Lipum

Sector: Biotech

An Exciting Debutant

Redeye initiates coverage of Lipum, a Swedish biotech company offering a unique approach to the USD 60 billion-plus inflammatory diseases market. Lipum is establishing a unique platform which will be the key driver for continued development and long-term growth. With lead candidate, SOL-116, now entering the clinic, we argue it has the potential to mark a new era in rheumatoid arthritis (RA). Should it manage to deliver encouraging clinical data, it could catch the eye of large industry players.

Multibillion USD market

Lipum's lead candidate SOL-116 offers a new approach to the USD 20 billion-plus rheumatoid arthritis (RA) market. While being one of the most significantly valued drug indications, the RA market is in desperate need of an efficacious treatment with limited side effects. Accordingly, we see a place for SOL-116 in rheumatic disorders and forecast peak annual global sales of more than USD 600 million by 2037.

Attractive licensing deal could be in company's future

SOL-116 is designed to provide a safer and more efficacious disease-modifying treatment than currently marketed options by blocking a previously overlooked target molecule. Following extensive preclinical evaluation of the candidates potential, the stage is now set, as it is entering clinical development. Should SOL-116 manage to deliver encouraging data in the upcoming phase I trial, we argue that it may attract interest from Big Pharma. Accordingly, we model a USD 200m licensing deal in 2024.

Base Case of SEK 22 per share

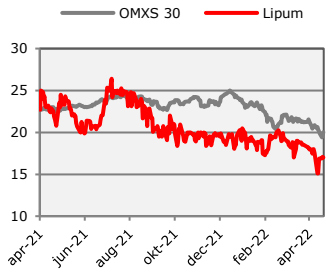
We base our valuation of Lipum on a DCF model of its current pipeline. We initiate coverage with a Base Case of SEK 22 per share, with respective Bull and Bear cases of SEK 35 and SEK 5. This suggests an upside potential of more than 35% from current share price levels (SEK 17). With interim- and top-line data from the upcoming phase Ia/Ib trials in the horizon, we see multiple inflection points ahead that could close our valuation gap.

Key Financials (SEKm)	2019	2020	2021	2022E	2023E
Net Sales	0	0	0	0	0
Revenue growth	N/A	N/A	N/A	N/A	N/A
EBITDA	-9	-21	-52	-57	-63
EBIT	-9	-21	-52	-57	-63
EBIT Margin (%)	neg	neg	neg	neg	neg
Net Income	-9	-21	-52	-45	-50

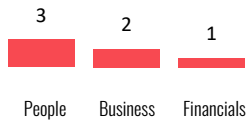
FAIR VALUE RANGE

BEAR	BASE	BULL
5	22	35

LIPUM VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	LIPUM
Market	First North
Share Price (SEK)	16
Market Cap (SEKm)	86
Net Debt (SEKm)	45
Free Float (%)	79
Avg. daily volume	89

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Investment Case

Case: Potential to satisfy market need

Lipum has its sight set for the multibillion dollar rheumatoid arthritis (RA) market with the aim of providing a new first-in-class treatment to a population in need of a paradigm shift. RA continues to be one of the largest pharmaceutical markets globally, yet, despite the vast number of approved drugs, the medical need remains high as no drug has been able to achieve disease-free remission. The demand for cost-effective and safe treatments is glaring as current standard of care entail multiple side-effects and lack efficacy in a significant part of the patient population.

However, we believe that Lipum's lead candidate, SOL-116, has the potential to eradicate this discrepancy and offer a resolution-based therapy. The candidate has a unique mechanism of action (MOA), targeting the previously-overlooked BSSL protein, suggested to play a central role in inflammation and inflammatory response. Should SOL-116 prove a good safety profile, and repeat signs of its efficacy shown in preclinical studies, in the upcoming phase Ia/Ib clinical trials, we believe that it is well-positioned to attract interest from the public and catch the eye of large industry players.

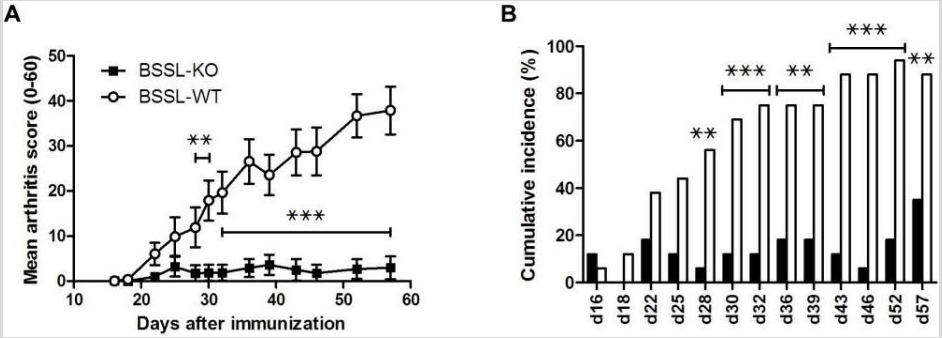
Evidence: Establishing a platform to broaden pipeline

Lipum is simultaneously establishing a platform of preclinical data on the therapeutic effect of SOL-116 in several other diseases and targets of interest. This could potentially lead to the discovery of further possible indications where the candidate could be developed as a novel treatment. The list of viable chronic inflammatory diseases and proinflammatory conditions can be made very long given the candidate's believed potential in both autoimmune and autoinflammatory illness. The company continually evaluates the indications and carries out selections for in-depth preclinical studies based on medical need, market potential and conditions for validating SOL-116 through suitable models.

Supportive analysis: Promising preclinical evidence

Preclinical studies performed by founders Prof. Olle Hernell, prof. Lennart Lundberg and prof. Susanne Lindqvist demonstrated strong support of BSSL being a key player in the inflammatory process and disease development of arthritis. The researchers used a Collagen-induced arthritis (CIA) model in rodents – a commonly used experimental model to reproduce the pathogenic features of human RA – to compare the response in BSSL wild type (BSSL-WT) mice with BSSL-deficient 'knock-out' (BSSL-KO) mice. In two consecutive trials, they found that BSSL-KO mice were significantly protected from developing arthritis, suggesting a direct correlation between BSSL levels and disease development.

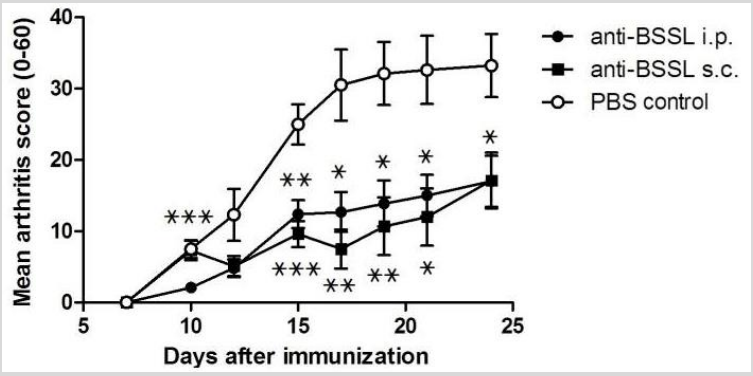
Disease development of arthritis in BSSL-KO mice



Source: Lindqvist, S. et al. (2012)

Moreover, they also found that injection with BSSL-neutralizing antibodies (similar to SOL-116) reduced both the incidence and severity of arthritis in rodents.

Disease development of arthritis in BSSL-KO mice



Source: Lindqvist, S. et al. (2012)

Challenge I: Unproven target

SOL-116 targets the BSSL protein, which is an unproven target in previous biopharmaceuticals. While showing great promise in preclinical models, there is no guarantee that the enzyme is an effective target in humans as well. However, the fact that SOL-116 is developed as a monoclonal antibody, as are the current biological disease-modifying antirheumatic drugs (TNFα-inhibitors), could prove to be an advantage when it comes to clinical implementation in patients.

Challenge II: Highly competitive market

The market for RA is one of the world's most competitive markets within the pharmaceutical industry – with many drugs approved, or under development, and an established treatment protocol. Should SOL-116 fail to show substantial safety or efficacy benefits over today's established treatments, it may struggle to gain meaningful market share even if it receives marketing authorization.

Valuation: Long-term value potential

Our Base Case fair valuation amounts to SEK 22 per share, suggesting more than 35% upside from today's share price levels. Further, our Bull and Bear Cases equal SEK 35 and 5 per share, respectively. We argue that the share trades at a discount to its fundamental value and offers an attractive entry point at current levels.

We foresee an exciting 2022 and beyond for Lipum as lead candidate SOL-116 enters clinical studies. Primarily, we judge that interim- and top-line data from the phase Ia/Ib studies and in-depth preclinical data on further indications could induce share price re-ratings.

Counter Points

Early-stage development

The company is currently in early-stage development with lead candidate SOL-116 as it is now entering the clinic. There are always significant risks associated with developing drug candidates, and SOL-116 is no exception. While the candidate offers a unique and promising MOA, failure to show a clinically meaningful effect or robust safety profile in clinical trials would be major setbacks.

Dependent on partners and investors

Lipum being a pre-revenue biotech company in research and development phase indicates that the company is far from receiving any recurring cash streams. Instead, the company will heavily rely on capital markets to finance its operations for the coming years. With the general risk appetite on the market having been suppressed during this year, raising capital will be a tougher task for the majority of biotech companies. Investors should be aware of this when considering early-stage biotech companies. There is a risk that the company may be squeezed for cash to finance its clinical studies and operations in the future, which could lead to heavily dilutive and rebated rights issues. Further, we judge that Lipum will heavily depend on finding and cooperating with a licensing partner in the future for the late-stage development of SOL-116, and ultimately, to bring it to the market.

One-trick pony characteristics

The company could be seen as a one-trick pony given the high dependency on lead candidate SOL-116. There is certainly a significant risk allocated to the upcoming Phase I trial, if the treatment fails to show a good safety profile (and clinically relevant efficacy indicators) in RA patients, the pipeline will have almost no residual value. However, the company's dual development strategy with a parallel track devoted to establishing a platform of several other potential target indications reduces some of the risk.

Key Catalysts

- **SOL-116 phase Ia interim data**
  The soon-to-start first clinical study of SOL-116 will be a major milestone for the company, an interim analysis of the trial is expected towards the end of this year.

  Timeframe: 6-9 months
  Impact: Major

- **SOL-116 phase Ib top-line data**
  Following the initial phase Ia study, Lipum is planning a phase Ib Multiple Ascending Dose (MAD) trial further studying safety, immunogenicity and selected biomarkers in RA patients. Top-line data is expected in 2024 and should have a big impact on the share.

  Timeframe: 18-24 months
  Impact: Major

- **Preclinical data on further indications**
  Lipum is establishing a platform of preclinical data on the therapeutic effect of SOL-116 in several other diseases and targets. This could potentially lead to the discovery of further possible indications for the candidate.

  Time frame: 9-18 months
  Impact: Moderate to major

Table of Contents

Company Description

Lipum AB is a research and development-stage biopharmaceutical company specialized in discovery and development of a novel treatment for chronic inflammatory diseases. The company was originally founded based on a discovery made by scientists at Umeå University. Co-founder and Board member Prof. Olle Hernell and his team discovered that a protein now known as bile salt-stimulated lipase (BSSL) is present in human white blood cells and plays an important role in inflammation. This novel and unexpected finding led to the development of Lipum's lead candidate drug SOL-116. The candidate is a fully humanized monoclonal antibody currently in development to become a safe and efficacious alternative to current therapy in, primarily, rheumatoid arthritis (RA). The treatment has a new and unique mechanism of action, operating through the blockage of the previously overlooked target molecule of the immune system.

Lipum was founded in 2010 in Umeå, Sweden, where it has its current headquarters. Since April 2021, the company has been listed on Nasdaq First North Growth Market (LIPUM).

Lipum: Historical highlights

2005	First novel findings suggesting that BSSL could be involved in inflammatory processes are published, from a study conducted by Professor Olle Hernell, Associate Professor Susanne Lindquist and Professor Lennart Lundberg, who would later become founders of Lipum.
2010	Lipum AB is founded in Umeå, Sweden.
2012	Findings from an animal model study conducted by the founders of Lipum, which strongly support BSSL as a key player in the inflammatory process, are published in the scientific journal "PLoS One".
2016	The BSSL research group at Umeå University begins a collaboration with the Drug Discovery and Development (DDD) platform at SciLifeLab. Dr. Einar Pontén is appointed new CEO of the company.
2018	Lipum receives EUR 2.2m grant from Horizon 2020, the EU framework program for research and development.
2019	Following extensive screening and development work, a humanized lead drug candidate, SOL-116, is selected. The project with SciLifeLab reaches its final (academic) milestone and the rights for SOL-116 are transferred to Lipum. Lipum signs integrated CMC agreement with Abzena for the GMP-production of SOL-116.
2020	Lipum initiates toxicology- and safety studies with SOL-116. The company submits a PCT application for SOL-116, which could provide protection for the candidate until 2040. The company raises SEK 8m in a share issue.
2021	Lipum's shares are listed on Nasdaq First North Growth Market, following an IPO which supplies Lipum a total of SEK 85.7m before emission costs.
2022	GMP-production of SOL-116 for clinical trials is successfully completed. Lipum enters partnership with QPS Netherlands B.V. for its upcoming phase I clinical trial with SOL-116.

Source: Lipum, Redeye Research

People and Ownership

Management and Board

We consider the people behind Lipum as a solid component of the company. Despite being small, the management team is dynamic and experienced. CEO Einar Pontén was co-founder and the former CEO of chromatography company SeQuant AB for more than 10 years. During his tenure, in 2008, the company was acquired by pharmaceutical giant Merck. We believe that this is a testament to his executive abilities in creating value and attracting interest from big industry players.

Furthermore, the three founders; prof. Olle Hernell (CMO), assoc. prof. Susanne Lindqvist (CSO) and prof. Lennart Lundberg are all still active in the company, being members of the Board of Directors, executive management and scientific advisory board, respectively. Beyond being the people behind the scientific foundation of SOL-116, the group has vast experience and expertise in inflammatory disease studies and the pharmaceutical and biotech industry.

In general, we view the company's management and board as competent, and we believe shareholders can be confident in its executive and strategic capabilities. We provide more detailed descriptions of management and the Board of Directors in the appendix.

Ownership

Looking at the ownership structure of Lipum, one of the largest shareholders is Thomas Eldered through the life science-focused investment company Flerie Invest AB. Furthermore, members of the board, management team and the three founders can be found among the major shareholders. In total, they hold some ~20 percent of outstanding shares. The company also has a long-term share option-based incentive plan for the Board, Executive Directors, employees and consultants.

Top 10 Shareholders – Lipum

Lipum: Top 10 shareholders		Total amount of shares: 5.1M	
Owners	Number of Shares	Value (MSEK)	% of capital
Nordnet Pensionsförsäkring*	910,154	14.56	18.00%
Avanza Pension	632,848	10.13	12.50%
Flerie Invest	484,361	7.75	9.60%
LGL-Bioconsult**	300,000	4.80	5.90%
Adam Dahlberg	224,947	3.60	4.50%
Crafoordska Stiftelsen	168,373	2.69	3.30%
Göran Källebo	160,943	2.58	3.20%
Tibia Konsult AB	125,786	2.01	2.50%
UBP Clients Assets-Sweden	121,549	1.94	2.40%
Ulf Andersson	109,649	1.75	2.20%
Other shareholders	1,813,882	29.02	35.9%
Total	5,052,492	80.84	100%

Source: Holdings, Redeye Research

**314,500 shares (6.3%) are owned by CMO Olle Hernell, 311.796 shares (6.2%) are owned by CSO Susanne Lindqvist and 93,504 shares (1.9%) are owned by CEO Einar Pontén.*

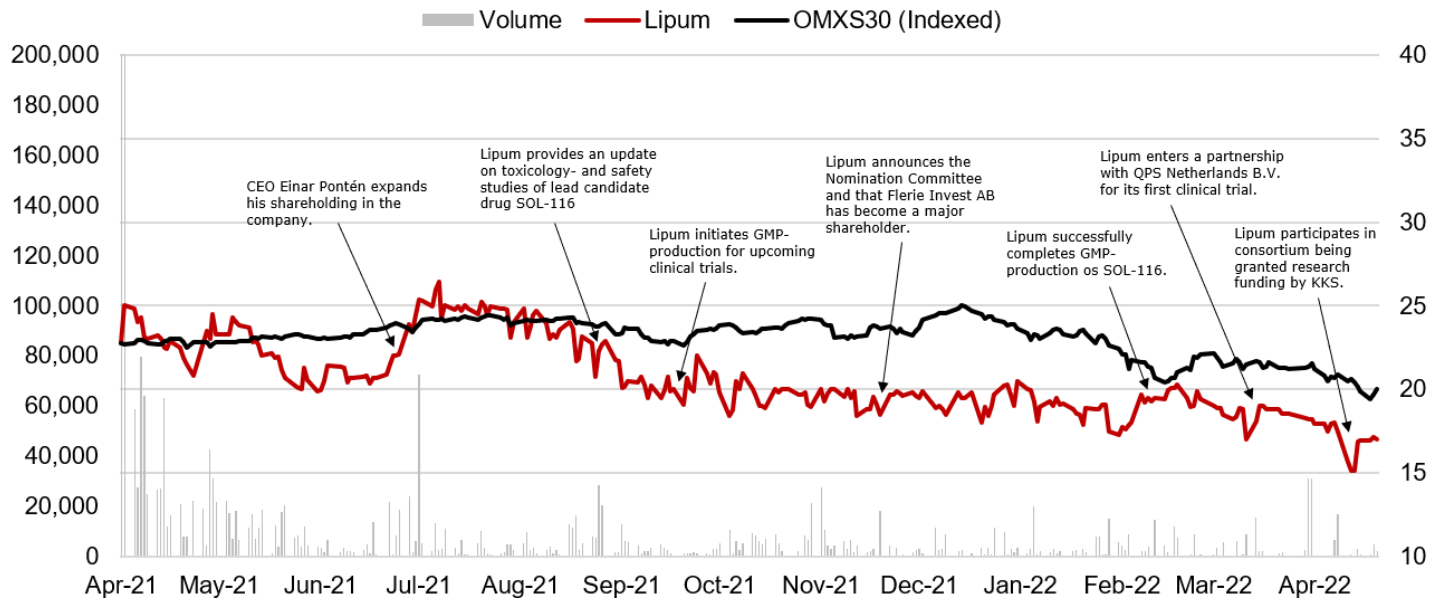
***Owned by co-founder Lennart Lundberg.*

Stock Performance

Lipum was listed on Nasdaq First North Growth in April 2021 with a subscription price of SEK 31.80 per unit, consisting of one share and one warrant. The IPO was subscribed for by 150 percent and saw the company raise SEK 85.7m before transactions costs. Since its listing, Lipum's share price has generally been quite stable. The share's performance was initially weak, trading below the listing price, before a temporary spike during July last year. It has since traded sideways, with a slight decline over time. We believe this is rather the product of a general discouraging sentiment on the market, in combination with the uncertainty stemming from the COVID-19 situation, than any company-specific decrease in fundamental value.

Looking forward, we think Lipum's share price has considerable upside potential. We judge that the company faces several catalysts in its near future. Primarily, we judge that interim- and top-line data from the phase Ia/Ib studies and in-depth preclinical data on further potential indications could induce share price re-ratings in the coming 12-24 months.

Share Price Performance Since IPO



Source: Redeye Research, Lipum

Medical Need and Project Description

Next Generations Treatment of Chronic Inflammatory Diseases

Lipum aims to develop the next-generation inflammatory disease-treatment. The company has developed a biological drug candidate, SOL-116, as a potential treatment of autoimmune and autoinflammatory diseases. After extensive preclinical progress, the candidate is now set to enter clinical studies with the initiation of a phase I trial expected in the near future.

SOL-116: A BSSL-targeting Antibody

Background

The theoretical and academical origin of SOL-116 stems from extensive research at the unit for pediatrics at Umeå University, conducted by Professor Olle Hernell, Associate Professor Susanne Lindqvist and Professor Lennart Lundberg, who would later become founders of Lipum. Their research on fat-splitting enzyme in breast milk led to the discovery of the enzyme Bile Salt-Stimulated Lipase (BSSL) and its significance for the breastfed baby's digestion of breast milk fat.

However, It turned out that BSSL is not only found in breast milk but also in the blood. When the researchers searched for the source of the protein's presence in the bloodstream, it was possible to note greatly elevated levels of BSSL in inflamed organs. Most prominently, there was on average a ten-fold increase of BSSL in the liver of patients with fatty liver, which is an inflammatory condition, in comparison to other subjects. Namely, these findings gave birth to the idea of BSSL potentially being an attractive drug target to control inflammation.

Inflammation is, in fact, a natural part of the body's healing processes. However, chronic inflammation occurs when the body is unable to heal the acute inflammation. Instead, it lingers and leaves the body in a constant inflammatory state. This is a significant problem in patients with both autoimmune and autoinflammatory diseases.[1]

While the drug candidate is considered to have the potential to treat several chronic inflammatory diseases, Lipum has chosen rheumatism in adults (rheumatoid arthritis) as its current main target indication for SOL-116, with a potential later expansion into the rare disease indication juvenile idiopathic arthritis (rheumatism in children). Both diseases are characterized by a great unmet medical need and a large market.

Disease Overview: Rheumatoid Arthritis

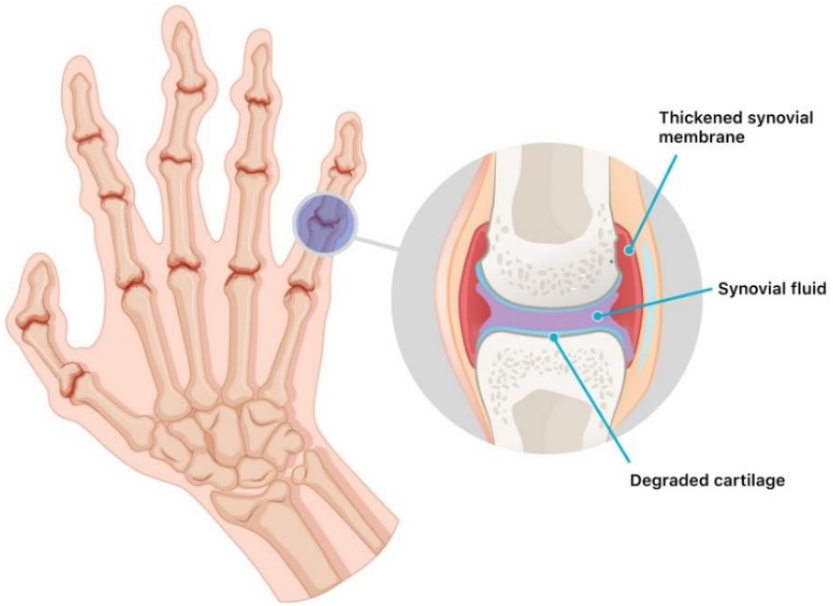
Rheumatoid arthritis (RA) is a chronic inflammatory disease that causes pain, swelling and stiffness in the joints. The condition most commonly affects the hands, feet and wrists of patients suffering from the disease and leads to reduced quality of life and increased mortality.

Typical symptoms include:

- Persistent joint stiffness, pain and swelling
- Symmetrical symptoms affecting multiple joints bilaterally
- Severe deformation of joints
- Loss of muscle strength around inflammation
- General feelings of being ill and tired

[1] It also occurs in, for example, cancer, obesity and diabetes.

How Rheumatoid Arthritis Affects Joints

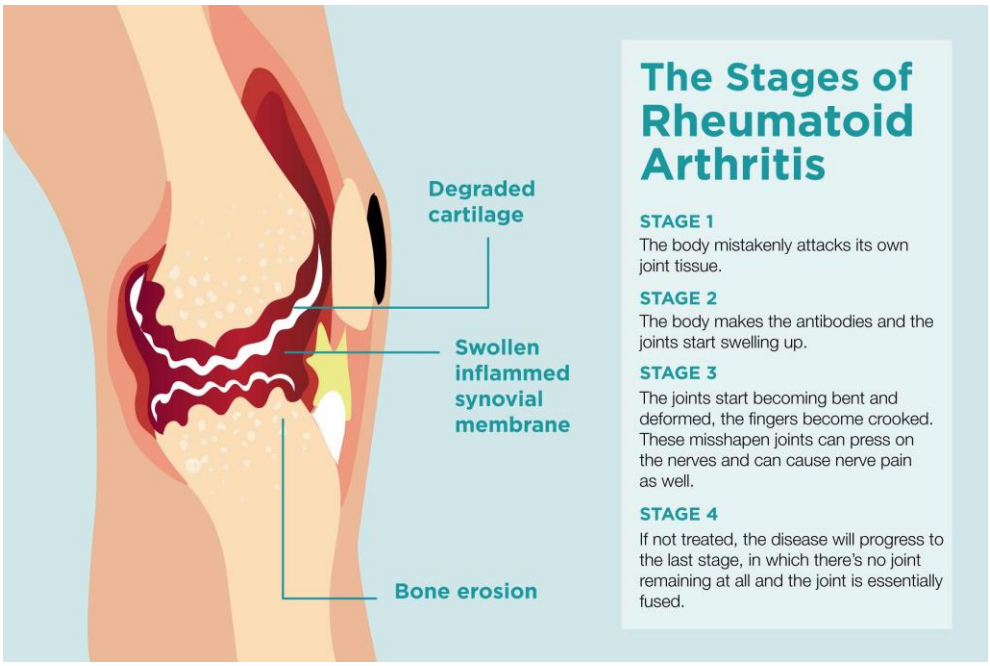


Source: Drugwatch

RA is an autoimmune disease, meaning that the immune system, which normally guards against germs like bacteria and viruses, mistakenly attacks the patient's own body. Normally, the immune system can tell the difference between foreign cells and the body's own cells. However, in autoimmune diseases, the immune system mistakes parts of the body as foreign and releases proteins called autoantibodies that attack healthy cells. In RA specifically, the immune system attacks the lining of the membranes that surround the joints (synovium tissue), leading to inflammation. Over time, the cartilage and bone within the joint are destroyed and the joints lose shape and alignment.

Furthermore, RA is a systemic disease, which means that it can affect the whole body. It can attack organs, such as the heart, the lungs, or other tissues like muscles, cartilage, and ligaments. The damage caused by the disease can be severe and, in some instances, lead to permanent disability. A study by Holmqvist, M.E. et al. (2010) found that the risk of heart attack for people with RA was 60 percent higher just one year after being diagnosed with RA. However, it was also found that therapies used to treat RA, by suppressing inflammation, may also reduce the risk of developing heart diseases.

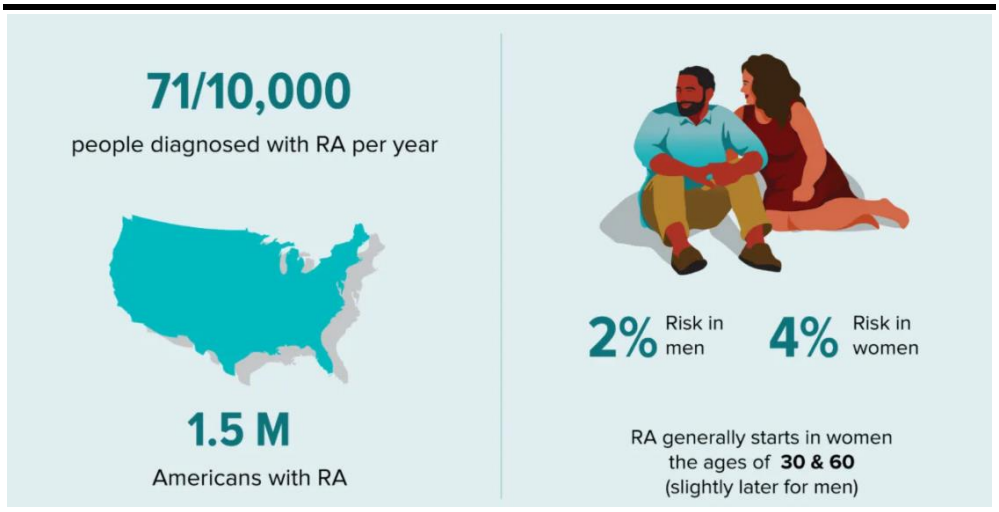
Rheumatoid Arthritis – Disease Development



Source: CreakyJoints

According to Healthline, 71 out of every 100,000 people are on average diagnosed with RA annually. This equates to approximately 235,000 new cases in the US and more than 530,000 in Europe each year. In total, 1.5 million Americans and 3.5 million Europeans are estimated to have RA today.

Rheumatoid Arthritis – Epidemiology



Source: Healthline

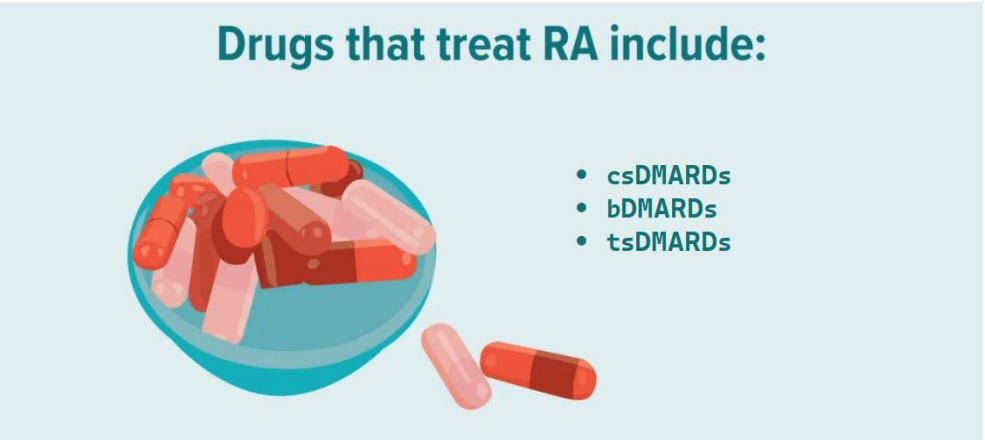
The risk of developing RA is genetically connected. Women are about two to three times more likely to get RA than men and people with close relatives who have suffered from RA are at an increased risk of developing the disease. Research suggests that those born with specific genes called human leukocyte antigen (HLA) class II genotypes are more likely to develop RA. In addition, having these genes can also make the experienced symptoms worse. Further, in people who are obese or who smoke, the risk for RA is also greatly increased.

Current Treatment Paradigm of RA

1st line Treatment – Synthetic DMARDs

There is currently no cure for RA. Early diagnosis and appropriate treatment enables some people with the condition to relieve parts of the symptoms. Today, methotrexate (MTX), a conventional synthetic disease-modifying anti-rheumatic drug (csDMARDs), is used as first-line treatment for most RA patients. MTX is an immune-system suppressant that reduces joint inflammation and slows the course of the disease. It has a relatively fast response and is considered to have decent efficacy and safety profile. Furthermore, it is convenient to administer and comes with a relatively low price tag. However, roughly 60 percent of patients have an inadequate response to MTX monotherapy and have to move on to more costly biologics and/or corticosteroids.

Current Treatments for Rheumatic Disorders



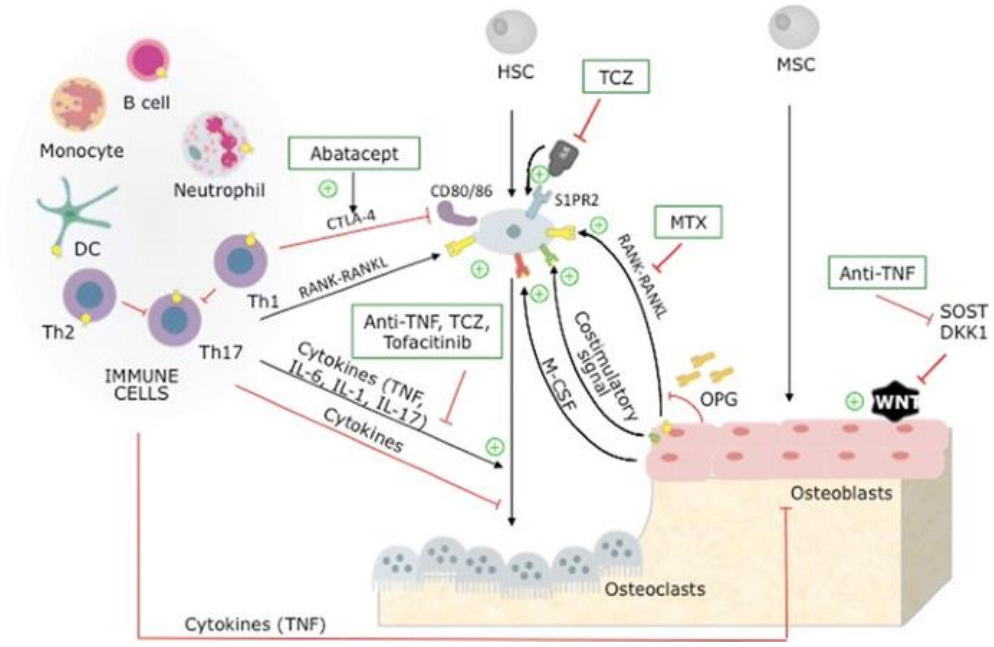
Source: Redeye Research, Healthline

2nd Line Treatment – Biologic DMARDs

Biological disease-modifying antirheumatic drugs (bDMARDs) are typically second-in-line treatments, used either as an alternative or an addition to MTX monotherapy. Biologics are produced through biological processes in living cells, or from biological material, and are usually large and complex molecules whose properties differ significantly from small synthetic drugs. Biologics are most commonly monoclonal antibodies (mAb), which are characterized by an ability to, very specifically, bind to a target molecule in the body and thereby canceling or slowing down an unwanted disease process. SOL-116 places in this treatment category, being developed as an alternative biological drug to current standard bDMARDs.

Tumor necrosis factor (TNF) alpha inhibitors, typically monoclonal antibodies, are the most established class of bDMARDs – with the blockbuster drugs AbbVie's Humira (adalimumab), Pfizer's Enbrel (etanercept), and Merck's Remicade (infliximab) as the most established choices in the key markets. While costly, TNF-α inhibitors have shown high efficiency in combination with DMARDs and have positive long-term safety data, putting them in a strong standing that may be difficult to shake. In the coming years, however, biosimilars are expected to take a larger share of this category following patent expires.

bDMARDs – Mechanism of Action



Source: S. Carvalho Barreira & J. Eurico Fonseca (2016).

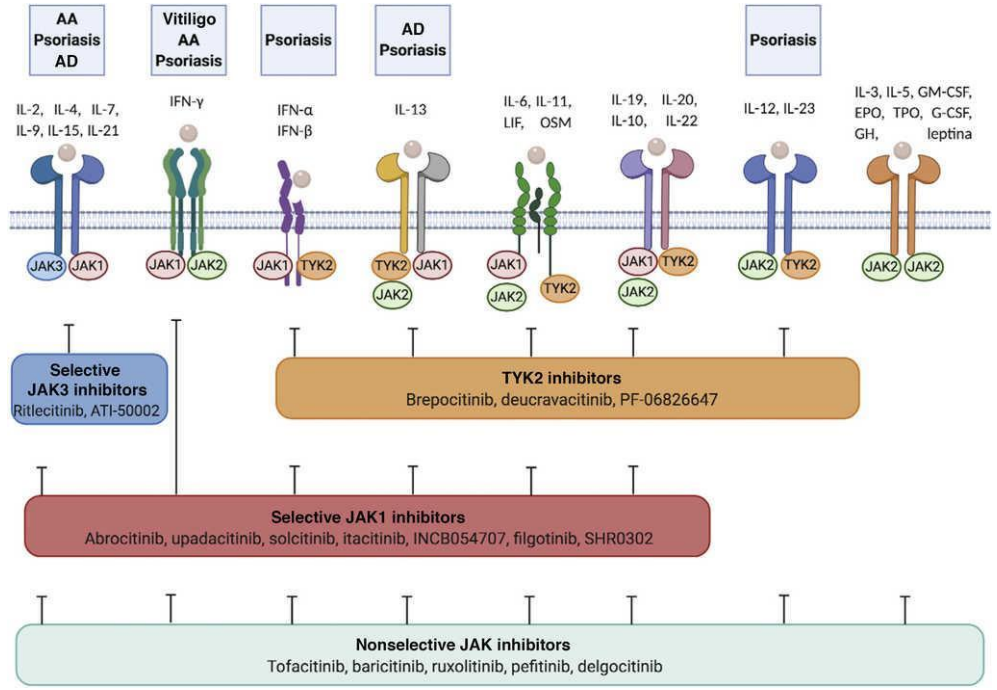
Moreover, a significant proportion of RA patients do not respond to TNF-α inhibitors or respond only temporarily. These can be classified into two groups of patients: those who are primary non-responders and those who initially respond but then exhibit secondary loss of response. Primary non-responders may or may not show some initial response, but never reach their treatment target with anti-TNFs. If these patients do not respond to one anti-TNF therapy, they are not likely to respond to other TNF-α inhibitors. Avoiding anti-TNF therapy could prevent disease progression and improve quality of life for primary non-responders, suggesting that they should switch to an alternative MOA therapy (K, Johnson. et al., 2019). Accordingly, we believe that there is a great unmet need for alternative biological treatment for non-responders. SOL-116 could potentially fill this gap in the market due to its unique MOA, differentiating it from currently marketed biologics.

3rd Line Treatment – Targeted Synthetic DMARDs (JAK-inhibitors)

Janus kinase (JAK) Inhibitors are a relatively new group of drugs for the treatment of chronic inflammatory diseases and are a part of the targeted synthetic disease-modifying antirheumatic drugs (tsDMARDs). Since certain proinflammatory cytokines use the JAK-pathway for signal transduction, it has become an increasingly popular therapeutic target in diseases where selective modulation of the immune system can be useful. JAK-inhibitors work by inhibiting the kinase activity of JAKs, effectively blocking certain cytokine receptor signaling dependent on specific JAK-pathways.

The treatment is today used in either second- or, most commonly, third-line therapy as an alternative to patients not responding to csDMARDs or bDMARDs. The most prominent currently marketed JAK-inhibitors are Pfizer's Xeljanz (tofacitinib), which was the first FDA approved treatment in the drug class in 2012, Eli Lilly's Olumiant (baricitinib) and AbbVie's Rinvoq (upadacitinib). First-generation JAK-inhibitors, such as Xeljanz and Olumiant, are generally poorly selective and inhibit various JAKs, whereas the second-generation inhibitors, such as Rinvoq, are more selective and predominantly block a single member of the JAK family, thus inhibiting a narrower range of cytokines.

Selectivity of Different Types of JAK-inhibitors



Source: C. Garcia-Melando, X. Cubiró & L. Puig (2021).

After the launches, however, it has been shown that JAK-inhibitors are associated with significant side effects that endanger patient safety. This ultimately caused the FDA to update its safety warnings for the entire drug class in September 2021. The revision was mainly based on a review of a large clinical post-approval study that showed an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with Xeljanz and Xeljanz XR. Notably, the FDA decided that the labels for *all* JAK-inhibitors should be updated with so-called "black box warnings" to alert doctors and patients to its potential side effects. Olumiant and Rinvoq have not been studied in similar trials, however, since they share mechanisms of action with Xeljanz, FDA considers that these medicines may have similar risks as seen in the Xeljanz safety trial.

As a result, nearly half (49 percent) of rheumatologists have reduced their prescriptions for Xeljanz in the past three months, according to Spherix Global Insight's first quarter report for 2022. We believe that this is a trend that is likely to continue as an increasing number of patients and rheumatologists refrain from using JAK-inhibitors following the safety concerns. Consequently, this will further induce the unmet medical need and create a vacancy to be filled by potential future treatments, such as SOL-116.

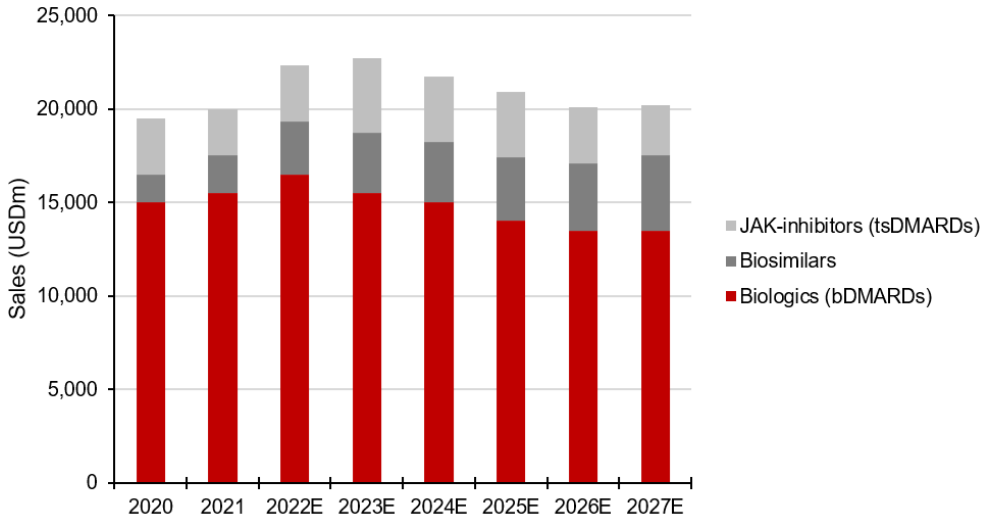
The Market for RA Treatment

RA is one of the world's highest valued drug indication. According to Datamonitor, The RA market in the US, Japan and EU5 was worth about USD 20bn in 2021. Yet development in the RA treatment market has been relatively stagnant in recent years, with only minor changes in the prescribing habits of doctors and a lack of market launches. However, one of the key drivers for the market over the last decade has been the introduction of biologics (bDMARDs). While biologics are second-in-line, they account for the majority of total revenue due to their premium pricing. Among them, Enbrel and Humira are estimated to maintain almost half of the market value alone.

Over recent years, JAK-inhibitors have gained traction in the medical community due to their convenient oral dose formulation. Appetite among payers to reimburse JAK-inhibitors has been quite low, however, as their safety profile has been highly questioned and they are generally more expensive than the widely used TNF-α inhibitors. Consequently, JAK-inhibitors are primarily used for patients who have failed with biologics.

As a whole, the RA market is not expected to showcase any significant growth over the coming years. Historically, growth has primarily been attributed to annual price increases and rising disease prevalence due to an ageing population. However, the increasing introductions of biosimilars (generics for biological drugs) is expected to put downward pressure on prices, which could lead to attrition in the of sales biologics. Accordingly, biosimilars are estimated to grab increasing market shares over the next few years as annual revenue from biologics faces a stagnation in the coming period.

Rheumatoid Arthritis Market 2020-2027, EU5, US and Japan (USDm)



Source: Datamonitor, Redeye Research

Disease Overview: Juvenile Idiopathic Arthritis

Juvenile idiopathic arthritis (JIA), formerly known as juvenile rheumatoid arthritis, is the most common type of arthritis in children and juveniles under the age of 16. The disease holds many similarities to RA, being a condition that causes persistent joint pain, swelling and stiffness. Due to the early onset of the condition, JIA can in some cases cause serious complications, such as growth problems, joint damage and eye inflammation.

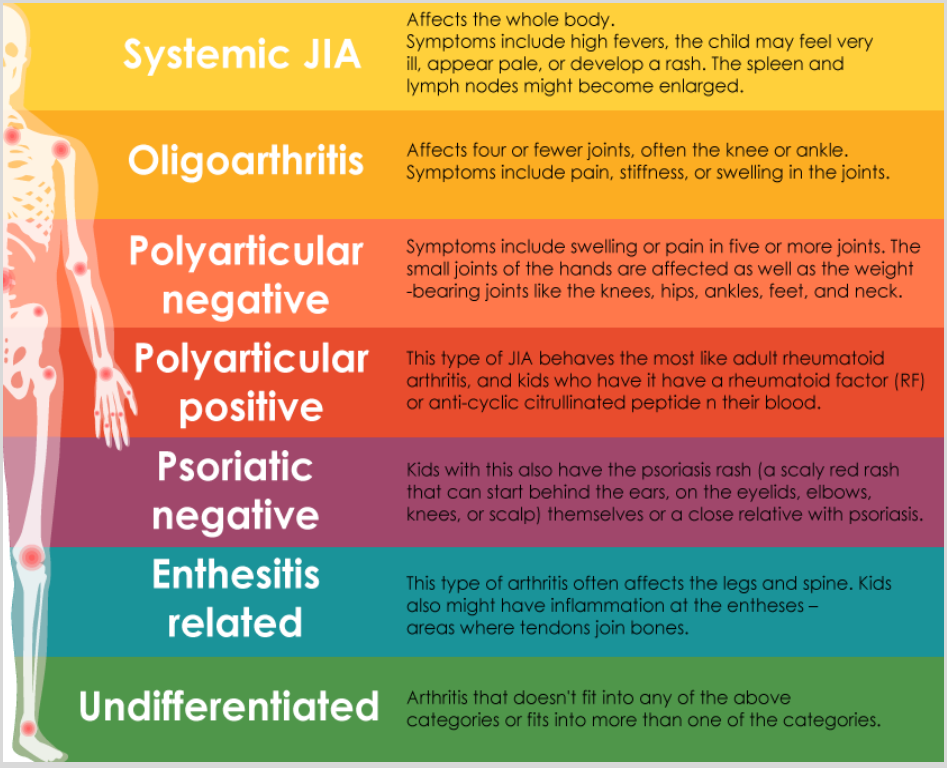
JIA types are also autoimmune, or autoinflammatory, diseases where the immune system attacks the body's own cells and tissues. Inflammatory chemicals are released that attack the synovium tissue lining around the joints, which causes the symptoms to appear.

The word 'idiopathic' means unknown, as researchers currently do not know with certainty exactly why children develop JIA. According to the Arthritis Foundation, the most common belief is that children with JIA have specific genes that are activated by a virus, bacteria or other external factors. However, there is no evidence that foods, toxins, allergies or a lack of vitamins directly cause the disease.

The Different Types of JIA

Unlike adult rheumatoid arthritis, which is ongoing (chronic) and lasts a lifetime, children often outgrow JIA. However, the disease can cause lasting effects on bone development in a growing child. Furthermore, dissimilar to the usual arthritis diseases older people experience, JIA has various different types:

The 7 Types of Juvenile Idiopathic Arthritis



Source: Abacare

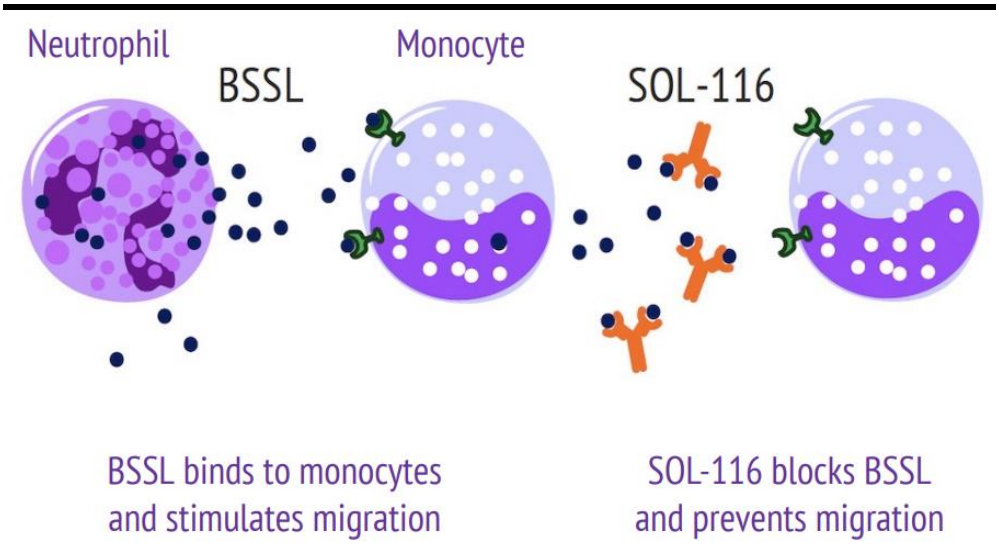
The medications used to help children with JIA are chosen to decrease pain, improve function and minimize potential joint damage. The treatment regimen for JIA is similar to that of RA. Some doctors recommend that patients begin treatment with Nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and naproxen. These are used to relieve pain and reduce inflammation and swelling. However, NSAIDs are primarily only conditionally recommended as adjunct therapy for symptom management, particularly during initiation or escalation of therapy with DMARDs or biologics. NSAIDs have been acknowledge as inappropriate as monotherapy for chronic, persistent synovitis (S. Ringold. et al., 2019). Usually, patients are prescribed MTX treatment, followed by combinational therapy with biologics (TNF-α inhibitors) and JAK-inhibitors for those resistant to initial treatment.

According to DataM Intelligence Analysis (2019), approximately 300,000 children are estimated to have some type of JIA in the US. The prevalence is increasing globally, with the annual incidence rate estimated to be 2–20 cases per 100,000 population.

SOL-116: Scientific Evidence and Mechanism of action

The significance of the BSSL protein in inflammation has been verified in four different and well-established animal models for arthritis. The work has further led to an explanatory model of the mechanism of action where an important step is that BSSL is secreted from a type of white blood cells (granulocytes) and bind to another (monocytes), which in turn are active in inflammation. It is proposed that BSSL can bind to the CXC motif chemokine receptor type 4 (CXCR4) and thus triggers the signaling pathway leading to migration and recruitment of inflammatory cells to the site of acute inflammation. While this initially may play a positive roll, when the inflammation is no longer controlled and becomes "chronic", BSSL is likely to sustain the inflammatory response and hence become a negative factor. As a result of this, BSSL has emerged as a highly interesting target for the treatment of inflammatory disease. The idea of being able to prevent and restrain these diseases by blocking the protein is the foundation of the anti-BSSL antibody.

SOL-116: Mechanism of Action



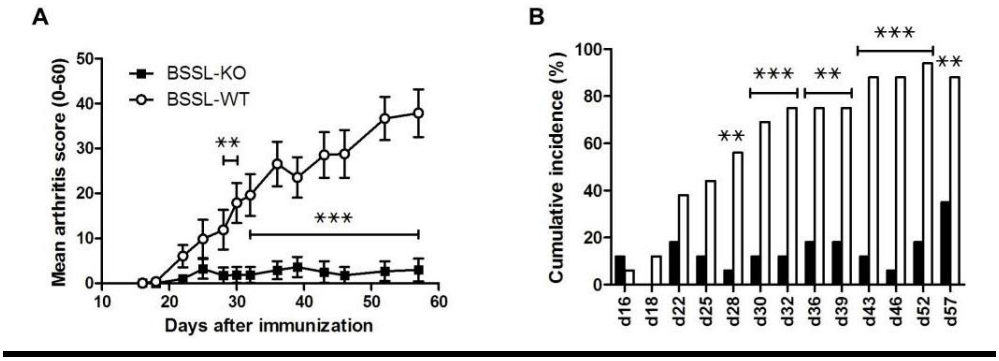
Source: Lipum

Preclinical Evidence

Preclinical studies performed by founders prof. Olle Hernell, prof. Lennart Lundberg and assoc. prof. Susanne Lindqvist demonstrated strong support of BSSL being a key player in the inflammatory process and disease development of arthritis. The researchers used a Collagen-

induced arthritis (CIA) model in rodents – a commonly used experimental model to reproduce the pathogenic features of human RA – to compare the response in BSSL wild type (BSSL-WT) mice with conventional BSSL 'knock-out' (BSSL-KO) mice. In two consecutive trials, they found that BSSL-KO mice were significantly protected from developing arthritis, suggesting a direct correlation between BSSL levels and disease development.

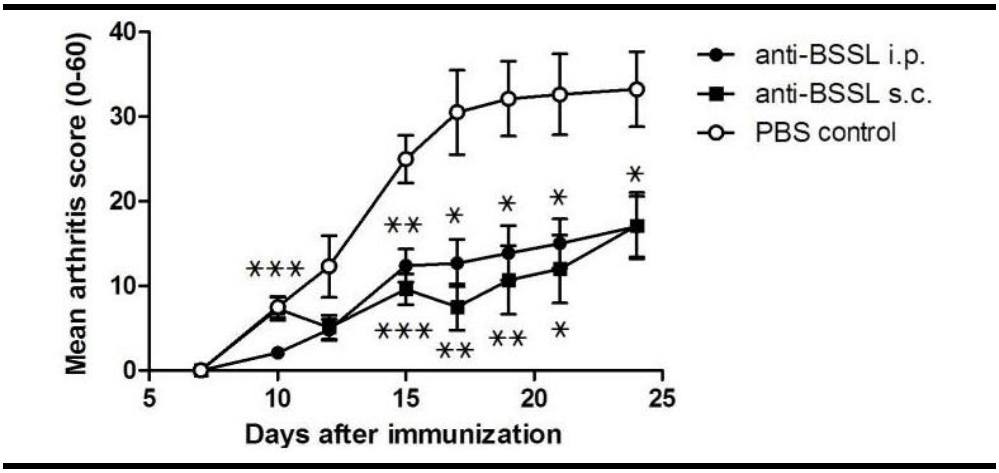
Disease development of arthritis in BSSL-KO mice



Source: Lindqvist, S. et al. (2012)

Moreover, they also found that injection with rabbit polyclonal anti-BSSL antibodies reduced both the incidence and severity of arthritis in rodents. In one of the trials, thirty male DA rats (age 8–10 weeks) were randomized into three groups (n = 10 per group) for treatment. The rats were given a single injection of pristane, known to induce arthritis within two weeks. BSSL-neutralizing antibodies (5 mg/kg) were then given through either intraperitoneal- or subcutaneous injection on days 5, 10, and 15 after pristane immunization, and the effect was compared to a placebo control. Blinded clinical scoring confirmed that treatment with anti-BSSL antibody significantly reduced disease severity as compared to PBS control. Treated animals also showed a marked decrease in the number of inflammatory cells present in the joint synovium and less cartilage destruction.

Disease development of arthritis in BSSL-KO mice



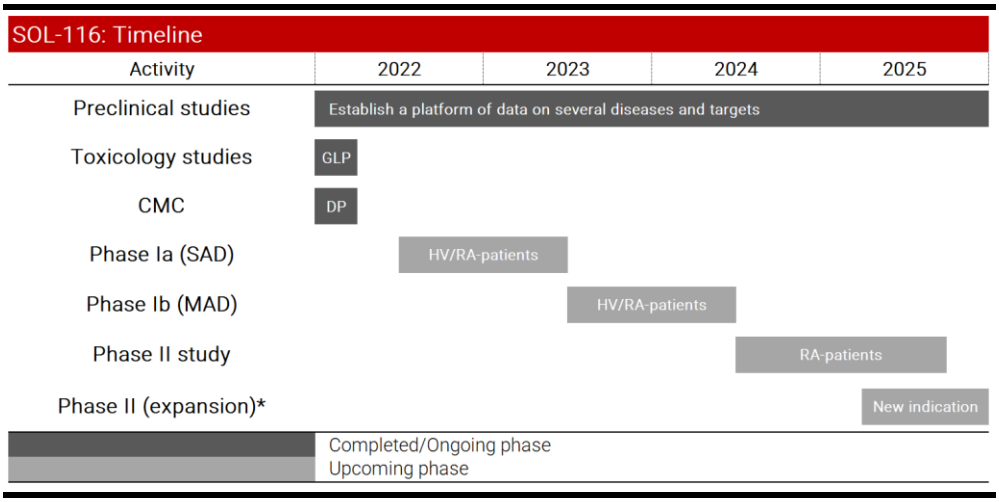
Source: Lindqvist, S. et al. (2012)

Development and Timeline

In 2016, via its anchorage at Umeå University, Lipum initiated a cooperation with the Drug Discovery and Development (DDD) platform at SciLifeLab with operations at the universities of Uppsala, Stockholm, and Lund. The aim was to develop a humanized therapeutic monoclonal antibody that binds to and inhibits the pro-inflammatory properties of BSSL. This was done by building an entirely new library of bacteriophages, from which five pre-nominated candidate

drug antibodies were selected. Following extensive screening and development work, a humanized lead drug candidate, SOL-116, was selected three years later. Now the candidate is set to enter clinical trials for the first time.

SOL-116: Estimated Development Plan



Source: Lipum, Redeye Research
** Potential expansion study in further indications.*

Simultaneously, the company is collecting further preclinical evidence of the importance of BSSL and the potential therapeutic effect of SOL-116 in other inflammatory diseases, with the aim of establishing a platform of data on several diseases and targets. This could potentially lead to the discovery of further possible indications for the clinical development of the candidate.

Phase Ia Clinical Trial

The soon-to-start first clinical study of SOL-116 will be a major milestone for the company. It is set to be a phase Ia trial conducted in collaboration with the contract research organization (CRO) QPS Netherlands in its facilities in Groningen and Leeuwarden, Netherlands. The study is randomized, double-blind and placebo-controlled, in healthy volunteers (HV) and patients with RA. The purpose of the study is to analyze and evaluate the safety, tolerability and pharmacokinetics after single dose escalation of SOL-116. An explorative objective is also to study the effect of SOL-116 on BSSL and inflammatory biomarkers in the blood of healthy subjects and RA-patients.

A final report is estimated to be ready around one year after the start of the study, with an interim analysis of the trial being expected in the second quarter of 2023.

Phase Ib Study

Following the initial phase Ia study, Lipum is planning a phase Ib study expected to be initiated in 2023. The trial is likely to be a so-called multiple ascending dose (MAD) study also involving adult patients with RA to further study SOL-116 in the intended patient population and provide an opportunity to study selected biomarkers.

Top-line data from Phase I-studies are expected in 2024 and will be a major inflection point for the company. Should SOL-116 prove a good safety profile, and repeat signs of its efficacy shown in preclinical studies, we believe that it could attract interest and catch the eye of large industry players already ahead of following proof-of-concept Phase II-study.

Commercialization and Marketing

Business strategy and Organization

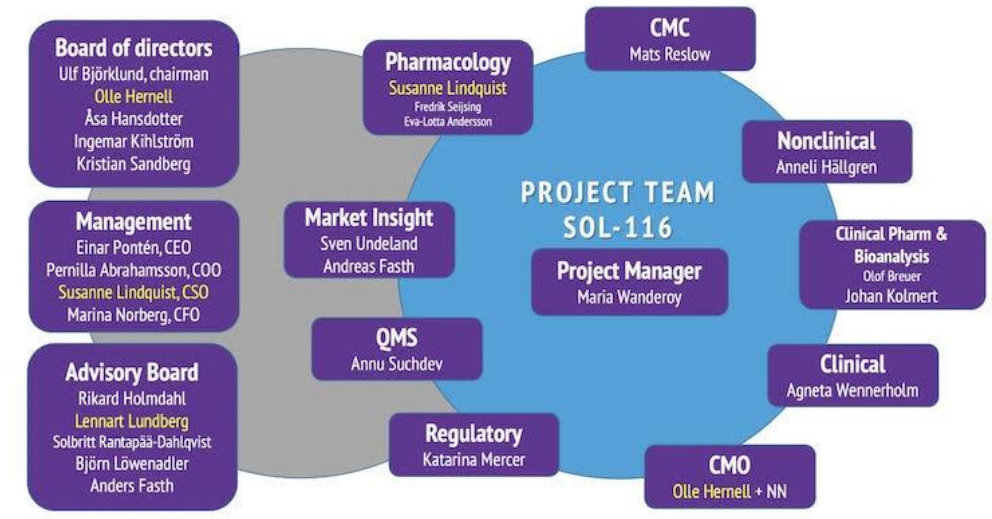
Lipum focuses on differentiating itself from competitors and staying competitive in the long run through superior functionality and operational excellence. The company intends to, in parallel with the development work to reach its clinical milestones, follow up previous results on other diseases and carry out in-depth studies on further selected indications. The objective is to increase knowledge of the mechanism of action and reach clinical development as quickly as possible in potential indications. This way, Lipum intends to create a unique platform which will be the key driver for continued development and growth.

Given the resources, organizational structure and competence required to run late-stage development, the company has stated that it intends to look for licensing agreements with a pharmaceutical partner in connection with phase II trials. Thus, future potential revenue is primarily expected to come in the form of upfront payments, development- and sales-based milestone payments and royalties on subsequent profits. The company intends to use the strengthened finances from a potential licensing deal to further develop its preclinical platform.

If it proves difficult to establish any fruitful partnership collaboration, Lipum has stated that it may choose to continue the clinical development plan independently. The focus would then primarily be RA, but with an option to proceed on JIA, with an intention of obtaining an orphan drug designation (ODD) for a more feasible regulatory pathway to the market.

Furthermore, Lipum puts emphasis on building important competitive advantages in the form of intangible assets. The company has made major investments to take advantage of opportunities for intellectual property protection. Specifically, in 2020, a very comprehensive international PCT patent application was filed concerning SOL-116 and therapeutic antibodies directed against the target molecule BSSL. This patent is expected to extend current protection with an additional 10 years, from ending in year 2030 to 2040. Intangible protection is important, especially for biotech companies, although biological drugs are generally relatively difficult to replicate compared to small chemical entities.

Lipum – Organization



Source: Lipum

Similar to many other biotech companies alike, Lipum's organizational structure is quite lean without excessive departments or personnel. The company only employs key members of staff and outsources wherever possible. Lipum had a total of four full-time equivalent (FTE) employed for the fiscal year 2021.

Manufacturing and Partnerships

Lipum has a collaboration with San Diego based manufacturer Abzena for the production of SOL-116. The development of a cell line and manufacturing method began in March 2019. Following successful upscaling, production under the regulations that apply to Good Manufacturing Practice (GMP) was initiated in the fall of 2021 and successfully completed earlier this year. The production entails a volume of 500 liters and is expected to provide a sufficient amount of SOL-116 to carry out planned Phase I clinical trials, at least.

The final step in the manufacturing process of SOL-116 was the aseptic fill. It is a specialized process which ensures that the product is sterile and ready for use in clinical trials, and was performed by the contract manufacturer Apotek Production & Laboratories (APL), locally at their facility in Umeå, Sweden.

Lipum - Partnerships

Source: APL, Abzena, Pelago Bioscience, Charles River Laboratories

Toxicology and safety studies of SOL-116 were conducted in collaboration with Charles River Laboratories, which is a leading global CRO. The studies were performed according to the regulations that apply to Good Laboratory Practice (GLP) and constituted the last part of the preclinical program before a clinical trial application (CTA) could be submitted.

Furthermore, Lipum recently initiated a collaboration with the Swedish bioanalytical company Pelago Bioscience. Pelago has capacity to provide LC-MS based protein quantification assays as a service for pharmacodynamic, pharmacokinetic or biomarker monitoring during drug development. Initially, the collaboration will focus on drug target monitoring during clinical studies of SOL-116 with the aim of strengthening the development work and increasing the opportunity for valuable results.

Recognition and Grants

In 2018, Lipum was selected as one of the projects included in Horizon 2020, the EU research and innovation funding program. As part of the framework program, the company received a total grant of EUR 2.2m to develop SOL-116 for treatment of chronic inflammatory diseases.

Moreover, the company recently announced that it is one of the partners contributing to the KKS-Synergy grant application "Drug discovery targeting inflammation – novel therapeutic aspects on vascular inflammation, thrombosis and breast cancer" that has been granted SEK 10m by the Swedish Knowledge foundation (KKS). Lipum is a member of the consortium together with both other industry and academic partners.

The project is led by the Cardiovascular Research Centre (CVRC) at Örebro University, which Lipum has an ongoing collaboration with. The grant primarily provides continued opportunities for the research collaboration, and contributes to the company's ambitions to study additional indications for SOL-116.

Financials

Short-term Future Financial Outlook

Being a biotech company in early-stage clinical development, Lipum is unlikely to post any recurring revenues in the next couple of years. We thus primarily focus on its cash position and operating costs in short to medium term. In connection with its IPO in April 2021, the company raised SEK 85.7m in cash issue proceeds (before issue costs). In the company's recent quarterly report, Lipum held some SEK 28m cash on its balance sheet.

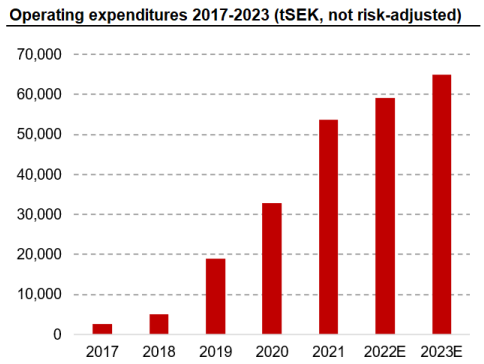
Financial Estimates – Lipum

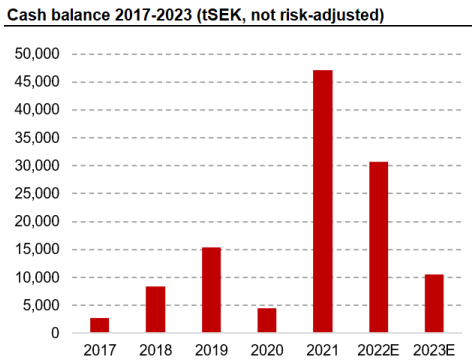
FY Estimates (not risk-adjusted)					
(tSEK)	2019	2020	2021	2022E	2023E
Net sales	51	15	-	-	-
Other income	9,643	11,708	1,583	1,789	1,986
Revenue	**9,694**	**11,723**	**1,583**	**1,789**	**1,986**
Research & development expenses	(15,413)	(27,889)	(48,693)	(53,562)	(58,919)
General & administrative expenses	(3,400)	(3,857)	(4,783)	(5,261)	(5,787)
Other Op. Expenses	(198)	(1,035)	(213)	(234)	(258)
Operating expenses	**(18,813)**	**(31,746)**	**(53,476)**	**(58,824)**	**(64,706)**
EBITDA	(9,317)	(21,058)	(52,106)	(57,269)	(62,978)
EBIT	(9,317)	(21,058)	(52,106)	(57,269)	(62,978)
Financial expenses	-	(40)	(150)	(165)	(182)
Financial income	-	-	-	-	-
EBT	**(9,317)**	**(21,098)**	**(52,256)**	**(57,434)**	**(63,160)**
Tax	-	-	-	-	-
Net income	**(9,317)**	**(21,098)**	**(52,256)**	**(45,603)**	**(50,149)**

Source: Redeye Research, Lipum
** 2022, and 2023 estimates are risk-adjusted.*

During 2021, the company's burn rate amounted to some SEK 13m per quarter. As can be seen below, we expect a slight continued increase in operating expenditures (OPEX) as SOL-116 enters the clinic. Although, we do not expect any radical increase, given that Lipum is unlikely to incur as many CMC expenses ahead following the completion of GMP production.

Operating Expenditures and Cash Balance





Source: Redeye Research, Lipum
** 2022, and 2023 estimates are risk-adjusted.*

In order to keep up with the expected cash burn, we believe that Lipum will need to raise some capital. Furthermore, the company itself has also stated that it is in need of additional capital and is likely to perform a financing round before the end of 2022. Accordingly, we factor in a share issue in the region of SEK 30-35m later this year in our valuation model.

Sales Models and Assumptions

Given the tough competition and already-established treatment regime in the field of rheumatism, the commercial success of SOL-116 will be largely dependent on the performance demonstrated in the upcoming clinical trials. Superior safety or efficacy to currently approved biologics (and JAK-inhibitors) would be highly encouraging considering SOL-116's first-in-class Profile. However, should the candidate only manage to demonstrate data in line with/worse than currently approved treatment options, we believe the anticipated late market entry in 2029 will restrict its patient share. Rheumatologists experience and practice with established bDMARDs and tsDMARDs is likely to provide such products with a leg-up on newly-approved drugs.

Furthermore, for now, our sales model of SOL-116 exclusively contains RA as the targeted indication. Should Lipum initiate clinical trials in any other indications in the future, such as JIA, we will evaluate and potentially add these to our sales model in upcoming research updates.

Valuation assumptions for SOL-116

Timeline and Licensing deal

Lipum has been clear in its intentions of finding a licensing partner for the mid/late-stage development of SOL-116 post phase Ib trials. We project that Lipum, in collaboration with its partner, will start phase II trials shortly after striking a licensing deal.

SOL-116 – Estimated Clinical Timeline

Anticipated clinical development timeline						
Year	2022	2024	2024	2026	2028	2029
Event	Initiation of phase I	Licensing deal	Initiation of phase II	Initiation of phase III	NDA filing	Market launch

Source: Redeye Research, Informa Pharma Intelligence

Contingent upon positive phase Ib top-line data, we model a USD 200m licensing deal for SOL-116 in 2024 following the conclusion of the upcoming phase Ib study. We also assume an upfront payment in the region of USD 20m, with the remaining USD 180m spread across development- and sales-based milestone payments. We model a royalty rate of some 12 percent on any potential profits for the program under the agreement and that the licensing partner bears all further development costs. As a reference point for our deal-related assumptions, we list a summary of recent comparable licensing deals within the RA space in the table below.

Recent Licensing Deals in RA

Recent licensing deals - RA							
(USDm)	Partner	Project	Phase	Upfront	Deal size	Royalty (%)	Year
Company							
Bio-Thera Solutions	Biogen	BAT1806	III	$30m	N/A	N/A	2021
Samsung Bioepis	Biogen	SB11/SB15	III	$100m	$310m	N/A	2019
Hanmi	Eli Lilly	HM71224	I/II	$50m	$690m	10-20%	2015
MorphoSys	GlaxoSmithKline	MOR103	I/II	$30m	$604m	13%	2013
Xbrane Biopharma	Biogen	Xcimzane	Preclin.	$8m	$88m	Undisc.	2022
Imcyse	Pfizer	RA Imotope	Preclin.	N/A	$180m	Undisc.	2018
Modern Biosciences	Janssen Biotech	Bone-protective compound	Preclin.	Undisc.	$277m	Undisc.	2014
Anaphore	Mitsubishi Tanabe	Atrimer	Preclin.	$5m	$115m	10-20%	2010
Average			I/II	$35m	$330m	14%	
Median			I	$25m	$275m	15%	

Source: Redeye Research

Likelihood of Approval

An essential part of the process of evaluating drug candidates in clinical progress is to assess the probability of success (PoS) for each upcoming phase, as well as the candidate's overall likelihood of approval (LoA). The LoA determines the risk-adjustment percentage used when discounting future cash flows and has an incremental impact on the overall valuation. Defining definite values for the PoS and LoA of biotech companies is tricky and riddled with uncertainty. When assessing a clinical candidate's LoA, our starting point is always in historical success rate data within the field.

SOL-116 – Probability of Success and Likelihood of Approval

	Ph I - PH II	Ph II - PH III	Ph III - NDA	NDA - Approval	LoA overall
Autoimmune	60%	32%	66%	93%	11%
SOL-116	60%	32%	66%	93%	11%

Source: Redeye Research, Informa Pharma Intelligence

We have found an average industry chance of reaching the market of roughly eleven percent for autoimmune disease treatments entering clinical development. This is ultimately the same LoA that we chose to assign SOL-116 as well, given that it is now approaching phase I development and is yet to showcase any clinical data.

Pricing

When determining a reasonable pricing for SOL-116, we use the price of currently approved biologics as benchmark drugs. Given that SOL-116 is mainly being developed as an alternative to current standard bDMARDs, and it being a monoclonal antibody, we see them as reasonable peers.

Biologics are generally quite expensive in comparison with csDMARDs (first-line treatment), with an average annual price of USD 22,000–44,000 per patient according to The Rheumatologist. However, the recent introduction of biosimilars could foster more competition and, in theory, lower these prices. Accordingly, we take a somewhat conservative stance, modelling an annual price of USD 18,000, USD 12,000 and USD 10,000 for SOL-116 in the US, EU5 and Japan, respectively.

Incidence

We have included the US, EU5 (France, Germany, Italy, Spain, and the UK) and Japan markets in our sales models of SOL-116. Furthermore, we consider patients who receive pharmacologic treatment today and have had an inadequate response to MTX monotherapy as the target patient population for the candidate. We use disease prevalence data from Datamonitor for all of the three markets. While EU5 has a slightly larger RA population (1,950,000) than the US (1,792,000), we still estimate the US to be the largest market due to its higher pricing possibilities.

According to Datamonitor Healthcare's 2016 survey results, RA patients receiving drug treatment have a compliance rate of 69-80 percent depending on region. Accordingly, we choose the middle of this range for our sales model and factor in a compliance rate of 75 percent.

SOL-116 Sales Model – RA

Our sales projections are based on a quite modest five-percent market penetration of the addressable patient population in the US and a three-percent ditto in the EU5 and Japan, owing to the increasing availability of biosimilars. We assume a six-year launch curve before reaching this market penetration, based on a study by Robey & David (2017) which analyses historical averages for prescription drugs. Our estimate for sales erosion from this point relates to patent expiry. SOL-116 is expected to be patent protected until 2040, following the company's international PCT-application. Considering our estimated market launch in 2029, this would provide eleven years of market exclusivity.

The key assumptions in our SOL-116 RA sales model are:

- Market Launch in 2029
- Peak market penetration of five percent in the US, and three percent in EU5 and Japan.
- Annual pricing of USD 18,000, USD 12,000, and USD 10,000 in the US, EU5 and Japan, respectively.
- Royalty rate of 12 percent
- Deal size of USD 200m
- Eleven percent likelihood of reaching the market

Based on these assumptions, we arrive at annual global peak sales of more than **USD 600m** for SOL-116 in RA by 2037.

SOL-116 Sales Model in RA – US, 5EU & Japan

		2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
US													
RA prevalence		2,058,445	2,099,614	2,141,606	2,184,438	2,228,127	2,272,689	2,318,143	2,364,506	2,411,796	2,460,032	2,509,233	2,559,417
Moderate/severe RA	75%	1,543,834	1,574,710	1,606,204	1,638,329	1,671,095	1,704,517	1,738,607	1,773,379	1,808,847	1,845,024	1,881,924	1,919,563
Patients on RA treatment	55%	849,108	866,091	883,412	901,081	919,102	937,484	956,234	975,359	994,866	1,014,763	1,035,058	1,055,760
2nd line patients	60%	509,465	519,654	530,047	540,648	551,461	562,491	573,740	585,215	596,920	608,858	621,035	633,456
Launch curve		0.10	0.25	0.50	0.70	0.90	1.00	1.00	1.00	1.00	0.90	0.80	0.70
Market share	5%	1%	1%	3%	4%	5%	5%	5%	5%	5%	5%	4%	4%
Treated patients		2,547	6,496	13,251	18,923	24,816	28,125	28,687	29,261	29,846	27,399	24,841	22,171
Compliance rate	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%
List price	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18000	18000	18000
Gross to net %	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Net price	14,400	14,400	14,400	14,400	14,400	14,400	14,400	14,400	14,400	14,400	14400	14400	14400
Revenue ($m)		**28**	**70**	**143**	**204**	**268**	**304**	**310**	**316**	**322**	**296**	**268**	**239**
growth		N/A	155%	104%	43%	31%	13%	2%	2%	2%	-8%	-9%	-11%
5EU													
RA prevalence		2,239,937	2,284,736	2,330,431	2,377,039	2,424,580	2,473,071	2,522,533	2,572,984	2,624,443	2,676,932	2,730,471	2,785,080
Moderate/severe RA	75%	1,679,953	1,713,552	1,747,823	1,782,779	1,818,435	1,854,804	1,891,900	1,929,738	1,968,332	2,007,699	2,047,853	2,088,810
Patients on RA treatment	45%	923,974	942,454	961,303	980,529	1,000,139	1,020,142	1,040,545	1,061,356	1,082,583	1,104,235	1,126,319	1,148,846
2nd line patients	60%	554,384	565,472	576,782	588,317	600,084	612,085	624,327	636,813	649,550	662,541	675,792	689,307
Launch curve		0.10	0.25	0.50	0.70	0.90	1.00	1.00	1.00	1.00	0.90	0.80	0.70
Market share	3%	1%	1%	3%	4%	5%	5%	5%	5%	5%	5%	4%	4%
Treated patients		2,772	7,068	14,420	20,591	27,004	30,604	31,216	31,841	32,477	29,814	27,032	24,126
Compliance rate	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%
List price	12,000	12,000	12,000	12,000	12,000	12,000	12,000	12,000	12,000	12,000	12000	12000	12000
Gross to net %	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Net price	9,600	9,600	9,600	9,600	9,600	9,600	9,600	9,600	9,600	9,600	9600	9600	9600
Revenue ($m)		**20**	**51**	**104**	**148**	**194**	**220**	**225**	**229**	**234**	**215**	**195**	**174**
growth		N/A	155%	104%	43%	31%	13%	2%	2%	2%	-8%	-9%	-11%
Japan													
RA prevalence		746,780	761,716	776,950	792,489	808,339	824,506	840,996	857,816	874,972	892,471	910,321	928,527
Moderate/severe RA	75%	560,085	571,287	582,712	594,367	606,254	618,379	630,747	643,362	656,229	669,353	682,741	696,395
Patients on RA treatment	46.5%	308,047	314,208	320,492	326,902	333,440	340,109	346,911	353,849	360,926	368,144	375,507	383,017
2nd line patients	60%	184,828	188,525	192,295	196,141	200,064	204,065	208,146	212,309	216,556	220,887	225,304	229,810
Launch curve		0.10	0.25	0.50	0.70	0.90	1.00	1.00	1.00	1.00	0.90	0.80	0.70
Market share	3%	1%	1%	3%	4%	5%	5%	5%	5%	5%	5%	4%	4%
Treated patients		924	2,357	4,807	6,865	9,003	10,203	10,407	10,615	10,828	9,940	9,012	8,043
Compliance rate	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%	75%
List price	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10000	10000	10000
Gross to net %	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Net price	8,000	8,000	8,000	8,000	8,000	8,000	8,000	8,000	8,000	8,000	8000	8000	8000
Revenue ($m)		**6**	**14**	**29**	**41**	**54**	**61**	**62**	**64**	**65**	**60**	**54**	**48**
growth		N/A	155%	104%	43%	31%	13%	2%	2%	2%	-8%	-9%	-11%

Source: Redeye Research

Valuation

Valuation Summary

In our valuation of Lipum, we estimate the sales potential in its main candidate SOL-116 and assign an associated likelihood of reaching market approval. We then incorporate this into a risk-adjusted discounted cash flow (DCF) valuation model, which provides us with our Base Case. We use a weighted average cost of capital (WACC) of 16%, based on both qualitative and quantitative aspects of the company using our Redeye Company Quality model.

Lipum – Valuation

DCF-model							
Project	Program	LOA	Royalty	Peak sales USDm	Launch	Deal size USDm	NPV SEKm
SOL-116							
	RA	11%	12%	621	2029	200	114
			Tech value (SEKm)				114
			Net cash (SEKm)				47
			Admin costs (SEKm)				-23
			Fair value (SEKm)				139
			No. Shares (million)				5.1
			Value per share (SEK)				27.5
			Est. Increase of shares (million)				2.5
			Est. Increase of cash (SEKm)				27.6
WACC: 16%			Base case per share				22

Source: Redeye Research

** Numbers may not add up due to rounding.*

Scenario Analysis

To provide a dynamic view of our valuation of Lipum, we also model both a pessimistic scenario (Bear Case) and an optimistic scenario (Bull Case). The differences in estimates between the scenarios are based on modifications of the assumptions used in the valuation process (see below).*

*The following assumptions apply to all three scenarios:

- A tax rate of 20.6% (Swedish corporate income tax from 2021)
- Per-share valuation is calculated on 7.6 million outstanding shares (after projected share issue).
- A WACC of 16%.

Bear Case 5 SEK

We factor in negative results from the SOL-116 phase Ia/Ib trials and see limited prospects in the rheumatism indications. The company's cash position and the candidates potential in other chronic inflammatory indications constitutes the company's remaining value.

Base Case 22 SEK

The DCF model above represents our Base Case scenario.

Bull Case 35 SEK

We factor in positive phase Ia/Ib top-line results for SOL-116 that strongly support ongoing development of the candidate. Consequently, Lipum finds a partner and commits on a licensing agreement for the mid-/late-stage development and commercialization of the candidate in RA.

Sensitivity Analysis

Our valuation of Lipum is highly affected by the WACC that we attribute to the company. WACC plays an essential part in calculating the discounted cash flow and reflects the uncertainties related to the company and the market. We illustrate the impact of applying changes to the WACC on our fair value range (Base Case, Bull Case, and Bear Case) valuation in a sensitivity analysis below.

Lipum: Sensitivity Analysis

Sensitivity analysis: WACC						
		14%	15%	16%	17%	18%
Value (SEK/share)	Bull	42.0	38.4	**35.0**	31.9	29.0
	Base	**26.4**	**24.1**	**22.0**	**20.0**	**18.2**
	Bear	6.0	5.5	**5.0**	4.6	4.1

Source: Redeye Research

Peer Valuation

To provide additional insight into the current valuation of similar biotech companies, we include a peer group analysis. The valuation of listed biotech companies in clinical development varies considerably, depending on project validation, potential, financial position, risk, etc. However, we base our relative valuation on the enterprise value (EV) (market cap minus net cash) of what we consider to be comparable drug development companies. Below we present a sample of Nordic peers.

Lipum: Peer Valuation

Peer Group Valuation					
(SEKm)	Market Cap	Cash*	EV	No. Projects	Dev. Stage
Company					
SynAct	1,290	24	1,266	2	Phase II
Active Biotech	233	38	196	3	Phase II
Coegin Pharma	161	26	135	2	Phase II
Alzecure	119	26	93	3	Phase I
Stayble Therapeutics	66	38	28	1	Phase II
Cyxone	64	69	-5	2	Phase II
Idogen	39	38	1	3	Phase I
Lipigon	24	17	8	4	Phase I
Average	**249**	**34**	**215**	**3**	**Phase I/II**
Median	**92**	**32**	**61**	**3**	**Phase II**
Lipum	**86**	**47**	**39**	**1**	**Phase I**

Source: Redeye Research
**Based on latest reports.*

Our peer valuation has no impact on our fair value range. It is instead a snapshot of comparable companies. However, based on the companies listed in the table, Lipum's valuation is currently below its peers. The median market cap (SEK 92m) is only slightly above the current market cap of Lipum (SEK 86m). However, the median EV of the listed peers (SEK 61m) is significantly higher than the EV of Lipum (SEK 39m). The discrepancy in value reflects a upside potential of some 55%, suggesting that the company is undervalued by the market in comparison to its peers. Although, it is worth noticing that the peer median number of projects in the pipeline is three and the median current development stage (for lead candidate) is phase II, while Lipum currently only has one project entering phase I development.

Appendix I – Executive Management

Name	Position	Shares	Options
Dr. Einar Pontén	Chief Executive Officer		
	Doctoral degree in analytical chemistry at Umeå University. Einar formerly worked as CEO and co-founder of SeQuant, a chromatography company. SeQuant was later acquired by Merck KGaA (Darmstadt). Thereafter CEO of Merck SeQuant AB.	113,500	35000
Marina Norberg	Chief Financial Officer		
	Broad experience with companies of different sizes and industries. Marina has been an approved auditor at PwC for years and has worked as an authorized accounting consultant within Aspia AB.	3,701	1,000
Assoc. Prof. Susanne Lindquist	Chief Scientific Officer		
	Doctoral degree in microbiology and associate professor in pediatrics at Umeå University. Susanne has spent more than 20 years on research work on BSSL and has written more than 20 original scientific articles. Expertise within preclinical models for arthritis and other inflammatory diseases.	311,796	300
Dr. Pernilla Abrahamsson	Chief Operating Officer		
	Doctoral degree in anaesthesiology and intensive care at Umeå University. Founder of MD Biomedical AB, and developer of advanced medical equipment (OnZurf Probe). MD Biomedical AB was later acquired by Senzime AB, where she continued to work until her assignment at Lipum.	3,000	300
Professor Olle Hernell	Chief Medical Officer		
	MD, Ph.D., Professor of Pediatrics and former head of Pediatrics at the Department of Clinical Sciences, Umeå University. 30+ years of experience as a senior consultant in pediatric gastroenterology, hepatology, and nutrition. Olle discovered the bile salt-stimulated lipase (BSSL) in human milk and is known for his clarification of BSSL structure, characteristics, and physiological function.	318,300	500

Appendix II – Board of Directors

Name	Position	Shares	Options
Ulf Björklund	Chairman of the board		
	M.Sc. in Pharmacy from Uppsala University. 30+ years of experience in the pharmaceutical industry. Experience ranges from pharmaceutical discovery and development of new drugs to diagnostics, research, and marketing. Prior work includes the CEO of Aprea and OxyPharma, and several positions within Pharmacia covering clinical research in many therapeutic areas. Current assignments include board member of TikoMed AB and MedicaNatumin AB	13,435	480
Professor Olle Hernell	Director		
	MD, Ph.D., Professor of Pediatrics and former head of Pediatrics at the Department of Clinical Sciences, Umeå University. 30+ years of experience as a senior consultant in pediatric gastroenterology, hepatology, and nutrition. Olle discovered the bile salt-stimulated lipase (BSSL) in human milk and is known for his clarification of BSSL structure, characteristics, and physiological function.	318,300	500
Dr. Kristian Sandberg	Director		
	Associate professor in immunology and an experienced leader in the pharmaceutical industry's research and development. Kristian har worked at AstraZeneca for 20+ years in various functions within R&D, primarily project leader responsibilities. Current assignments include a board member of Toleranzia AB and a co-founder and Board member of PharmaPrecision AB.	0	0
Åsa Hansdotter	Director		
	Attorney-at-law and partner of the business law firm HWF advokater AB in Helsingborg, where Åsa works with company and equity capital markets law, international M&A, and corporate commercial matters as external legal counsel for listen and non-listed companies. Previously worked as a partner at Mannheimer Swartling. Current assignments include board members to Dizlin Pharmaceuticals AB, P Capital Partners AB, and the Swedish Chamber of Commerce for Russia & CIS.	0	0
Dr Ingemar Kihlström	Director		
	Doctoral degree in physiology/toxicology from Uppsala university. Previously worked with research and development and business development at Astra AB and Pharmacia AB followed by a career as a pharmaceutical analyst in the finance industry at Swedbank, Aros Securities, and ABG Sundal Collier. Ingemar is currently a board member of several listed companies, mainly on Nasdaq First North in Stockholm.	0	0

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: 3

We view the company's management and board as competent, and we believe shareholders can be confident in its execute and strategic abilities. Despite being small, the management team is dynamic and experienced. CEO Einar Pontén has "done it before", having been co-founder and CEO of chromatography company SeQuant AB for more than 10 years, as it was acquired by pharmaceutical giant Merck.

Business: 3

Lipum is a biotech company in research and development stage. Consequently, the company is yet to register any recurring revenue. Instead, the company is highly dependent on capital markets for near-term funding and potential licensing partners for future late-stage development. However, we argue that the future sales potential for SOL-116 is significant as our sales model estimates global annual peak sales of more than USD 600m.

Financials: 1

The company is in need of capital to carry on operations until completion of phase Ia/Ib trials with SOL-116. Accordingly, Lipum has stated that it intends on raising capital later on this year.

	2020	2021	2022E	2023E
INCOME STATEMENT				
Revenues	11723	1583	1789	1986
Cost of Revenues	0	0	0	0
Gross Profit	11723	1583	1789	1986
Operating Expenses	32781	53689	59058	64964
EBITDA	-21058	-52106	-57269	-62978
Depreciation & Amortization	0	0	0	0
EBIT	-21058	-52106	-57269	-62978
Net Financial Items	-40	-150	0	0
EBT	-21098	-52256	-57269	-62978
Income Tax Expenses	0	0	-11797	-12973
Non-Controlling Interest	0	0	0	0
Net Income	-21098	-52256	-45472	-50005
BALANCE SHEET				
Assets				
Current assets				
Cash & Equivalents	4440	47053	30831	10827
Inventories	0	1560	1716	1888
Accounts Receivable	5247	135	0	0
Other Current Assets	401	914	1005	1106
Total Current Assets	10088	49662	33553	13820
Non-current assets				
Property, Plant & Equipment, Net	0	0	0	0
Goodwill	0	0	0	0
Intangible Assets	0	0	0	0
Right-of-Use Assets	0	0	0	0
Shares in Associates	0	0	0	0
Other Long-Term Assets	0	0	0	0
Total Non-Current Assets	0	0	0	0
Total Assets	10088	49662	33553	13820
Liabilities				
Current liabilities				
Short-Term Debt	182	155	171	188
Short-Term Lease Liabilities	0	0	0	0
Accounts Payable	653	1375	1513	1664
Other Current Liabilities	4550	17125	18838	20721
Total Current Liabilities	5385	18655	20521	22573
Non-current liabilities				
Long-Term Debt	1476	1566	1723	1895
Long-Term Lease Liabilities	0	0	0	0
Other Long-Term Liabilities	0	1560	1716	1888
Total Non-current Liabilities	1476	3126	3439	3782
Non-Controlling Interest	0	0	0	0
Shareholder's Equity	3227	27881	9594	-12535
Total Liabilities & Equity	10088	49662	33553	13820
CASH FLOW				
NOPAT	-16720	-41372	-45472	-50005
Change in Working Capital	147	16336	1738	1763
Operating Cash Flow	-19370	-34296	-45472	-50005
Capital Expenditures	0	0	0	0
Investment in Intangible Assets	0	0	0	0
Investing Cash Flow	0	0	0	0
Financing Cash Flow	0	76909	29250	30000
Free Cash Flow	-19370	-34296	-45472	-50005

DCF Valuation Metrics	**Sum FCF (SEKm)**
Initial Period (2021–2023)	-92
Momentum Period (2024–2033)	79
Stable Period (2034–)	79
Firm Value	67
Net Debt	-45
Equity Value	112
Fair Value per Share	22.00

	2020	2021	2022E	2023E
CAPITAL STRUCTURE				
Equity Ratio	0.3	0.6	0.3	-0.9
Debt to equity	0.5	0.1	0.2	-0.2
Net Debt	-2782	-45332	-28938	-8744
Capital Employed	4703	31007	13032	-8752
Working Capital Turnover	26.3	-0.1	-0.1	-0.1
GROWTH				
Revenue Growth	21%	-86%	13%	11%
Basic EPS Growth	126%	148%	-37%	-14%
Adjusted Basic EPS Growth	126%	148%	-37%	-14%
PROFITABILITY				
ROE	-221%	-336%	-243%	3400%
ROCE	-448%	-168%	-439%	720%
ROIC	-3225%	536%	271%	270%
EBITDA Margin (%)	-180%	-3292%	-3202%	-3172%
EBIT Margin (%)	-180%	-3292%	-3202%	-3172%
Net Income Margin (%)	-180%	-3301%	-2542%	-2518%
VALUATION				
Basic EPS	-4177.8	-10347.7	-6496.0	-5556.1
Adjusted Basic EPS	-4177.8	-10347.7	-6496.0	-5556.1
P/E	neg	neg	neg	neg
EV/Revenue	neg	neg	neg	neg
EV/EBITDA	0.1	0.9	0.5	0.1
EV/EBIT	0.1	0.9	0.5	0.1
P/B	0.0	0.0	0.0	0.0

SHAREHOLDER STRUCTURE	**CAPITAL %**	**VOTES %**
Avanza Pension	9.9%	9.9%
Flerie Invest AB	7.6%	7.6%
Biolacum AB	5.0%	5.0%
Susanne Lindqvist	4.9%	4.9%
Lennart Lundberg	4.7%	4.7%

SHARE INFORMATION	
Reuters code	LIPUM
List	First North
Share price	17.25
Total shares, million	5.05

MANAGEMENT & BOARD	
CEO	Einar Pontén
CFO	Marina Norberg
Chairman	Ulf Björklund

ANALYSTS
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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 (2022-06-01)

Rating	People	Business	Financials
5p	32	15	4
3p - 4p	155	138	48
0p - 2p	5	39	140
Company N	192	192	192

Duplication and distribution

CONFLICT OF INTERESTS

Kevin Sule owns shares in the company : No
Fredrik Thor 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.