

**Equity Research** 29 September 2021

# **Inhalation Sciences**

Sector: Medtech

# **Breathtaking Potential**

Redeye initiates coverage of Inhalation Sciences (ISAB), a Swedish medtech company whose technologically sophisticated PreciseInhale system enables scientists to efficiently measure how inhaled particles behave in human lungs. We argue that the share offers investors exposure to exciting growth in the inhalation therapies market and see the current share price as an attractive entry point for the long-term investor.

### A Unique System with Attractive Properties

ISAB was founded with the mission of solving the problem of unreliable and unprecise data when studying how inhaled particles behave in human lungs - a particularly important factor in drug development. Its proprietary PreciseInhale system provides researchers with precise results and high correlation between laboratory results and clinical testing. This enables more cost-efficient development of inhaled medicines, primarily targeting asthma and chronic obstructive pulmonary disease (COPD).

#### Ready for the Commercialization Phase

As of today, ISAB Sciences has sold 20 PreciseInhale systems to customers globally and conducts three to five contract research assignments per year. Sales have been around SEK 5-10m over the past three years, but we argue that the company is ready to scale up and we forecast a sales ramp-up from next year.

#### **Attractive Entry Point**

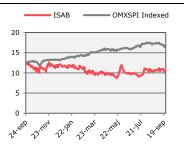
We consider the current share price an attractive entry point that does not fully reflect ISAB's long-term growth prospects. Using a DCF model, our fundamental analysis suggests upside potential of some 125 percent from our Base Case of SEK 23 (with respective Bull and Bear cases of SEK 35 and SEK 7).

Key Financials (SEKm)	2019	2020	2021E	2022E	2023E
Sales	9	10	12	18	32
Sales growth	64%	13%	17%	55%	75%
EBITDA	-8	-9	-14	-5	2
EBIT	-8	-9	-16	-6	1
EBIT Margin (%)	-88%	-86%	-132%	-35%	2%
Net Income	-4	-10	-16	-6	1
EV/Sales	7.6	12.4	8.5	5.4	3.1

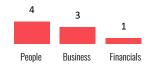
#### FAIR VALUE RANGE

BEAR	BASE	BULL
7	23	35

#### ISAB VERSUS OMXS30 (LTM)



#### **REDEYE RATING**



#### **KEY STATS**

Ticker	ISAB-SE
Market	Spotlight
Share Price (SEK)	10.2
Market Cap (SEKm)	115
Net Debt 21E (SEKm)	-20
Free Float	92%
Avg. daily volume ('000)	35

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## Investment Case

#### A System Facilitating the Development of Inhalation Therapies

The PreciseInhale system from Inhalation Sciences (ISAB) enables more cost-efficient development of inhaled medicines – an ever more popular treatment regime. Thanks to their convenience for patients and the lower required doses, inhaled drugs are currently being evaluated beyond the scope of respiratory diseases, for example migraine, diabetes, and influenza, implying additional potential beyond the current target markets.

#### Strong Underlying Growth

An investment in Inhalation Sciences provides investors with exposure to the global aerosol delivery devices market, which according to Allied Market Research was valued at USD 31bn in 2019 and is expected to reach around USD 47bn in 2027, representing a CAGR of 4.9%. We argue that ISAB has a strong outlook for the coming years and estimate sales of around SEK 110m by 2026, growing at a CAGR of 56% from this year, where we expect sales of SEK 12m.

#### **Attractive Business Model with Recurring Revenues**

ISAB's business model is both to sell its PreciseInhale system, including different modules, and to provide contract research services for customers within pharma, research, and academia. Each sold PreciseInhale system brings recurring revenues in the form of an annual service fee along with sales of high-margin consumable products. In addition, the contract research business can act as a gateway to new customers.

#### Low Competition

The competition is still very limited in this field and alternative technologies that generate and dose aerosols for different in-vitro and in-vivo applications have been on the market for many years and are based on technologies from the 1950s. Moreover, the company has distribution agreements in place with some of its potential competitors. Germany's TSE is currently a global distributor of ISAB's products, suggesting that TSE views PreciseInhale and its additional modules as a strong complement to its current portfolio rather than a threat.

#### **Clinical Market Opportunity**

ISAB currently focuses on the discovery and pre-clinical phases, areas that it has valued at around SEK 2bn. In June 2021, it initiated a clinical study to validate PreciseInhale for the clinical phase, and we expect a read-out in late 2021. An approval would expand the potential market to around SEK 8bn, roughly quadrupling the market it currently operates in. Although the first sales of PreciseInhale for clinical application could realistically take place in late 2023 or early 2024, we see this as a strong value driver in the longer term.

## Bear Case

Understanding the risks of an investment can lead to better decisions being made. Below, we list some potential risks associated with an investment in Inhalation Sciences.

#### **Lengthy Negotiations**

The company operates in an industry characterized by long negotiations and extended decision-making processes, as well as high barriers to entry. Negotiations can often last for one to two years and any delays, such as the coronavirus crisis, could slow the ramp-up of sales.

#### **Production Hurdles**

ISAB's products are currently being manufactured by well-reputed Swedish contract manufacturers. As some of these also work with large, global companies, there is a risk that ISAB would be prioritized lower should large-volume orders from global players require high production capacity from the manufacturer.

#### **Capital Needs**

Although ISAB is already generating sales, we expect the company to remain unprofitable until 2023. It recently raised SEK 27.5m<sup>1</sup> through a directed share issue but may need additional funding in the coming two years. Such a scenario could result in dilution and poor share price development.

# Catalysts

#### Clinical Trial

ISAB is currently conducting a clinical trial in order to obtain an approval for using its PreciseInhale system in the clinical phase. We expect a read-out in late 2021 and argue that a positive outcome will have a strong positive impact on the share price.

#### PreciseInhale Sales

Sales have been around SEK 5-10m over the past three years, but we argue that the company is ready to scale up. We expect to see more PreciseInhale orders in the coming twelve months, which we believe will act as a strong catalyst for the stock.

<sup>&</sup>lt;sup>1</sup> In addition to the directed share issue, ISAB issued 1,137,573 warrants (TO1) that can bring in additional SEK 11.4-17.1m in June 2022.

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# **Company Description**

Founded in 2004, Inhalation Sciences (ISAB) is a Swedish medtech company that develops and sells highly innovative lab equipment for inhalation research. The company was founded by Associate Professor Per Gerde PhD, who has more than three decades of experience in inhalation research. While working at the Lovelace Respiratory Research Institute in New Mexico, US, in 1991, Mr. Gerde faced a dilemma: he needed a machine so sensitive that it could show how the tiniest particles of radioactive dust behave in our lungs when inhaled. As no such device existed, Mr. Gerde began to build it. This was the first step in the development of ISAB's proprietary PreciseInhale system (CE-marked). With the PreciseInhale system, scientists are able to gain information with unprecedented accuracy about how inhaled particles behave in our lungs, whether this be drugs under development or new air pollutants. The system has been developed in collaboration with Karolinska Institutet and is today the core product in ISAB's product portfolio.

PreciseInhale was launched on the market in 2014 and the first systems were sold in 2016 when King's College in London and Dow Chemicals placed their first orders. Over the years, other reputable customers, such as AstraZeneca, Chiesi, Hovione, and Karolinska Institutet, have been joined the company's customer base.

In addition to product sales, ISAB also conducts contract research in the inhalation field. Aside from generating revenues (30 percent of total sales in 2020), this segment also contributes to the further development of the company's products and is an important channel for establishing contact with new customers.

Today, ISAB employs eight staff and is headquartered in Huddinge, Sweden. The company's shares were listed on Spotlight Stock Market (previously Aktietorget) in 2017.

#### Timeline

2004	- Inhalation Sciences is founded by Dr. Per Gerde
2008	- Patent application for DissolvIt
2014	- PreciseInhale is launched on the market
2016	- Delivery of PreciseInhale systems to King's College in London and Dow Chemicals in the United States
	- The patent application of DissolvIt is approved by the European Patent Office (EPO)
2017	- IPO on Aktietorget (now Spotlight Stock Market)
	- The patent application for XposeALI is approved in China
2018	- The patent application for XposeALI is approved by the European Patent Office (EPO)
2019	- Manoush Masarrat becomes the new CEO
	- PreciseInhale shows exceptional precision in an inhalable nicotine study
2020	- ISAB divests its holdings in Ziccum and secures long-term financing
	- The company signs a global distribution agreement with TSE Systems GmbH
	- ISAB and Astra Zeneca publish positive results from a PreciseInhale study on large animals
2021	- ISAB signs an exclusive distribution agreement with Apex Inhalation for sales expansions into India, Bangladesh and Sri Lanka
	- Signs exclusive distribution agreement with Sanyo Trading, Japan
	- CTA approval for clinical trial of PreciseInhale
	- All 12 healthy volunteers enrolled in the clinical trial

Source: Redeye Research

# Management, Board, and Ownership

#### **Ownership**

The CSO and founder Per Gerde is among the ten largest shareholders of ISAB, something we consider a positive factor. However, none of the largest shareholders own more than 10 percent and no institutional owners hold a significant stake in the company. This lack of a strong owner could pose a challenge, in our view, especially in times of uncertainty. However, we believe it will be easier for ISAB to attract more long-term institutional owners once sales start to pick up and its market capitalization increases.

#### Shareholders

#	Name or institution	No. of shares	Capital (%)	Votes (%)
1	Nordnet Pensionsförsäkring	1,129,045	10.06%	10.06%
2	Per Gerde	771,140	6.87%	6.87%
3	Avanza Pension	744,454	6.63%	6.63%
4	Robert Joki	470,800	4.19%	4.19%
5	Tobias Granberg	370,000	3.30%	3.30%
6	Georg Petersen	332,640	2.96%	2.96%
7	Futur Pension	311,000	2.77%	2.77%
8	John Fällström	235,975	2.10%	2.10%
9	Magnus Ljungblad	200,000	1.78%	1.78%
10	Jan Christer Dahlström	190,180	1.69%	1.69%
	Others	6,620,500	57.65%	57.65%

Source: Holdings as of 28 September 2021

#### **Management and Board**

In our view, ISAB has a solid management team that brings with it a combination of broad experience and deep sector knowledge. It applies a business-oriented mindset, with a strong focus on creating long-term shareholder value – something we appreciate.

CEO Manoush Masarrat joined ISAB in 2018 as a board member. Ten months later, in September 2019, he was appointed CEO, bringing with him 15 years of experience in executive roles in the medtech sector. He has previously been CEO of ExScale BioSpecimen Solutions AB and has held several roles in sales and marketing in multinational organizations.

CSO and founder of the company Per Gerde is an Associate Professor of Inhalation Toxicology and Scientist at the Division of Physiology, Institute of Environmental Medicine at Karolinska Institutet. Mr. Gerde has an impressive background as a scientist and postdoctoral fellow at the Lovelace Respiratory Research Institute and as a scientist at the Swedish National Institute of Occupational Health before he began with the development of PreciseInhale. He has also published some 50 peer-reviewed scientific papers.

The board consists of five members with extensive experience across different fields. Chairman Daniel Spasic is a life sciences entrepreneur with more than 25 years of experience in the sector. He founded the global CRO company TFS Trial Form Support International, which, under his leadership, reached USD 100m in revenue, established a presence in 20 countries, employed 800 staff, and served 250 customers worldwide.

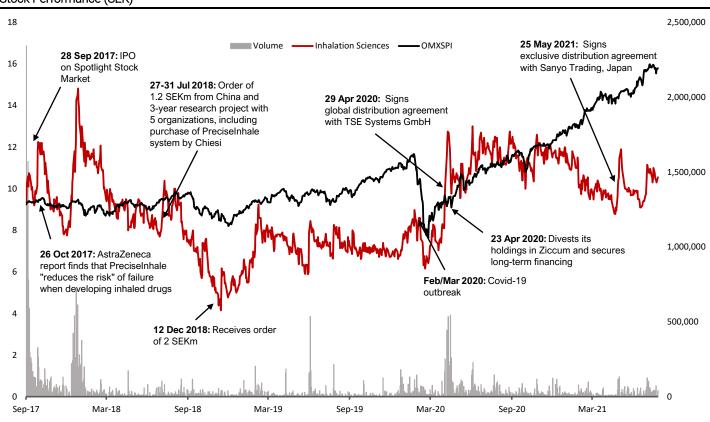
For a full overview of the management team and board, please see Appendix I.

## Stock Performance

The ISAB share was listed on Spotlight Sock Market (previously Aktietorget) on 28 September 2017. The share price rose on the initial day of trading from SEK 5.0 to SEK 9.3, an increase of 85%. Since then, the share price has been volatile, reaching an all-time high in January 2018 of SEK 15.5, but then dropping to around SEK 4.0 in December the same year.

Like many other stocks, the share price experienced a dramatic fall following the outbreak of COVID-19 in 2020, down some 30% between February and March. In April of the same year, the company announced plans to dispose of all its shares in its subsidiary Ziccum AB (total value of SEK 21.2m) to secure financing until the end of 2021, in accordance with the financial plan. The news had a positive effect on the ISAB share price, which rose by around 60% in the week the news was announced. Since then, the stock performance has been largely flat but with volatile movements. The pandemic has had a negative impact on ISAB's business, resulting in difficulties meeting customers and selling products. Unlike many other companies though, ISAB has weathered the storm quite well. If things return to normal, we expect to see a sales ramp-up for ISAB next year, and we argue that new orders will act as a strong catalyst for the stock.

#### Stock Performance (SEK)



Source: Yahoo Finance and Redeye Research

## Product Portfolio

ISAB serves customers within the fields of pharma, research, and academia, and its product portfolio consists of the PreciseInhale system and additional modules. Moreover, the company enjoys aftermarket potential from selling high-margin consumable products, plus from the annual service it performs after the initial order.

#### Systems and Modules

Systems	Modules
PreciseInhale	Dissolvlt
	XposeALI
	Nose-only inhalation
	Intratracheal intubation
	Isolated perfused and ventilated lung (IPL)

Source: Inhalation Sciences and Redeye Research

The company's products are protected by several patent families, three of which relate to technical solutions for generating and dosing high-quality aerosols. A further two patents relate to applications and modules. Patents have been granted in the most important markets, including the US, and the company's key patents are valid until 2033.

Below, we describe the PreciseInhale system and its additional modules in more detail.

## PreciseInhale

ISAB's core product is PreciseInhale, a technically sophisticated system that enables scientists to efficiently measure how inhaled particles behave in our lungs and, in turn, affect our health. Many scientists are still using technologies from the 1950s, providing them with varied and, in many cases, unreliable information. Our lungs have an impressive ability to distribute drugs into our body in a quicker and more efficient manner than many other therapies, but the development of inhaled therapies has been hampered by poor data (low correlation between early lab results and later clinical results). Since drug development is very costly², unreliable data is highly problematic and can cost pharma companies millions of dollars in lost investments. The need for reliable systems is thus huge.

#### PreciseInhale



<sup>&</sup>lt;sup>2</sup> The average cost of getting a new drug to the market is around USD 1.3bn

The PreciseInhale system provides researchers with precise results and high correlation between laboratory results and clinical testing. Accordingly, it enables more cost-efficient development of inhaled medicines, primarily targeting asthma and chronic obstructive pulmonary disease (COPD). However, inhaled drugs are currently being evaluated in areas beyond these, including migraine, diabetes, and influenza, offering further potential beyond lung indications.

The PreciseInhale system is based on two core innovations:

#### It separates aerosol generation and dispensing

The system generates aerosols using a high-power air jet with 10-160 bar pressure, with deagglomeration of even tough substances. The energy is subsequently siphoned off, leaving a plume of aerosol settling downwards. An adjustable airflow, through a vacuum pump, pulls the settling cloud into a fine, free-flowing stream of particulate aerosol that can be dispensed across a range of exposure modules.

## II. Real-time monitoring and measurement of the tailored aerosol through PreciseInhale's software

A light-scattering device and automated proprietary software enable real-time measurement and mapping of aerosol concentration and breathing patterns. Accordingly, researchers are able to customize the aerosol to their specific needs. The system also generates detailed pharmacokinetic (PK) data, including particle size distribution and Cmax and Tmax curves.

#### **Precision Dosing**

The PreciseInhale system is built around the precision dosing methodology. By using this technique with adjustable air pressure, settings can be optimized, and aerosols can be generated precisely in accordance with the desired dose. Higher air pressure generates finer aerosols through more powerful particle deagglomeration. This will be expressed as a smaller Mass Median Aerodynamic Diameter (MMAD) when the particle size distribution is routinely determined. Aerosols can be sourced from marketed inhalers, dry powders, or nebulized solutions.

With this method, as little as 100 milligrams of costly test substance can be sufficient to perform a complete PK study; traditional methods use 100g. Precision dosing suggests clear cost benefits. The generated aerosol is a free-flowing, fine particulate and controllable stream that can be used in a wide range of exposures. As illustrated below, the PreciseInhale system provides precise and predictive data with low standard deviation.

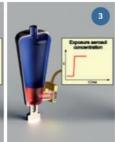
#### Precision Dosing - Overview



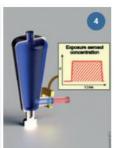
A jet of high pressure air is shot through the powder chamber, aerosolising the powder upwards into the holding chamber.
The energy of the jet is siphoned off.



The aerosol rises upwards in a plume, then settling downwards in the holding chamber where a controlled air flow "pulls" the API past a real-time aerosol monitor.



The real-time aerosol concentration and dose is logged.



The precise exposure is controlled.

Source: Inhalation Sciences

Using the PreciseInhale system provides clear benefits, the six most distinctive of which are shown below.

## Benefits of Using PreciseInhale



As little as 100 mg or less of test substance can run a full PK study.



PreciseInhale® reduces development time by identifying the right candidate drug early on.



Generates data on precise dosing with a typical standard deviation of less than 10%.



One aerosol across a range of exposure modules producing predictive, comparable data, with less translational issues.



Customized dose setting gives consistent particle size distribution from nano particles upwards.



One-animal-at-a-time method plus in vitro capabilities reduces, refines & replaces animals.

Source: Inhalation Sciences

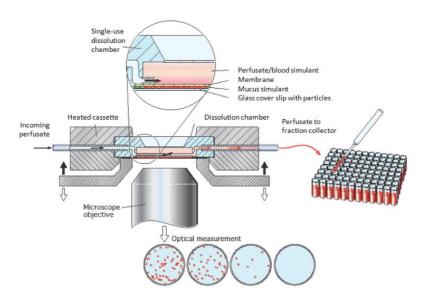
Since the production of aerosols using the PreciseInhale system is well controlled, it can easily be supplied to a wide range of exposure modules. As aerosols can be sourced from inhalers, nebulized solutions, or dry powders, researchers can optimize conditions using many different substrates. As such, PreciseInhale acts as an exposure platform for small-scale inhalation experiments by precisely dosing animals in vivo, lungs ex vivo, and by depositing aerosolized material for in-vitro exposure and dissolution testing.

## Dissolvlt

Dissolvlt is a patented in-vitro module through which dry powder particles can be deposited on a coverslip with the PreciseInhale system. After this, the particles are brought into contact with simulated/airway mucus and the dissolution is studied from the luminal side using optical microscopy and from the vascular side using chemical analysis of a flow-past perfusion medium.

As can be seen in the diagram below, the system includes a single-use dissolution chamber, a precision-controlled peristaltic pump, and an inverted microscope including a high-resolution camera. The whole system is thermostated to 37°C and the artificial lung/barrier delivers prominent absorption and dissolution data.

#### Dissolvlt



# XposeALI

With the XposeALI module, the PreciseInhale system exposes cells with respirable size aerosols without the aerosol reaching the cell media or contaminating the transwell walls. Following aerosol exposure, the cells are transferred back to the incubator for an appropriate time period, allowing for investigation and analysis of the cells or the media. The aerosol-induced effects on the cells can thus be studied.

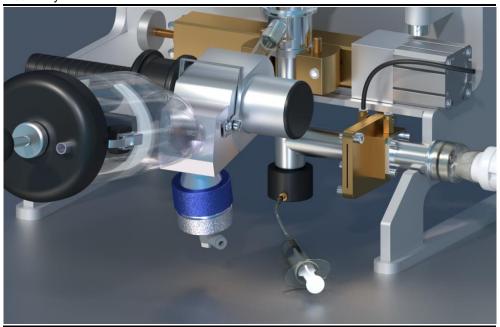
## **XposeALI**



# Nose-Only Inhalation

The Nose-Only inhalation module is an in-vivo module that exposes single rodents to respirable aerosols from the PreciseInhale system. The rodents are exposed one at a time in a precise safety process, reducing the standard deviation. This allows fewer test animals to be used and provides precise and highly reliable pharmacokinetic data. Unlike ex-vivo experiments in the IPL model, in-vivo experiments enable researchers to investigate how inhaled drugs are distributed to the blood and other tissues and to explore the subsequent metabolism and clearance.

## Nose-Only Inhalation



## Intratracheal Intubation

Intratracheal intubation is an in-vivo module that bypasses the nose to ensure inhalation exposure directly to the lung. This avoids a substantial loss of substance to the nose and subsequently to the gastrointestinal tract. The module offers good control of the dose delivered, a distribution pattern of the administered materials in the lungs resembling that obtained during clinical inhalation exposures, and low substance consumption. This allows researchers to study the distribution of inhaled drugs to the blood and other tissues as well as the subsequent metabolism and clearance.

## Intratracheal Intubation

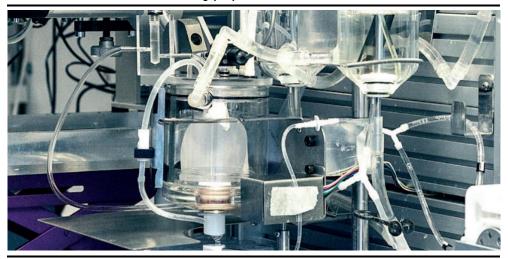


## Isolated Perfused and Ventilated Lung (IPL)

The Isolated perfused and ventilated lung module is an ex-vivo module designed specifically for exposures of respirable aerosols from PreciseInhale. IPL is a commonly used model in toxicological and pharmacological studies. Thanks to a tailored version of IPL, the module allows for analysis of the effects of different agents in an intact organ, allowing the study of the lung-specific effects of toxicants and drugs.

Airway resistance, vascular resistance, and gas exchange can be monitored at the same time. The module is advantageous for PK studies of inhaled drugs and the perfusate can be collected over the course of the perfusion period using a fraction collector, which also makes it possible to monitor the perfusate flow rate. Conversion to a recirculation mode, to facilitate detection of an accumulating substance or metabolites in smaller perfusate volume, is also possible.

#### Isolated Perfused and Ventilated Lung (IPL)



## **Business Model**

ISAB's business model can be split into two segments:

- System sales
- Inhalation Research Services (IRS)

## System Sales

Part of ISAB's business model is the sale of its PreciseInhale system to research organizations, academic institutions, and global healthcare companies. Sales are primarily conducted by its own sales force, although the company does work with a few selected partners. A few years ago, it signed a non-exclusive, global distribution agreement with Germany's TSE, providing ISAB with access to almost 70 markets globally. Furthermore, ISAB has two exclusive distribution agreements in place covering the Japanese and Indian markets, and it has contracted two lead-generating agents in the US. Together, these provide the company with access to almost all the relevant markets.

#### Selected Customers













Source: Inhalation Sciences and Redeye Research

Even though distribution agreements are efficient in the upscaling phase, ISAB aims to sell as much as possible through its own sales force in the future. We see this strategy as particularly compelling since it enables the company to build strong relationships and have close interaction with its customers. In this way, ISAB can remain at the forefront and swiftly transform customer needs into new products and services.

With each PreciseInhale sale to a customer, ISAB customizes the order according to the customer's specific requirements. The right modules are included and a service agreement spanning over a few years (generally five) is signed. Following delivery, an aftermarket opportunity arises, through which ISAB can sell high-margin consumable products. Each order thus generates annual recurring revenues.

The sales price of a PreciseInhale is SEK 1-3m, depending on which modules are included. After that, ISAB charges around SEK 200,000-400,000 annually for consumables and SEK 100,000 for annual servicing. Accordingly, each sold system implies an additional SEK 200,000-500,000 in potential annual revenues. However, when selling through distributors, the company earns around 70% of the list price of each product. We estimate that gross margins are around 50% for PreciseInhale and approximately 95% for the consumable products.

## Inhalation Research Services (IRS)

ISAB also conducts services in contract research on a consulting basis and has had assignments with Philip Morris, Celon Pharma, and AstraZeneca in recent years. Contract research has historically been an important source of income for ISAB, accounting for half of the company's sales in 2016 compared with around 30 percent today. For example, Chiesi bought consulting services for several years before it invested in its own PreciseInhale system. Contract research can thus serve as a gateway for new customers.

In this segment, ISAB charges around SEK 500,000-700,000 per substance examined and tested by its research personnel using the PreciseInhale system. The average CRO contract includes two to three substances and, with its current workforce, ISAB can take on around three to five contracts a year. This segment currently provides an annual sales opportunity of SEK 3-8m.

ISAB is an agile and innovative company that strives to constantly improve and develop new products. The company works with reputed contract manufacturers, with its PreciseInhale system being manufactured by AQ in Uppsala. The modules are produced by ten to twenty subcontractors, while the disposable cells are developed in Tyresö. In total, around 90% of ISAB's products are made in Sweden. It takes approximately three to six months from order of a PreciseInhale to delivery. While this might seem long, bear in mind that negotiations typically take from a couple of months up to a year or two. This means that ISAB can, in many cases, predict and plan for its orders ahead of time. Furthermore, it always has two or three systems in stock at its office in Huddinge to ensure production and delivery time do not cause bottlenecks.

ISAB has traditionally targeted the discovery and preclinical phases, but it is now increasingly focusing on making advances into the clinical phase. The company is currently conducting a clinical study (12 healthy volunteers) to get approval to use PreciseInhale in clinical phase I. We expect a read-out in late 2021. Following a potential approval, it will take approximately two years before ISAB can get all the regulatory requirements, such as the CE mark and MDR approval, in place to commercialize the product for clinical use. Going into clinical use will provide new opportunities and increase the market potential three- or four-fold, we judge. However, the main focus in the next few years will be on scaling up in the preclinical market.

# **Inhalation Therapies**

Drug delivery through inhalation, known as aerosol therapy, has long been used, becoming mainstream in respiratory care during the 20<sup>th</sup> century. As early as 1929, inhaled epinephrine for the relief of asthma was reportedly in use in the UK, and in the 1950s, a dry powder inhaler was used to administer penicillin dust to treat respiratory infections.

Today, three common types of aerosol generators are used in inhaled drug delivery:

- Small-volume nebulizers: These convert liquid drug solutions or suspension into aerosol using compressed air, a compressor, oxygen, or an electrical device.
- **Pressurized Metered-Dose Inhalers:** These are small, portable drug devices that dispense multiple doses by a metered value.
- Dry-powder inhalers: These aerosol devices deliver the drug in a powdered form, commonly with a breath-actuated dosing system

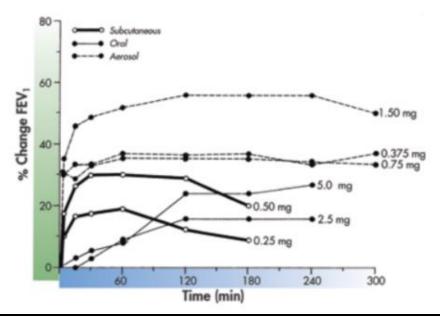
#### **Aerosol Generators**



Source: Redeye Research

Treating pulmonary diseases with inhaled aerosol drugs comes with both benefits and drawbacks. The primary benefit is that the lungs can be treated with a smaller dose, resulting in fewer side effects than with oral delivery. Moreover, a greater clinical effect can be obtained in certain cases. In the figure below, inhalation of terbutaline, a short-acting beta-2 agonist, from a pressurized metered-dose inhaler is shown to enhance the airflow in the patient compared with a significantly larger oral dose or subcutaneous injection of the drug.

#### Aerosol Delivery vs. Oral and Subcutaneous



Source: Lewis RA, Fleming JS. "Fractional deposition from a jet nebulizer: how it differs from a metered-dose inhaler" Br J Dis Chest 1985; 79(4):361-367

In conclusion, the benefits and drawbacks can be summarized as follows:

## Benefits:

- Generally smaller doses
- Faster onset than oral doses
- Direct delivery to the lungs, with minimal systemic exposure
- Lower frequency and less severe side effects
- Less painful and more convenient for the patient

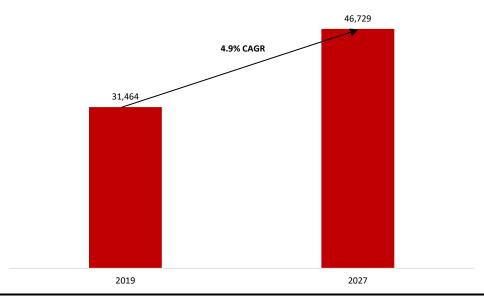
#### Drawbacks:

- A relatively low fraction of the total dose is deposited in the lungs
- Dose reproducibility and lung deposition can be affected by a number of factors, such as the use of device and breathing patterns
- Lack of knowledge about optimal usage among both clinicians and patients can reduce the effectiveness

## Market Overview

According to Allied Market Research, the global aerosol delivery devices market was worth USD 31bn in 2019 and is expected to reach around USD 47bn in 2027, representing a CAGR of 4.9%.

### Global Aerosol Delivery Devices Market, 2019-2027 (USDm)



Source: Allied Market Research

This growth is mainly expected from a rise in the prevalence of asthma and COPD (see Appendix II for a description of asthma and COPD). Moreover, an increasing demand for home healthcare devices, a growing geriatric population, a larger degree of air pollution, and a higher awareness of inhalation therapies among patients are additional factors that are likely to fuel the market growth.

We believe there are four specific factors that will drive demand for ISAB's products and services in the coming years:

- Asthma
- COPD
- Inhaled drugs
- Air pollution

#### **Asthma**

According to the Global Asthma Network, more than 338 million people globally suffer from asthma today and it is also the most common chronic disease among children. Asthma is a particularly extensive problem for people living in both developing and urbanized parts of the world. The disease is one of the largest research areas for drug development and PreciseInhale can help identify appropriate and inappropriate drug candidates at an early stage.

#### COPD

Chronic obstructive pulmonary disease (COPD) is expected to become the world's fourth most common cause of death by 2030, driven in particular by smoking and an aging global population. As of today, one in ten people over the age of 40 worldwide has been diagnosed

with COPD and this number is growing. PreciseInhale can identify realistic aerosol exposures at an early stage in the drug development process, ensuring that the results demonstrated in the preclinical phase are also achieved in the clinical phase.

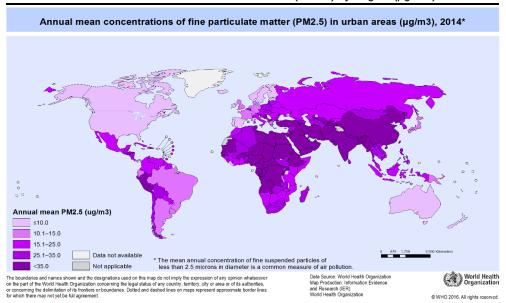
#### **Inhaled Drugs**

Inhaled drugs are used today primarily to treat pulmonary diseases such as asthma and COPD. However, the lung is an organ of great interest in many more types of treatment where rapid drug effect is crucial, such as migraine and diabetes. Moreover, inhalation of drugs is also an attractive substitute to other therapies thanks to its convenience for the patient. With the development of the in-vitro modules of PreciseInhale, the need for animal experiments to produce inhaled medicines is greatly reduced thanks to the system's greater accuracy. A reduced number of animal experiments is one important goal for pharmaceutical companies and research institutes alike.

#### **Air Pollution**

In 2015, the World Health Organization (WHO) presented a resolution stating that all national health authorities must carry out advanced research focusing on the health effects and impact of air pollution. The WHO's report also highlighted air pollution as the world's single-largest environmental health risk. Around 92% of the earth's population breathes hazardous air every day, and every year more than six million people die from diseases associated with air pollution.

According to new research, exposure to particulate matter from burning fossil fuels such as coal and oil accounted for 18 percent of global deaths in 2018, totaling 8.7 million<sup>3</sup>.



Annual Mean Concentration of Fine Particulate Matter (PM2.5) by Region (µg/m3)

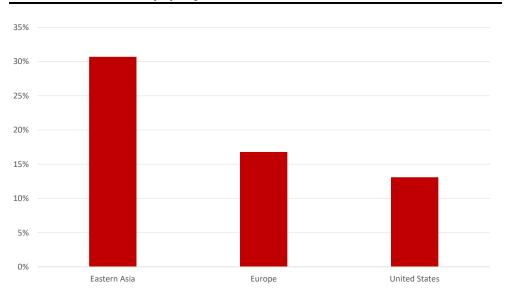
Source: WHO

Burning fossil fuels produces greenhouse gases, which trap radiation from the sun and are, to a large extent, responsible for the climate crisis. Moreover, this produces a toxic cocktail of tiny particles capable of entering the lungs, causing asthma, lung cancer, and other health

<sup>&</sup>lt;sup>3</sup> José L. Domingo, PhD, Robert Letcher, BSc, MSc, PhD, Aijie Wang, PhD; *Environmental Research* 

issues. As much as 30.7% of the deaths in Eastern Asia, 16.8% in Europe, and 13.1% in the US can be attributed to fossil fuel pollution.

#### Fossil Fuel Related Mortality By Region

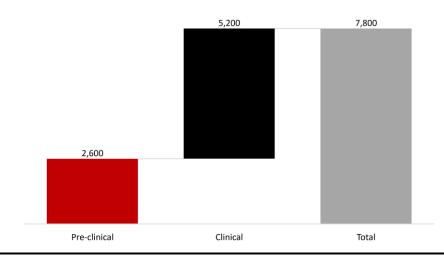


Source: WHO

However, air pollution is present not only outdoors; over the last three decades, humans have invented a large number of new materials that are being used in clothes and buildings, among other applications. No one knows what happens when we inhale particles from these materials. Investments in research are increasing and the PreciseInhale system can help create an understanding of the effects of particles and their possible health hazards.

As mentioned previously, ISAB currently focuses on the discovery and pre-clinical phases, a market that it has valued at around SEK 2bn. In June, ISAB initiated a clinical study to validate PreciseInhale for the clinical phase, and we expect a read-out in late 2021. According to the company's valuation, approval would expand the potential market to around SEK 8bn, approximately four times larger than the market the company currently operates in. However, it is important to keep in mind that an approval for clinical application takes time as a CE marking and MDR approval will be required following positive study results. This generally takes a year or two. We thus believe the first sales of PreciseInhale for clinical application could take place in late 2023 or early 2024.

## Addressable Market for PreciseInhale, EU and US (No. of Systems)



Source: Inhalation Sciences and Redeye Research

Today, ISAB operates mainly towards Europe and the US, where the company believes there is a potential need for up to 2,600 PreciseInhale systems. However, the market potential increases when considering the growth markets – mainly China, India, and South America – where the company sees great expansion possibilities in the longer term. Expanding into these geographies could potentially double the market potential, we judge.

# Competition

ISAB's PreciseInhale system competes with several alternative technologies that generate and dose aerosols for different in-vitro and in-vivo applications. These other technologies have been on the market for many years and have a great number of scientific references. Among the vendors that deliver advanced laboratory equipment for the inhalation market are Germany's TSE Systems and Cultex.

#### **Dust Generator (Cultex)**

This device is recommended as an essential peripheral equipment for the exposure of cells to dry powder aerosols and is based on the dust feeder. It is specifically designed for in-vitro exposure systems and is able to provide uniform airborne concentrations of dust for long periods of time.



#### Inhalation Exposure Equipment (TSE Systems)

This equipment includes cigarette smoke generators, for example, which are used for continuous smoking of cigarettes for chronic inhalation exposure tests, and nose-only units that are special solutions for bigger animals for the application of particulate test air. However, TSE's equipment is more of a complementary product to PreciseInhale as it targets a later stage of the drug development process.



PreciseInhale provides researchers with data that improves toxicological understanding, which is important, particularly from a cost perspective, before advancing to the next stage where TSE's equipment is applicable. Furthermore, TSE is currently a global distributor of ISAB's products, suggesting that TSE views PreciseInhale and its additional modules as a strong complement to its current portfolio.

ISAB operates in a conservative market that is controlled by regulatory guidelines and strict regulatory requirements. Scientific references are crucial when projects are to be performed and methods and systems to be selected. PreciseInhale is CE-marked, and generated data in recent years has highlighted knowledge about the company and its methods. Moreover, strong academic groups have used PreciseInhale and its additional modules, bringing references in renowned scientific publications.

As mentioned previously, in May 2021, the Swedish Medical Product Agency approved an application from ISAB for a clinical trial (12 healthy volunteers) of PreciseInhale. The company initiated the trial in June 2021 and should complete the study by the end of the year. If the study results are satisfactory and PreciseInhale receives approval for clinical usage, the product has the potential to become a leading, low-risk, high-precision aerosol delivery system on the market in a few years' time. We have not identified any direct competitors in that stage, and given a market valued at SEK 8bn, the potential is enormous.

## Clinical Fyidence

Over the past years, PreciseInhale has been used and evaluated in many different studies. Feedback from users has generally been positive, with three distinctive characteristics highlighted:

- More precise results
- Smaller doses required
- Less time-consuming

In 2017, Italy's largest pharmaceutical company, Chiesi Farmaceutici, published a scientific article proving that PreciseInhale delivered better results and precision than alternative technologies. Administration of micronized CHF6001 (drug candidate) using the PreciseInhale system yielded lung exposures in the same range as the other tested devices, but the reproducibility in lung deposition was improved. The initial amount of CHF6001 in the lungs at the first sampling time point was close to the predetermined target dose. Tracheal deposition with PreciseInhale  $(0.36 \pm 0.22 \,\mu\text{g})$  was significantly less than with other tested delivery systems: PennCentury  $(23.7 \pm 3.2 \,\mu\text{g})$  and Airjet  $(25.6 \pm 7.2 \,\mu\text{g})$ .

AstraZeneca published research the same year showing that PreciseInhale delivered results that make it safer and quicker for scientists to choose which drug candidates to continue developing. Dose levels could be selected with confidence before moving to the toxicology study and reduced the risk for tolerability limitations. This showed that PreciseInhale has the ability to deliver data that can save time and reduce costs and risks for the pharmaceutical industry when developing inhaled drugs.

In 2019, a pre-clinical study by Philip Morris International analyzed and measured the pharmacokinetics of two formulations of dry powder nicotine intended for inhalation delivery. As a water-soluble substance, nicotine is transported and dissolved quickly over the lung's air blood barrier so that much vital data, including Cmax and Tmax curves, has not previously been able to be captured using conventional in-vivo experiments. With PreciseInhale's in-vitro Dissolv/t, ex-vivo IPL (isolated perfused rat lung IPL), and in-vivo IT module, voluminous, detailed data, including Tmax and Cmax curves, was delivered.

Moreover, PreciseInhale and the XposeALI module were highlighted in Nanomaterials, the international, peer-reviewed, open access journal, in March 2020. The article covered a study that investigated the cytotoxic and inflammatory potential of CeO2 nanoparticles (NM-212) in a co-culture of A549 lung epithelial cells and differentiated THP-1 cells in both air-liquid interface (ALI) and submerged conditions. By using PreciseInhale and the XposeALI module, an aerosol of CeO2 nanoparticles was generated and deposited on the co-culture (see diagram below).

#### Exposure to Cells Using the PreciseInhale System and XposeALI Module

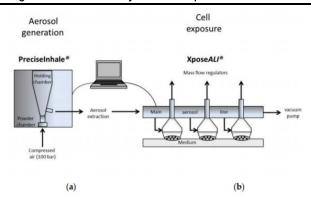


Figure 1. Exposure of cells to an aerosol of cerium dioxide nanoparticles (CeO<sub>2</sub> NPs) generated from dry powders in the PreciseInhale system (a) in combination with the XposeALI cell exposure unit (b). A small amount of powder (typically 2 mg) is loaded into the powder chamber. An aerosol is generated using rapid decompression of powder agglomerates, and the delivered mass can be estimated by a light dispersion instrument. Deposition on cells (5 mL/min flow rate) is analyzed offline using inductively coupled plasma mass spectrometry (ICP-MS).

Source: Cappellini et al, "Dry Generation of CeO2 Nanoparticles and Deposition onto a Co-Culture of A549 and THP-1 Cells in Air-Liquid Interface—Dosimetry Considerations and Comparison to Submerged Exposure; Nanomaterials"; 2020

In general, experiments using ALI systems are both more time-consuming and challenging than submerged exposures. However, the study showed that some advantages could be obtained by using the PreciseInhale system with the XposeALI module. Firstly, a smaller amount of powder was needed for the whole study. Secondly, the deposition in the XposeALI module required a relatively short time (around five to twenty minutes depending on dose).

## Images of CeO2 Nanoparticles Aerosolized in the PreciseInhale System

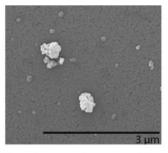


Figure 2. Scanning electron microscopy (SEM) images of  $CeO_2$  NPs aerosolized in the PreciseInhale system and deposited on collagen-coated cover slips put in transwells in the XposeALI unit.

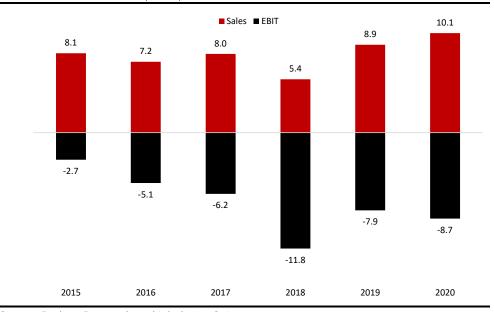
Source: Cappellini et al, "Dry Generation of CeO2 Nanoparticles and Deposition onto a Co-Culture of A549 and THP-1 Cells in Air-Liquid Interface—Dosimetry Considerations and Comparison to Submerged Exposure; Nanomaterials"; 2020

In summary, the study demonstrated both that PreciseInhale is applicable for the generation of dry aerosols from particle powders and that the XposeALI module is useful for the exposure of cell cultures to these aerosols. Accordingly, a detailed comparison between ALI and submerged exposure conditions can be performed, which is important to gain a better understanding of the differences between the two exposure methodologies in terms of toxicological responses. As production and use of different nanoparticles is constantly increasing in society, in turn resulting in an increasing need for reliable assessments of their toxicological effects, PreciseInhale provides a valuable contribution.

## **Financials**

Inhalation Sciences is still early in the commercialization phase and is not currently profitable. As of today, the company has sold 20 PreciseInhale systems and its CRO segment is generating some revenue. Sales have been around SEK 5-10m over the past three years, but we argue that the company is ready to scale up, and we expect to see a sales ramp-up from next year.

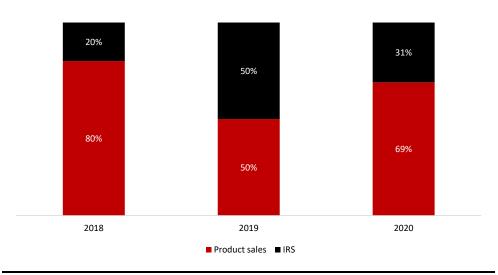
## Sales and EBIT, 2015-2020 (SEKm)



Source: Redeye Research and Inhalation Sciences

The segment split has been relatively volatile over the past three years, partly due to the low sales base. One order or contract can consequently have a huge impact. The company's goal in the coming years is for around 70 percent of its sales to stem from the product segment and 30 percent from the CRO business (IRS), a target it hit in 2020.

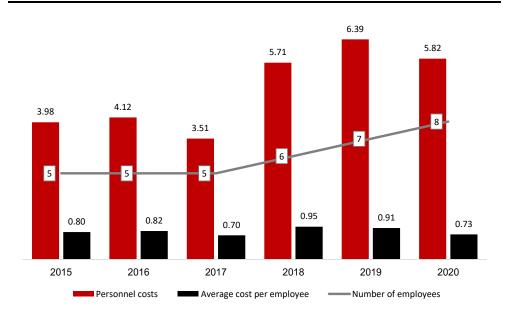
#### Segment Split, 2018-2020 (%)



Source: Redeye Research and Inhalation Sciences

When it comes to personnel costs, ISAB has kept the average cost per employee relatively stable since 2015. The company currently employs eight staff but intends to double its workforce over the coming five years as part of its expansion and scaling up.

## Personnel Costs, 2015-2020 (SEKm)



Source: Redeye Research and Inhalation Sciences

If the situation returns to normal, we expect ISAB's sales to start ramping up in the next two years and believe that the company can be profitable in 2023.

## **Estimates**

We estimate sales over the coming ten years by splitting the business into four different income sources: *PreciseInhale, Consumables, Annual Service*, and *Inhalation Research Services*. At this stage, we only include sales on the preclinical market.

#### Sales Estimates, 2021-2031 (SEK)

SEK	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
PreciseInhale											
No. of sold PreciseInhale systems	4	7	14	19	25	38	47	52	53	54	55
Total outstanding systems	24	31	45	64	89	127	174	226	279	333	388
Sales price	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000	1,500,000
PreciseInhale sales	6,000,000	10,500,000	21,000,000	28,500,000	37,500,000	57,000,000	70,500,000	78,000,000	79,560,000	81,151,200	82,774,224
% of total sales	51%	57%	65%	63%	49%	52%	49%	45%	41%	37%	34%
Consumables											
Sales per system	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000
Sales from Consumables	900,000	2,400,000	4,500,000	7,800,000	26,700,000	38,100,000	52,200,000	67,800,000	83,712,000	99,942,240	116,497,085
% of total sales	8%	13%	14%	17%	35%	35%	37%	39%	43%	45%	47%
Annual Service											
Service fee	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000
Sales from Annual Service	1,920,000	2,480,000	3,600,000	5,120,000	7,120,000	10,160,000	13,920,000	18,080,000	22,323,200	26,651,264	31,065,889
% of total sales	16%	13%	11%	11%	9%	9%	10%	11%	11%	12%	13%
Inhalation Research Services											
Number of contracts	3	3	3	4	5	5	6	8	10	12	15
Average number of substances per contract	2	2	2	2	2	2	2	2	2	2	2
Price per substance	500,000	500,000	500,000	500,000	500,000	500,000	500,000	500,000	500,000	500,000	500,000
Sales from Inhalation Research Services	3,000,000	3,000,000	3,000,000	4,000,000	5,000,000	5,000,000	6,000,000	8,000,000	10,000,000	12,000,000	15,000,000
% of total sales	25%	16%	9%	9%	7%	5%	4%	5%	5%	5%	6%
Total sales	11,820,000	18,380,000	32,100,000	45,420,000	76,320,000	110,260,000	142,620,000	171,880,000	195,595,200	219,744,704	245,337,198

Source: Redeye Research

As of today, Inhalation Sciences has sold 20 PreciseInhale systems. However, we see a more widespread sales ramp-up from next year, with an annual sales potential of around 55 systems by the end of our forecast period (2031). We expect a product lifetime of around eight years and a replacement rate of 80 percent. Throughout our forecast period, we apply a sales price of SEK 1.5m per system, which is in the middle of the SEK 1-3m range.

Sales of consumables are driven by the number of outstanding PreciseInhale systems. According to the company, each sold system gives rise to around SEK 300,000 in annual consumable sales. However, far from all customers buy consumables today, but we expect this to become more popular in the future and assume that around 90% of the company's PreciseInhale customers buy consumables by the end of the forecast period.

For annual services, we apply an average service fee of SEK 100,000 per system throughout the forecast period. As with consumables, some customers do not buy the annual service today, but again we expect to see a stronger uptake in the future.

With the current workforce, ISAB's Inhalation Research Services is today able to take on three to five service contracts per year, each contract consisting of analysis of an average of two substances. The company charges around SEK 500,000 per substance, meaning that each contract typically generates SEK 1m in revenue. Although it is difficult to find appropriate personnel with the right skills, we believe ISAB will be able to expand in this segment and take on around 15 contracts per year by 2031.

We estimate peak sales of approximately SEK 245m by 2031, of which 60 percent will be recurring (47 percent consumables and 13 percent annual service).

## **Valuation**

## **DCF**

We value Inhalation Sciences using a DCF model with a WACC of 13%. We set the terminal year to 2031 and apply a terminal growth rate of 2%. Our Base Case operates purely on sales in the pre-clinical market since the company's PreciseInhale system is not yet approved for clinical application. However, we view the clinical market as an additional potential and intend to include it in our estimates and valuation once the company receives market approval.

#### **DCF Valuation**

Inhalation Sciences: Base case assumpt	tions (SEKm)				
Assumptions	2021-2031	2021-2024	2024-2031	DCF value	
Sales CAGR	35%	57%	27%	WACC	13%
EBIT margin (avg.)	5%	-40%	27%	PV of FCF	37
				PV of Terminal value	204
Terminal				EV	240
Growth of FCF	2%			Net cash	20
EBIT margin	39%				
				DCF Value	260
				Number of shares (m)	11
				Fair value per share (SEK)	23

Source: Redeye Research

Given an estimated net cash position of SEK 20m, our DCF model suggests a fair value of SEK 23 per share in our Base Case scenario. We also provide a sensitivity analysis to show how sensitive our valuation is to changes in WACC and the terminal growth rate.

#### Sensitivity Analysis

		WACC							
		11.0%	12.0%	13.0%	14.0%	15.0%			
	1.00%	29	25	21	19	16			
Terminal growth rate	1.50%	30	26	22	19	17			
	2.00%	32	27	23	20	17			
	2.50%	33	28	24	20	18			
	3.00%	35	29	25	21	18			

Source: Redeye Research

## Peer Group

To further validate the value of ISAB, we provide a peer group analysis that includes a number of Nordic medtech companies operating in various fields. Even though it is difficult to find a fully comparable company to ISAB and the peer group includes larger companies, we see this approach as a good complement to our DCF model. As ISAB is still some years away from profitability, we see the EV/Sales multiple as the most relevant measure.

#### Peer Valuation

Peer valuation									
		EV/Sales			Sales CAGR	EE	BIT margi	n	
Company	EV (SEKm)	2021E	2022E	2023E	20-23E	2021E	2022E	2023E	
Nordic									
Vitrolife AB	53,087	33.9x	20.4x	19.2x	32%	29%	29%	33%	
Biotage AB	16,208	13.7x	12.0x	10.9x	12%	24%	23%	24%	
CellaVision AB	10,411	18.6x	15.6x	13.6x	18%	28%	31%	32%	
Sedana Medical AB	8,768	60.5x	31.4x	19.6x	46%	-47%	5%	25%	
Xvivo Perfusion AB	11,745	36.3x	27.1x	20.8x	47%	5%	10%	14%	
Surgical Science Sweden AB	8,905	28.8x	13.4x	11.5x	95%	17%	17%	23%	
Genovis AB	4,218	52.1x	30.2x	24.5x	42%	19%	38%	44%	
Boule Diagnostics AB	1,181	2.6x	2.2x	2.0x	14%	9%	15%	16%	
SyntheticMR AB	2,832	43.9x	28.8x	21.1x	39%	22%	40%	48%	
Senzime AB	1,214	48.5x	11.5x	5.9x	178%	-302%	-26%	9%	
IRRAS AB	188	5.1x	1.8x	0.9x	195%	-400%	-113%	-32%	
OssDsign AB	236	1.6x	0.7x	0.4x	78%	-285%	-92%	-28%	
Median	6,493	31.3x	14.5x	12.5x	44%	13%	16%	23%	
Inhalation Sciences	100	8.5x	5.4x	3.1x	47%	-132%	-33%	-3%	

Source: FactSet and Redeye Research

Applying the peer group median EV/Sales multiple for 2022E of 14.5x to our estimated 2022 sales for ISAB of SEK 18.4m, we arrive at an EV of SEK 267m. Given the company's net cash position of SEK 20m, this corresponds to an equity value of SEK 287m and an implied share price of SEK 25. This is fairly in line with our DCF value of SEK 23 per share.

# Valuation

## Bear Case: SEK 7

Our Bear Case scenario assumes a sales CAGR of 28% for 2021-2031.

We assume annual sales of 30 PreciseInhale systems by 2031 and an outstanding base of 200 systems by that point.

We set the terminal year to 2031 and apply a terminal growth rate of 2 percent, with an EBIT margin of 35 percent.

# Base Case: SEK 23

Our Base Case scenario assumes a sales CAGR of 35% for 2021-2031.

We assume annual sales of 55 PreciseInhale systems by 2031 and an outstanding base of around 400 systems by that time.

We set the terminal year to 2031 and apply a terminal growth rate of 2 percent and an EBIT margin of 39 percent.

# Bull Case: SEK 35

Our Bull Case scenario assumes a sales CAGR of 38% for 2021-2031.

We assume annual sales of 70 PreciseInhale systems by 2031 and an outstanding base of around 500 systems by that point.

We set the terminal year to 2031 and apply a terminal growth rate of 2 percent, with an EBIT margin of 44 percent.

# **Income Statement**

Income Statement	2018	2019	2020	2021E	2022E	2023E
Revenues	5	9	10	12	18	32
Y/Y Growth (%)	(32.2%)	64.5%	13.3%	16.6%	55.5%	74.6%
Cost of Revenues	2	3	3	4	7	12
Gross Profit	4	6	7	8	12	20
Gross Profit Margin (%)	68.8%	65.0%	66.7%	65.5%	64.2%	61.8%
Selling Expenses	5	4	4	7	7	8
Administrative Expenses	4	4	4	11	8	8
R & D Expenses	6	6	7	4	3	2
Other Op. Expense / (Income)		-	1	-	-	-
Exchange Rate Differences	-	-	-	-	-	-
EBITDA	(12)	(8)	(9)	(14)	(5)	2
EBITDA Margin (%)	(216.5%)	(88.2%)	(86.2%)	(120.6%)	(28.3%)	5.7%
Depreciation	-	-	-	0	0	0
Amortization	•	-	-	1	1	1
Amortization of Right-to-Use Assets	-	-	-	-	-	-
EBIT	(12)	(8)	(9)	(16)	(6)	1
EBIT Margin (%)	(216.5%)	(88.2%)	(86.2%)	(132.2%)	(34.7%)	2.2%
Associated Income / (loss)		5	-	-	-	-
Interest Income	0	0	-	-	-	-
Interest Expenses	0	1	1	-	-	-
Interest Expenses, Lease Liabilities		-	-	-	-	-
Exchange Rate Differences	-	-	-	-	-	-
Non-recurring Income / (Expenses)		-	-	-	-	-
EBT	(12)	(4)	(10)	(16)	(6)	1
Income Tax Expenses	-	-	-	-	-	-
Effective Tax Rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Non-Controlling Interests	-	-	-	-	-	
Net Income	(12)	(4)	(10)	(16)	(6)	1

# **Balance Sheet**

Balance Sheet	2018	2019	2020	2021E	2022E	2023E
Current Assets						
Cash & Equivalents	2	5	8	20	32	30
Inventories	1	3	2	2	5	8
Accounts Receivable	3	2	2	2	3	5
Other Current Assets	1	1	1	0	0	1
Total Current Assets	7	10	13	24	40	44
Non-Current Assets						
Property, Plant & Equipment, Net	1	1	1	1	1	1
Goodwill	-	-	-	-	-	-
Intangible Assets	3	5	4	4	3	3
Right-of-Use Assets	-	-	-	-	-	-
Shares in Associates	9	7	-	-	-	-
Other Long-Term Assets	-	-	-	-	-	-
Total Non-Current Assets	12	13	6	5	4	4
Total Assets	20	24	18	29	44	49
Current Liabilities						
Short-Term Debt	1	13	0	29	-	1
Short-Term Lease Liabilities	-	-	-	-	-	-
Accounts Payable	0	1	2	1	2	4
Advances From Customers	2	3	3	-	-	-
Prepaid Income	-	-	-	-	-	-
Accrued Expenses	-	-	-	1	1	1
Other Current Liabilities	0	0	1	1	1	2
Total Current Liabilities	4	16	6	32	4	8
Non-Current Liabilities						
Long-Term Debt	5	2	2	2	2	2
Long-Term Lease Liabilities	-	-	-	-	-	-
Other Long-Term Liabilities	-	-	-	-	-	-
Other Long-Term Liabilities, % of Rev.	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total Non-current Liabilities	5	2	2	2	2	2
Non-Controlling Interest	-	-	-	-	-	-
Shareholder's Equity	11	5	10	(5)	38	39
Book Value Per Share	1.3	0.6	0.9	(0.5)	3.4	3.4
Total Liabilities & Equity	20	24	18	29	44	49

# Appendix I – Management and Board

Name	Position	Holdings	Experience
Management			
Manoush Masarrat	CEO	12,800 shares	Manoush Masarrat has been the CEO of Inhalation Sciences since 2019. Mr. Masarrat has extensive executive and management experience in the medtech industry and prior to joining Inhalation Sciences, he was CEO of ExScale BioSpecimen Solutions AB. His career has included several strategic roles in sales and marketing. Mr. Masarrat holds a BSc. in Industrial Economics from Gävle University (Sweden) and MSc. Courses in International Business Management from Macquarie University in Sydney, Australia.
Per Gerde	CSO	771,140 shares	Dr. Per Gerde is an Associate Professor of Inhalation Toxicology and Scientis at the Division of Physiology, Institute of Environmental Medicine at the Karolinska Institutet. Previous assignments include scientist at the Lovelace Respiratory Research Institute (1993—1998), scientist at the Swedish National Institute of Occupational Health (1991—1996), and postdoctoral fellow at the Lovelace Respiratory Research Institute (1989—1991). Dr. Gerde has published around 50 peer reviewed scientific papers, and he is also the main inventor of six patent families with related patent applications.
Paolo Raffaelli	ссо	No holding	Paolo Raffaelli has over 20 years of executive experience in the life science and medical device industry, with extensive sales and marketing management experience, across European and international markets. Mr. Raffaelli holds a BSc. in Computer Science from La Sapienza University in Rome, and an MBA from IMD Business School in Lausanne, Switzerland.

Source: Inhalation Sciences and Holdings

Name	Position	Holdings	Experience
Board of Directors			
Daniel Spasic	Chairman of the Board	150,000 shares	Daniel Spasic is a life science entrepreneur with 25 years of experience from senior executive roles. Mr. Spasic joined the industry in 1996 with Pharmacia & Upjohn, working with clinical drug development in CNS and oncology in Sweden and Italy. He founded the global CRO company TFS Trial Form Support International in 1996, and under his leadership the company's revenue grew to USD 100m, with presence in 20 countries, 800 employees and around 250 customers worldwide. In 2010, Spasic received the Swedish National Award for 'Man of The Year' by Ernst & Young and was named 'Entrepreneur of The Year' by Founders Alliance and Grant Thornton. Mr. Spasic serves as Executive Chairman of Trialbee, and Non-Executive Board Director of NuvoAir. He holds a technical degree in chemical engineering and an OPM from Harvard Business School.
Per Gerde	Board Member	771,140 shares	Dr. Per Gerde is an Associate Professor of Inhalation Toxicology and Scientist at the Division of Physiology, Institute of Environmental Medicine at the Karolinska Institutet. Previous assignments include scientist at the Lovelace Respiratory Research Institute (1993–1998), scientist at the Swedish National Institute of Occupational Health (1991–1996), and postdoctoral fellow at the Lovelace Respiratory Research Institute (1989–1991). Dr. Gerde has published around 50 peer reviewed scientific papers, and he is also the main inventor of six patent families with related patent applications.
Klaus Gottwald	Board Member	14,581 shares	Klaus Gottwald is a systems analyst and economics alumnus from Stockholm University. Mr. Gottwald is co-founder and CEO of Stockholms Affärsänglar (STOAF/Stockholm Business Angels), one of Sweden's most prestigious and successful early-stage investment funds, financing high technology and life science ventures. He is also CEO of Sustainable Energy Angels, an early-stage investment fund focused on smart grid and renewable energy solutions. Mr. Gottwald has extensive strategic, board and executive experience and has been instrumental in establishing, leading and developing companies in strong and rapid growth across a range of industries.
Sonja Gerde	Board Member	46,750 shares	Sonja Gerde holds a MSc. in Industrial Economics from Linköping University and is currently working as an Investment Manager at Impilo. Prior to joining Impilo, she worked as a consultant at the Boston Consulting Group in Stockholm (2014-2017).
Mårten Winge	Board Member	No holding	Mårten Winge is a senior life science executive with extensive experience of commercializing innovative new technology internationally. He has held senior executive and board positions in numerous private and public companies, managing multiple strategic processes, including financing rounds and exits through trade sales as well as IPOs. Mr. Winge is currently CEO of Strike Pharma AB and member, advisory board member, and chairman of a number of highly innovative life science companies. Winge holds a BSc. in chemistry from the University of Stockholm and an MSc. in molecular biology from Karolinska Institutet, Sweden.

Source: Inhalation Sciences and Holdings

# Appendix II – Respiratory Diseases

There are a number of diseases that affect the respiratory system, but the two most prevalent are asthma and COPD (chronic obstructive pulmonary disease), which we briefly describe below.

## Asthma

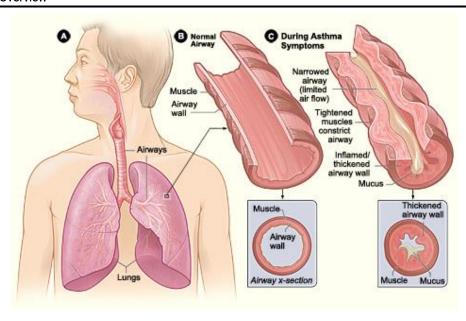
Asthma is an inflammatory, long-term pulmonary disease that affects the airways of the lungs. According to the Global Asthma Network, approximately 338 million people around the world suffer from asthma today. Asthma has a high global burden of death and disability, with some 1,000 people dying from the disease each day. It is believed to be caused by a combination of environmental and genetic factors, often running in families. Asthma is characterized by variable and recurring symptoms, airflow obstruction, and easily triggered bronchospasm.

During an asthma attack, the airways narrow and swell and may produce extra mucus, which can cause breathing difficulties, coughing, wheezing, and shortness of breath. These symptoms typically occur a few times per day or week depending on the person, and symptoms can be more severe at night or during physical activity.

Asthma is usually divided into two different types: allergic and non-allergic. Allergic asthma is triggered by hypersensitivity to allergens (substances that trigger allergies). Allergy sufferers have antibodies that do not work properly and react to natural substances in the environment that are not dangerous. The most common allergens come from cats, dogs, and birch and grass pollen. Grains that contain gluten, crustaceans, or milk and lactose can also cause problems. Allergic symptoms usually manifest themselves in the gastrointestinal tract, skin, or respiratory tract (asthma).

Non-allergic asthma may be due to respiratory tract infections, physical exertion, cold air, or tobacco smoke. During an asthma attack, the resistance in the airways increases and the sufferer has to make more effort to get in air and to breathe. The smooth muscles of the airways, which are controlled by the autonomic nervous system, contract in spasms. The body then consumes more oxygen and produces more carbon dioxide, which can lead to oxygen deficiency. Asthma can occur at any time in life, but it usually starts early in childhood. Asthma in children and adolescents is usually of the allergic type.

#### Asthma Overview



Source: NIH

When asthma is suspected, an investigation is made with a skin-prick test (SPT). If the skin reacts with swelling and redness, it means the person may be allergic. If a patient has elevated levels of antibodies in the blood against a certain antigen, it indicates an allergy.

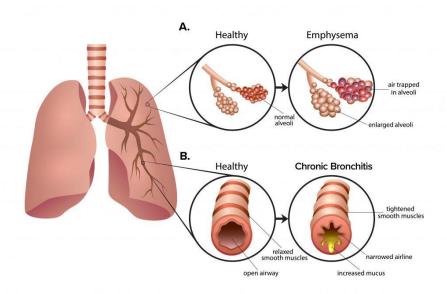
Usually, reversibility tests are also performed, which means that a patient's lung function is measured before and after inhalation of bronchodilators. Lung function can also be measured by spirometry, COPD6 measurement, and PEF measurement. Asthma cannot be cured, but it is treated with anti-inflammatory and bronchodilators. Cortisone is common and is used by many patients regularly. Beta-2-stimulating drugs are used to dilate the trachea and avoid asthma attacks.

## Chronic Obstructive Pulmonary Disease (COPD)

COPD is an obstructive lung disease, causing long-term respiratory symptoms and airflow limitation. It progressively worsens with everyday activities, and the main symptoms include coughing and shortness of breath. It is most common in its mild form and many people live without diagnosis. According to the WHO, around 175 million people across the globe suffer from COPD and it is the third most common cause of death worldwide, at around 3.2 million deaths in 2019. Some 80 percent of these deaths occurred in low- and middle-income countries. COPD is a so-called umbrella diagnosis, meaning that it includes several disease states and is caused by various risk factors. The common denominator is that the disease leads to airway obstruction and the inflammation destroys alveoli walls, which impedes airflow. Ongoing destruction of the alveoli results in emphysema.

Inflammation of the bronchi (the major airways) is called bronchitis, while inflammation of the small airways is called bronchiolitis. Emphysema and bronchiolitis are the most common disease processes that together cause airway obstruction, which in turn results in COPD. A chronic inflammation can also lead to fibrosis, which makes the lungs less elastic.

#### **COPD Overview**



Source: ISSCR

Chronic bronchitis often occurs together with COPD. Accordingly, early onset of smoking is a clear risk factor. Other known risk factors are passive smoking, premature birth, recurrent respiratory infections, asthma during childhood, and prolonged exposure to air pollutants. Damaged airways and alveoli do not heal after smoking cessation, but it does prevent new injuries from occurring. Moreover, symptoms such as coughing usually disappear after smoking cessation.

There is no cure for COPD, which makes it important to identify those with early symptoms. Symptoms of COPD creep in and usually occur later in life, unlike asthma, which usually occurs early, typically in adolescence.

# 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 point. The maximum score for a valuation key is 5 points.

# Rating changes in the report

## People: 4

ISAB has an experienced board and management team with good knowledge of the industry. The long-term goals are realistic, and sound and the management team is enthusiastic about the company and its products.

#### Business: 3

ISAB has an attractive business model with a high degree of its potential revenues being recurring. However, the company is still in the beginning of its commercialization phase and the business model has not been fully proven yet.

#### Financials: 1

ISAB is currently focusing on commercializing the PreciseInhale system and is not yet profitable.

	2020	2021E	2022E	2023E	DCF Valuation Metrics			Sum	FCF (SEKm)
INCOME STATEMENT	-0-0				Initial Period (2021–2030)			<b>54</b>	37
Revenues	10	12	18	32	Stable Period (2031–)				204
Cost of Revenues	3	4	7	12	Firm Value				240
Gross Profit	7	8	12	20	Net Debt				-20
Operating Expenses	16	22	17	18	Equity Value				260
EBITDA	-9	-14	-5	2	Fair Value per Share				23
Depreciation & Amortization	0	1	1	1					
EBIT	-9	-16	-6	1					
Net Financial Items	-1	0	0	0		2020	2021E	2022E	2023E
EBT	-10	-16	-6	1	CAPITAL STRUCTURE				
Income Tax Expenses	0	0	0	0	Equity Ratio	0.6	-0.2	0.9	8.0
Non-Controlling Interest	0	0	0	0	Debt to equity	0.2	-6.0	0.0	0.1
Net Income	-10	-16	-6	1	Net Debt	-6	11	-30	-27
					Capital Employed	12	-3	40	41
BALANCE SHEET					Working Capital Turnover	-10.8	12.1	4.7	4.2
Assets									
Current assets					GROWTH				
Cash & Equivalents	8	20	32	30	Revenue Growth	13%	17%	55%	75%
Inventories	2	2	5	8	Basic EPS Growth	67%	63%	-59%	-111%
Accounts Receivable	2	2	3	5	Adjusted Basic EPS Growth	67%	63%	-59%	-111%
Other Current Assets	1	0	0	1					
Total Current Assets	13	24	40	44	PROFITABILITY				
					ROE	-122%	-588%	-38%	2%
Non-current assets				_	ROCE	-71%	479%	-16%	2%
Property, Plant & Equipment, Net	1	1	1	1	ROIC	-170%	-304%	-311%	-47%
Goodwill	0	0	0	0	EBITDA Margin (%)	-86%	-121%	-28%	6%
Intangible Assets	4	4	3	3	EBIT Margin (%)	-86%	-132%	-35%	2%
Right-of-Use Assets	0	0	0	0	Net Income Margin (%)	-95%	-132%	-35%	2%
Shares in Associates	0	0	0	0					
Other Long-Term Assets	0	0	0	0	VALUATION				
Total Non-Current Assets	6	5	4	4	VALUATION	0.0	1.4	0.0	0.1
T-1-1 A1-	10	20	44	40	Basic EPS	-0.8	-1.4	-0.6	0.1
Total Assets	18	29	44	49	Adjusted Basic EPS P/E	-0.8	-1.4	-0.6	0.1 169.0
Liabilities					EV/Revenue	neg 12.4	neg 10.9	neg 4.8	2.8
Current liabilities					EV/EBITDA				2.o 49.6
Short-Term Debt	0	29	0	1	EV/EBIT	neg	neg	neg	130.2
Short-Term Lease Liabilities	0	0	0	0	P/B	neg 12.5	neg neg	neg 3.1	3.0
Accounts Payable	2	1	2	4	170	12.0	iiug	3.1	5.0
Other Current Liabilities	4	2	2	3					
Total Current Liabilities	6	32	4	8	SHAREHOLDER STRUCTURE			CAPITAL %	VOTES %
Total Gallont Empirition	·		•	ŭ	Nordnet Pensionsförsäkring			10.1%	10.1%
Non-current liabilities					Per Gerde			6.9%	6.9%
Long-Term Debt	2	2	2	2	Avanza Pension			6.6%	6.6%
Long-Term Lease Liabilities	0	0	0	0	Robert Joki			4.2%	4.2%
Other Long-Term Liabilities	0	0	0	0	Tobias Granberg			3.3%	3.3%
Total Non-current Liabilities	2	2	2	2	C				
					SHARE INFORMATION				
Non-Controlling Interest	0	0	0	0	Reuters code				ISAB-SE
Shareholder's Equity	10	-5	38	39	List				Spotlight
Total Liabilities & Equity	18	29	44	49	Share price				10.2
					Total shares, million				11.4
CASH FLOW									
NOPAT	-9	-16	-6	1					
Change in Working Capital	3	-2	-3	-4	MANAGEMENT & BOARD				
Operating Cash Flow	-5	-16	-8	-2	CEO			Manous	h Masarrat
					CSO				Per Gerde
Capital Expenditures	0	0	0	0	Chairman			Da	aniel Spasic
Investment in Intangible Assets	-1	0	-1	-1					
Investing Cash Flow	-1	0	-1	-1					
					ANALYSTS				Redeye AB
Financing Cash Flow	9	29	21	1	Erik Nordström		Mäste	er Samuelsgat	an 42, 10tr
Free Cash Flow	-6	-17	-9	-3	Oscar Bergman			111 57	Stockholm

# 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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#### Redeye Rating (2021-09-29)

Rating	People	Business	Financials
5р	32	16	4
3p - 4p	130	115	42
0p - 2p	5	36	121
Company N	167	167	167

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Erik Nordström owns shares in the company : No

Oscar Bergman 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.