Active Biotech

Sector: Biotech

Derisked and Repurposed

Redeye initiates coverage of Active Biotech with a cautiously optimistic view on the new strategic direction. Increased clinical activity sets the shares up for several catalysts during next year. The Company is currently raising SEK 76m in a Rights Issue. If the capital raise is fully subscribed, we calculate a base case of SEK 3 per share.

Neglected Biotech Re-Emerging from Obscurity

Redeye believes the market has so far overlooked Active Biotech's new focused direction and increased project activities. We argue that the repurposing of the core compounds tasquinimod and laquinimod to orphan cancer indication Multiple Myeloma and inflammatory eye disorders, respectively, makes scientific and commercial sense. Also, we consider the projects as less risky than average from a safety perspective due to extensive clinical evidence in other indications. The current valuation is at the bottom end of clinical stage biotech peers, implying low expectations.

Short Term Factors Shroud Value of Core Projects

The shares have dropped about 50 percent in recent months on the back of major shareholder Nordstjernan reducing its holdings > 60 percent, the announcement of a share issue, and a changed protocol for partnered cancer project naptumomab to address antidrug antibody issues. We see upside potential if these concerns are attenuated. We view tasquinimod in Multiple Myeloma as a more valuable project (almost half of the portfolio value). If the current preclinical development of the new formulation of laquinimod is successful, investors should also start to acknowledge the prospects in eye disease Uveitis.

Upside Following Completed Rights Issue

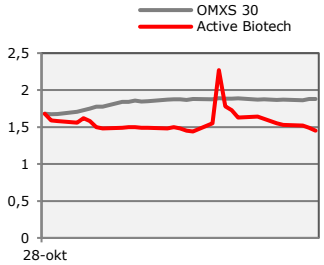
When the rights issue is completed, we see room for a recovery in the shares as clinical and preclinical activity ramps up. In a bull case, where ongoing preclinical and clinical studies are successful, there is further upside to SEK 4.4 in our valuation model. In a cautious scenario, where naptumomab fails and other project development is delayed, the fair value drops to 1.4 SEK.

KEY FINANCIALS (SEKm)	2018	2019	2020E	2021E	2022E	2023E
Net sales	20	8	7	9	0	104
EBIT	-30	-32	-31	-45	-44	66
EPS (adj.)	-0.3	-0.2	-0.2	-0.2	-0.2	0.3
EV/Sales	30.7	32.2	27.9	18.0	NA	1.7
EV/EBIT	NA	NA	NA	NA	NA	2.7
P/E	NA	NA	NA	NA	NA	4.8

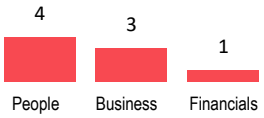
FAIR VALUE RANGE

BEAR	BASE	BULL
1.4	3.0	4.4

ACTI.ST VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	ACTI.ST
Market	Small cap
Share Price (SEK)	1.4
Market Cap (MSEK)	209
Net Debt 20E (MSEK)	-17
Free Float	74 %
Avg. daily volume ('000)	1

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Investment Thesis

Swedish veteran drug developer Active Biotech ("Active" or "the Company") is embarking in a new direction and repurposing its core assets in new indications in blood cancer and eye disorders. To support the new strategy, Active is currently raising some SEK 75m in a Rights Issue at a pre-money valuation of SEK 152m.

Since 2017, when Active Biotech lost 80 percent of its market value on disappointing clinical results for laquinimod in Multiple Sclerosis patients, the shares have been volatile and in a downward trend. Partner NeoTx has initiated clinical development of naptumomab in solid cancers, but the strategy for the internal projects has until recently been a question mark.

The majority of Board members have joined in the last two years and have added substantial international industry experience from, e.g., Novo Nordisk, Celgene, AstraZeneca, and Lilly. Following a review of the projects, the new Board in 2020 decided to streamline the portfolio and adopt a new development strategy for the core compounds.

New Strategy for Extended Mileage of Old Compounds

The new strategy builds on the extensive preclinical and clinical data to repurpose the old compounds in new niche indications. Some advantages are smaller study populations and relatively low clinical costs. Ongoing commercial and academic collaborations also contribute to cost-efficiency. A vital component of the strategy is improving market protection through Orphan Drug Designations and new medical use and formulation patents. The original substance patents for tasquinimod and laquinimod have expired.

Drug Development Credentials

The Active organization has more than 20 years of history in developing drugs for modulating the immune system. Alone and together with partners, it has conducted some 30 clinical trials. Historically, Active has been successful in striking partnerships with larger partners, including Teva and Ipsen.

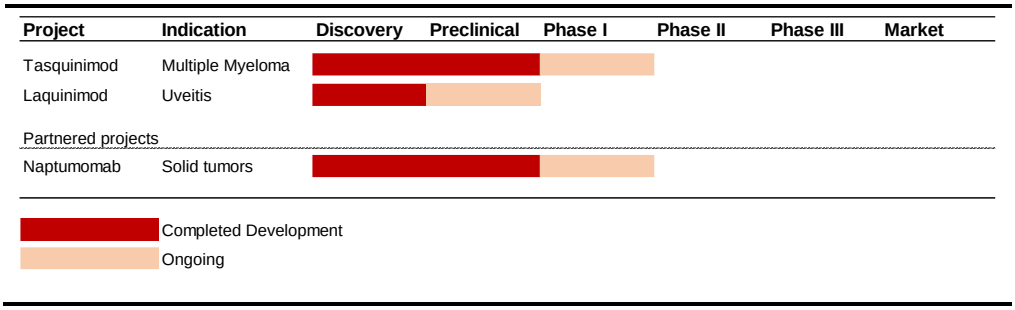
Rising to New Challenges

While Active's projects have a chequered history, all have demonstrated some level of clinical efficacy. We believe the mode of action and new supportive preclinical evidence provides a good rationale for investigating tasquinimod and laquinimod in new indications Multiple Myeloma and inflammatory eye disorder, respectively. Active's internal projects are first-in-class, have well-documented safety profiles, and generally permit easy administration. We consider these characteristics promising to complement current treatment. Active already has two projects (naptumomab and tasquinimod) in clinical development and plans to add another (laquinimod) in twelve months.

Depressed Valuation

The current market cap of about SEK 220m is at multi-year lows and reflects modest expectations, in our view. The implied technology value is significantly lower than most clinical-stage peers. The current valuation is also a fraction of the SEK 3.3bn that shareholders have invested in the Company. Investor concern about long term financing has likely been a factor, and the Rights Issue will lower perceived risks. If the current Rights Issue is fully subscribed, we calculate a base case of SEK 3.

Project Pipeline



Source: Active Biotech

Besides the current projects, the Company has paused the development of paquinimod (Systemic Sclerosis – completed Phase I trials) and the SILC-project (new substances targeting S100A9 in cancer treatment – preclinical development).

Key Catalysts

Safety Update From Partnered Project. Partner NeoTx plans a safety update regarding an ongoing Phase Ib trial with naptumomab in solid tumors (combination with checkpoint inhibitor Imfinzi) in Q1, 2021. Recently, NeoTx has revised the study protocol to include premedication to eliminate anti-drug antibodies. Arguably, this issue could raise the hurdle for further clinical development.

Capital Raise. We estimate that the recently announced Rights Issue (some SEK 75m) will fund operations for about two years if fully subscribed. The subscription period is from 7 January to 21 January 2021.

Updates on Internal Projects. During 2021, we expect crucial news flow for the internal projects, including i) a safety update on tasquinimod monotherapy in Multiple Myeloma and possible subsequent expansion to combination therapy (H2 2021) ii) completion of preclinical development for topical laquinimod iii) possible initiation of two clinical trials in eye disorder uveitis.

Counter Thesis

Early Stage Projects. Active Biotech's project portfolio is still at an early stage of development. Consequently, there is a high risk of attrition, and timelines are still uncertain by nature. Active and its partner NeoTx are targeting competitive markets in cancer treatment.

"Damaged Goods." Previous failures in late-stage clinical development could mean an uphill struggle to attract potential investors' interest before the old, repurposed compounds have demonstrated positive clinical evidence in the new indications.

Potential Selling Pressure From Nordstjernan. Long-term major shareholder Nordstjernan has, during recent months, reduced its holding from 13 percent to below five percent. It is the first time Nordstjernan is a seller of Active Biotech shares since 2004. Nordstjernan has communicated it wants to concentrate its portfolio on larger companies (market capitalization over SEK 1bn). Likely further selling over the market could create a share overhang in the short term.

Company Description

Active Biotech is a Swedish clinical-stage Biotech company developing drugs to treat cancer, inflammatory eye disease, and autoimmune diseases. The Company was founded when investment company Active acquired SBL Vaccin AB from the Swedish Government and Lund Research Center AB from Pharmacia & Upjohn in 1997-98.

Clinical Development Resulted in Several Partnering Deals

During the following years, activities focused on clinical development in oncology and neurodegenerative diseases. A significant milestone was the global licensing agreement for the laquinimod (LAQ) project with Israeli pharmaceutical company Teva in 2004 for up to USD 92m in upfront and milestone payments, plus double-digit royalties on sales. Teva developed laquinimod mainly in CNS indications (Multiple Sclerosis (MS) and Huntington's Disease) and started clinical trials in autoimmune diseases.

In oncology, Active developed tasquinimod (TASQ), an immune-modulating and anti-angiogenic compound, in prostate cancer. Following a successful Phase II trial, French Ipsen in 2011 licensed the rights to tasquinimod in castrate-resistant prostate cancer outside North and South America and Japan for EUR 200m.

Also in oncology, Active developed the biological immunotherapy ANYARA through a Phase II/III trial in metastatic renal cell carcinoma. Although a posthoc analysis revealed clinical efficacy in a subgroup, ANYARA treatment did not improve overall survival in the intention-to-treat population, and Active subsequently abandoned development. However, the molecule generated outside interest, and in 2016 Israeli biotech company NeoTX licensed the rights to ANYARA in cancer treatment for around USD 71m in potential milestone payments. NeoTx has subsequently dropped the name and refers to the project as naptumomab estafenatox ("naptumomab").

Regained Rights to Laquinimod and Tasquinimod after Clinical Setbacks

Teva abandoned the development of laquinimod in MS after three Phase III trials, after three Phase III trials with similar results but with primary endpoint reached only in one study. In 2018, Teva returned the rights to laquinimod to Active Biotech after a Phase II trial in Huntington's Disease where laquinimod did not meet the primary endpoint.

In a Phase III trial in metastatic prostate cancer, TASQ demonstrated a benefit in the primary endpoint Progression-Free Survival. However, as overall survival did not improve vs. placebo, Ipsen did not proceed with an application for marketing approval and returned the rights to Active in 2015.

Over the years, the Company has streamlined operations, and the organization now consists of eight employees, about one-tenth compared to ten years ago. In 2019, Active sold its Lund property of research facilities. It currently operates as a virtual biotech organization.

Following a strategic review in 2019 by external consultants, Active Biotech will focus on tasquinimod's clinical development in Multiple Myeloma and laquinimod in inflammatory eye disorder. Also, partner NeoTx develops naptumomab (previously referred to as ANYARA) in solid tumors as combination therapy with anti-PD-L1 treatment.

People and Ownership

The management consists of a small, experienced team. The CEO was previously Chief Scientific Officer and has led the research and clinical development of the Company's projects in neurodegenerative diseases and cancer.

Active Biotech Management Group

Name	Position	Experience
Management		
Helén Tuvesson	CEO	Helén Tuvesson is the CEO since 2017. She has been employed by Active Biotech since 1998 and was previously CSO for six years. Tuvesson has a PhD in cell and molecular biology in medical science from Lund University. Tuvesson holds 36,892 shares.
Hans Kolam	CFO	Hans Kolam was appointed CFO in 2000. Prior to Active Biotech, Hans was employed at Pharmacia. He as a BSc in Business Adminstration from Uppsala University. He has more than 40 years of experience from leading financial positions in the pharmaceutical industry. He also has extensive experience from Business Development. Hans holds 63,461 shares.
Helena Eriksson	Chief Scientific Officer	Helena Eriksson was appointed Head of Research in 2017 and has been employed by the Company since 1998. She has a PhD in experimental hematology from Lund University. Previously, Helena was Head of Biology operations at Active Biotech. She has more than 15 years of experience of leadership roles in projects, science and line operations. Helena owns 23,294 shares.

Source: Active Biotech, Redeye

The Board composition has changed significantly since 2018, adding considerable relevant international BioPharma experience. We view these steps as positive and believe an active board with the right background is instrumental in supporting the new strategic direction of Active Biotech.

Active Biotech Board

Name	Position	Experience
Board of Directors		
Michael Shalmi	Chairman	Dr Michael Shalmi is Chairman since 2019. He is a Danish citizen and has extensive experience from research, clinical development and investment in the BioPharma industry. Between 2009 and 2009, Dr Shalmi held leading postitions in Novo Holding A/S, most recently as Head of Principal investments. He spent 15 years at Novo Nordisk e.g., as Vice President, Global Development, Clinical Operations Management. Michael Shalmi holds 93,906 shares in Active Biotech.
Aleksandar Danilovski	Director	Aleksandar Danilovski was appointed Director in 2020. He has a PhD in Chemistry from Cambridge University and University of Zagreb. He is CSO of Danish Xellia Pharmaceuticals, specialized in production of anti-biotics. Aleksandar owns 39,350 shares.
Axel Glasmacher	Director	Dr Alex Glasmacher was appointed Director in 2020. He is an adjunct professor of medicine at the University of Bonn. Dr Glasmacher has been Head of Global Clinical R&D and Senior Vice President for Celgene. He is member of the Clinical Advisory Board of Oncopeptides AB, and member of the Board of Cancer DrugDevelopment Forum. He owns 40,000 shares.
Uli Hacksell	Director	Uli Hacksell was between 2018 and 2020 interim CEO of Medivir and sits on the board of Medivir. He served as CEO of US ACADIA Pharmaceuticals for 15 years. In the 1990s, he held senior positions at Astra AB, prior to which he was a Professor of Organic Chemistry at Uppsala University. Uli was appointed Director in 2019 and holds 21,000 shares.
Elaine Sullivan	Director	Dr Elaine Sullivan has a Ph.D. in Molecular Virology from the University of Edinburgh. She is the CEO and Co-Founder of Curadh Pharmaceuticals and was previously CEO of Carrick Pharmaceuticals, which she also co-founded. Dr Sullivan has been Vice President Global External Research & Development at Lilly and held senior positions in R&D at AstraZeneca. She currently sits on the board of Evotec AG. She holds no shares in Active Botech.
Peter Thelin	Director	Peter Thelin has been on the board since 2011. He holds 2.9m shares in Active Biotech. Peter is the CEO of Carve Capital AB and has extensive experience from the financial industry and has ownership in, and sits on the board of, Brummer & Partners AB.

Source: Active Biotech, Redeye

The largest shareholder is MGA Holding AB, controlled by Mats Arnhög. MGA are long-term holders for almost 20 years. Investment company Nordstjernan is the second largest owner and is a long-term investor since 2004. It has reduced its holdings by more than 60 percent (per 11 December 2020) to less than five percent of the capital in recent months. According to holdings.se, this year is the first time Nordstjernan is a seller. The Third and Fourth National Pension Funds are the largest institutional shareholders. Active Biotech has a large shareholder base of small owners (about 13,800) concerning its market cap.

Ownership Structure

Ownership structure as of 30 Nov, 2020	Holdings	Capital
MGA Holding AB	38 001 405	26.2%
Nordstjernan	9 893 532	6.8%
Avanza Pension	8 695 094	6.1%
Handelsbanken Liv	8 311 189	5.7%
Fjärde AP-fonden	3 908 724	2.7%
Tredje AP-fonden	3 893 722	2.7%
Peter Thelin	2 920 000	2.0%
SEB-Stiftelsen	1 838 460	1.3%
Vidarstiftelsen	1 745 692	1.2%
Madeleine Lennhammer	1 484 226	1.0%
Total	**145 236 480**	**100.0%**

Source: Holdings

Share Price Development

The share price tells a cautionary tale of drug development and reflects the impact of the clinical setbacks. Currently, the valuation is at the lowest point since the end of 2017. Still, until recently, none of the principal shareholders have capitulated.

During 2017, the share price fell sharply following the read-out from two clinical trials with laquinimod in two different Multiple Sclerosis (MS) populations. In May 2017, top-line results got the Phase III CONCERTO trial in relapsed patients (RRMS) were announced. Although laquinimod treatment reduced the risk of relapse and brain atrophy compared to placebo, the study did not meet the primary endpoint of reduced disease progression. In December the same year results from a Phase II trial in primary progressive MS (PPMS) demonstrated no benefit in brain atrophy over placebo.

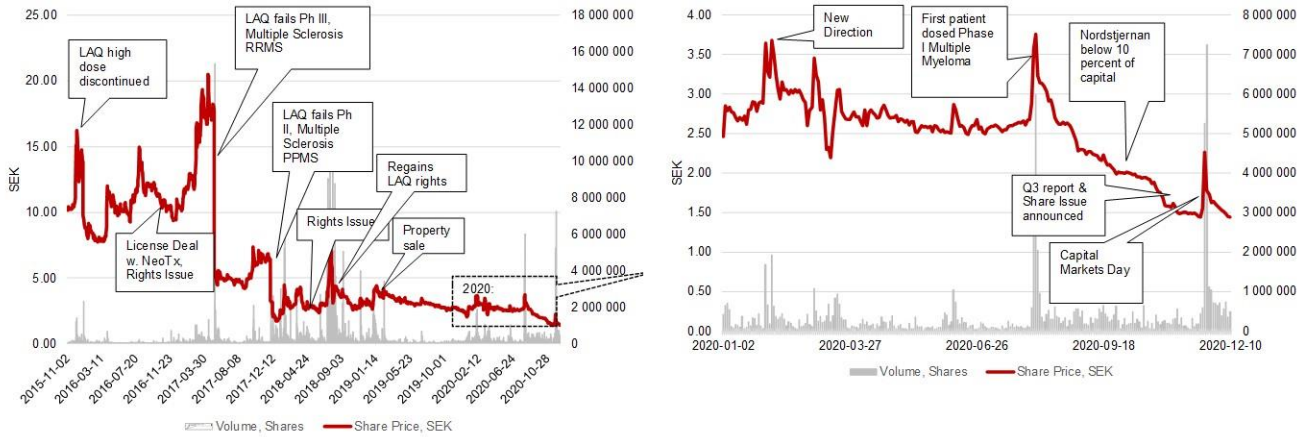
New Direction from 2020, But Nordstjernan Opts Out

Following a detailed analysis of the internal project portfolio in collaboration with external consultants Catenion, Active Biotech at the beginning of 2020 announced the decision to focus development to tasquinimod and laquinimod to Multiple Myeloma and inflammatory eye disease, respectively. Simultaneously, Active announced an academic partnership with The Perelman School of Medicine, University of Pennsylvania, for the clinical development of tasquinimod as a new immunomodulatory product to treat Multiple Myeloma. The Company would also explore potential partnerships for laquinimod in Crohn's disease based on promising clinical data in this indication.

The shares reacted positively to the news, but the pandemic struck global stock markets shortly after. While Active stated that it had funds to finance operations until the end of 2021, there was a need for longer-term financing to support the new clinical ambitions.

During the second half of 2020, the shares have resumed a downward trend. We believe the main reason is selling from Nordstjernan as well as the share issue.

Share Price Development



Source: Bloomberg, Redeye Research

Tasquinimod – Potential First-in-Class Myeloma Treatment

Two-Pronged Anti-Cancer Mechanism

Tasquinimod is a small molecule that binds to a protein, S100A9, secreted by immune cells. S100A9 is involved in many biological processes, including inflammation, migration, invasion, and angiogenesis.

Extracellular S100A9 can interact with RAGE and Toll-like Receptor 4 to initiate inflammatory cascades through the NFkB pathway, inducing immune cells to secrete pro-inflammatory cytokines TNFα, IL-1β, IL-6, and IL-8. This process also recruits immunosuppressive Myeloid-Derived Suppressor Cells. These cells reduce the immune response to tumors, leaving room for tumor growth and metastasis. By blocking S100A9, tasquinimod may inhibit tumor-promoting inflammation.

Preclinical studies indicate that tasquinimod has an additional mechanism of action in cancer treatment by blocking the formation of histone deacetylase complexes and thereby suppressing angiogenesis (formation of blood vessels).

Clinical Evidence So Far

Active Biotech and partner Ipsen have investigated tasquinimod as a monotherapy in some 1,000 metastatic prostate cancer patients. In a Phase III trial, there was a significant improvement in Progression-Free Survival versus placebo. However, this did not translate into any Overall Survival benefit. The program, a co-development with partner Ipsen, was subsequently terminated. The clinical evidence suggests that tasquinimod has limited efficacy as a monotherapy in solid tumors.

Tasquinimod has demonstrated overall good tolerability. Patients treated with tasquinimod had a higher incidence of cardiovascular events versus the control group (serious adverse advents: 3.9 % vs. 1.9%) in the Phase III trial. These observations are common among anti-angiogenic treatments.

Academic Collaboration Holds Back Development Costs

In 2015, the Company filed for a method patent for tasquinimod for the treatment of Multiple Myeloma, following promising preclinical observations. The following year Active Biotech was granted Orphan Drug Designation by the FDA in this indication.

In 2018, Active initiated a collaboration with The Wistar Institute in Philadelphia for preclinical research to guide clinical development in Multiple Myeloma. The Wistar Institute is a non-profit research institution in biomedical research and a designated cancer center in the US National Cancer Institute (NCI) network.

In 2020, The Wistar research group presented results at the EHA conference showing potent anti-tumor-activity from tasquinimod treatment in several preclinical multiple myeloma models (see below).

For the initial clinical development, Active is collaborating with Abramson Cancer Center, University of Pennsylvania. The collaboration has received grants for a Phase Ib/IIa trial from the Leukemia & Lymphoma Society. Active Biotech supplies the clinical material of tasquinimod and pays for drug administration and data management.

Multiple Myeloma: Many Treatments, No Cure

Multiple Myeloma is a hematological malignancy characterized by the proliferation of malignant plasma cells in the bone marrow. These crowd out normal cells out of the marrow. As the bone marrow is the primary site of new blood cell production, there are severe consequences over time. Multiple Myeloma symptoms include low blood count, increased susceptibility to infections and bleeding, bone destruction, and renal damage. Multiple Myeloma cells produce specific antibodies called M-protein with little function, and high levels of M-proteins is a biomarker for the disease.

Multiple Myeloma is relatively rare and primarily affects adults over 40. Less than one percent of the population will be diagnosed during their lifetime.

Autologous hematopoietic stem cell transplant (ACT) is the standard of care for newly diagnosed patients for some 25 years. It consists of collecting stem cells from the blood or the bone marrow, treating high-dose chemotherapeutics to kill myeloma cells, and subsequent infusion of the collected stem cells. ACT has dramatically improved responses, but not all patients are eligible due to the severe myeloablative therapies required for a successful transplant.

Before ACT, patients receive induction drug therapy. Patients also receive consolidation and maintenance therapy post-transplant.

Recommendations for transplant-ineligible patients are a minimum of an immunomodulatory drug plus steroids. Triplets with proteasome inhibitors should be considered.

Today's main classes of drug treatment are immune-modulatory imide drug (IMiDs), alkylating agents, proteasome inhibitors, and anti-CD38 antibodies. Successful combinations with some or several of these drug classes are essential to penetrate earlier treatment lines in Multiple Myeloma.

Major Drug Classes in Multiple Myeloma

IMiDs

FDA approved lenalidomide (Revlimid) in 2006 for relapsed/refractory Myeloma. Subsequently, use has expanded into front-line and maintenance treatment in transplant eligible and transplant-ineligible patients. Revlimid is a remarkable commercial success, and sales in 2019 were USD 10.8bn.

Lenalidomide is a derivative of thalidomide, the sedative drug infamously banned in the 1960s for causing severe birth defects. Thalidomide was reintroduced as an anti-inflammatory and anti-cancer agent at the end of the 1990s, which in turn spurred research into developing safer and more potent analogs. Regulators approved lenalidomide before its mechanism of action was fully understood. However, it is considered an immune modulator, both stimulating immune response and inhibiting pro-inflammatory cytokines and angiogenesis (growth of new blood vessels).

Pomalidomide (Pomalyst) is a third-generation IMiD, and similar to lenalidomide, Celgene developed it. Pomalyst is indicated for later lines of treatment. Although considered best-in-class, Celgene/Bristol Myers is unlikely to put it head-to-head with its flagship drug lenalidomide for some time yet.

IMiDs are small molecules administered orally.

Proteasome inhibitors

Clinicians often prescribe Proteasome inhibitors (PIs) in combination with IMiDs. They bind to proteasome in the cells, i.e., structures that dispose of protein waste. In cancer cells, the amount of waste protein produced is much more considerable than in healthy cells. By inhibiting proteasomes, PI:s disrupts the disposal process, and the cells blow up from accumulated waste. Approved PIs include Kyprolis, Ninlaro, and Velcade.

Alkylating agents

Melphalan is a chemotherapeutic that belongs to the class of nitrogen mustard alkylating agents. It is primarily used as a conditioning treatment before stem cell transplantation in Multiple Myeloma. Swedish Oncopeptides is developing a prodrug of melphalan (melflufen).

Anti-CD38

CD38 is a target on the surface of many immune cells. It is highly expressed on myeloma cells. In 2015, Daratumumab (Darzalex) became the first approved antibody treatment targeting CD38. It kills CD38-expressing tumor cells by direct anti-tumor effect as well as indirect immune-modulatory mechanisms. Darzalex has become the second best-selling drug in Multiple Myeloma and is the preferred drug for treating patients resistant to IMiDs and PIs. It has shown competitive activity across all treatment lines, and the safety profile is benign compared to many other Myeloma drugs, making it suitable for combinations.

Emerging Treatments

Emerging therapies under development include drugs targeting BCMA, a target on B-cells responsible for B-cell maturation. It is only expressed on plasma cells and overexpressed on multiple myeloma cells, making it a "clean" drugable target. There is currently a rush to bring BCMA-targeting drugs to the market, including antibodies, antibody-drug conjugates, bispecific antibodies, and CAR-T-cell therapies.

Rationale For Tasquinimod in Multiple Myeloma

Differentiated Mode of Action

Historically, immune-modulating drugs have been the most successful approach in Multiple Myeloma besides stem cell transplant. As tasquinimod also is an *immune modulator*, but with *a differentiated mechanism of action* compared to, e.g., Revlimid, there is a rationale to investigate it either as a complement to IMiDs or as a substitute for patients that respond poorly to this drug class. Cross-resistance within the dominating drug classes hampers current therapies' efficacy, underlining the need for new treatment modalities.

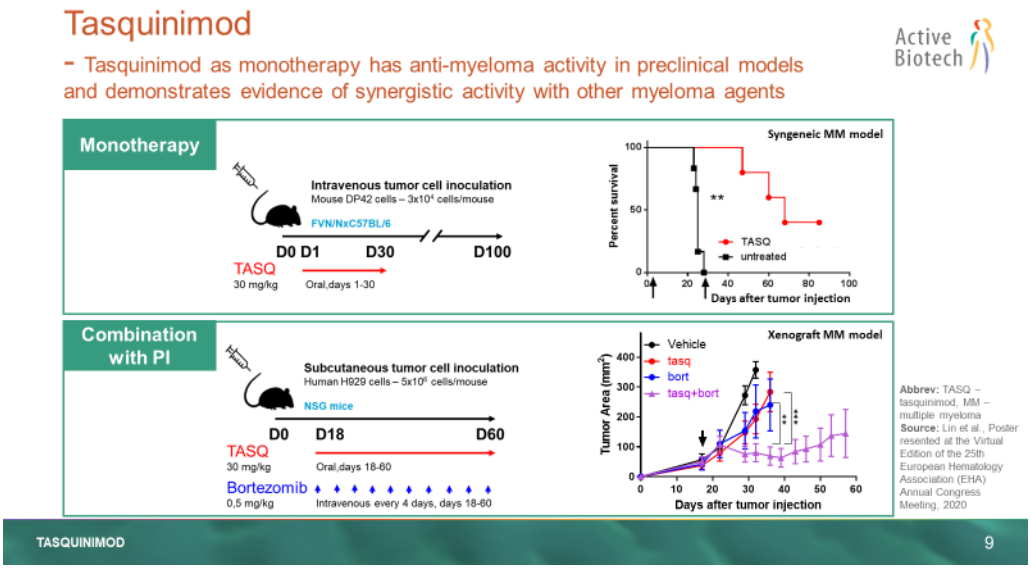
Well Tolerated and Easy Administration

Tasquinimod is an oral treatment and has shown good tolerability in previous clinical trials. In the ongoing Phase I/IIa-trial, Active will investigate tasquinimod as an all-oral combination treatment with approved regimen IRd in advanced-stage patients.

Preclinical Evidence

Preclinical investigations by researchers at renowned The Wistar Institute demonstrated that tasquinimod monotherapy resulted in a significant tumor growth reduction and increased survival compared to placebo in Multiple Myeloma disease models. There were also synergies in efficacy in combining tasquinimod with established multiple myeloma treatments lenalidomide and (especially) bortezomib, as the combination therapies reduced tumor growth more efficiently than the single agents on their own. The preclinical evidence suggested that tasquinimod activity was mediated by alterations in the tumor microenvironment by inhibiting S100A9. We note that the "proof of principle" in the preclinical tests was based on a relatively high 30 mg/kg dose.

Proof of Principle in Preclinical Models of Multiple Myeloma: Tasquinimod monotherapy (" tasq") (top) and tasquinimod in combination with Proteasome Inhibitor Velcade/bortezomib (" tasq+bort").



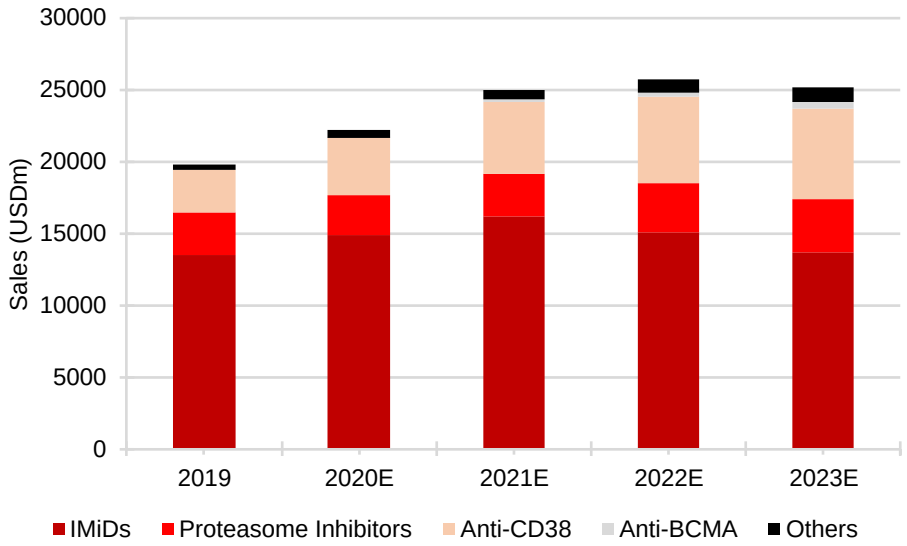
Source: Active Biotech

A Growing USD 20bn Market

SEER expects some 32,000 new cases of Multiple Myeloma in the US in 2020. The prevalence is 140,000.

The market is growing as i) survival trends are improving ii) most patients eventually relapse and progress through several lines of treatment iii) there is an increasing number of (highly-priced) treatment modalities. Median life expectancy is some 7-8 years and has about doubled during the last 20 years due to the introduction of more effective treatments as alternatives to traditional cytotoxic agents.

Multiple Myeloma Drug Market



Source: Biomedtracker August 2020

According to consensus estimates collected by Datamonitor, the market is currently valued at about USD 20bn and is expected to surpass USD 25bn in the next couple of years. The expected main growth driver is antibody treatment Darzalex (anti-CD38) penetrating multiple lines of treatment. Analysts also expect oral proteasome inhibitor Ninlaro to gain share. Pipeline drugs such as Melflufen and several BCMA-targeting modalities are not included in the forecast.

The Patient Pool of Advanced Cases is Growing

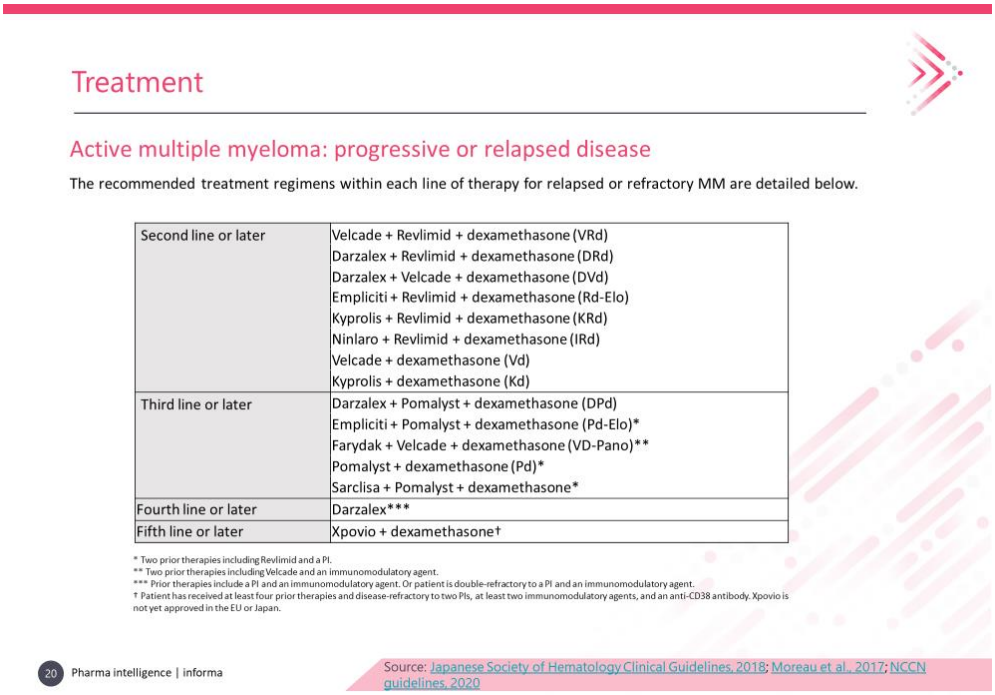
Many newly diagnosed Multiple Myeloma patients initially go into long term remission or are not actively treated beyond stem cell therapy or induction therapy. For example, in the US, only roughly half of around 140,000 prevalent cases are actively treated with drugs.

However, there is no cure for Multiple Myeloma, and patients inevitably relapse despite advances in treatment options. As a result, the patient pool of drug-treated relapsed/refractory patients is larger than the number of first-line patients. According to various estimates, the drug-treated population in second-line treatment and beyond is between 40,000 and 80,000 in the US alone.

This field is dynamic and competitive, with a multitude of treatment options. There is no standard treatment, and drug regimens depend on many factors such as age, prior

therapies, and general performance status. A challenge for patients is acquired drug resistance and the need to switch therapy due to repeated relapses. Further, there is substantial cross-resistance within the major drug classes, i.e., a patient that has progressed on one immunomodulatory drug is less likely to respond to another. Hence, there is a demand for even more treatment modalities. Unlike first-line treatment, where Revlimid is ubiquitously prescribed, there are no dominant drug regimens in the second-line or later.

Treatment Options for Progressive or Relapsed Disease



Treatment

Active multiple myeloma: progressive or relapsed disease

The recommended treatment regimens within each line of therapy for relapsed or refractory MM are detailed below.

Second line or later	Velcade + Revlimid + dexamethasone (VRd) Darzalex + Revlimid + dexamethasone (DRd) Darzalex + Velcade + dexamethasone (DVd) Empliciti + Revlimid + dexamethasone (Rd-Elo) Kyprolis + Revlimid + dexamethasone (KRd) Ninlaro + Revlimid + dexamethasone (IRd) Velcade + dexamethasone (Vd) Kyprolis + dexamethasone (Kd)
Third line or later	Darzalex + Pomalyst + dexamethasone (DPd) Empliciti + Pomalyst + dexamethasone (Pd-Elo)* Farydak + Velcade + dexamethasone (VD-Pano)** Pomalyst + dexamethasone (Pd)* Sarclisa + Pomalyst + dexamethasone*
Fourth line or later	Darzalex***
Fifth line or later	Xpovio + dexamethasone†

* Two prior therapies including Revlimid and a PI.
** Two prior therapies including Velcade and an immunomodulatory agent.
*** Prior therapies include a PI and an immunomodulatory agent. Or patient is double-refractory to a PI and an immunomodulatory agent.
† Patient has received at least four prior therapies and disease-refractory to two PIs, at least two immunomodulatory agents, and an anti-CD38 antibody. Xpovio is not yet approved in the EU or Japan.

20 Pharma intelligence | informa

Source: Japanese Society of Hematology Clinical Guidelines, 2018; Moreau et al., 2017; NCCN guidelines, 2020

Source: Datamonitor

Single-Agent Activity Could Lead to Accelerated Approval

The fastest road to market approval in Multiple Myeloma is by demonstrating single-agent activity (+/- dexamethasone) in late-stage relapsed/refractory patients. Several examples (daratumumab, selinexor, Blenrep) show that regulators accept Phase II results as the basis for an Accelerated Approval (no control required) and Objective Response Rate as the primary endpoint. It is subsequently feasible to direct clinical development towards combination therapy for earlier lines of treatment.

As illustrated below, data from recently approved agents and pipeline projects show response rates of 25%+ in advanced RRMM settings. We believe that the benchmark for tasquinimod as a single agent is tumor response in 20-25 percent of patients (the range depending on the patient population's status). New emerging therapies targeting BCMA have shown promising responses; however, newly approved BLENREP comes with a high risk of eye disorders.

Clinical Results in Advanced Relapsed/Refractory Patients (RRMM)

Single Agent activity in RRMM					
Treatment	**Drugs**	**Prior Lines of therapy**	**ORR**	**mPFS**	**mOS**
Prot. Inhibitor	Carfilzomib	5	24%	3.7	15.6
Anti-CD38	Daratumumab	5	29%	3.7	17.5
IMiD	Pomalidomide+ dex	5	33%	4.2	16.5
Alkylating Agent	Melflufen + dex	5	29%	4.2	11.6
SINE	Selinexor	7	26%	3.7	8.6
anti-BCMA ADC	Blenrep	7	31%	NA	NA
anti-BCMA CAR-T	ide-cel	6	73%	8.8	19.4

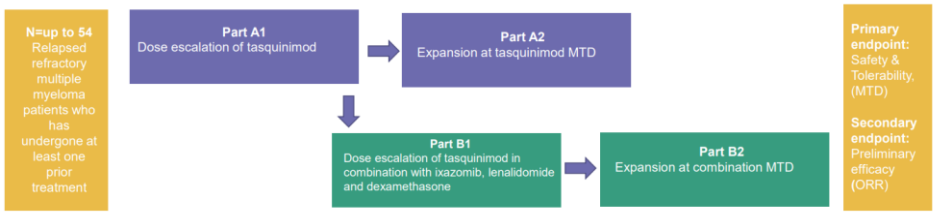
Source: Redeye. ORR: Objective Response Rate. mPFS: median Progression-Free Survival (months). mOS: median Overall Survival (months)

For combination therapy, we believe regulators will require a controlled Phase III trial.

Clinical Development has Started

In July, the first patient was enrolled in a Phase Ib/IIa trial to investigate tasquinimod +/- IRd therapy in relapsed or refractory Multiple Myeloma. For the trial, Active collaborates with Abramson Cancer Center at the University of Pennsylvania, the clinical site. The study will enroll up to 54 patients and consists of two parts – dose-escalation and dose-expansion – in two treatment arms (monotherapy and combination therapy, respectively).

Phase I/IIa Study Design



Source: Active Biotech. MTD: Maximum Tolerated Dose. ORR: Objective Response Rate.

Active Biotech expects the first read-out in H2, 2021, from "Part A1", i.e., monotherapy dose escalation. If there are no significant safety issues, the investigators will start monotherapy dose expansion ("Part A2") and combination therapy dose escalation ("Part B1") studies. The aim is to explore higher doses than those used in the prostate cancer trials (up to 1.5 mg daily compared to 0.5 to 1 mg previously).

If the "Part A" trials are successful, Active Biotech plans a larger Phase II monotherapy trial. As mentioned above, Phase II results could serve as a basis for Accelerated Approval in advanced-stage patients. From similar examples (HORIZON (Oncopetides) and STORM (Karyopharm) trials), we expect 120 to 160 patients to be required. We believe the most likely scenario is that Active will need to conduct a Phase II trial on its own before partnering.

Possibility for an All-Oral Treatment

IRd is a triplet combination of proteasome inhibitor ixazomib (brand name: Ninlaro), lenalidomide, and dexamethasone. It is an all-oral therapy indicated for patients who have received at least one prior treatment. IRd is generally considered more tolerable than other triplets such as VRd (Velcade + lenalidomide and dexamethasone) and KRd (Kyprolis + lenalidomide and dexamethasone) and thus an option for older and frailer patients.

However, Kyprolis is considered more efficacious. Velcade and Kyprolis are administered intravenously or subcutaneously.

Clinical Results Proteasome Inhibitor Triplets

Proteaseome Inhibitors						
Treatment	**Proteasome Inh.**	**Prior Lines of therapy**	**ORR**	**mPFS**	**mOS**	**SAE vs control**
IRd	Ixazomib	1	78%	20.6	NR	-2%
KRd	Carfilzomib	2	87%	26.3	NR	3%

Source: Redeye. ORR: Objective Response Rate. mPFS: median Progression-Free Survival. mOS: median Overall Survival. SAE: Serious Adverse Events.

The rationale for the chosen combination is to develop an all-oral treatment for second-line treatment or later. In theory, tasquinimod looks like a good fit with Ninlaro. Datamonitor expects Ninlaro sales to reach USD 2bn in 2023.

Sales Forecasts for Tasquinimod

We believe the main sales potential for tasquinimod is as a combination therapy with the Ninlaro triplet IRd. Biomedtracker expects Ninlaro to reach a penetration of 8-10 percent in second-line or later drug treatment. We assume that tasquinimod if the clinical development is successful, can become an established add-on to Ninlaro.

We expect lower sales as monotherapy due to expected fierce competition in advanced stage Multiple Myeloma and shorter average time on therapy. Still, monotherapy is an opportunity to get to the market, likely through an Accelerated Approval pathway.

We base drug-treated populations on estimates from Datamonitor. Price per treatment is assumed net prices, assuming some inflation. As a comparison, ixazomib has a list price of some USD 11,000 per four-week cycle in the US.

Sales Forecasts for Tasquinimod

Peak sales, MM	USA	5EU	JAP
Peak sales year	2032	2036	2035
Monotherapy 4L+			
Drug treated population	12 000	5 000	
% treated with TASQ	11%	13%	
Patients treated with TASQ	1 350	625	
Price per month (USD)	8 900	6 800	
Avg. months of treatment	4	4	
Sales TASQ (USDm)	**48**	**17**	
Combination, 2L+			
Drug treated population	61 000	41 100	
% treated with ixazomib	8%	10%	
% treated with TASQ	4%	7%	
Patients treated with TASQ	2 395	2 874	1 400
Price per month (USD)	8 900	6 800	6 800
Avg. months of treatment	9.7	9.2	9.6
Sales TASQ (USDm)	**208**	**180**	**92**
Total sales TASQ (USDm)	**256**	**197**	**92**

Sources: Redeye, Datamonitor

In sum, we forecast peak sales of USD 400-500m.

Eyeing New Opportunity for Laquinimod

Laquinimod is the oldest and most thoroughly investigated substance in the Active Biotech portfolio. It is a quinoline derivative. Laquinimod is modified roquinimex; a compound investigated in multiple sclerosis (MS) until the monitors halted the development due to severe cardiac adverse events in a phase III trial.

Preclinical research has demonstrated that laquinimod has anti-inflammatory properties. It activates the aryl hydrocarbon receptor (Ah) on antigen-presenting immune cells (APCs), skewing the APCs towards an anti-inflammatory phenotype. This results in an increase in regulatory T-cells and a reduction in pro-inflammatory effector T-cells. Preclinical and clinical studies in neuroinflammatory and neurodegenerative diseases such as MS and Huntington's disease have demonstrated laquinimod's ability to cross the blood-brain barrier.

Teva further conducted a clinical Phase II trial in moderate to severe Crohn's disease, i.e., Inflammatory Bowel Disease. Low dosing of laquinimod (0.5 mg) showed promising efficacy; 48 percent were in clinical remission per patient-reported outcome after eight weeks vs. 16 percent for placebo. Sixty-two percent responded to treatment. These rates were encouraging, albeit from a small subgroup (26 evaluable patients) and a short follow-up. However, higher doses were unexpectedly inefficacious.

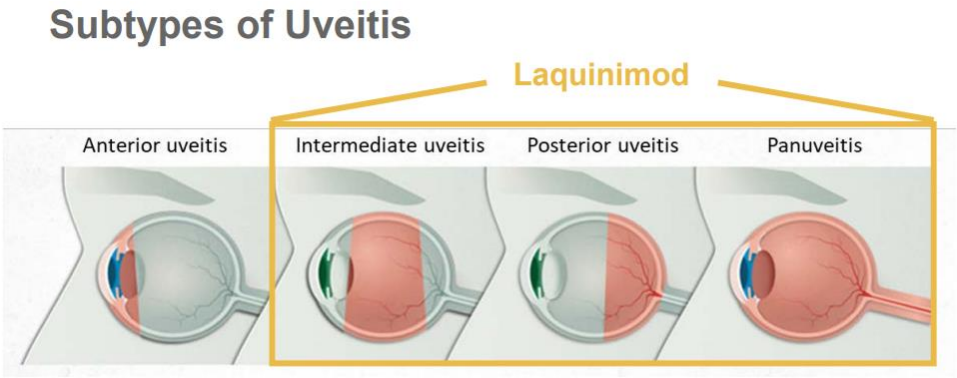
In 2018, Teva returned all rights to laquinimod to Active. Following the strategic review in 2019-2020, Active has identified inflammatory eye disorders, primarily Uveitis, as the focus area for further development.

Unmet Medical Need for Severe Uveitis

Uveitis is inflammation of the uveal, middle layer of the eye. Parts of the uvea include the iris, the ciliary body, and the choroid. Infections sometimes cause Uveitis, but the non-infectious type is more common (idiopathic or a complication from, e.g., autoimmune disease). Symptoms include eye redness, pain, and blurred vision. Severe cases can cause significant visual impairment or blindness from, e.g., Macular Edema, retina scarring, retina detachment, glaucoma, and cataracts. It is categorized based on location; Uveitis in the front of the eye is the more common and milder form, while back of eye uveitis often leads to severe complications.

Thorne, J. et al.," Prevalence of Non-infectious Uveitis in the United States," *JAMA Ophthalmology*, 2015, estimates 322,000 prevalent cases of non-infectious Uveitis in the US, based on a US insurance claims database. A minority of manifestations (20-40 percent) are non-anterior (Thorne, J. et al. (, 2015), Boughardt-Peebo, B., et al.," Uveit kan vara tecken på allvarlig systemsjukdom," *Lakartidningen.se* 2016-09-20).

Uveitis is Categorized Based on Location



Source: Active Biotech

Around 40 percent of non-anterior uveitis patients develop Macular Edema. Macular Edema is fluid building up in the macula, the area in the center of the retina at the back of the eye. The consequent swelling of the macula distorts vision. Symptoms are blurry vision in the center of the field of vision. The direct cause is leakage from damaged blood vessels in the retina.

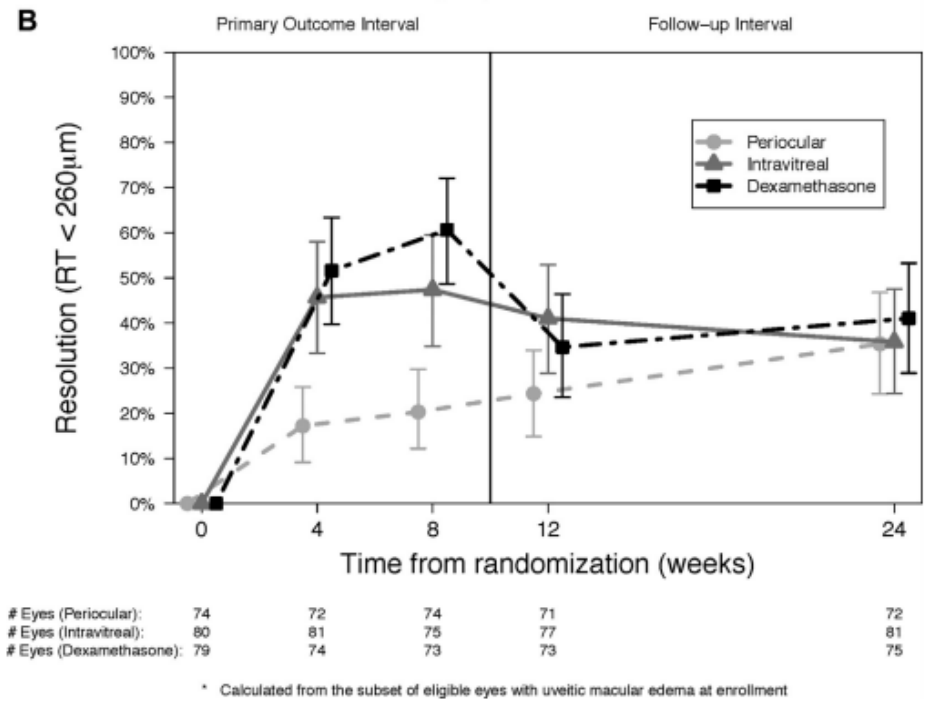
Eye-Injected Steroids The Most Effective Treatment Currently

Initial treatment usually is a high-dose of oral corticosteroids to control the inflammation. If the Macular Edema persists despite control of inflammation (which happens in around 50 percent of cases), patients might require corticosteroid injections in or around the eye. For difficult to treat cases, Ozurdex is an extended-release biodegradable ocular implant

containing dexamethasone (corticosteroid). For refractory patients, immune suppression or anti-TNF antibody therapy are options.

In a randomized trial comparing three different corticosteroid treatments - injection adjacent into the eye, injection into the eye, and implant in the eye (Ozurdex) - resolution (as measured by central subfield retina thickness, i.e., swelling) was achieved in up to 40 percent of cases after 24 weeks. Administration in the eye was superior to injection outside the eye.

Uveitic Macular Edema Resolution with Local Corticosteroid Treatment



Source: Thorne, J. et al.," Periocular Triamcinolone vs. Intravitreal Triamcinolone vs. Intravitreal Dexamethasone Implant for the Treatment of Uveitic Macular Edema", American Academy of Ophthalmology, 2018. Periocular: Steroid injection adjacent to the eye. Intravitreal: Injection of a steroid into the eye. Dexamethasone: Eye implant (Ozurdex).

New Formulation Shows Promise

In 2020, Active Biotech has successfully developed a topical eye drop formulation of laquinimod for ophthalmology. In this process, the Company has hired a specialized formulation technology company, German Leukocare AG. The challenge to administer the drug to the eye effectively makes formulation a crucial issue.

Can Laquinimod Overcome Low Drug Permeability in the Eye?

In ophthalmology, eye drop formulations are standard due to ease of administration. The drawback is very low bioavailability as the eye's anatomical and physiological barriers impede the permeation of drugs. Reaching the back of the eye is even more complicated, a major challenge because the eye's posterior usually is the site of severe eye disorders. Intravitreal injection is currently the most effective administration route to treat diseases of the back of the eye, despite side effects and inconvenience for patients. Systemic administration is often inefficient since the blood-retina-barrier hinders the passage of large molecules to the retina; however, it is an option if the eye disorder is a symptom of systemic autoimmune disease. Given these challenges, we view it as an encouraging sign that laquinimod eye drops have shown promising efficacy in an experimental model of Uveitis, decreasing inflammation in the back of the eye.

Rationale For Laquinimod in Eye Disorders

Extensive Documentation of Safety

More than 5,000 patients have received laquinimod, and Active Biotech estimates more than 14,000 patient-years of exposure at a daily dose of 0.6 mg. It has been well-tolerated, and no signs of severe adverse cardiac events have been reported, in contrast to "the predecessor " roquinimex. Investigators have observed elevations of liver enzymes. In animal studies, there was a higher occurrence of cancer after long-term exposure to the compound. The EMA expressed concerns about potential effects on the unborn from treatment (again from animal studies) when it refused marketing authorization for laquinimod. However, the regulators considered these risks acceptable, provided laquinimod had demonstrated a clear benefit (in Multiple Sclerosis). Investigators have not detected an increased risk for cancer in human trials.

Neuroprotective Effect Promising for Eye Disorders

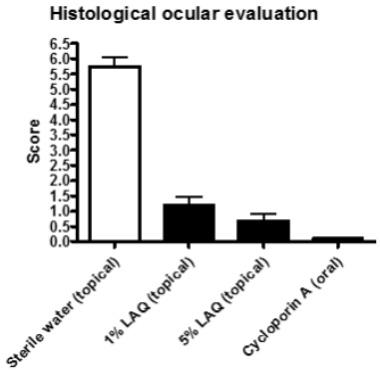
Laquinimod has in clinical trials demonstrated efficacy as a neuroprotective agent by reducing brain atrophy, i.e., the loss of neurons and the connections between them, in MS patients. Thus, there is evidence of anti-inflammatory action and the ability to cross the blood-brain barrier. This ability is key to targeting immune cells in the Central Nervous System, including microglia. Microglia are also resident in the retina of the eye. They play an essential role in repairing retina tissue in case of inflammation from oxidative stress or hypoxia. However, if the inflammatory response is chronic, microglia can become pathologically activated and release excessive amounts of inflammatory mediators that promote tissue damage and disease progression.

Preclinical Evidence in Uveitis

In 2020, a research group at the US National Eye Institute has published preclinical data in *Journal of Immunology* showing that oral laquinimod significantly inhibits the development of autoimmune Uveitis vs. placebo in a mice model. The disease was measured by funduscopy and histological analysis.

Further, preclinical investigations of induced Uveitis demonstrate reduced inflammation in the back of the eye in histological evaluation from treatment with an eye drop formulation of laquinimod .

Laquinimod Reduces Posterior Uveitic Inflammation in Preclinical Model



Source: Active Biotech

Active Targets Start of Clinical Development in H2 2021

Active is consulting internationally renowned field experts from UCL, University of Tübingen, and the US National Eye Institute for the upcoming preclinical and clinical development.

Simultaneously, Active seeks regulatory advice for clinical development in Uveitis with laquinimod. Active runs two tracks in parallel with the target to initiate *two* clinical trials in about 12 months:

- Preparations for a Phase IIa trial with *oral* laquinimod to demonstrate "proof of principle."
- Preclinical development, including pharmacology and toxicity studies, of the *topical* formulation. A Phase I trial with the topical formulation could start in H2 2021.

We believe the reason for Active to run multiple clinical trials in ophthalmology is that a combination treatment (oral + topical) could be feasible. A Phase IIa trial could bring forward preliminary evidence of clinical efficacy and attract potential partners early. Of course, there is a risk that oral administration alone is sub-optimal and that a Phase IIa will produce inconclusive or disappointing results.

Based on epidemiology studies cited above, we estimate a target population in second-line uveitic macular Edema of about 57,000 in the 7MM. We assume a 25 percent share as we consider laquinimod to be differentiated compared to local steroid treatment and antibody therapy. We calculate a list price of USD 15,000 per year in the US, in the range between established ophthalmology treatments Ozurdex and Lucentis (USD 6,000 to USD 25,000).

Sales Forecast for Laquinimod

Peak Sales Uveitis	USA	5EU	JAP
2L Uveitic Macular Edema (UME)			
UME Prevalence (Patients)	38600	60100	14900
Progression after 1L treatment	50%	50%	50%
Eyes treated/patient	1.5	1.5	1.5
2L Drug treated Eyes	28 950	45 075	11 175
% treated with LAQ	25%	25%	25%
Eyes treated with LAQ	7 200	11 300	2 800
Price per year (USD) (net)	13 400	9 500	9 500
Sales LAQ (USDm)	**96**	**107**	**27**

Source: Redeye

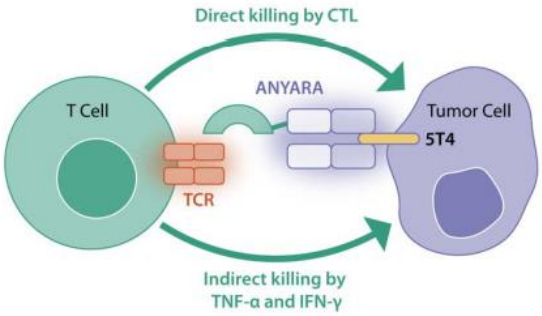
We forecast peak sales of some USD 230m. As a comparison, Allergan reported USD 400m in sales for steroid implant Ozurdex in 2019; however, a large part of sales (unknown) is attributable to Diabetic Macular Edema patients.

Naptumomab Facing Crucial Test

Naptumomab estafenatox ("naptumomab) is a therapeutic fusion protein that consists of the Fab-fragment of a tumor-targeting antibody, combined with a modified bacterial super-antigen (staphylococcal enterotoxin A, or SEA). Fab is the antigen-binding region of an antibody. The concept is named "Tumor-Targeting Super-antigen" (TTS). The rationale is to bind the drug via the Fab-fragment to a protein highly expressed on tumors called 5T4. In turn, the bacterial antigen binds to T-cell receptors (TCRs) to induce a powerful, tumor-directed immune (T-cell) response.

Wild-type SEA is a potent activator of non-specific T-cell reaction, likely a bacterial defense mechanism that "fools" the adaptive immune system. The excessive immune activation often causes severe illness. With naptumomab, the idea is to redirect this harmful immune response to attack the tumor instead. Active Biotech has engineered the super-antigen moiety to have a low binding to human antibodies to reduce toxicity and avoid immunogenicity, i.e., that the protein is cleared from circulation by the patient's immune system.

Naptumomab Estafenatox Mechanism of Action



Source: Active Biotech

The expression of 5T4 is associated with worse outcomes in cancer patients. It is expressed in many cancers, such as NSCLC, Renal cell carcinoma, and Pancreatic cancer. Research has shown that 5T4 protein influences cell adhesion and motility.

In a Phase I trial, naptumomab as a single agent demonstrated limited tumor response but was associated with promising survival outcomes in renal cell carcinoma and lung cancer. A larger Phase II/III trial (513 patients) investigating naptumomab as a combination treatment with interferon-alpha (IFNα) in metastatic renal cell carcinoma patients did not meet the primary endpoint of improved overall survival vs. IFNα alone. One likely contributing factor was a high baseline level of antibodies to the bacterial antigen in the study population, mainly Eastern European. There is cross-reactivity between naptumomab and staphylococcus enterotoxin A, i.e., common food poisoning from Staphylococcus Aureus bacteria. Despite Active having engineered the antigen to lower immunogenicity, it appears many patients rapidly became immune to treatment due to earlier bacterial infection. The immunogenicity to naptumomab may have been further increased through the combination treatment with IFNα, a cytokine that stimulates the immune system. Indeed, exploratory subgroup analysis indicated that patients with low baseline plasma levels of antibodies responded much better to naptumomab treatment than the overall study population. In conclusion, the study design and combination treatment for naptumomab was not optimal but reflected the standard of care when Active Biotech initiated the trial in 2006.

Adverse events were transient and related to increased levels of cytokines. Side effects included pyrexia, vomiting, nausea, chills, and back pain.

Partner NeoTx Responsible for Clinical Development

Active did not pursue further development following the kidney cancer study. In October 2016, Active Biotech licensed the global rights to develop and commercialize Naptumomab estafenatox in cancer to private Israeli Biotech NeoTx Therapeutics.

Active Biotech has received an upfront of USD 250,000 at the time of signing and, recently, a milestone payment of USD 750,000, likely related to the start of a combination dose-escalation trial with anti-CD20 treatment. The deal is worth USD 71m in total in clinical, regulatory, and sales milestones. Further, Active is entitled to tiered double-digit royalties on future sales.

Safety Update Early Next Year

For clinical development, NeoTx is collaborating with AstraZeneca, who supplies the approved PD-L1 antibody durvalumab (trade name: Imfinzi). In October 2019, NeoTx dosed the first patient in a Phase Ib trial investigating naptumomab + durvalumab in solid cancers. NeoTx expects a safety update at the beginning of next year. Following dose escalation, NeoTx plans several expanded cohort trials and a Phase II trial in combination with Docetaxel.

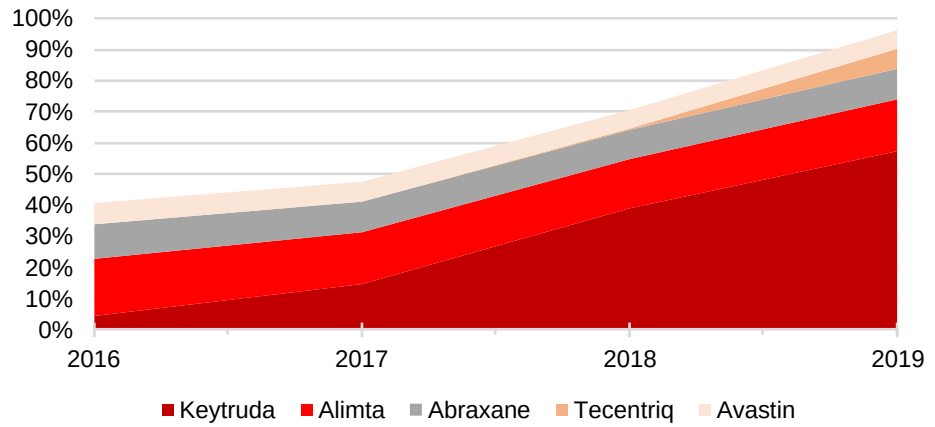
NeoTx has presented preclinical in vitro data demonstrating synergistic anti-tumor efficacy from combining naptumomab and anti-PD-L1 (breast cancer and colorectal cancer cell lines).

Forecast Assumptions

NeoTx is enrolling solid tumor patients broadly in the Phase I trial and has not yet prioritized indications, except for lung cancer in combination with chemotherapy for a planned Phase II trial. Based on 5T4 antigen expression and clinical results so far, indeed lung cancer, and kidney cancer, are likely candidates, in our view. In a Phase I trial, there was a promising survival outcome in these patients. Due to the lengthy clinical development times in kidney cancer, we believe lung cancer is the preferred path.

We model a target population in first-line (1L) metastatic, wild-type non-small cell lung cancer. According to Datamonitor, this represents some 200,000 drug-treated patients in the seven major markets. Datamonitor also forecasts a 15 percent penetration of anti-PD-L1 therapies Bavencio, Imfinzi, and Tecentriq in 1L. Imfinzi has not yet been approved in metastatic non-small cell lung cancer.

US: Penetration of Branded Drugs in First-Line Advanced Lung Cancer (NSCLC, wild-type)



Source: Datamonitor

Immunogenicity Could Hamper Outlook

As mentioned above, anti-drug-antibodies (ADAs) for naptumomab has been a concern in previous clinical development. One possible solution is screening to exclude patients with high levels of SEA antibodies from treatment, as they are likely non-responders. NeoTx has used an alternate approach in the ongoing trial and premedicated some patients with CD20-antibodies to eliminate ADAs. While such desensitizing protocols improve outcomes in, e.g., transplantation, they might render treatment complex in cancer patients, with an increased risk of side effects as well as higher cost. Treatment with naptumomab is already cumbersome, with four daily intravenous doses at the start of each 21-day treatment cycle.

Instead, we believe regulators will require testing to exclude patients with a high level of SEA antibodies. Based on epidemiology studies, we assume some 60 percent to be eligible (Kluytmans, J., et al.," Nasal Carriage of Staphylococcus aureus: Epidemiology, Underlying Mechanisms, and Associated Risks," *Clinical Microbiology Reviews*, July 1997). All in all, we project 4-5% penetration for naptumomab (1L mNSCLC, wild-type) if clinical development is successful.

Assuming a list price of USD 10,700 per month (in line with targeted therapies) in the US before a gross-to-net reduction of 40 percent, we calculate a net income per patient of some USD 58,000 per year. Here we assume an average of 9 months of treatment. In the ROW, we pencil in 30 percent lower prices. We calculate peak sales of USD 500-600m.

IP & Market Protection

Patent protection is a significant consideration in drug repurposing. Often, as in the case of Active Biotech, the remaining original substance patent life is short or has expired. Applying for method-of-use patents in new indications is a common strategy. However, they require that further medical use is indeed new and non-obvious (e.g., has not been described in the scientific literature), which leaves them more vulnerable to challenge. New formulation patents are another way to fight off potential generic competition.

Pursuing an Orphan indication is a lucrative opportunity, if feasible, as it provides market protection for seven and ten years of marketing protection in the US and EU, respectively, following approval.

Tasquinimod – Clear Orphan Drug Opportunity

For tasquinimod, the original substance patent has expired. As Multiple Myeloma is an orphan indication, Active will benefit from market exclusivity if no generic reaches the market first, which seems highly unlikely. Also, method-of-use-patents are valid until 2035-36. FDA has granted Orphan Drug Designation (ODD) for tasquinimod in Multiple Myeloma. Active has not yet applied for an ODD in Europe, but we believe this could happen when Active has gathered clinical data from the Phase Ib trial.

Laquinimod – New Formulation Could Play a Crucial Role

The original patent expired in 2019. Former partner Teva invested in several method-of-use patent applications, including ophthalmology and inflammatory bowel disease. If granted, the use in ophthalmology patent application expires in 2033. Active is developing a topical formulation for administration in the eyes, which could provide added protection if an application for a formulation patent is approved. Orphan Drug Designation could be a possibility for the US market. However, it is a borderline case, we argue.

Naptumomab

For Naptumomab, the original patent expires in 2022. NeoTx manages the patent portfolio and has applied for a method-of-use patent for the combination with checkpoint inhibitors. If approved, it will expire in 2036.

Financials

Active Biotech has never generated any income from product sales and has not been profitable on an annual basis since 2001. As a result, it has accumulated loss carry-forwards of SEK 3.4bn and has a favorable tax position for the foreseeable future.

By the end of Q3, 2020, Active Biotech had a cash position around SEK 31m.
In recent years, the cash burn has come down due to a leaner organization and more focused R&D activities and research collaborations with academic collaborations.

We expect laquinimod to be the main cost driver in 2021 and 2022 from increased preclinical and clinical development activities. The other projects are financed externally to a large extent.

We project higher R&D costs in 2021 from increased clinical and preclinical activity. Our forecasts are risk-adjusted. We have penciled in another possible milestone payment from NeoTx during next year, which we expect to be triggered when and if a phase II trial with naptumomab starts. Active has not communicated on the timing or distribution of milestone payments.

Financial Forecasts, risk-adjusted

Full-year estimates							
(SEKm)	**2017**	**2018**	**2019**	**2020e**	**2021e**	**2022e**	**2023e**
Net sales	20	20	8	7	9	0	104
Research and dev. costs	-49	-39	-28	-25	-32	-30	-24
Sales and adminitrative costs	-20	-11	-12	-13	-13	-14	-14
Other operating income/costs	-53	0	0	0	0		
Operating expenses	-123	-50	-41	-38	-45	-44	-38
EBIT	**-103**	**-30**	**-32**	**-31**	**-36**	**-44**	**66**
Financial net	-7	-7	-2	0			
EBT	**-110**	**-37**	**-34**	**-31**	**-36**	**-44**	**66**
Tax	1		0	0	0	0	0
Net earnings	**-109**	**-37**	**-34**	**-31**	**-36**	**-44**	**66**

Source: Active Biotech, Redeye Research

Rights Issue

On 5 November, the Board proposed a Rights Issue of about SEK 76m. Active will use the proceeds to pursue the planned preclinical and clinical research activities for tasquinimod and laquinimod, including a Phase IIa in non-infectious Uveitis (expected start H2 2021).

The issue is about 50 percent covered by subscription commitments and issue guarantees from existing shareholders MGA Holding AB, the Third and Fourth AP-Funds, and Peter Thelin. We note that the second-largest shareholder until recently, Nordstjernan, is not included in the list of committed subscribers. However, guarantees of SEK 14m from other large shareholders fill "the gap" from Nordstjernan.

Two existing shares entitle to subscription for one new share. Thus Active will issue up to 72,6m new shares. The subscription price amounts to SEK 1.05 per share. If the issue is fully subscribed, we believe it will help fund operations to H2 2022.

Valuation

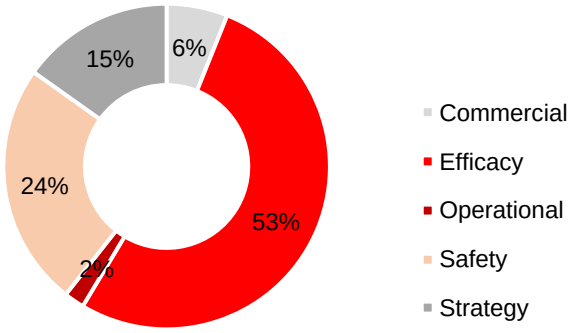
Our valuation of Active Biotech involves a risk-adjusted NPV sum-of-the-parts (SOTP) model. We believe this is the best approach to valuing drug development companies like Active Biotech as their fortunes are highly dependent on each clinical asset with no recurring income. For our valuation, we have included the projects tasquinimod in Multiple Myeloma, laquinimod in Uveitis, and naptumomab in Lung Cancer.

Likelihood of Approval

We have based our assumptions on Likelihood of Approval (LOA) on statistics from relevant indications as reported by BIO and BioMedtracker. We believe laquinimod has the highest likelihood of approval as the clinical risks are comparatively favorable in ophthalmology.

Active Biotech and partners have extensively investigated the safety and tolerability of all compounds. While the parties did not develop the programs beyond late-stage trials in the original medical indications, we argue that the repurposed drug candidates are now less likely to fail from a safety point of view. According to Harrison, R., "Phase II and phase III failures: 2013–2015", Nature Reviews Drug Discovery, 2016, safety is the reason for 24 percent of failures in Phase II and Phase III trials.

Reasons for Failure in Phase II and Phase III trials



Source: Harrison (2016)

We have assumed a lower risk of failure due to toxicity than average in our assessment of LOA. This is to account for the fact that all compounds have previously been in clinical development.

For the time being, we assume a lower LOA for naptumomab compared to the other projects considering the issue with ADAs. Also, solid tumor cancer projects historically have high attrition rates.

Assumed Project Risk and Development Phase

	Precl.	Phase I	Phase II	Phase III	NDA	Market
Year			2022	2023	2025	2026
Tasquinimod	100%	70%	35%	60%	100%	**15%**
Year		2021	2022	2023	2025	2026
Laquinimod	75%	85%	50%	60%	80%	**15%**
Year			2021	2023	2025	2026
Naptumomab	100%	85%	40%	30%	85%	**9%**

Source: Redeye Research, BIO, BioMedtracker

Reference Deals

Active Biotech's strategy for project development is similar to many small biotech companies, i.e., to partner projects following a successful Phase II/" Proof of Concept."

Below we have included some reference deals in Multiple Myeloma and Ophthalmology.

Reference Deals

Deals regarding Multiple Myeloma Pipeline Drugs						
Licensor/Acquiree	**Partner**	**Project**	**Phase**	**Value (USDm)**	**Upfront (USDm)**	**Royalties**
Genmab	Janssen	daratumumab	I/II	1135	135	12-20%
Genmab	Janssen	HexaBody CD38	Precl.	275	150	20%
TeneoBio	AbbVie	Bispecfic BCMA/CD3	Precl.	Not Disclosed	90	Not Disclosed
Spectrum	Acrotech	Several	Market	300	160	None
Proteolix	Onyx	carfilzomib	II	851	276	None
Average				**640**		
Median				**576**	**150**	

Deals regarding Uveitis/Edema Drugs						
Licensor/Acquiree	**Partner**	**Project**	**Phase**	**Value (USDm)**	**Upfront (USDm)**	**Royalties**
Clearside Biomedical	Bausch Health	Xipere	III	112.8	9	10-20%
Clearside Biomedical	Regenxbio	SCS	I	138	2	5%
Molecular Partners	Allergan	MP0112	II	420	45	Tiered double digit
Average				**224**	**19**	
Median				**138**	**9**	

Source: Redeye Research

We conclude that deal values in Multiple Myeloma are several times higher than Ophthalmology, likely reflecting the large commercial market for MM drugs.

Sum of the Parts

We assume a WACC of 13 percent from the Redeye Rating Model. If the current rights issue is fully subscribed, we calculate a base case value of SEK 3 per share.

Valuation of Active Biotech

Project	Indication	Peak Sales (USDm)	LOA	Royalty	Launch	rNPV (SEKm)*
Tasquinimod	Multiple Myeloma	450	15%	20%	2026	336
Naptumomab	Solid tumors	560	9%	15%	2026	165
Laquinimod	Ophthalmology	230	15%	20%	2026	207
Total		1240				709
	Shared costs, incl taxes					-164
	Net cash, Jan 2021e					99
	Total					**644**
	Shares outstanding (issue fully subscribed)					217.9
	Value Per Share					**3.0**

Source: Redeye Research

Project Estimates

For tasquinimod

- As previously reported, Peak Sales of USD 450m.
- We assume 15% LOA
- US launch in 2026
- A licensing deal following a Phase II monotherapy trial

- A total potential deal value of USD 580m (median of Multiple Myeloma reference deals cited above) and upfront/early milestone payments of USD 130m (similar to the daratumumab deal between Genmab and Janssen). We assume that Active receives 50 percent of the deal value.

For laquinimod

- An LOA of 15 percent
- Market launch as a treatment of Uveitis in 2026
- Partner agreement in 2023: A total deal value of USD 125m and an upfront payment of ten percent

For naptumomab

- An LOA of 9 percent
- For the moment, we only consider Non-Small Cell Lung Cancer and assume a US launch is possible in 2026.
- The total deal value of USD 71m is known, and we assume milestone payments are back-loaded

Peer Group Valuation

We base our relative valuation of drug development companies in oncology and ophthalmology on technology value (market value less net cash). Compared to other listed peers, Active's valuation appears attractive with a considerably lower EV than the average and median – though we acknowledge differences in project potential and risk.

Peer Group Valuation

Peer group valuation						
(SEKm)	Market Cap	Share price	Net Cash	EV	No. Projects*	Dev. Stage
Alligator Bioscience	548	7.67	137	411	4	Phase I-II
BioInvent	1700	1.78	642	1058	4	Phase I
Cantargia	5870	64.5	458	5412	1	Phase II
Clearside Biomedical	764	1.94	111	654	3	NDA
Medivir	214	8.8	93	121	4	Phase I-II
Redwood Pharma	103	6.5	8	95	1	Phase II
Active Biotech	211	1.45	31	180	2	Phase I
Average (ex Active Bio.)	1344			**1292**		
Median (ex Active Bio)	1700			**532**		
**in clinical development*						

Source: Redeye Research

Scenario Analysis

Active Biotech is facing several potential catalyst events in the next two years that will significantly impact its valuation and share performance. To illustrate their potential impact, we also calculate optimistic and pessimistic scenarios for the Company.

Our **bear case** scenario, which gives a fair value of SEK 1.4, assumes these negatives:

- Development of naptumomab is discontinued in Phase I

- The Phase Ia study for tasquinimod takes longer than expected, and there is dose-limiting toxicity at lower doses than planned, entailing a reduction of LOA to ten percent.

Our optimistic **bull case** scenario, which gives a fair value of SEK 4.4, assumes:

- The Phase I part A trial in Multiple Myeloma is successfully completed, and there are promising early efficacy signals. We increase LOA to 20 percent and raise peak sales expectations by 40 percent
- Naptumomab also completes Phase I
- Laquinimod enters clinical development

Catalysts

Completed Preclinical Development Laquinimod

We expect Active Biotech to complete the preclinical development of an eye drop formulation of laquinimod in H1, 2021

IMPACT				
Downside		Upside		Time Frame
Significance	Likelihood	Significance	Likelihood	
Major	Unlikely	Moderate	Highly likely	Short

Safety Update Naptumomab

Partner NeoTx plans a safety update regarding an ongoing Phase Ib trial with naptumomab in solid tumors (combination with checkpoint inhibitor Imfinzi) in Q1, 2021.

IMPACT				
Downside		Upside		Time Frame
Significance	Likelihood	Significance	Likelihood	
Major	Unlikely	Moderate	Possible	Short

Rights Issue

Active Biotech is raising SEK 76m in a Rights Issue. We expect the capital raise if fully subscribed to fund operations through 2022.

IMPACT				
Downside		Upside		Time Frame
Significance	Likelihood	Significance	Likelihood	
Major	Unlikely	Major	Highly likely	Short

Safety Update Multiple Myeloma

We expect a safety update on tasquinimod monotherapy in Multiple Myeloma and possible subsequent expansion to combination therapy in H2 2021

IMPACT				
Downside		Upside		Time Frame
Significance	Likelihood	Significance	Likelihood	
Major	Unlikely	Major	Possible	Mid

IMPACT				
Downside		Upside		Time Frame
Significance	Likelihood	Significance	Likelihood	

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 4

The management consists of a small, experienced team. The CEO was previously Chief Scientific Officer and led the research and clinical development of the Company's projects in neurodegenerative diseases and cancer. The Board composition has changed significantly since 2018 and has also been extended by two members adding extensive relevant international BioPharma background. We view these steps as positive and believe an active and experienced board is instrumental in supporting the new strategic direction of Active Biotech.

Business: 3

Active Biotech is a clinical-stage biotech, developing first-in-class treatments in oncology and inflammatory eye disorders. Management has extensive experience in clinical, as well as business development. Current commercial and academic partnerships enable low-cost development of tasquinimod (Multiple Myeloma) and naptumomab (solid tumors).

Financials: 1

Active Biotech has never generated any income from product sales and has not been profitable on an annual basis since 2001. The Company has announced a rights issue of SEK 75m before costs for January 2021. We believe the capital raise will fund operations through 2022.

INCOME STATEMENT	2018	2019	2020E	2021E	2022E
Net sales	20	8	7	9	0
Total operating costs	-49	-40	-37	-54	-44
EBITDA	-29	-31	-30	-45	-44
Depreciation	0	-1	-1	0	0
Amortization	0	0	0	0	0
Impairment charges	0	0	0	0	0
EBIT	-30	-32	-31	-45	-44
Share in profits	0	0	0	0	0
Net financial items	-7	-2	0	0	0
Exchange rate dif.	0	0	0	0	0
Pre-tax profit	-37	-34	-31	-45	-44
Tax	0	0	0	0	0
Net earnings	-37	-34	-31	-45	-44

BALANCE SHEET	2018	2019	2020E	2021E	2022E
Assets					
Current assets					
Cash in banks	26	60	20	51	7
Receivables	0	1	0	0	0
Inventories	0	0	0	0	0
Other current assets	3	3	3	3	3
Current assets	29	63	22	54	10
Fixed assets					
Tangible assets	1	0	0	0	0
Associated comp.	0	0	0	0	0
Investments	272	0	0	0	0
Goodwill	0	0	0	0	0
Cap. exp. for dev.	0	0	0	0	0
O intangible rights	0	0	0	0	0
O non-current assets	0	0	0	0	0
Total fixed assets	273	3	3	3	0
Deferred tax assets	1	0	0	0	0
Total (assets)	302	67	26	58	10
Liabilities					
Current liabilities					
Short-term debt	204	1	0	0	0
Accounts payable	10	10	0	0	0
O current liabilities	0	0	0	0	0
Current liabilities	214	11	0	0	0
Long-term debt	0	2	0	0	0
O long-term liabilities	0	0	0	0	0
Convertibles	0	0	0	0	0
Total Liabilities	214	13	0	0	0
Deferred tax liab	0	0	0	0	0
Provisions	0	0	0	0	0
Shareholders' equity	88	54	23	54	10
Minority interest (BS)	0	0	0	0	0
Minority & equity	88	54	23	54	10
Total liab & SE	302	67	26	58	10

FREE CASH FLOW	2018	2019	2020E	2021E	2022E
Net sales	20	8	7	9	0
Total operating costs	-49	-40	-37	-54	-44
Depreciations total	0	-1	-1	0	0
EBIT	-30	-32	-31	-45	-44
Taxes on EBIT	0	0	0	0	0
NOPLAT	-30	-32	-31	-45	-44
Depreciation	0	1	1	0	0
Gross cash flow	-29	-31	-30	-45	-44
Change in WC	-5	-1	-9	0	0
Gross CAPEX	0	272	-1	0	0
Free cash flow	-34	240	-40	-45	-44

CAPITAL STRUCTURE	2018	2019	2020E	2021E	2022E
Equity ratio	29%	80%	89%	94%	97%
Debt/equity ratio	232%	6%	12%	6%	0%
Net debt	179	-56	-17	-48	-7
Capital employed	267	-3	3	3	3
Capital turnover rate	NA	NA	NA	NA	NA

GROWTH	2018	2019	2020E	2021E	2022E
Sales growth	-1%	-58%	-18%	31%	-100%
EPS growth (adj)	NA	NA	NA	NA	NA

DCF VALUATION	
WACC (%)	13.0 %
Fair value e. per share, SEK	3.0
Share price, SEK	1.4

PROFITABILITY	2018	2019	2020E	2021E	2022E
ROE	NA	NA	NA	NA	NA
ROCE	NA	NA	NA	NA	NA
ROIC	NA	NA	NA	NA	NA
EBITDA margin	NA	NA	NA	NA	NA
EBIT margin	NA	NA	NA	NA	NA
Net margin	NA	NA	NA	NA	NA

DATA PER SHARE	2018	2019	2020E	2021E	2022E
EPS	-0.25	-0.23	-0.21	-0.21	-0.20
EPS adj	-0.25	-0.23	-0.21	-0.21	-0.20
Dividend	0.00	0.00	0.00	0.00	0.00
Net debt	1.23	-0.39	-0.12	-0.22	-0.03
Total shares	145.24	145.24	145.24	217.85	217.85

VALUATION	2018	2019	2020E	2021E	2022E
EV	616.0	270.4	192.1	161.6	202.2
P/E	NA	NA	NA	NA	NA
P/E diluted	NA	NA	NA	NA	NA
P/Sales	21.8	38.9	30.4	34.9	NA
EV/Sales	30.7	32.2	27.9	18.0	NA
EV/EBITDA	NA	NA	NA	NA	NA
EV/EBIT	NA	NA	NA	NA	NA
P/BV	5.0	6.1	9.2	3.9	21.1

SHAREHOLDER STRUCTURE %	CAPITAL	VOTES
Mats Arnhög & Bolag	26.2 %	26.2 %
Avanza Pension	6.0 %	6.0 %
Handelsbanken Liv Försäkring AB	5.7 %	5.7 %
Nordstjernan	4.9 %	4.9 %
Fjärde AP-fonden	2.7 %	2.7 %
Tredje AP-fonden	2.7 %	2.7 %
Peter Thelin	2.0 %	2.0 %
Efg Bank / Geneva	1.6 %	1.6 %
SEB-Stiftelsen	1.3 %	1.3 %
Vidarstiftelsen	1.2 %	1.2 %

SHARE INFORMATION	
Reuters code	ACTI.ST
List	Small cap
Share price	1.4
Total shares, million	145.2
Market Cap, MSEK	209.1

MANAGEMENT & BOARD	
CEO	Helén Tuvesson
CFO	Hans Kolam
IR	Hans Kolam
Chairman	Michael Shalmi

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Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Disclaimer

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Redeye Rating (2020-12-13)

Rating	People	Business	Financials
5p	19	15	3
3p - 4p	109	90	38
0p - 2p	5	28	92
Company N	133	133	133

Duplication and distribution

CONFLICT OF INTERESTS

Niklas Elmhammer owns shares in the company : No
Filip Einarsson owns shares in the company : No
Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.