



Atossa Therapeutics, Inc.

Initiating Coverage with BUY and \$7.00 Target

Strong potential for its drugs to treat COVID-19 and breast cancer. We believe expected positive milestones and clinical data over the next year to be positive catalysts for stock.

Initiating with BUY: We are initiating coverage of Atossa Therapeutics with a BUY rating. Atossa is a clinical-stage biopharmaceutical company focused on developing drugs to treat coronavirus ("COVID-19") and breast cancer.

Focused on 3 drugs in development: Atossa has three main therapeutic drug candidates, two for COVID-19 and one for breast cancer (for 2 settings).

COVID-19: Atossa has two COVID-19 drugs under development: 1) AT-H201, to improve lung function of moderate to severely ill, hospitalized COVID-19 patients by inhalation; and 2) AT-301, a nasal spray for COVID-19 patients who are not sufficiently ill to require hospitalization.

Breast cancer: Atossa's breast cancer drug under development is its proprietary form of Endoxifen which is being developed primarily in two settings: 1) to reduce tumor cell activity in breast cancer patients in the "window of opportunity" between diagnosis of breast cancer and surgery; and 2) for women with high mammographic breast density ("MBD") to reduce the density and/or to act as an adjunct to mammography.

Large market potential: The World Health Organization (WHO) declared the COVID-19 outbreak a pandemic on March 11, 2020. As of September 2020, ~30 million cases have been reported in almost every country in the world causing almost 1 million deaths. Cancer is the 2nd leading cause of death in the U.S. (behind heart disease) with ~600,000 deaths a year. For woman, breast cancer is the most common cancer. The American Cancer Society estimates that in 2020, ~280,000 women will be diagnosed with breast cancer in the U.S. and ~42,000 die each year.

Ramp up in clinical trials: Atossa currently has 2 ongoing clinical trials (AT-301 (Phase 1) and Endoxifen in WOO (Phase 2)), with 2 additional trials (AT-H201 (Phase 1) and Endoxifen for MBD (Phase 2)) expected to start soon (by Q4).

Positive data so far: Both AT-301 and Endoxifen in WOO have recently reported positive interim data (AT-301 in September and Endoxifen in WOO in May). In May, Atossa completed in vitro testing of AT-H201 which showed that AT-H201 inhibit SARS-CoV-2 infectivity of VERO cells, which is a standard cell type being used to study infectivity of the coronavirus. In July, Atossa completed in vitro testing of AT-301 which showed that AT-301 inhibits SARS-CoV-2 infectivity of VERO cells in a laboratory culture.

Clinical data can be catalyst: Atossa anticipates starting/finishing its various clinical trials over the next year. We believe achieving key milestones and strong positive data will likely be catalysts for the stock.

However, challenges exist: Atossa operates in a highly competitive environment and competes against a wide range of other drugs and therapeutics. There is the chance that the coronavirus will dissipate by itself, or that an effective vaccine or other therapeutic treatments for COVID-19 may be developed and launched before the company's drugs are launched.

Positive high risks versus high rewards: Overall, concerns outweighed by growth prospects and valuation. Atossa's drugs still have long development roads left and the high risks of clinical trials failures, but we believe the ~billion dollars market potential presents high rewards for the risks.

Current valuation attractive: We calculate a 12-month price target for shares of Atossa to be \$7.00 based on a NPV analysis, representing significant upside from the current share price. We believe this valuation appropriately balances out the company's high risks with the company's high growth prospects and large upside opportunities.

Company Description

Based in Seattle, WA, Atossa Therapeutics is a clinical-stage biopharmaceutical company focused on COVID-19 and breast cancer drugs development.

United States
Healthcare

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COVERAGE INITIATION

Rating: **BUY**

Ticker: ATOS

Price: \$2.25

Target: \$7.00

Stock Data

Exchange:	NasdaqGS
52-week Range:	\$0.76 – 5.08
Shares Outstanding (million):	11
Market cap (\$million):	\$25
EV (\$million):	\$17
Debt (\$million):	\$0
Cash (\$million):	\$8
Avg. Daily Trading Vol. (\$million):	~\$2
Float (million shares):	10
Short Interest (million shares):	~0.2
Dividend, annual (yield):	\$0 (NA%)

Revenues (US\$ million)

	<u>2019A</u> (Cur.)	<u>2020E</u> (Cur.)	<u>2021E</u> (Cur.)
Q1 Mar	0A	0A	0E
Q2 Jun	0A	0A	0E
Q3 Sep	0A	0E	0E
Q4 Dec	<u>0A</u>	<u>0E</u>	<u>0E</u>
Total	0A	0E	0E
EV/Revs	N/A	N/A	N/A

Earnings per Share (pro forma)

	<u>2019A</u> (Cur.)	<u>2020E</u> (Cur.)	<u>2021E</u> (Cur.)
Q1 Mar	(0.62)A	(0.32)A	(0.35)E
Q2 Jun	(0.80)A	(0.43)A	(0.35)E
Q3 Sep	(0.36)A	(0.37)E	(0.34)E
Q4 Dec	<u>(0.29)A</u>	<u>(0.38)E</u>	<u>(0.34)E</u>
Total	(2.03)A	(1.50)E	(1.38)E
P/E	N/A	N/A	N/A

Important Disclosures

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For analyst certification and other important disclosures, refer to the Disclosure Section, located at the end of this report, beginning on page 27.

Exhibit 1: Atossa Therapeutics, Inc. Stock Price (5-years)



Source: Nasdaq.com

INVESTMENT THESIS

We are initiating coverage of Atossa Therapeutics with a BUY rating and a 12-month price target of \$7.00.

Based in Seattle, WA, Atossa Therapeutics is a clinical-stage biopharmaceutical company focused on discovering and developing innovative medicines with a focus on coronavirus ("COVID-19") and breast cancer. Atossa has two COVID-19 drugs under development: 1) AT-H201, to improve lung function of moderate to severely ill, hospitalized COVID-19 patients by inhalation; and 2) AT-301, a nasal spray for COVID-19 patients who are not sufficiently ill to require hospitalization.

Atossa's breast cancer drug under development is its proprietary form of Endoxifen which is being developed primarily in two settings: 1) to reduce tumor cell activity in breast cancer patients in the "window of opportunity" between diagnosis of breast cancer and surgery; and 2) for women with high mammographic breast density ("MBD") to reduce the density and/or to act as an adjunct to mammography.

COVID-19 is an infectious disease caused by the virus SARS-CoV-2. It was first identified in December 2019 in Wuhan, China, and has spread around the world quickly since then. The World Health Organization (WHO) declared the COVID-19 outbreak a pandemic on March 11, 2020. As of September 2020, ~30 million cases have been reported in almost every country in the world causing almost 1 million deaths. In the U.S., there has been ~7 million reported cases and ~200,000 deaths. We note that there has been an unprecedented amount of money and national and global focus in developing a vaccine and therapies.

AT-H201 is a proprietary combination of two drugs previously approved by the FDA to treat other diseases. It is intended to improve compromised lung function for moderate to severely ill, hospitalized COVID-19 patients by inhalation. There are five known key steps the coronavirus must take to signal the cell to open up and let the virus in. AT-H201 is being designed to function like a “chemical vaccine” by blocking all five of those steps, similar to what antibodies would be expected to do when a vaccine is administered.

AT-301 is Atossa’s proprietary drug intended for nasal administration in patients immediately following diagnosis of COVID-19 but have not yet exhibited symptoms severe enough to require hospitalization. It is intended for at-home use to proactively reduce symptoms and slow the infection rate so that a person’s immune system can more effectively fight COVID-19. Atossa also intends to conduct testing to determine whether AT-301 can be used as a prophylaxis to prevent or mitigate SARS-CoV-2, with the goal that it could become a “bridge to the vaccine”.

Exhibit 2: Atossa Therapeutics, Inc.

ABOUT ATOSSA THERAPEUTICS



Clinical-stage
biopharma company focused
on breast cancer and COVID-19



CLINICAL SUMMARY

Breast Health:

- Positive Phase 2 results Apr. 2020
- Two Phase 2 studies underway in breast cancer
- Phase 2 for breast density/mammography adjuvant planned for Q4 2020

COVID-19: TWO Therapeutic Programs

- AT-301 nasal spray – Ph 1 underway
- AT-H201 inhalation therapy
- Positive *in vitro* test results for both programs



Source: Company reports.

Cancer is the 2nd leading cause of death in the U.S. (behind heart disease) with ~600,000 deaths a year. For woman, breast cancer is the most common cancer. The American Cancer Society estimates that in 2020, ~280,000 women will be diagnosed with breast cancer in the U.S. and ~42,000 die each year.

Endoxifen is the most active metabolite (ingredient) of the FDA approved drug tamoxifen. Tamoxifen has been used since its approval in 1977 for breast cancer survivors to prevent recurrence as well as to prevent breast cancer in high risk women. Tamoxifen is a “pro-drug,” in that it must be metabolized by the liver into active metabolites in order to have activity in the body. Despite the success of tamoxifen in reducing the risk of estrogen receptor-positive breast cancer, its side effects have led to generally low acceptance as a therapy to reduce the risk of breast cancer.

Atossa believes Endoxifen may provide an option for women to proactively reduce the density of their breasts. Atossa is also developing oral Endoxifen to potentially treat breast cancer in the “window of opportunity” (WOO) phase between diagnosis of breast cancer and surgery.

Exhibit 3: Atossa Market Opportunities

LARGE MARKET OPPORTUNITIES



<u>Program</u>	<u>Opportunity</u>
AT-H201 for COVID-19 Ventilated Patients	>852K deaths world-wide from COVID-19 as of Aug. 31(1), many on ventilators
AT-301 Nasal Spray	>25M COVID-19 cases world-wide(1)
Oral Endoxifen – for MBD	39 M Annual Mammograms/ 10M High MBD in U.S. (BI-RAD C/D)(2)
Oral Endoxifen – Window Opportunity	200k ER+ Breast Cancers/ Yr. in U.S.

Source: Company reports.

Atossa currently has 2 ongoing clinical trials (AT-301 and Endoxifen in WOO), both of which has recently reported positive interim data (AT-301 in September and Endoxifen in WOO in May). 2 additional clinical trials (AT-H201 and Endoxifen for MBD) are expected to start soon (by Q4).

Atossa has key upcoming milestones for its 3 drugs under development that we believe should be achieved by the end of 2020:

1. AT-H201 - Receive regulatory approval to initiate a Phase 1 clinical study of AT-H201 and begin enrollment.
2. AT-301 – Complete enrollment and dosing in its ongoing Phase 1 clinical study of AT-301 in Australia.
3. Endoxifen - Receive regulatory approval to initiate a Phase 2 clinical study of Endoxifen for MBD in Sweden and begin enrollment.
4. Endoxifen - Complete enrollment and dosing in its ongoing Phase 2 clinical study of Endoxifen in the window of opportunity (WOO) in Australia.


The company’s near term plans over the next year is to advance (AT-H201 and AT-301) in its clinical trials towards a FDA approval for COVID-19. The company also plans to further clinical trials for Endoxifen for breast cancer. Atossa’s share price YTD has been strong (~+40% from \$1.57 on December 31, 2019), but we believe that there are near term catalysts that can drive the stock much higher (particularly for key milestones expected in 2020 and the high valuations given to biopharmaceutical companies working on COVID-19).

Exhibit 4: Atossa Drug Development Pipeline

DRUG DEVELOPEMENT PIPELINE



LEAD PROGRAMS:

	Program	Product	Preclinical	Phase 1	Phase 2	Phase 3	NDA/MAA (Target)	Commercial
	COVID-19 Nasal Spray	AT-301		Symptom reducing nasal spray				
	COVID-19 HOPE	AT-H201		Improve lung function on Ventilators				
	Endoxifen	Oral		Females (AUS)	Window of Opportunity (Pre-surgery) (AUS)			
					Mammographic Breast Density (Sweden)			

Source: Company reports.

Atossa's recent financial performance is reflective of its developmental stage. The company does not generate revenue and has operating expenses of ~\$4 million per quarter. The company's balance sheet had ~\$8 million in cash and no debt as of June 2020. In July 2020 (current Q3), the company sold 1.1 million shares of common stock under an ATM for \$4.5 million (~\$4.10/share). The company should have enough cash through Q2 2021.

Our investment thesis factors in an uncertain drug development process and very competitive industry which is offset by the very large potential upside opportunities created from a successful drug. We believe that the current valuation for Atossa has already factored in many of its risks (principally drug approval and successful commercialization) but is under valuing its overall growth prospects and product portfolio, resulting in a positive risk versus reward scenario for an investment in Atossa.

We believe the current valuation is attractive.

Our \$7.00 price target is based on a NPV analysis. Based on our expectations and assumptions, we calculate a 12-month price target for shares of Atossa to be \$7.00, representing significant upside from current share price. We believe this valuation appropriately balances out the company's high risks with the company's high growth prospects and large upside opportunities. We acknowledge that Atossa is still at an early stage in its drug development and product commercialization, but we believe key milestones over the next year should be positive catalysts for the stock.

INVESTMENT RISKS

Long and Uncertain Drug Development Cycles

Atossa is highly dependent upon securing drug approvals for its products in order to sell them (produce revenue). The drug development cycle can be long (average of 12 years), expensive (average of \$350 million), complicated, and uncertain. On average only about 10% of drugs entering clinical trials ever make it to final approval. Because Atossa's main 3 drugs are in various Phase 1/2 trials, there are still significant risks and a long time horizon to receive FDA approval (even with shorter/emergency regulatory pathways for COVID-19 therapies). For Endoxifen, we estimate that it may be at least two years before the drug can receive FDA approval. With a high likelihood of binary outcomes (either success or failure), the risks are high but the potential rewards can also be very high as well.

Product Commercialization Risks

Even after obtaining drug approvals, there is still a chance that commercial success will not be achieved (due to competition, changes in the market, lack of reasonable reimbursements, or lack of market acceptance). Atossa's COVID-19 drugs (AT-H201 and AT-301) aims to be leading treatments for COVID-19 patients globally. However, there is the chance that the coronavirus will dissipate by itself, or that an effective vaccine or other therapeutic treatments for COVID-19 may be developed and launched before the company's drugs are launched. Endoxifen has a more stable market opportunity with breast cancer, but there are already significant drugs and therapies being used currently as existing standards of care. Like most health care drugs, the company will also need to get suitable insurance and government reimbursements for its products.

High Level of Competition

Atossa operates in a highly competitive environment and competes against a wide range of other biopharmaceutical companies that are attempting to replicate or already have similar treatments as the company's drugs. Some of these competitors are much larger or have greater resources, and proprietary technology; which could result in lower projected sales for its drugs and higher costs, reduced margins, and lowered profitability for the company. Even if Atossa were to be successful with its drug development, its products will have to compete with existing or new standards of care.

Concentrated Product Pipeline

The company is currently developing 3 drug therapeutics (AT-H201, AT-301, and Endoxifen). If Atossa were to experience difficulties with development of any of these, then it may have a material negative impact on its business and financials as there are no meaningful products which can offset.

Coronavirus and Economic Uncertainties

While healthcare costs tends to be less correlated with economic activity and income levels due to their nondiscretionary nature, major deterioration in economic conditions tends to result in an overall decline in consumer spending. This was demonstrated during the 2008 and 2009 Great Recession and global economic slowdown. While consumer spending levels and economic conditions have rebounded since and have been strong the past several years, the global macroeconomic environment has turned significantly weaker recently with the start of the pandemic in March. Since then (in the past 7 months), there is now huge uncertainties with the current coronavirus pandemic and its effects. This has negatively impacted many businesses and has been a huge disruption to the U.S. (and global) economy. Though, we also note that the current coronavirus pandemic has brought significant potential business opportunities for the company as well. Further economic weakness may result in depressed enterprise and consumer spending levels; this may have a negative impact on Atossa, its business partners, government, and consumers.

Capital Markets Risks

We believe Atossa has enough cash to fund its operations through Q2 2021, but we estimate that it will need to raise capital by Q3 2021. We believe that it will be at least several years before the company can be cash flow self-sufficient from operations. Many biopharmaceutical companies fund their operations from the sale of equity or debt capital until their products reach commercial success or until they sell off the commercial rights to other companies. Biopharmaceuticals (“biotechs”) valuations tend to fluctuate widely, and though they are reasonably strong now (due to a strong M&A market for biotechs and large government funding for COVID-19), there is always the chance that market interests and valuations for companies in this industry decline significantly. The share price volatility in the past year (with a stock price range of \$0.76 – 5.08) in Atossa’s share price may make capital raising much more difficult and expensive, though we note its YTD share price performance has been strong (~+40%).

VALUATION

We are initiating coverage of Atossa Therapeutics with a BUY rating and a 12-month price target of \$7.00, which is based on a NPV analysis. As the company is a clinical stage drug development company, it currently generates no revenue and significant losses so traditional valuation metrics are not useful. We believe a more accurate valuation should take into consideration the potential value of its product pipeline. We do acknowledge that this valuation is complex and requires a large number of forward assumptions that we have to estimate that may be imprecise and may vary significantly from actual results. This is particularly so for a company like Atossa which is still in early clinical trials with its 3 main drugs.

However, we believe our assumptions are fair and provide a reasonable basis for our valuation analysis. Our analysis considers future estimated revenue from each of its major product pipelines (based on estimated future sales, a probability rate of success, and discounted this back to a current value), currently focused on its Endoxifen (breast cancer) and COVID-19 (AT-H201 & AT-301) drugs. We apply a high discount rate and about average probability of success to capture the uncertainties associated generally with drugs in development. We then added up the values, made an assumption about future investments required and allocated the value based on current share count. Based on our NPV analysis, we arrived at our 12-month price target of \$7.00, which we believe appropriately balances out the company’s risks with its high growth prospects.

Atossa’s share price YTD has been strong (~+40% from \$1.57 on December 31, 2019), but it has traded in a wide volatile range (\$0.76 on March 12 to \$5.08 on August 3). However, we believe that there are near term catalysts that can drive the stock (particularly for key milestones expected in 2020). As the company is likely to make significant progress (and milestones) in its drug development and product commercialization over the next several years, we believe this will result in much improved visibility into future cash flows.

We expect valuations for Atossa to improve as visibility into cash flow generation becomes clearer, resulting in significant upside to the current share price.

Exhibit 5: Company Valuation (DCF)

Valuation of Products (in millions)

Product	Estimated NPV	% of Success	Calculated NPV	Discount Rate	Estimated Annual Sales	% of Market Share	Market Potential per year
Endoxifen - Breast Cancer	\$ 89	50%	\$ 179	70%	\$ 125	25%	\$ 500
COVID-19 (AT-H201 & AT-301)	\$ 23	50%	\$ 45	70%	\$ 32	20%	\$ 160
Total	\$ 112						
Estimated additional investments required	\$ 35						
Current Value for existing shareholders	\$ 77						
Shares Outstanding (mils)	11						
Estimated Value per share	\$ 7.00						

Source: Ascendant Capital Markets estimates

COMPANY

Based in Seattle, WA, Atossa Therapeutics is a clinical-stage biopharmaceutical company focused on discovering and developing innovative medicines with a focus on coronavirus ("COVID-19") and breast cancer. Atossa has two COVID-19 drugs under development: 1) AT-H201, to improve lung function of moderate to severely ill, hospitalized COVID-19 patients by inhalation; and 2) AT-301, a nasal spray for COVID-19 patients who are not sufficiently ill to require hospitalization.

Atossa's breast cancer drug under development is a proprietary form of Endoxifen which is being developed primarily in two settings: 1) to reduce tumor cell activity in breast cancer patients in the "window of opportunity" between diagnosis of breast cancer and surgery; and 2) for women with high mammographic breast density ("MBD") to reduce the density and/or to act as an adjunct to mammography.

The company was originally founded as Atossa Genetics Inc. in 2009 to develop and market medical devices, laboratory and diagnostic tests, and therapeutics to address breast health conditions. In January 2020, the company changed its name from Atossa Genetics to Atossa Therapeutics to reflect its transition to focus on developing therapies to treat breast cancer, breast density, and other breast conditions. The company is named for Princess Atossa, a queen of the Achaemenid Empire, who reigned in the fifth century BC and is the earliest recorded woman with breast cancer.

The company completed its IPO in November 2012. As of March 2020, the company had 6 employees.

Its key Executive Officers are:

- Steven Quay, M.D., Ph.D. (age 69) - Chairman of the Board, President and Chief Executive Officer
- Kyle Guse, Esq., CPA (inactive) (age 56) - Chief Financial Officer, General Counsel and Secretary

Exhibit 6: Atossa Management Team



Steven Quay, MD, PhD, Chairman, CEO and President - Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, complete both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital, and is a former faculty member of the Department of Pathology, Stanford University School of Medicine. Dr. Quay is a named inventor on 87 U.S. patents, 130 pending U.S. patent applications, and is named inventor on patents covering five pharmaceutical products that have been approved by the U.S. Food and Drug Administration. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan. He received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971.



Kyle Guse, CPA, ESQ, MBA, CFO and General Counsel, has served as Chief Financial Officer, General Counsel and Secretary since January 2013. His experience includes more than 20 years of counselling life sciences and other rapid growth companies through all aspects of finance, corporate governance, securities laws and commercialization. Mr. Guse has practiced law at several of the largest international law firms, including from January 2012 through January 2013 as a partner at Baker Botts LLP and, prior to that, from October 2007 to January 2012, as a partner at McDermott Will & Emery LLP. Before working at McDermott Will & Emery, Mr. Guse previously served as a partner at Heller Ehrman LLP. Mr. Guse began his career as an accountant at Deloitte & Touche and he is a licensed Certified Public Accountant in the state of California. Mr. Guse earned a B.S. in Business Administration and an M.B.A. from California State University, Sacramento, and a J.D. from Santa Clara University School of Law.



Dr. Fraser, VP Clinical, Regulatory and CMC, brings over 20 years of extensive industry experience in the biotech industry to the Company, recently serving in a leadership role as VP Clinical Operations & Program Management at Cerecor, Inc. She held positions with increasing levels of responsibility at Anthera Pharmaceuticals and CV Therapeutics (acquired by Gilead Sciences) where the roles included preclinical and clinical sciences and regulatory affairs. Dr. Fraser has experience in drug development across diverse therapeutic areas including psychiatry, central nervous system disorders, cardiovascular disorders, and rare diseases; and she has been involved in all stages of drug development from pre-clinical through Phase 4. Dr. Fraser received her BS in Zoology from the University of British Columbia, her MS in Pharmaceutical Sciences from the University of Montana and her PhD in Pharmacology from the University of Alberta. She also completed a post-doctoral fellowship at Johns Hopkins University School of Medicine.

Source: Company reports.

DRUG PIPELINE

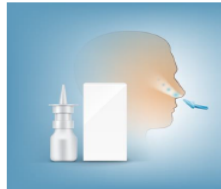
Atossa has three main therapeutic drug candidates, two for COVID-19 and one for breast cancer. AT-H201 is used to improve lung function of moderate to severely ill, hospitalized COVID-19 patients by inhalation. AT-301 is a nasal spray for COVID-19 patients who are not sufficiently ill to require hospitalization. Endoxifen is being developed for two settings for breast cancer: 1) to reduce tumor cell activity in breast cancer patients in the "window of opportunity" ("WOO") between diagnosis of breast cancer and surgery; and 2) for women with high mammographic breast density ("MBD") to reduce the density and/or to act as an adjunct to mammography.

Atossa currently has 2 ongoing clinical trials (AT-301 and Endoxifen in WOO), with 2 more (AT-H201 and Endoxifen for MBD) expected to start soon (by Q4).

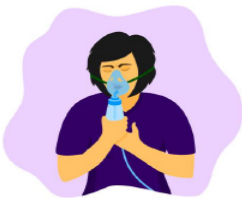
Atossa was also developing Endoxifen to prevent and/or reduce gynecomastia, which is male breast enlargement and pain, and a proprietary intraductal delivery technology to target the delivery of therapies, including fulvestrant, immunotherapies and CAR-T therapies, close to the site of breast cancer in the breast ducts. However, both are on hold as the company focuses on Endoxifen for breast cancer and its COVID-19 programs.

Exhibit 7: COVID-19 Therapeutic Needs

FOUR COVID-19 THERAPEUTIC NEEDS



Nasal Spray Before Dx or upon Dx
To prevent disease
To treat early disease
To prevent pulmonary disease



Inhalation drug
To treat post-infection
pulmonary disease

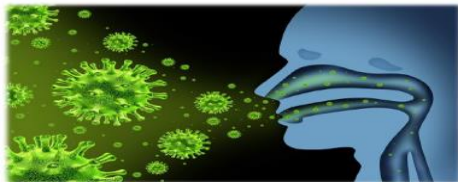
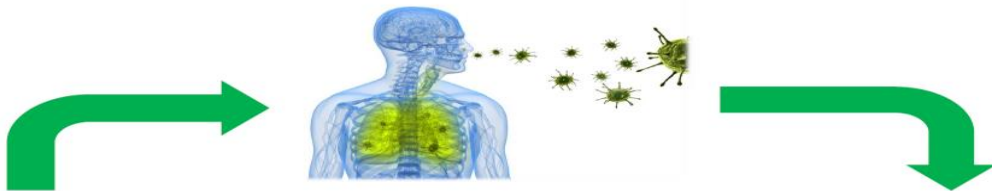


Systemic drug upon entry to hospital
To treat pneumonia
To prevent blood stream infection

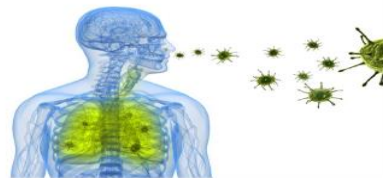


Inhalation drug
To prevent using ventilator
To wean from ventilator

COVID-19 PROGRESSION



Stage One
Day 0 to 3
Infection in nasal cavity



Stage Two
Day 3 to 10
Pulmonary disease/
pneumonia



Stage Three
Day 10 to ??
Systemic disease

Source: Company reports.

The coronavirus disease 2019 (commonly referred to as COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (actual name of the virus is SARS-CoV-2). It was first identified in December 2019 in Wuhan, China, and has spread around the world quickly since then. The World Health Organization (WHO) declared the COVID-19 outbreak a pandemic on March 11, 2020. As of September 2020, ~30 million cases have been reported in almost every country in the world causing almost 1 million deaths. In the U.S., there has been ~7 million reported cases and ~200,000 deaths.

Common symptoms include fever, cough, fatigue, shortness of breath or breathing difficulties, and loss of smell and taste. While most people have mild or no symptoms (~80%), some people (particularly those with pre-existing health conditions) develop acute respiratory distress syndrome (ARDS), cytokine storm, multi-organ failure, septic shock, and blood clots which can ultimately lead to death. The estimated death rate of those infected is ~0.6% (vs. ~0.1% for the flu). The incubation period range from 2 – 14 days. Infected people can recover (no longer sick, infected, or able to transmit the virus) in about 2 weeks, while those with severe cases can take ~6 weeks.

The virus is spread primarily via small droplets from coughing, sneezing, talking, and breathing in very close quarters with infected people. Recommended measures to prevent infection include frequent hand washing, social distancing, quarantine, covering coughs, and wearing face coverings and masks.

There are no proven vaccines or specific treatments for COVID-19. Management involves the treatment of symptoms, supportive care, isolation, drug therapies, and experimental measures. Drug therapies include Remdesivir, Favipiravir, chloroquine, and other treatments include mechanical ventilators and plasma therapy. There are many (hundreds) additional drug therapies being investigated as potential drug treatments that are in various phases of clinical trials globally.

There are currently seven vaccines in development that have been fast tracked into Phase 3 studies (with many more in Phase 1 and Phase 2), with expectations of published results by October and a potential approval and release before the end of 2020. We note that most vaccines take an average of 10 years to develop with one of the fastest ever at 4 years for a vaccine for mumps in 1967. However, we also note that there has been a hugely unprecedented amount of money and national and global focus in developing a vaccine.

Exhibit 8: Atossa's AT-H201 For COVID-19

ATOSSA'S AT-H201



- For COVID-19 patients on ventilators to improve lung function
- Successful *in vitro* tests
- Consists of two drugs approved by the FDA for other diseases
- Development path for combination drugs includes studies and clinical trials of each component separately and then together
- Contracted with NY Hospital for clinical study
- Applied to FDA to open initial study of AT-H201 key component; exploring ex-US
- Provisional patent applications filed

Source: Company reports.

AT-H201 is a proprietary combination of two drugs (low molecular weight heparin (LMWH) and N-acetyl-cysteine (NAC)) previously approved by the FDA to treat other diseases. It is intended to improve compromised lung function for moderate to severely ill, hospitalized COVID-19 patients by inhalation. There are five known key steps the coronavirus must take to signal the cell to open up and let the virus in. AT-H201 is being designed to function like a “chemical vaccine” by blocking all five of those steps, similar to what antibodies would be expected to do when a vaccine is administered.

In May 2020, Atossa completed *in vitro* testing of AT-H201 which showed that the components of AT-H201 inhibit SARS-CoV-2 infectivity of VERO cells, which is a standard cell type being used to study infectivity of the coronavirus. The AT-H201 components were found to be at least four times more potent than remdesivir and at least 20 times more potent than hydroxychloroquine. Potency was measured by microscopic examination of the cytopathic effect caused by SARS-CoV-2 in VERO cells.

Atossa is in the process of providing the necessary information to the FDA and expects receiving approval to commence the initial clinical study of AT-H201 in the second half of 2020.

Exhibit 9: Atossa's AT-301 For COVID-19

AT-301 COVID-19 NASAL SPRAY



- Nasal spray delivery – targets infections in nasal passage “nasal mucosa vaccine”
- Out-patient/home use
- TID usage planned for
- Successful *in vitro* study
- Clinical study with CRO Avance in AUS; first cohort dosed and positive safety review
- Provisional patent applications filed
- Summit Biosciences developing formulation/device



Source: Company reports.

AT-301 is Atossa's proprietary drug intended for nasal administration in patients immediately following diagnosis of COVID-19 but have not yet exhibited symptoms severe enough to require hospitalization. It is intended for at-home use to proactively reduce symptoms and slow the infection rate so that a person's immune system can more effectively fight COVID-19. Atossa also intends to conduct testing to determine whether AT-301 can be used as a prophylaxis to prevent or mitigate SARS-CoV-2, with the goal that it could become a “bridge to the vaccine”.

AT-301 is being developed with a nasal spray delivery mechanism because many COVID-19 patients are infected via the nasal passage. Collectively, the components of AT-301 are believed to help maintain a protective mucosal like layer within the nasal cavity with both anti-viral properties and protective mucosal like barrier that may lead to lower infectivity and reduced symptoms in COVID-19 patients due to their interference with the virus in the nasal cavity and upper respiratory tract.

AT-301 is designed to contain ingredients that can potentially block SARS-CoV-2 viral entry gene proteins in nasal epithelial cells by interfering with spike protein activation by host proteases, by masking receptor binding domains (RBD) via electrostatic mechanisms, and by providing a generalized mucoadhesive epithelial barrier.

In July 2020, Atossa completed in vitro testing of AT-301 which showed that AT-301 inhibits SARS-CoV-2 infectivity of VERO cells in a laboratory culture.

Atossa is conducting a Phase 1 study in Australia of AT-301 which is designed as a double-blinded, randomized, and placebo-controlled safety study of AT-301 nasal spray in 32 healthy adult subjects divided into two study groups. The primary objective of the study is to evaluate the safety and tolerability of single and multiple doses of AT-301 administered via nasal instillation to healthy volunteers. Secondary objectives are to assess the incidence and severity of local irritation and bronchospasm following administration of AT-301 via nasal instillation.

In August 2020, Atossa received regulatory approval to commence its Phase 1 study in Australia. In early September 2020, Atossa announced positive interim safety assessment from the first cohort of healthy participants in the Phase 1 clinical study.

Exhibit 10: Breast Cancer

THE BREAST CANCER PROBLEM

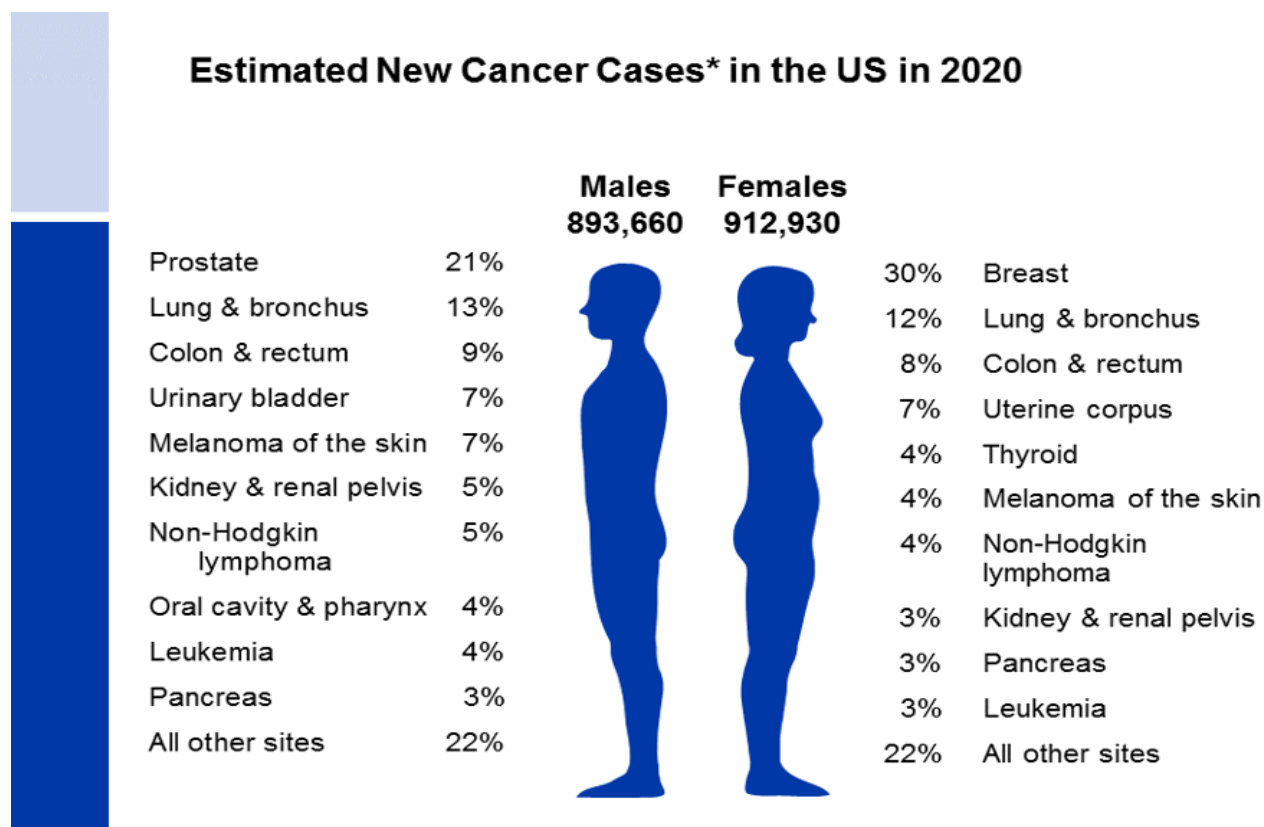


- 1 in 8 women experience breast cancer
- 268,000 women diagnosed in US this year
- 2nd leading cause of cancer death in American women



Source: Company reports.

Exhibit 11: New Breast Cancer Cases in the U.S. in 2020



Source: American Cancer Society.

Cancer is the result of rapid and uncontrolled cell growth in your body. A normal cell multiplies and divides and grows in a controlled manner. When cells begin to divide and grow at an uncontrolled rate, this can develop into cancer which attacks and interferes with normal body functions. Cancer is the 2nd leading cause of death in the U.S. (behind heart disease) with ~600,000 deaths a year. For woman, breast cancer is the most common cancer. The American Cancer Society estimates that in 2020, ~280,000 women will be diagnosed with breast cancer in the U.S. and ~42,000 die each year.

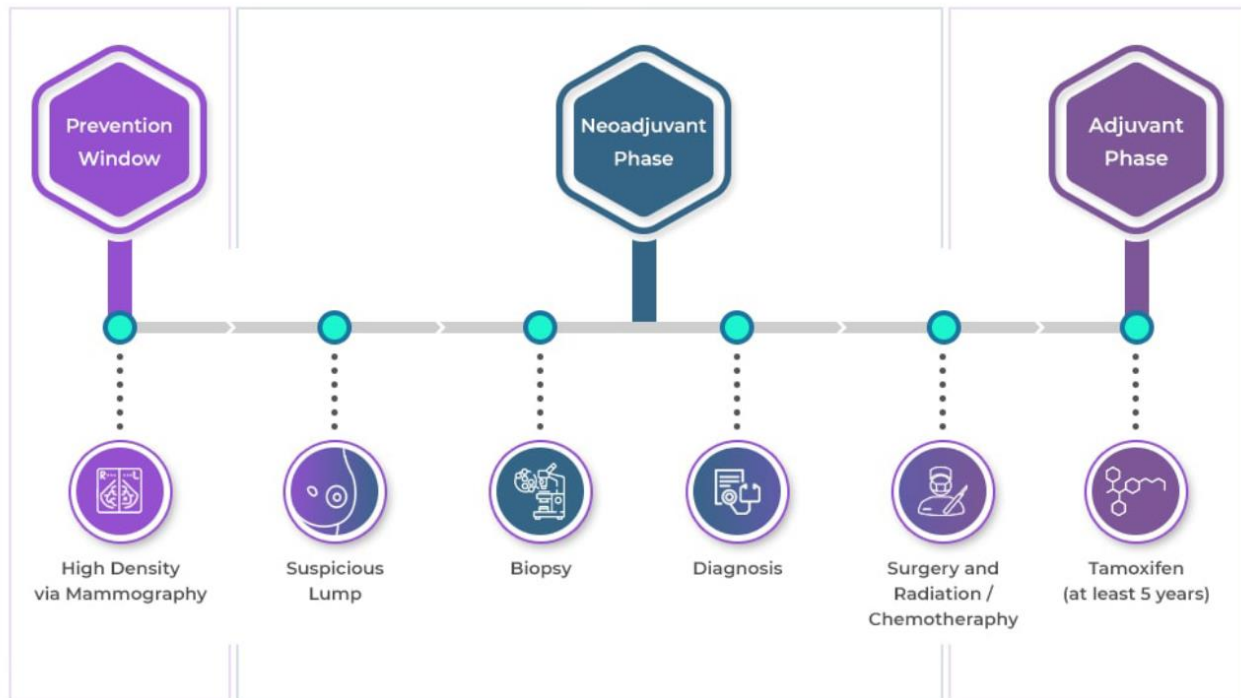
Endoxifen is the most active metabolite (ingredient) of the FDA approved drug tamoxifen. Tamoxifen has been used since its approval in 1977 for breast cancer survivors to prevent recurrence as well as to prevent breast cancer in high risk women. Tamoxifen is a “pro-drug,” in that it must be metabolized by the liver into active metabolites in order to have activity in the body. Despite the success of tamoxifen in reducing the risk of estrogen receptor-positive breast cancer, its side effects have led to generally low acceptance as a therapy to reduce the risk of breast cancer.

Many patients do not properly metabolize tamoxifen which means they receive little or no benefit from tamoxifen. Up to 50% of breast cancer survivors who are taking tamoxifen do not produce therapeutic endoxifen levels (meaning they are “refractory”) for a number of reasons including that they, due to their genotype, do not have the requisite liver enzymes. Additionally, it can take from 50 - 200 days for tamoxifen to reach “steady-state” meaning that the drug may be providing little or no benefit for up to several months after starting treatment. By providing endoxifen directly to the body, Atossa's early studies have shown that a steady-state may be achieved in as little as seven days and the need for liver metabolism is bypassed.

In 2017, Atossa successfully completed an initial Phase 1 placebo-controlled clinical trial of its proprietary oral and topical formulations of Endoxifen in 48 healthy women, supporting the continued development of this drug. Results from Atossa’s Phase 1 study show that its orally administered endoxifen gets to a “steady-state” in as little as seven days whereas studies by other have shown that steady-state levels of endoxifen from oral tamoxifen can take up to 120 days.

Atossa is developing both topical and oral forms of its Endoxifen, though the focus now is on the oral form. Its proprietary Endoxifen aims to reduce mammographic breast density (“MBD”) and to potentially treat breast cancer in the “window of opportunity” (“WOO”) between diagnosis of breast cancer and surgery.

Exhibit 12: Endoxifen and Breast Cancer Phases



Source: Company reports.

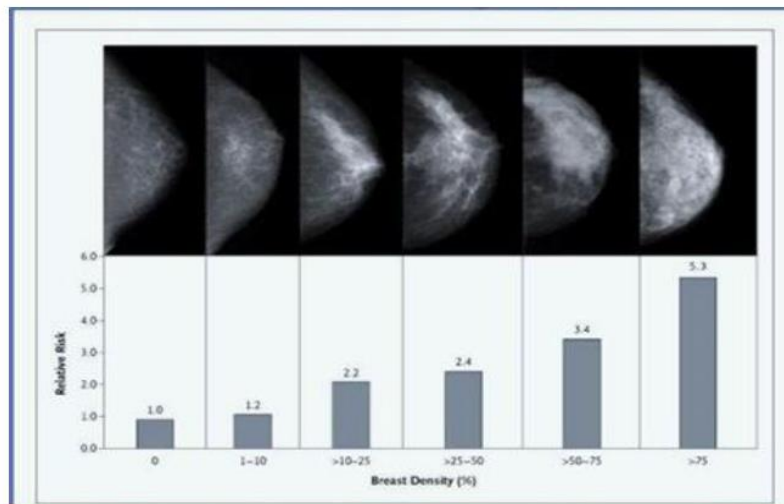
Exhibit 13: Atossa's Endoxifen For Mammographic Breast Density ("MBD")

ENDOXYFEN - MBD



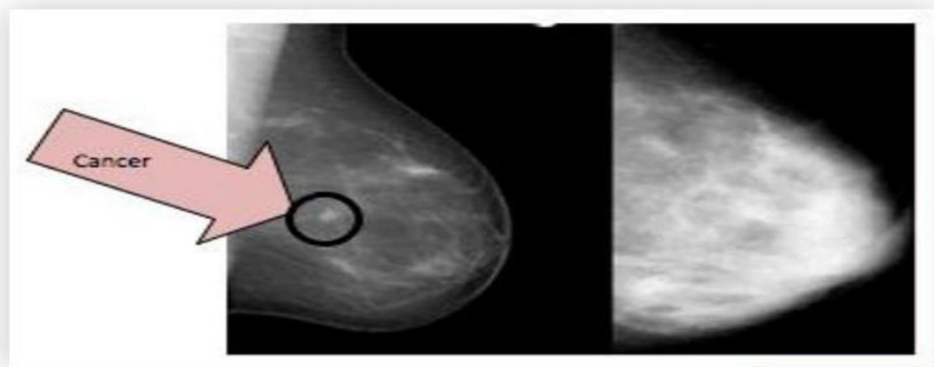
AS ADJUNCT TO MAMMOGRAPHY FOR REDUCTION OF MBD

A NEWLY RECOGNIZED BREAST CANCER RISK FACTOR : MAMMOGRAPHIC DENSITY



FEDERAL AND STATE LAWS REQUIRE WOMEN THAT BE NOTIFIED OF THEIR DENSITY

AS ADJUNCT TO MAMMOGRAPHY FOR REDUCTION OF MBD Mammograms need help!



MBD CAN MASK TUMORS

Source: Company reports.

Mammographic Breast Density (“MBD”) is an emerging public health issue affecting over 10 million women in the U.S. Women who have dense breast tissue have a higher risk of breast cancer compared to women with less dense breast tissue. Studies conducted have shown that MBD increases the risk of developing breast cancer and that reducing MBD can reduce the incidence of breast cancer.

There is no FDA-approved treatment for MBD. Although oral tamoxifen is approved to prevent breast cancer in “high-risk” women, it is used by less than 5% of women with increased risk because of the side effects and risks of tamoxifen. Atossa believes Endoxifen may provide an option for women to proactively reduce the density of their breasts. Moreover, Endoxifen may improve mammography accuracy and patient care by unmasking cancerous tumors that are otherwise hidden by breast density. In two separate reports of film-screen mammography, mammographic sensitivity decreased from a level of 85.7 – 88.8% in patients with almost entirely fatty tissue to 62.2 – 68.1%.

In June 2019, Atossa reported preliminary analysis from its Phase 2 study in Sweden of proprietary daily topical Endoxifen to reduce MBD, showing significant ($p=0.02$) and rapid reduction in MBD at the 20mg daily dose level. MBD was reduced by an average of 14.3% in the group applying 20mg daily topical Endoxifen. Approximately 70% of patients receiving 20mg topical Endoxifen experienced a reduction in MBD, and of those, the mean reduction in MBD was 27%. Many participants in this study, however, experienced adverse skin reactions and dropped out of the study. Because of this, the company has switched to oral Endoxifen instead of topical Endoxifen.

In December 2019, Atossa contracted with Stockholm South General Hospital (in Sweden) to conduct a double-blinded, placebo-controlled Phase 2 study of its oral Endoxifen in premenopausal women with MBD who will be dosed over six months. Atossa expects receiving regulatory approval and opening this study in the second half of 2020. In May 2020, Atossa reported that the FDA provided regulatory input on its clinical path for oral Endoxifen to reduce MBD. The input received from the FDA will be used for clinical trial strategy and study design both in the U.S. and in Sweden.

Atossa is also developing oral Endoxifen to potentially treat breast cancer in the “window of opportunity” (WOO) phase between diagnosis of breast cancer and surgery. The goal of pharmaceutical treatment in patients with non-metastatic breast cancer after surgery (also called adjuvant therapy), for example by chemotherapy or hormone therapy, is typically to reduce the risk of the cancer recurring. Administering therapy in the window of opportunity prior to surgery (also called neoadjuvant therapy) may also reduce the risk of recurrence.

Downstaging the tumor may convert a large, inoperable tumor in selected patients into an operable tumor that may allow breast conserving surgery in place of mastectomy, improve cosmetic outcomes, and reduce postoperative complications. Successful neoadjuvant therapy may allow some patients to avoid surgery altogether or defer surgery under a “watch and wait” strategy.

Atossa has an ongoing Phase 2 study in Australia of its oral Endoxifen in the window of opportunity between diagnosis of breast cancer and surgery. The study will enroll up to 25 newly-diagnosed patients with ER+ and human epidermal growth factor receptor 2 negative (HER2-) stage 1 or 2 invasive breast cancer, requiring mastectomy or lumpectomy. Patients will receive oral Endoxifen for at least 14 days from the time of diagnosis up to the day of surgery.

The primary endpoint is to determine if the administration of oral Endoxifen reduces the tumor activity as measured by Ki-67 (a recognized standard measurement of breast cancer cell proliferation and prognostic value for predicting overall survival in ER+ breast cancer patients). The secondary endpoints are safety and tolerability and assessment of the study drug on expression levels of both estrogen and progesterone receptors.

In May 2020, Atossa reported interim results from its Phase 2 study of oral Endoxifen in the window of opportunity. A statistically significant ($p=0.031$) reduction of ~74% in tumor cell proliferation, as measured by Ki-67, over the 22 days of dosing was achieved in the initial patients.

A summary of these results include:

- Ki-67 was reduced by more than 50% in every patient in the window of opportunity between initial biopsy and surgery, with an overall relative reduction of 74%.
- All six patients had a Ki-67 below 25% after treatment. Ki-67 levels below 25% are generally associated with the lowest risk of death.
- Treatment ranged from 16 - 40 days with an average of 22 days.
- There were no safety or tolerability issues, including vasomotor symptoms such as hot flashes and night sweats, which are often a tolerability challenge for patients on tamoxifen.
- This study continues to be open for enrollment (only 6 of the planned 25 patients have been enrolled as of May 2020).

In December 2018, Atossa began providing its oral Endoxifen to a pre-menopausal, estrogen-receptor positive (ER+), lacking CYP2D6 function, breast cancer patient under an FDA-approved expanded access or "compassionate use" program, and which was restricted solely to a single patient. The purpose was to reduce activity of the cancer cells prior to breast cancer surgery. The patient received daily doses of oral Endoxifen for approximately three weeks prior to surgery. The cancer cell biological activity was reduced, based on the estrogen receptor activity of the tumor cells and a 50% reduction in Ki-67. The FDA also permitted use of Endoxifen for this patient following her surgery as part of her long-term breast cancer treatment regimen.

In July 2020, Atossa reported an update on this patient, who has received Endoxifen for 18 months post-surgery. To date, the patient has not had a recurrence of breast cancer, has not had treatment-related changes in periodic laboratory blood tests and the treatment has been well tolerated, including an absence of typically seen vasomotor symptoms (night sweats and hot flashes).

Exhibit 14: Endoxifen In The WOO Interim Phase 2 Data (May 2020)

ORAL ENDOXIFEN - PHASE 2 "WOO" STUDY SUMMARY



- Window of Opportunity (WOO) – time period between diagnosis and surgery
- Endoxifen 4 mg PO daily
- Primary Endpoint: Reduced Ki67 tumor activity
- Secondary Endpoints: safety and tolerability



ORAL ENDOXIFEN - WOO INTERIM RESULTS



- 74% overall reduction in Ki-67 activity
- **Statistically significant** P=.031; N=6
- All pts had >50% reduction
- All pts <25% Ki-67 at surgery
- **Clinically significant**
- 22 days average Tx
- Range 16-40 days
- **No Safety signals**



Source: Company reports.

Upcoming Milestones

Atossa has key upcoming milestones for its 3 drugs under development that we believe should be achieved by the end of 2020:

5. AT-H201 - Receive regulatory approval to initiate a Phase 1 clinical study of AT-H201 and begin enrollment.
6. AT-301 – Complete enrollment and dosing in its ongoing Phase 1 clinical study of AT-301 in Australia.
7. Endoxifen - Receive regulatory approval to initiate a Phase 2 clinical study of Endoxifen for MBD in Sweden and begin enrollment.
8. Endoxifen - Complete enrollment and dosing in its ongoing Phase 2 clinical study of Endoxifen in the window of opportunity (WOO) in Australia.

Exhibit 15: Upcoming Milestones

UPCOMING MILESTONES



COVID-19 - AT-H201:

- Q4 2020 IRB and regulatory approval to open study
- Q4 2020 Commence initial AT-H201 study

COVID-19 – AT-301:

- Q4 2020 Complete enrollment in Phase 1 AUS study
- Q4 2020 Complete dosing in Phase 1 AUS study

Breast Health - Oral Endoxifen:

- Q4 2020 regulatory approval to open Phase 2 MBD study
- Q4 2020 begin enrollment in Phase 2 study to reduce MBD

Source: Company reports.

FINANCIALS

Atossa's fiscal year ends on December 31. We expect its next earnings report (for Q3 2020) to be in mid-November. Because the company is a clinical stage drug development company, it currently generates no revenue and significant losses as it funds its drug development.

Exhibit 16: Atossa Therapeutics' Historical Financials

FYE December 31				
(in millions except EPS)	2018A	2019A	2020E	2021E
Operating income (loss)	(11.4)	(17.3)	(14.6)	(14.8)
Net income	(22.9)	(17.2)	(14.6)	(14.8)
EPS	\$ (5.50)	\$ (2.03)	\$ (1.50)	\$ (1.38)
Cash flow from operations	(9.0)	(9.1)	(11.1)	(10.6)

Source: Company reports and Ascendant Capital Markets estimates.

Recent Results (fiscal Q2 ending June 2020)

Atossa's recent financial performance is reflective of its developmental stage. In its Q2 2020 report (on August 13, 2020), the company reported no revenue and net loss was \$3.9 million. Operating expenses were \$4 million, mainly due to drug development costs and general and administrative expenses. Q2 EPS was \$(0.43).

The company does not provide specific quarterly financial guidance, but did state that R&D expenses should increase as the company expands clinical trial activities. However, we believe Q2's operating expenses of \$4 million is a reasonable near term quarterly burn rate. The company expects continued progress on its drug development milestones in 2020. We do not expect the company to experience revenue until its drugs make significant progress towards FDA approval (either from product sales or from the sales of drug marketing rights to new partners). We have modeled relatively steady operating costs over the next year, primarily driven by its expected three drug clinical trials expenses.

For 2020, we expect a net loss of \$15 million and EPS of \$(1.50). For 2021, we expect a net loss of \$15 million and EPS of \$(1.38).

Its near term plans over the next several years is to advance Endoxifen (currently in/starting Phase 2 trials) in its clinical trials towards a FDA approval. Its plans for its COVID-19 drugs (AT-H201 and AT-301 currently in/starting Phase 1 trials) are more immediate in nature due to the current ongoing COVID-19 pandemic. We believe that if initial clinical trials activities and results are positive, the company may be able to seek Emergency Use Authorization (EUA) from the FDA (or its worldwide equivalents) to begin commercialization and patient treatment by the end of 2020.

However, we note that there are significant uncertainties (along with key opportunities) with the current coronavirus pandemic. Initial clinical activity for the company's drugs are still early in Phase 1, and there is the chance that the coronavirus will dissipate by itself, or that an effective vaccine or other therapeutic treatments for COVID-19 may be developed and launched before the company's drugs are launched.

We believe that the biggest potential variable in our financial model is the ability of the company to get FDA (or equivalent) approval for its COVID-19 and breast cancer drugs under development. It is these approvals that are ultimately how Atossa will be able to finally be able to generate revenue. If the company can make significant progress towards these goals, then revenue and earnings will likely be able to grow significantly. However, if the company has difficulties in making progress towards getting drug approvals, then revenue and profitability may not be achieved or will likely grow at a moderate rate or even not at all. Even after drug approvals, Atossa faces a big challenge to successfully commercialize its products.

The company's balance sheet had ~\$8 million in cash and no debt as of June 2020. In July 2020 (current Q3), the company sold 1.1 million shares of common stock under an ATM for \$4.5 million (~\$4.10/share), which completed its \$5.0 million ATM (entered into February 2020). The company should have enough cash through Q2 2021, but will likely need to raise additional cash to fund its operations by Q3 2021.

Exhibit 17: Atossa Therapeutics' Key Financial Metrics

Recent Share Price (9/16/20)	\$ 2.25
52-Weeks Share Price (Low - High)	\$0.76 - 5.08
Shares Outstanding	11 million
Market Capitalization	\$25 million
Enterprise Value	\$17 million
Cash (6/30/20)	\$8 million
Debt (6/30/20)	\$0 million
2019A Net loss	\$17 million
2019A EPS	\$ (2.03)
2020E Net loss	\$15 million
2020E EPS	\$ (1.50)

Source: Company reports and Ascendant Capital Markets estimates.

Exhibit 18: Consensus Expectations

	EPS	
	2020E	2021E
Q1 Mar	\$(0.32)A	
Q2 Jun	\$(0.43)A	
Q3 Sep	\$(0.32)E	
Q4 Dec	\$(0.35)E	
Total	\$(1.28)E	\$(0.84)E

*Quarterly estimates may not add to annual estimates due to variations in contributing estimates and rounding.

Source: Company report, Thomson Reuters, and Ascendant Capital Markets estimates

FINANCIAL MODEL

Atossa Therapeutics, Inc.

Income Statement (\$ mils)	Mar-18	Jun-18	Sep-18	Dec-18	2018	Mar-19	Jun-19	Sep-19	Dec-19	2019	Mar-20	Jun-20	Sep-20	Dec-20	2020	Mar-21	Jun-21	Sep-21	Dec-21	2021	
Fiscal Year End: December 31	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E	
Total Revenue	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
<u>Cost of Revenues</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>
Gross Profit	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Research and development	0.471	1.468	1.422	0.849	4.210	1.451	2.612	1.684	0.898	6.645	0.939	1.653	1.800	2.000	6.392	1.700	1.700	1.700	1.700	6.800	6.800
General and administrative	1.403	2.675	1.888	1.258	7.224	2.613	4.674	1.614	1.719	10.620	1.998	2.283	1.900	2.000	8.181	2.000	2.000	2.000	2.000	8.000	8.000
<u>Restructuring and other</u>					<u>0.000</u>					<u>0.000</u>					<u>0.000</u>					<u>0.000</u>	<u>0.000</u>
Total operating expenses	1.874	4.143	3.310	2.107	11.434	4.064	7.286	3.298	2.617	17.265	2.937	3.936	3.700	4.000	14.573	3.700	3.700	3.700	3.700	14.800	14.800
Operating income (loss)	(1.874)	(4.143)	(3.310)	(2.107)	(11.434)	(4.064)	(7.286)	(3.298)	(2.617)	(17.265)	(2.937)	(3.936)	(3.700)	(4.000)	(14.573)	(3.700)	(3.700)	(3.700)	(3.700)	(14.800)	(14.800)
Interest income (expense)					0.000					0.000					0.000					0.000	0.000
<u>Other income (expense)</u>	<u>0.000</u>	<u>(11.479)</u>	<u>0.000</u>	<u>0.029</u>	<u>(11.450)</u>	<u>(0.009)</u>	<u>0.024</u>	<u>0.012</u>	<u>(0.001)</u>	<u>0.026</u>	<u>(0.010)</u>	<u>0.030</u>	<u>0.000</u>	<u>0.000</u>	<u>0.019</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>	<u>0.000</u>
Income before income taxes	(1.874)	(15.622)	(3.310)	(2.078)	(22.884)	(4.073)	(7.263)	(3.286)	(2.618)	(17.240)	(2.947)	(3.906)	(3.700)	(4.000)	(14.554)	(3.700)	(3.700)	(3.700)	(3.700)	(14.800)	(14.800)
<u>Income taxes</u>					<u>0.000</u>					<u>0.000</u>					<u>0.000</u>					<u>0.000</u>	<u>0.000</u>
Net income (loss)	(1.874)	(15.622)	(3.310)	(2.078)	(22.884)	(4.073)	(7.263)	(3.286)	(2.618)	(17.240)	(2.947)	(3.906)	(3.700)	(4.000)	(14.554)	(3.700)	(3.700)	(3.700)	(3.700)	(14.800)	(14.800)
<u>Nonrecurring/noncash adjustments</u>					<u>0.000</u>					<u>0.000</u>					<u>0.000</u>					<u>0.000</u>	<u>0.000</u>
Net income (pro forma)	(1.874)	(15.622)	(3.310)	(2.078)	(22.884)	(4.073)	(7.263)	(3.286)	(2.618)	(17.240)	(2.947)	(3.906)	(3.700)	(4.000)	(14.554)	(3.700)	(3.700)	(3.700)	(3.700)	(14.800)	(14.800)
EBITDA																					
Shares, Basic	0.2	3.1	5.2	5.8	4.2	6.6	9.1	9.1	9.1	8.5	9.1	9.2	10.0	10.5	9.7	10.6	10.7	10.8	10.9	10.8	10.8
Shares, Diluted	0.2	3.1	5.2	5.8	4.2	6.6	9.1	9.1	9.1	8.5	9.1	9.2	10.0	10.5	9.7	10.6	10.7	10.8	10.9	10.8	10.8
EPS Basic (pro forma)	(\$8.48)	(\$5.08)	(\$0.64)	(\$0.36)	(\$5.50)	(\$0.62)	(\$0.80)	(\$0.36)	(\$0.29)	(\$2.03)	(\$0.32)	(\$0.43)	(\$0.37)	(\$0.38)	(\$1.50)	(\$0.35)	(\$0.35)	(\$0.34)	(\$0.34)	(\$1.38)	(\$1.38)
EPS Diluted (pro forma)	(\$8.48)	(\$5.08)	(\$0.64)	(\$0.36)	(\$5.50)	(\$0.62)	(\$0.80)	(\$0.36)	(\$0.29)	(\$2.03)	(\$0.32)	(\$0.43)	(\$0.37)	(\$0.38)	(\$1.50)	(\$0.35)	(\$0.35)	(\$0.34)	(\$0.34)	(\$1.38)	(\$1.38)
Margins																					
Gross margin																					
Research and development																					
General and administrative																					
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Tax rate, GAAP	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
YY % change																					
Total Revenue																					
Gross margin																					
Research and development						208%	78%	18%	6%	58%	-35%	-37%	7%	123%	-4%	81%	3%	-6%	-15%	6%	
General and administrative						86%	75%	-15%	37%	47%	-24%	-51%	18%	16%	-23%	0%	-12%	5%	0%	-2%	
Operating income (loss)						117%	76%	0%	24%	51%	-28%	-46%	12%	53%	-16%	26%	-6%	0%	-8%	2%	
Net income (loss)						117%	-54%	-1%	26%	-25%	-28%	-46%	13%	53%	-16%	26%	-5%	0%	-8%	2%	
EPS Diluted (pro forma)						-93%	-84%	-44%	-19%	-63%	-48%	-47%	3%	33%	-26%	8%	-19%	-7%	-11%	-8%	

Source: Company reports and Ascendant Capital Markets estimates.

Atossa Therapeutics, Inc.

Balance Sheet (\$ mils)	Mar-18	Jun-18	Sep-18	Dec-18	Mar-19	Jun-19	Sep-19	Dec-19	Mar-20	Jun-20	Sep-20	Dec-20	Mar-21	Jun-21	Sep-21	Dec-21
Fiscal Year End: December 31	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Assets																
Cash and cash equivalents	4.780	15.237	12.936	10.380	19.568	17.059	15.290	12.581	9.351	7.463	9.615	6.657	4.000	1.342	(1.316)	(3.974)
Short term investments											0.000	0.000	0.000	0.000	0.000	0.000
Restricted cash	0.055	0.055	0.055	0.110	0.110	0.110	0.110	0.110	0.110	0.110	0.110	0.110	0.110	0.110	0.110	0.110
Research and development tax rebat	0.396	0.626	0.480	0.518	0.238	0.406	0.569	0.740	0.734	0.761	0.761	0.761	0.761	0.761	0.761	0.761
Deferred income taxes											0.000	0.000	0.000	0.000	0.000	0.000
Prepaid expenses and other	0.505	0.490	0.452	0.541	0.863	0.813	0.432	0.888	1.472	1.728	1.728	1.728	1.728	1.728	1.728	1.728
Total current assets	5.735	16.408	13.923	11.549	20.780	18.388	16.401	14.319	11.667	10.062	12.214	9.256	6.598	3.941	1.283	(1.375)
Property and equipment, net	0.060	0.061	0.058	0.054	0.048	0.044	0.039	0.034	0.030	0.029	0.024	0.018	0.012	0.006	0.001	(0.005)
Intangibles, net	0.071	0.060	0.055	0.099	0.092	0.084	0.076	0.069	0.061	0.053	0.053	0.053	0.053	0.053	0.053	0.053
Deferred income tax											0.000	0.000	0.000	0.000	0.000	0.000
Other	0.115	0.049	0.089	0.017	0.105	0.093	0.081	0.068	0.055	0.061	0.061	0.061	0.061	0.061	0.061	0.061
Total assets	5.980	16.578	14.124	11.720	21.025	18.609	16.597	14.490	11.812	10.206	12.352	9.389	6.725	4.062	1.398	(1.265)
Liabilities and stockholders' equity																
Accounts payable	0.168	0.191	0.551	0.353	0.464	0.318	0.501	0.293	0.356	1.033	1.033	1.033	1.033	1.033	1.033	1.033
Accrued expenses	0.529	2.797	2.938	2.522	0.967	0.643	0.995	0.977	0.519	0.748	0.748	0.748	0.748	0.748	0.748	0.748
Deferred income tax											0.000	0.000	0.000	0.000	0.000	0.000
Other	0.023	0.023	0.066	0.040	0.061	0.072	0.068	0.052	0.033	0.046	0.046	0.046	0.046	0.046	0.046	0.046
Short term debt											0.000	0.000	0.000	0.000	0.000	0.000
Total current liabilities	0.721	3.011	3.555	2.915	1.491	1.033	1.564	1.323	0.908	1.827	1.827	1.827	1.827	1.827	1.827	1.827
Deferred income taxes											0.000	0.000	0.000	0.000	0.000	0.000
Warrant liabilities											0.000	0.000	0.000	0.000	0.000	0.000
Other long term liabilities					0.037	0.024	0.014	0.011	0.008	0.005	0.005	0.005	0.005	0.005	0.005	0.005
Long term debt											0.000	0.000	0.000	0.000	0.000	0.000
Total other liabilities	0.000	0.000	0.000	0.000	0.037	0.024	0.014	0.011	0.008	0.005	0.005	0.005	0.005	0.005	0.005	0.005
Preferred stock		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Common stock	0.477	0.877	0.994	1.052	1.642	1.643	1.644	1.644	1.644	1.675	2.711	3.748	4.784	5.821	6.857	7.894
Additional paid-in capital	72.083	84.133	84.328	84.584	98.759	104.076	104.828	105.583	106.271	107.624	107.624	107.624	107.624	107.624	107.624	107.624
Retained earnings	(67.301)	(71.443)	(74.753)	(76.831)	(80.905)	(88.167)	(91.453)	(94.071)	(97.018)	(100.925)	(104.625)	(108.625)	(112.325)	(116.025)	(119.725)	(123.425)
Accumulated other comprehensive income											4.810	4.810	4.810	4.810	4.810	4.810
Total stockholders' equity	5.260	13.567	10.569	8.805	19.496	17.552	15.018	13.156	10.896	8.374	10.521	7.557	4.894	2.230	(0.433)	(3.097)
Total stockholders' equity and liabili	5.980	16.578	14.124	11.720	21.025	18.609	16.597	14.490	11.812	10.206	12.352	9.389	6.725	4.062	1.398	(1.265)

Balance Sheet Drivers

	Mar-18	Jun-18	Sep-18	Dec-18	Mar-19	Jun-19	Sep-19	Dec-19	Mar-20	Jun-20	Sep-20	Dec-20	Mar-21	Jun-21	Sep-21	Dec-21
	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Book & Cash Value (per share)																
Book Value per Share (diluted)				\$1.51	\$2.97	\$1.92	\$1.64	\$1.44	\$1.19	\$0.91	\$1.05	\$0.72	\$0.46	\$0.21	-\$0.04	-\$0.28
Cash per Share (diluted)				\$1.78	\$2.98	\$1.87	\$1.67	\$1.38	\$1.02	\$0.81	\$0.96	\$0.63	\$0.38	\$0.13	-\$0.12	-\$0.36
Net cash per Share (diluted)				\$1.78	\$2.98	\$1.87	\$1.67	\$1.38	\$1.02	\$0.81	\$0.96	\$0.63	\$0.38	\$0.13	-\$0.12	-\$0.36

Source: Company reports and Ascendant Capital Markets estimates

Atossa Therapeutics, Inc.

Cash Flow Statement (\$ mils)	Mar-18	Jun-18	Sep-18	Dec-18	2018	Mar-19	Jun-19	Sep-19	Dec-19	2019	Mar-20	Jun-20	Sep-20	Dec-20	2020	Mar-21	Jun-21	Sep-21	Dec-21	2021	
Fiscal Year End: December 31	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E	
Cash flow from operating activities																					
Net income	(1.874)	(4.143)	(3.310)	(2.078)	(11.405)	(4.073)	(7.263)	(3.286)	(2.618)	(17.240)	(2.947)	(3.906)	(3.700)	(4.000)	(14.554)	(3.700)	(3.700)	(3.700)	(3.700)	(14.800)	
Depreciation	0.008	0.010	0.011	0.016	0.044	0.014	0.014	0.013	0.013	0.053	0.012	0.012	0.012	0.012	0.049	0.012	0.012	0.012	0.012	0.050	
Amortization					0.000					0.000					0.000					0.000	
Debt related amortization expense					0.000					0.000					0.000					0.000	
Stock comp	0.215	0.179	0.332	1.737	2.464	0.276	5.319	0.752	2.498	8.844	0.688	1.036	1.036	1.036	3.797	1.036	1.036	1.036	1.036	4.146	
Deferred rent					0.000					0.000					0.000					0.000	
A/R reserves					0.000					0.000					0.000					0.000	
Deferred income taxes					0.000					0.000				0.000	0.000	0.000	0.000	0.000	0.000	0.000	
Change in fair value of warrant liability		1.557	0.623	(2.181)	0.000	1.742			(1.742)	0.000				0.000	0.000	0.000	0.000	0.000	0.000	0.000	
Writedowns and impairments					0.000		0.006			0.006			0.002		0.002					0.002	
Other gains/losses					0.000					0.000					0.000					0.000	
Other					0.000					0.000					0.000					0.000	
Changes in operating assets and liabilities:																					
Prepaid expenses & other curre	(0.245)	0.055	0.150	(0.220)	(0.259)	(0.326)	0.022	0.383	(0.432)	(0.353)	(0.475)	(0.127)	0.000	0.000	(0.602)	0.000	0.000	0.000	0.000	0.000	
Research and development tax	(0.038)	(0.230)	0.146	(0.038)	(0.160)	0.280	(0.168)	(0.163)	(0.171)	(0.222)	0.005	(0.026)			(0.021)					0.000	
Income tax					0.000					0.000					0.000					0.000	
Other assets	0.052	0.005	(0.171)	0.189	0.074	0.003	0.028	(0.002)	(0.024)	0.005	(0.108)	(0.129)	0.000	0.000	(0.238)	0.000	0.000	0.000	0.000	0.000	
Accounts payable	(0.167)	0.023	0.359	(0.197)	0.018	0.111	(0.146)	0.183	(0.208)	(0.060)	0.063	0.676	0.000	0.000	0.740	0.000	0.000	0.000	0.000	0.000	
Accrued expenses	(0.346)	0.710	(0.482)	0.354	0.237	(0.146)	(0.324)	0.352	(0.018)	(0.135)	(0.458)	0.229	0.000	0.000	(0.229)	0.000	0.000	0.000	0.000	0.000	
Other liabilities	0.008	0.000	0.043	(0.026)	0.024	(0.030)	0.010	(0.001)	(0.006)	(0.027)	(0.009)	0.003	0.000	0.000	(0.007)	0.000	0.000	0.000	0.000	0.000	
Net cash (used in) provided by	(2.387)	(1.833)	(2.298)	(2.444)	(8.962)	(2.149)	(2.502)	(1.769)	(2.708)	(9.128)	(3.230)	(2.229)	(2.651)	(2.951)	(11.062)	(2.651)	(2.651)	(2.651)	(2.651)	(10.605)	
Cash flow from investing activities																					
Purchases of property and equi	(0.051)	(0.000)	(0.003)	(0.056)	(0.111)		(0.008)			(0.008)		(0.007)	(0.007)	(0.007)	(0.020)	(0.007)	(0.007)	(0.007)	(0.007)	(0.026)	
Purchases of short-term investments					0.000					0.000					0.000					0.000	
Acquisitions					0.000					0.000					0.000					0.000	
Other					0.000					0.000					0.000					0.000	
Net cash used in investing acti	(0.051)	(0.000)	(0.003)	(0.056)	(0.111)	0.000	(0.008)	0.000	0.000	(0.008)	0.000	(0.007)	(0.007)	(0.007)	(0.020)	(0.007)	(0.007)	(0.007)	(0.007)	(0.026)	
Cash flow from financing activities																					
Issuance of debt					0.000					0.000				0.000	0.000	0.000	0.000	0.000	0.000	0.000	
Repayment of debt					0.000					0.000				0.000	0.000	0.000	0.000	0.000	0.000	0.000	
Issuance of stock		12.291			12.291					0.000	0.348	0.000	0.000	0.348	0.000	0.000	0.000	0.000	0.000	0.000	
Proceeds from stock option exercises					0.000	11.337				11.337			4.700	4.700	4.700					0.000	
Other					0.000					0.000				0.000	0.000					0.000	
Dividends and distributions					0.000					0.000				0.000	0.000					0.000	
Cash provided by (used in) fina	0.000	12.291	0.000	0.000	12.291	11.337	0.000	0.000	0.000	11.337	0.000	0.348	4.700	0.000	5.048	0.000	0.000	0.000	0.000	0.000	
Effect of exchange rate on cash					0.000					0.000					0.000					0.000	
Net increase (decrease) in cash	(2.438)	10.457	(2.301)	(2.500)	3.218	9.188	(2.510)	(1.769)	(2.708)	2.201	(3.230)	(1.888)	2.042	(2.958)	(6.034)	(2.658)	(2.658)	(2.658)	(2.658)	(10.631)	
Beginning cash and equivalents	7.272	4.835	15.292	12.991	7.272	10.490	19.678	17.169	15.400	10.490	12.691	9.461	7.573	9.615	12.691	6.657	4.000	1.342	(1.316)	6.657	
Ending cash and equivalents	4.835	15.292	12.991	10.490	10.490	19.678	17.169	15.400	12.691	12.691	9.461	7.573	9.615	6.657	6.657	4.000	1.342	(1.316)	(3.974)	(3.974)	

Source: Company reports and Ascendant Capital Markets estimates

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Atossa Therapeutics, Inc.

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HOLD: We expect the stock to provide a total return of negative 15% to positive 15% within a 12-month period.

SELL: We expect the stock to have a negative total return of more than 15% within a 12-month period.

Total return is defined as price appreciation plus dividend yield.

Ascendant Capital Markets, LLC Rating System

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Speculative Buy: This rating is reserved for companies we believe have tremendous potential, but whose stocks are illiquid or whose equity market capitalizations are very small, often in the definition of a nano cap (below \$50 million in market cap). In general, for stocks ranked in this category, we expect the stock to provide a total return of 50% or more within a 12-month period. However, because of the illiquid nature of the stock's trading and/or the nano cap nature of the investment, we caution that these investments may not be suitable for all parties.

Total return is defined as price appreciation plus dividend yield.

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Rating	Count	Percent	Investment Banking Services Past 12 months	
			Count	Percent
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Sell	0	0%	0	0%
Total	39	100%	14	36%

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