EDISON

Atossa Genetics

Clinical trial update

IDMC-fulvestrant trial site change, new timelines

Pharma & biotech

Atossa announced this week that it is transferring the site of its ongoing 30-pt Phase II study on intraductal catheter (IDMC) administered fulvestrant to the Montefiore Medical Center in New York City, from the Columbia University Medical Center where it had been initiated in March 2016. This move follows the relocation of the study's primary investigator, Dr Sheldon M Feldman, from Columbia to Montefiore. Atossa believes this move will hasten patient recruitment, which it acknowledges had been slower than expected. It now expects to finish enrolment by August 2017, whereas it previously guided completion by March 2017.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/14	0.0	(7.3)	(4.57)	0.0	N/A	N/A
12/15	0.0	(9.8)	(5.15)	0.0	N/A	N/A
12/16e	0.0	(7.7)	(2.57)	0.0	N/A	N/A
12/17e	0.0	(14.2)	(3.57)	0.0	N/A	N/A

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

The ongoing open-label IDMC-fulvestrant study is comparing the safety, tolerability and pharmacokinetics following the IDMC instillation of fulvestrant, compared to intramuscular (IM) administration, in patients with breast cancer or ductal carcinoma in situ who are scheduled for mastectomy or lumpectomy. The primary outcome measure is the number and severity of adverse events at four weeks using the National Cancer Institute's CTCAE v4.0 protocol.

Atossa believes that IDMC administration of fulvestrant (already an FDA-approved drug) could provide more effective targeting, potentially resulting in lower doses to achieve therapeutic efficacy and/or a less frequent dosing schedule. Following the current open-label study, we continue to expect that a larger pivotal study would be required for approval under the FDA 505(b)2 process. While we previously modelled that this pivotal study could start in late 2017 or early 2018, given the push back in expected recruitment completion, we now expect that the pivotal study would start in H218, which pushes back our potential launch forecast to H220 or early 2021 (from 2020 previously). We are reviewing our forecasts and valuation.

11 January 2017

Price	**$2.08**
Market cap	**$8m**
Net debt ($m) at Q316	4.4
Shares in issue	3.8m
Free float	92%
Code	ATOS
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance

Business description

Based in Seattle, WA, Atossa Genetics is focused on the development of locally administered pharmaceuticals for the treatment of pre-cancer and breast cancer. Intraductal microcatheter-delivered fulvestrant is currently under investigation in a Phase II study.

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