EDISON

Atossa Genetics

Q418 update

Endoxifen catalysts expected in 2019

Pharma & biotech

Atossa Genetics' endoxifen programs are awaiting key catalysts in the coming year. Top-line data from a Phase II study in women with elevated mammographic breast density (MBD) is expected in Q219. The high rate of dropouts due to skin irritation/rashes may prompt a formulation change. The firm is also advancing an oral endoxifen formulation to reduce cancer cell activity in the window of opportunity between breast cancer diagnosis and surgery, and in women refractory to tamoxifen. Our rNPV-derived equity valuation is $37.3m, or $3.81 per fully diluted share, up from $3.66/share previously.

Year end	Revenue (US$m)	PBT* (US$m)	EPS* (US$m)	DPS (US$)	P/E (x)	Yield (%)
12/17	0.0	(7.2)	(10.01)	0.0	N/A	N/A
12/18	0.0	(11.4)	(5.51)	0.0	N/A	N/A
12/19e	0.0	(11.6)	(1.28)	0.0	N/A	N/A
12/20e	0.0	(7.0)	(0.77)	0.0	N/A	N/A

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

$11.3m warrant exercise extends financial runway

In March 2019, Atossa received exercise requests for 2.8m outstanding warrants (at the $4.05 per warrant exercise price), resulting in $11.3m in proceeds. We estimate the proceeds will strengthen the firm's financial runway, enabling it to continue operations into 2021 prior to requiring additional capital. If the company is successful in partnering its endoxifen programs before then (as is our current assumption), this would reduce future capital needs.

MBD study could be affected by high dropouts

Many participants have chosen to exit the current MBD Phase II study trial before receiving a full six months of drug or placebo. As of March 2019, Atossa reports that approximately 72 (out of 90 recruited) participants have exited the study primarily because of skin rashes and irritation. All patient dosing was completed in April 2019, and topline results will be reported in Q219. Given that c 80% of enrolled patients have discontinued due to skin rashes or irritation, we believe that there is a high probability that the product will require a formulation change prior to subsequent clinical studies, potentially leading to development delays.

Valuation: Equity valuation of $37.3m

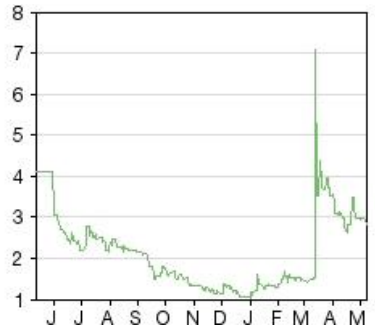
We continue to apply a 12.5% discount rate in our rNPV valuation approach, which includes the prospect of the firm's topical and oral endoxifen programs for women, its intraductal microcatheter-delivered fulvestrant program and its gynecomastia program. After rolling forward our estimates and reducing long-term G&A expenses on the back of FY18 results, we now obtain an rNPV valuation of $18.4m, above our prior valuation of $10.9m. After including Q119e net cash of $18.9m, we obtain an equity valuation of $37.3m, or $3.81 per fully diluted share (which assumes full conversion of 2,379 currently outstanding Series B convertible preferred shares into 0.676m common shares), up from $3.66 per share previously.

9 May 2019

Price	**US$2.82**
Market cap	**US$26m**

Net cash ($m) at Q418* *Adjusted to include $11.3m Q119 warrants exercise	21.8
Shares in issue	9.1m
Free float	99.5%
Code	ATOS
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(9.6)	80.8	(28.1)
Rel (local)	(9.1)	70.0	(33.2)
52-week high/low	US$7.07		US$0.92

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

Phase II MBD data	Q219
Start oral endoxifen Phase II in tamoxifen-refractory women	2019

Analysts

Pooya Hemami, CFA +1 646 653 7026

Maxim Jacobs, CFA +1 646 653 7027

healthcare@edisongroup.com

Edison profile page

Funded to meet near-term endoxifen milestones

Atossa Genetics has been focused on advancing its breast health programs, primarily its programs on endoxifen, but also programs on intraductal microcatheter (IDMC)-administered fulvestrant, and its early research activities on delivering CAR-T therapeutics to breast tissue. In 2018, the company reported lower than expected operating costs and losses. It reported an $11.4m operating loss, driven by $7.2m in G&A costs and $4.2m in R&D expenses. This compares to our prior estimates of a $12.9m operating loss, $7.4m in G&A costs, and $5.5m in R&D expenses. Atossa reported a $22.8m net loss (or $5.50 per share) in 2018, but this net loss would be reduced to $11.4m if the $11.5m dividend attributable to preferred stock holders were excluded.[1]

Exhibit 1: Atossa Genetics pipeline

Product	Status
Topical Endoxifen	
Phase II female study to determine effects on mammographic breast density (MBD)	Enrolment complete; study ongoing
Phase II male study to treat gynecomastia in men being treated for prostate cancer	Start date to be determined based on results of Phase II MBD study
Oral Endoxifen (in females)	
Phase II study to determine if tumor activity reduced in early stage breast cancer	Recruitment underway in Australia
Phase II study in patients who are refractory to tamoxifen	Start date to be determined based on results of Phase II MBD study
Intraductal delivery	
Phase II study of fulvestrant in cancer patients prior to surgery	Enrolment underway
Immuno-oncology (CAR-T research)	Preclinical

Source: Company reports

Endoxifen programs continue to move forward

Endoxifen is a tamoxifen metabolite that is responsible for much of the oral drug's selective estrogen receptor modulation (SERM) action. Atossa believes that topical endoxifen can exert SERM effects to breast tissue and reduce elevated mammographic breast density (MBD), with fewer significant adverse events. It also believes that topical endoxifen can safely reduce gynecomastia (male breast enlargement).

Atossa is also developing an oral endoxifen formulation with the aim to reduce breast cancer risk. About 20% of the 300,000 US women currently taking tamoxifen (largely to prevent recurrence of breast cancer) do not achieve sufficient concentrations of endoxifen and may have increased risk of cancer recurrence. Atossa believes that oral endoxifen can reduce recurrence risk in these patients, having completed a Phase I oral endoxifen trial in 2017, and we believe it plans to start a Phase II study in tamoxifen-refractory women in 2019. The oral formulation is also being evaluated in a pilot Australia-based study (which began in July 2018) designed to assess the drug in the 'window of opportunity' (WOO) between estrogen receptor-positive (ER+) breast cancer diagnosis and surgery (in patients requiring mastectomy or lumpectomy). The primary endpoint is to determine if the administration of oral endoxifen reduces the tumor activity as measured by Ki-67, which is a marker of cellular proliferation. The study plans to recruit eight patients and if at least two of these show a Ki-67 response (suggestive of tumor activity reduction), it will be increased to 25 subjects.

Topical Phase II MBD study could be affected by dropout rate

Atossa is conducting a double-blinded, placebo-controlled Phase II study of its topical endoxifen formulation in women with elevated MBD at Stockholm South General Hospital in Sweden (affiliated

[1] Atossa Genetics had issued convertible preferred shares and warrants as part of a Q218 equity financing initiative, and the accounting treatment of the convertible preferred shares prompted the issuance of an $11.5m deemed dividend to the preferred shareholders in 2018.

with Karolinska Institute). The study follows a Phase I trial completed in Q317 showing that topical endoxifen was safe and well tolerated in women and that it can generate an increase is blood endoxifen in a dose-dependent manner. The primary endpoint of the Phase II study is to determine if daily topical endoxifen administration results in changes in MBD, which will be measured after three and six months of study commencement. The secondary endpoints are safety and tolerability. Enrollment was completed in October 2018, and 90 participants were randomized to one of three 30-participant groups (one placebo arm and two endoxifen dosage arms).

If the study shows a reduction in MBD, the firm's intent is to use the resulting data to drive sample size calculations for a future pivotal Phase III study. However, reports of skin irritations with the topical formulation and a higher than expected dropout rate raise uncertainty as to whether the study's data can be used in this regard. Atossa disclosed in November 2018 that some participants in the current MBD Phase II study have reported skin rashes and irritation and have withdrawn from the trial. Some participants have chosen to exit the trial before receiving a full six months of drug or placebo. As of March 2019, Atossa reports that approximately 72 participants have exited the study primarily because of skin rashes and irritation. Because the study is double blinded and results to date are not known, the firm does not yet know whether the study results will result in sufficient data to design a subsequent study. All patient dosing within the study was completed in April 2019, and top line results will be reported in Q219.

Altogether, it is relatively premature to speculate on whether or not the skin reactions observed to date will require a formulation change for future clinical development (leading to product development delays), or whether the same reaction would occur in men with the existing formulation. However, given that c 80% of enrolled patients have discontinued due skin rashes or irritation, we believe that there is a high probability that the product will require a formulation change prior to subsequent clinical development.

Management had also previously planned to start a Phase II gynecomastia study in male prostate cancer patients in 2019, but we believe they will await the results of the Phase II MBD study (and to determine whether formulation modifications are warranted for the topical product candidate) before proceeding with the Phase II study in men.

FDA approves continued endoxifen use for single US patient

Atossa announced in March 2019 that it received a "Safe to Proceed" letter under the FDA's expanded access program (EAP), which allowed the use of oral endoxifen as a post-mastectomy treatment in a single pre-menopausal, ER+ breast cancer patient who had previously already completed a three-week course of endoxifen prior to surgery under an FDA EAP. Tumor activity from the initial biopsy was compared to activity at surgery, and results showed the cancer cell biological activity was reduced by two measures: the Ki-67 activity decreased by 50 percent, and ER content decreased by over 20 percent. There were no reported safety or tolerability issues. These results suggest that the endoxifen course may have benefited the patient prior to surgery and management reported that the FDA agreed that continued endoxifen therapy may be appropriate for this patient. Under the FDA EAP, the use of endoxifen is restricted solely to this patient for the time being. We expect that the company is continuing to evaluate study options for oral endoxifen in the US beyond its planned cancer recurrence prevention study in patients refractory to tamoxifen.

Warrants exercise boosts cash runway

Atossa's stock price reacted very positively (more than tripling) in the days following the announcement of the FDA EAP in March, although most of the gains have since reversed. However, during this brief period, the company received exercise requests for outstanding warrants (at the $4.05 per warrant exercise price). All in, it received $11.3m in proceeds in March 2019 for

the exercise of about 2.8m common share warrants. As 3.87m warrants (at $4.05 exercise price) had been outstanding as of YE18, we estimate that about 1.07m of these warrants remain outstanding (but they are no longer in-the-money).

Financials and valuation

Atossa reported Q418 net cash of $10.5m. Given its 2018 operating cash burn rate of $8.96m and the $11.3m received as per the warrants exercise, we assume Atossa's Q119 net cash level is $18.9m. We assume this level of cash on hand will be sufficient to fund the company's operations into 2021.

We expect the firm's 2019 operating cash burn rate (excluding net interest) will increase to $12.2m (from $8.7m previously). This is primarily due to us pushing some of our endoxifen R&D cost expenses from 2018 into 2019. We continue to believe Atossa's burn rate will decrease after 2019 (to $7.1m in 2020), as we model the company to have partnered the endoxifen programs (oral and topical) in H219, which would reduce its R&D expense needs. Of course, if the skin irritation/rash issues suggested in the preliminary endoxifen responses in the Phase II MBD study persist and a formulation revision becomes desirable or required, this could impede or delay the realization of a partnership agreement, and may result in the need to raise more funds to internally develop the endoxifen program further prior to a partnership transaction.

We previously assumed that Atossa would raise $10m in 2019 (modelled as long-term debt) to fund its operations, and we have now revised our assumptions to include the $11.3m equity financing from the exercise of warrants (and removed any other financing sources from our 2019 estimates).

Our rNPV valuation continues to include the prospects of the company's topical and oral endoxifen programs, and its IDMC-delivered fulvestrant program. Our 4% (unchanged) probability of success estimate for the topical MBD endoxifen already factors in the skin irritation issue that has been raised and that, as explained previously, may provoke development delays beyond our current assumptions. We also reiterate 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. We continue to apply a 20% probability of success estimate for the oral endoxifen program. Our 10% success probability estimate for the IDMC-fulvestrant program is unchanged.

Exhibit 2: Atossa Genetics rNPV valuation

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	17.7	1.81	4.0%	2021	15%	922 in 2026
Topical endoxifen	Gynecomastia	10.9	1.11	4.0%	2022	15%	691 in 2027
Oral endoxifen	Breast cancer	17.1	1.74	20.0%	H221	12.5% of patients taking tamoxifen	166 in 2026
Intraductal Microcatheter (for Fulvestrant)	Breast cancer	8.1	0.83	10.0%	H222	25%	182 in 2026
SG&A expenses		(30.2)	(3.08)				
Net capex, NWC & taxes		(5.3)	(0.54)				
Total rNPV		18.4	1.88				
Net cash (debt) (Q119e)		18.9	1.93				
Total equity value		**37.3**	**3.81**				
FD shares outstanding (000)*		9,792					

Source: Edison Investment Research. Note: *Includes adjustment for dilutive effect of 2,379 outstanding Series B Convertible Preferred shares by assuming their full conversion into 0.676m common shares.

We continue to apply a 12.5% discount rate in our rNPV approach. After rolling forward our estimates and reducing long-term G&A expenses (on the back of FY18 results), we now obtain an rNPV valuation of $18.4m, above our prior valuation of $10.9m. After including Q119e net cash of

$18.9m, we obtain an equity valuation of $37.3m, or $3.81 per fully diluted share (which assumes full conversion of 2,379 currently outstanding Series B convertible preferred shares into 0.676m common shares),[2] up from $3.66 previously.

Exhibit 3: Financial summary

US$000s	2015	2016	2017	2018	2019e	2020e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	2	0	0	0	0	0
Cost of Sales	(132)	0	0	0	0	0
General & Administrative	(9,996)	(6,176)	(4,730)	(7,180)	(5,100)	(5,202)
Research & Development	(2,360)	(770)	(2,328)	(4,210)	(6,700)	(1,850)
EBITDA	(9,484)	(6,946)	(7,058)	(11,390)	(11,800)	(7,052)
Depreciation	(273)	(303)	(129)	(44)	(40)	(56)
Amortization	0	0	0	0	0	0
Operating Profit (before exceptionals)	(9,756)	(7,250)	(7,187)	(11,434)	(11,840)	(7,108)
Exceptionals	0	881	(935)	29	0	0
Other	(3,002)	0	0	0	0	0
Operating Profit	(12,758)	(6,369)	(8,123)	(11,405)	(11,840)	(7,108)
Net Interest	0	0	0	0	213	105
Profit Before Tax (norm)	(9,756)	(7,250)	(7,187)	(11,434)	(11,627)	(7,003)
Profit Before Tax (FRS 3)	(12,758)	(6,369)	(8,123)	(11,405)	(11,627)	(7,003)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(9,756)	(7,250)	(9,756)	(22,914)	(11,627)	(7,003)
Profit After Tax and minority interests (FRS 3)	(12,758)	(6,369)	(10,691)	(22,884)	(11,627)	(7,003)
Average Number of Shares Outstanding (m)	0.2	0.2	1.0	4.2	9.1	9.1
Share options and other dilutive equity outstanding (m)	0.0	0.0	0.0	0.0	0.7	0.7
EPS - normalised ($)	(61.78)	(29.52)	(10.01)	(5.51)	(1.28)	(0.77)
EPS - normalised and fully diluted ($)	(61.78)	(29.52)	(10.01)	(5.51)	(1.28)	(0.77)
EPS - (IFRS) ($)	(80.78)	(25.93)	(10.97)	(5.50)	(1.28)	(0.77)
Dividend per share ($)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	1,948	890	266	171	253	331
Intangible Assets	1,701	640	76	99	99	99
Tangible Assets	248	249	190	72	154	232
Current Assets	4,295	3,255	7,898	11,549	10,787	3,706
Short-term investments	275	55	55	110	110	110
Cash	3,716	3,028	7,217	10,380	9,618	2,537
Other	304	172	626	1,059	1,059	1,059
Current Liabilities	(2,502)	(1,047)	(1,225)	(2,915)	(2,562)	(2,562)
Creditors	(2,502)	(1,047)	(1,225)	(2,915)	(2,562)	(2,562)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	0	0	0	0	0	0
Long term borrowings	0	0	0	0	0	0
Other long term liabilities	0	0	0	0	0	0
Net Assets	3,742	3,097	6,939	8,805	8,478	1,475
CASH FLOW						
Operating Cash Flow	(13,953)	(5,375)	(6,594)	(8,962)	(12,153)	(7,052)
Net Interest	0	0	0	0	213	105
Tax	0	0	0	0	0	0
Capex	(131)	(9)	0	(111)	(122)	(134)
Acquisitions/disposals	(158)	0	0	0	0	0
Financing	9,457	4,696	10,783	12,291	11,300	0
Net Cash Flow	(4,785)	(688)	4,190	3,218	(762)	(7,081)
Opening net debt/(cash)	(8,501)	(3,991)	(3,083)	(7,272)	(10,490)	(9,728)
HP finance leases initiated	0	0	0	0	0	0
Other	275	(220)	0	(0)	0	0
Closing net debt/(cash)	(3,991)	(3,083)	(7,272)	(10,490)	(9,728)	(2,647)

Source: Edison Investment Research, Atossa Genetics reports

[2] Each Series B Convertible preferred share is convertible to 284 common shares.

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
1,185 Avenue of the Americas
3rd Floor, New York, NY 10036
United States of America

Sydney +61 (0)2 8249 8342
Level 4, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia