

Atossa Genetics

Atossa raises \$13.4m in rights offering

Financing update

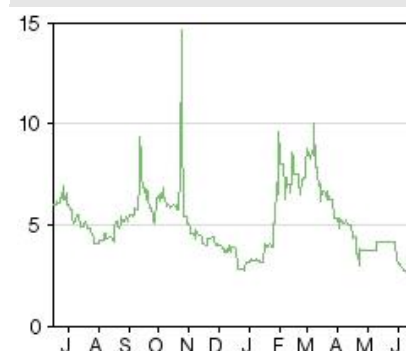
Pharma & biotech

14 June 2018

Price **US\$2.60**
Market cap **US\$17m**

Estimated pro-forma net cash (\$m) at Q118	16.9
Shares in issue (FD) at Q218e	6.44m
Free float	99%
Code	ATOS
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(36.7)	(62.6)	(57.1)
Rel (local)	(37.8)	(62.8)	(62.3)
52-week high/low	US\$14.6	US\$2.6	

Business description

Based in Seattle, WA, Atossa Genetics is a clinical-stage pharmaceutical firm developing therapeutics and delivery methods to treat breast cancer and other breast conditions. Intraductal microcatheter-delivered fulvestrant and endoxifen are both in clinical stages of development.

Next events

Start Phase II study of oral endoxifen	Mid-2018
Start Phase II study of topical endoxifen	Mid-2018

Analysts

Pooya Hemami, CFA	+1 646 653 7026
Maxim Jacobs, CFA	+1 646 653 7027

healthcare@edisongroup.com
[Edison profile page](#)

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Atossa's previously announced rights offering closed on 30 May 2018, generating \$13.3m in gross proceeds (\$12.1m net) through the issue of 13,324 shares of Series B convertible preferred stock (SBCPS) and 3,784,016 warrants exercisable at \$4.05 per share. We believe the funds raised could sustain operations into early 2020. Each SBCPS is immediately convertible into 284 common shares. Assuming the full conversion of all SBCPS into common shares, the number of Atossa's fully diluted (FD) common shares outstanding has increased by 143% to 6.44m. While our rNPV (\$24.4m) is largely unchanged, our per-share equity valuation has reduced to \$5.87 per share (from \$11.30 previously) due to the dilutive impact of the equity raise.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	DPS (\$)	P/E (x)	Yield (%)
12/16	0.0	(7.2)	(29.52)	0.0	N/A	N/A
12/17	0.0	(7.2)	(10.01)	0.0	N/A	N/A
12/18e	0.0	(11.4)	(4.29)	0.0	N/A	N/A
12/19e	0.0	(7.0)	(2.57)	0.0	N/A	N/A

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

Q118 financials largely unremarkable

Atossa reported Q118 results on 14 May 2018, with a net loss of \$1.9m and an operating cash burn rate of \$2.4m for the quarter. Q118 R&D costs were \$0.47m, and we continue to expect the R&D cost rate to increase in future quarters as the company commences larger Phase II studies on topical and oral endoxifen. We continue to expect FY18 R&D expenses of \$7.0m (as R&D spending rates should rise once the Phase II studies commence enrolment). We now assume an operating cash burn rate (excluding net interest income) of \$12.1m in 2018 and \$6.8m in 2019, versus our prior estimates of \$11.5m and \$7.0m respectively. We expect Atossa's total current funds on hand to last into early 2020, and we assume it will raise \$10m in 2019 to fund future operations. As per our usual policy, for modelling purposes, we assign these financings to long-term debt.

Valuation: Equity valuation of \$37.8m

After making minor adjustments to our G&A cost estimates, we now obtain an rNPV valuation of \$24.4m, broadly unchanged from our prior \$24.7m estimate. Atossa had \$4.8m net cash at 31 March 2018 and we estimate Q218 net cash at \$13.4m. After including Q218 estimated net cash, we obtain an equity valuation of \$37.8m, or \$5.87 per fully diluted (FD) share (which assumes full conversion of the recently issued SBCPS into common shares). The dilutive impact of the recent equity raise (with full conversion of the SBCPS into common shares reflecting a lower value per common share than our previous valuation) explains the reduction compared to our previous \$11.30 per-share equity valuation.

Fund-raising could sustain operations into early 2020

The subscription period for Atossa's previously announced rights offering expired on 24 May 2018, and on 30 May 2018 the offering was closed, generating \$13.3m in gross proceeds through the issue of 13,324 units, consisting of 13,324 shares of Series B convertible preferred stock (SBCPS) and 3,784,016 warrants. Net proceeds after all expenses were \$12.1m. We believe the funds raised could sustain operations into early 2020, although our model assumes the firm will still raise \$10m in 2019. Each warrant is exercisable for up to four years, for the purchase of one common share at an exercise price of \$4.05 per share. Each SBCPS has a face value of \$1,000 and is immediately convertible into 284 common shares at a conversion price of \$3.52 per share. Assuming the full conversion of all SBCPS into common shares, the number of Atossa's fully diluted (FD) common shares outstanding has increased by 143% to 6.44m.

Review of financials

Atossa reported Q118 results on 14 May 2018, with a net loss of \$1.9m and an operating cash burn rate of \$2.4m for the quarter. Q118 R&D costs were \$0.47m, and we continue to expect the R&D cost rate to increase in future quarters as the company proceeds with larger Phase II studies on topical and oral endoxifen (recruitment sizes still unknown), as well as the recently started 24-patient Phase I study on topical endoxifen in men. Atossa announced on 15 May 2018 that it had received a second positive interim safety review on this trial, which concluded that the study may advance to the third and final dosing level of the trial. The company expects to announce results assessing the safety and pharmacokinetics of 28 days of treatment, in Q318.

Atossa continues to anticipate starting Phase II studies in mid-2018 for both topical and oral endoxifen in women, for high mammographic breast density (MBD) and breast cancer recurrence prevention indications, respectively. We continue to expect FY18 R&D expenses of \$7.0m (as R&D spending rates should rise once the Phase II studies commence enrolment) and we have increased our 2018 G&A forecast to \$4.4m (from \$4.2m, previously).

We now assume an operating cash burn rate (excluding net interest income) of \$12.1m in 2018 and \$6.8m in 2019, versus our prior estimates of \$11.5m and \$7.0m respectively. We believe the burn rate will decrease in 2019, as we expect the company to have partnered the endoxifen programs (oral and topical) in H119, which would reduce its R&D expense needs.

Atossa had \$4.8m net cash at 31 March 2018. Given the recent (Q218) completion of the rights offering (with \$12.1m in net proceeds), we expect Atossa's total current funds on hand (excluding any possible exercise from the outstanding warrants) to last into early 2020. Our model previously assumed that Atossa would raise \$10m (through debt financing) in 2018 but, given the Q218 financing, we have removed this assumption from our model. We continue to assume that Atossa will raise \$10m in 2019 to fund its operations, and as per our usual policy, for modeling purposes, we assign these financings to long-term debt.

Valuation: rNPV largely unchanged at \$24.4m

Our rNPV valuation continues to include the prospects of the company's topical and oral endoxifen programs for women, and its intraductal microcather (IDMC) delivered fulvestrant program. Given the early stage of its men's topical endoxifen program, with no human proof-of-concept data thus far in gynecomastia and with certain studies suggesting that oral tamoxifen use in men does not

result in substantial treatment discontinuations when used (albeit off-label) for gynecomastia, we prefer to wait for further advancement in this program before including it in our valuation.

Our revenue assumptions for topical and oral endoxifen, as well as IDMC-fulvestrant, are unchanged. We assume that Atossa will out-license the oral and topical endoxifen programs in H119, on the conclusion of the currently planned Phase II studies, and will be entitled to 20% royalties on net sales. Following a subsequent pivotal study (to be funded by the partner), topical endoxifen could be launched in 2021.

For oral endoxifen, we continue to assume a potential launch in 2020, and that the target market will be 20% of the 300,000 US women (and approximately one million women worldwide) currently taking tamoxifen and who we estimate do not achieve sufficient plasma endoxifen concentrations. For IDMC-fulvestrant we continue to assume a potential launch in 2023.

We continue to assume that Atossa will spend \$3.6m on R&D on the topical female endoxifen program (primarily for the planned Phase II study) between Q218 and Q219. We assume it will spend \$2.9m on R&D for oral endoxifen over the same period before partnering it, and that it will spend \$2.8m in R&D costs on the IDMC-fulvestrant program between Q218 and H219 before also partnering this program.

We continue to apply a 20% probability of success estimate for the oral endoxifen program, a 5% probability for topical endoxifen in MBD (since proof-of-concept in terms of MBD reduction has not been shown and our forecasts depend on building significant support and recognition among patients, physicians and stakeholders of the benefits of treating MBD as a preventative approach to lowering cancer risk), and a 10% probability for the IDMC-fulvestrant program.

Exhibit 1: Atossa Genetics rNPV assumptions

Product contributions (net of R&D costs)	Indication	rNPV (\$m)	rNPV/share (\$)	Probability of success	Launch year	Peak US market share	Peak WW sales (US\$m)
Topical endoxifen	High breast density	22.0	3.43	5.0%	2020	15%	922 in 2026
Oral endoxifen	Breast cancer	23.3	3.61	20.0%	2021	12.5% of patients taking tamoxifen	161 in 2025
Intraductal microcatheter (for fulvestrant)	Breast cancer	8.0	1.24	10.0%	H222	25%	182 in 2026
SG&A expenses		(21.9)	(3.41)				
Net capex, NWC & taxes		(7.0)	(1.09)				
Total rNPV		24.4	3.79				
Net cash (debt) (Q218e)		13.4	2.08				
Total equity value		37.8	5.87				
FD shares outstanding (000)*		6,436					

Source: Edison Investment Research. Note: *Includes adjustment for dilutive effect of Series B convertible preferred shares by assuming their full conversion into 3.78m common shares.

We continue to apply a 12.5% discount rate. After making minor adjustments to our G&A cost estimates, we now obtain an rNPV valuation of \$24.4m, slightly changed from our prior \$24.7m estimate. After including Q218 estimated net cash of \$13.4m, we obtain an equity valuation of \$37.8m, or \$5.87 per fully diluted (FD) share (which assumes full conversion the recently issued SBCPS into common shares). The dilutive impact of the recent equity raise (with full conversion of the SBCPS into common shares reflecting a lower value per common share than our previous valuation) explains the reduction compared to our previous \$11.30 per-share equity valuation.

Exhibit 2: Financial summary

	US\$(000)	2015	2016	2017	2018e	2019e	2020e
31-December		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS							
Revenue	2	0	0	0	0	0	5,590
Cost of Sales	(132)	0	0	0	0	0	(0)
General & Administrative	(9,996)	(6,176)	(4,730)	(4,446)	(3,000)	(3,000)	(3,060)
Research & Development	(2,360)	(770)	(2,328)	(7,000)	(4,000)	(4,000)	(1,000)
EBITDA	(9,484)	(6,946)	(7,058)	(11,446)	(7,000)	(7,000)	1,530
Depreciation	(273)	(303)	(129)	(50)	(66)	(66)	(80)
Amortization	0	0	0	0	0	0	0
Operating Profit (before exceptionals)	(9,756)	(7,250)	(7,187)	(11,495)	(7,066)	(7,066)	1,450
Exceptionals	0	881	(935)	0	0	0	0
Other	(3,002)	0	0	0	0	0	0
Operating Profit	(12,758)	(6,369)	(8,123)	(11,495)	(7,066)	(7,066)	1,450
Net Interest	0	0	0	107	62	62	(7)
Profit Before Tax (norm)	(9,756)	(7,250)	(7,187)	(11,388)	(7,004)	(7,004)	1,442
Profit Before Tax (FRS 3)	(12,758)	(6,369)	(8,123)	(11,388)	(7,004)	(7,004)	1,442
Tax	0	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(9,756)	(7,250)	(9,756)	(11,388)	(7,004)	(7,004)	1,442
Profit After Tax and minority interests (FRS 3)	(12,758)	(6,369)	(10,691)	(11,388)	(7,004)	(7,004)	1,442
Average Number of Shares Outstanding (m)	0.2	0.2	1.0	2.7	2.7	2.7	2.8
Share options and other dilutive equity outstanding (m)	0.0	0.0	0.0	3.8	3.8	3.8	3.8
EPS - normalised (\$)	(61.78)	(29.52)	(10.01)	(4.29)	(2.57)	(2.57)	0.52
EPS - normalised and fully diluted (\$)	(61.78)	(29.52)	(10.01)	(4.29)	(2.57)	(2.57)	0.22
EPS - (IFRS) (\$)	(80.78)	(25.93)	(10.97)	(4.29)	(2.57)	(2.57)	0.52
Dividend per share (\$)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET							
Fixed Assets	1,948	890	266	273	340	340	406
Intangible Assets	1,701	640	76	71	71	71	71
Tangible Assets	248	249	190	203	270	270	336
Current Assets	4,295	3,255	7,898	8,125	11,273	11,273	12,873
Short-term investments	275	55	55	55	55	55	55
Cash	3,716	3,028	7,217	7,169	10,317	10,317	10,057
Other	304	172	626	901	901	901	2,761
Current Liabilities	(2,502)	(1,047)	(1,225)	(552)	(552)	(552)	(552)
Creditors	(2,502)	(1,047)	(1,225)	(552)	(552)	(552)	(552)
Short term borrowings	0	0	0	0	0	0	0
Long Term Liabilities	0	0	0	0	(10,000)	(10,000)	(10,000)
Long term borrowings	0	0	0	0	(10,000)	(10,000)	(10,000)
Other long term liabilities	0	0	0	0	0	0	0
Net Assets	3,742	3,097	6,939	7,846	1,061	1,061	2,727
CASH FLOW							
Operating Cash Flow	(13,953)	(5,375)	(6,594)	(12,134)	(6,781)	(6,781)	(107)
Net Interest	0	0	0	107	62	62	(7)
Tax	0	0	0	0	0	0	0
Capex	(131)	(9)	0	(121)	(133)	(133)	(146)
Acquisitions/disposals	(158)	0	0	0	0	0	0
Financing	9,457	4,696	10,783	12,100	0	0	0
Net Cash Flow	(4,785)	(688)	4,190	(49)	(6,852)	(6,852)	(260)
Opening net debt/(cash)	(8,501)	(3,991)	(3,083)	(7,272)	(7,224)	(7,224)	(372)
HP finance leases initiated	0	0	0	0	0	0	0
Other	275	(220)	0	0	0	0	0
Closing net debt/(cash)	(3,991)	(3,083)	(7,272)	(7,224)	(372)	(372)	(112)

Source: Edison Investment Research, Atossa Genetics reports

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