48.8) |
| Other long term liabilities | (55.7) | (37.6) | (37.3) | (46.6) | (51.0) | (50.0) |
| Net Assets | 20.4 | 10.9 | 48.9 | (20.0) | 40.9 | 8.7 |
| **CASH FLOW** | | | | | | |
| Operating Cash Flow | (45.4) | (34.4) | (64.3) | (49.3) | (50.3) | (45.5) |
| Net Interest | 0.0 | 0.1 | 0.1 | 0.2 | 1.5 | 1.0 |
| Tax | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Capex | (0.6) | (0.8) | (1.4) | (2.3) | 0.0 | 0.0 |
| Acquisitions/disposals | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Financing | 61.8 | 4.7 | 83.2 | 5.1 | 114.3 | 7.5 |
| Dividends | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net Cash Flow | 15.8 | (30.4) | 17.5 | (46.3) | 65.5 | (37.0) |
| Opening net debt/(cash) | (67.5) | (83.3) | (52.8) | (70.2) | (21.7) | (86.3) |
| HP finance leases initiated | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | 0.0 | (0.1) | (0.1) | (2.2) | (1.0) | (0.5) |
| Closing net debt/(cash) | (83.3) | (52.8) | (70.2) | (21.7) | (86.3) | (48.8) |

Source: Halozyme reports, Edison Investment Research

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