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The originality of our formulations is essentially based on our technological platform BioChaperone®. We have thus pursued the development of our five products currently in clinical trials: BC Lispro, BC Combo, M1Pram, BC Ins Pram and BC Glucagon, while developing new projects, currently in the preclinical stage: BC Lispro Pram, BC Glargine Liraglutide, BC Glucagon GLP-1 and other undisclosed formulations.

2019 was marked by major clinical results from our bi-hormonal M1Pram product, a combination of a prandial insulin and pramlintide (an amylin analogue). These clinical results in type 1 diabetic patients treated for 3 weeks show that this co-formulation makes it possible to restore some essential physiological functions during the digestion phase, such as the restoration of gastric emptying time, abnormally short in people with type 1 diabetes, the inhibition of glucagon secretion (trigger of endogenous glucose synthesis) and a feeling of satiety. This restoration of normal metabolism results in improved control of post-prandial glycemia levels, with a significant reduction in insulin consumption and weight loss in overweight / obese patients, generating improved well-being.

In addition, we are planning the launch of the Phase 2 clinical trial for three months in the last quarter of 2020. On the basis of this upcoming study, we believe that we will be able to define the protocol for a Phase 3 study for the use of M1Pram in pen application for people with type 1 diabetes.

In the second half of 2020, we also plan to launch a pump study to evaluate this M1Pram combination, given the very promising results obtained by university teams in exploration studies in pump. However, we believe that it would also be appropriate to test our second combination BioChaperone® Pram associated with Lispro or with Aspart in a pump trial in order to select the best formulation to be used in artificial pancreas. To achieve this goal, we are planning a clinical study in early 2021 with a formulation combining Lispro with pramlintide and our BioChaperone® technology (BC Lispro Pram).

This strategic choice to prioritize and invest in the combination of insulin and pramlintide is justified by a need to improve the treatment of type 1 diabetic patients with the objective of reducing the long-term consequences of this disease. This choice is also based

Letter from the Chairman

In 2019, we worked successfully to consolidate our diabetes products portfolio, in order to provide people with type 1 and type 2 diabetes with more effective treatments and better compliance.

Gérard Soula

In 2019, we worked successfully to consolidate our diabetes products portfolio, in order to provide people with type 1 and type 2 diabetes with more effective treatments and better compliance.
on market research conducted in the United States, which revealed the expectations of patients and doctors for such treatment. To date, we are witnessing a real interest in our two combinations from both the scientific community and pharmaceutical companies.

We also made important advances on our ultra-fast insulin BioChaperone® Lispro (BC Lispro) for the Chinese market in collaboration with our partner Tonghua Dongbao (THDB) in China. Work was focused on the industrialization of manufacturing processes and the preparation of Phase 3 clinical studies in China. At the end of the COVID crisis, our partner submitted the BC Lispro dossier to the Chinese regulatory authorities, “CDE”. At the same time, major qualification work of THDB’s lispro API was carried out in order to rapidly launch Phase 3 clinical studies in Europe and the United States. However, over the first six months of 2020 a bridging clinical study needed to be conducted.

As for BioChaperone® Combo, a co-formulation of Glargine (basal insulin) and Lispro (prandial insulin), we have completed the technology transfer to our partner Tonghua Dongbao, which has carried out the industrialization of the manufacturing process itself. We are currently collaborating with Tonghua Dongbao on the clinical development plan and on the preparation of the regulatory file for its commercialization in China, a market with strong potential.

Our BioChaperone® Glucagon «ready-to-use» formulation for intramuscular injection is still unique in its mode of administration. It is recognized that the intramuscular route is the safest and quickest route of administration when a life-threatening condition exists and is the preferred route of administration for anaphylactic shock. In this competitive developing market, we are convinced that our choice of intramuscular route of administration is a major asset in ensuring the success of our product. We are looking for a partner to develop and commercialize this product.

Finally, in preclinical studies, we have confirmed the potential of BioChaperone® Glargine Liraglutide (BC Gla Lira), a formulation comprising a basal insulin and a GLP-1. This product is now ready to enter Phase 1 clinical trials in China. It aims to compete with Xultophy®, the only product combining basal insulin with liraglutide. A search for a partner is also underway to finance the development and commercialization of this product.

In August 2019, we announced the results of the arbitration of the proceedings initiated against Eli Lilly. We received recognition in respect of our first claim, with financial compensation of $11.3 million plus interest. However, we were very disappointed and surprised by the rejection of our second claim by the same arbitral tribunal. Nonetheless, we are pleased to have recently been granted a US patent by the US Patent Office with claims based on the surprising effect of citrate described in our 2012 patent application.

Finally, on the financial side, the company took out a €15 million bond issue with IPF Partners in 2019, enabling us to actively pursue our clinical research efforts.

The combination of an amylin analogue with insulin will be the next major leap in the treatment of diabetic patients.

The road to innovation is long and strewn with obstacles. This period of confinement due to the coronavirus has momentarily slowed us down, but we expect only a few months’ delay in the completion of our new partnerships and clinical studies. We have once again demonstrated our resilience and determination.

Before concluding, on behalf of myself and the entire Adocia team, I would like to thank Rémi Soula, co-founder with Olivier and myself, for his significant contributions to the innovations and development of Adocia over the last 14 years, and who has now decided to pursue new professional objectives.

On behalf of the Board of Directors, I would also like to thank very warmly our shareholders for their continued support, but also the employees of Adocia who have spared no effort throughout this year and especially during this COVID 19 crisis which has seriously affected us all, but from which we have emerged stronger.

Gérard Soula
Chairman and Chief Executive Officer
Adocia’s mission is to improve everyday life for people with diabetes and other metabolic diseases by developing innovative, more physiological, and easy-to-use treatments. To this end, Adocia has developed BioChaperone®, a proprietary technology platform enabling the development of high-performance medical products based on previously approved therapeutic proteins and peptides. This reformulation approach builds on the accumulated safety and efficacy data of these approved proteins. It also fits Adocia’s vision to make its innovations accessible to as many people as possible, by limiting the time and costs of development and avoiding expensive investments in new manufacturing facilities. BioChaperone molecules are easy to manufacture and relatively inexpensive.

To date, Adocia’s research team has developed more than 500 BioChaperone molecules which can be selected to suit specific therapeutic proteins and the targeted medical requirement. BioChaperone molecules interact physically with proteins and peptides to form reversible complexes which retain the biological activity of the active ingredient.
Four potential properties of these complexes have been demonstrated:

- Increased solubility of proteins that are insoluble at physiological pH
- Stabilization of proteins during storage
- Faster sub-cutaneous absorption.
- Combination of incompatible therapeutic proteins

BioChaperone technology therefore makes it possible to improve the performance of active products, or makes them easier to use, or even combines together several synergetic therapeutic agents considered physically incompatible.
The Adocia business model

Adocia’s business model leverages BioChaperone technology through a portfolio of proprietary products and targeted collaborations with partners.

In 2020, Adocia’s proprietary portfolio included five clinical and three preclinical programs.

The company’s strategy is to license these innovations, based on proof of concept in humans, to pharmaceutical companies which will oversee late-stage development and commercialization.

This business model, which focuses on the early stages of development, is less capital-intensive than full development to commercialization and can provide a faster return on investment.
An approach that meets current healthcare challenges

Our “innovative formulation” development strategy is aligned with three key trends in the current healthcare environment.

Large pharmaceutical companies looking for innovation

Increased development of biosimilars and generics is obliging pharmaceutical companies to quickly replace their flagship products that have fallen into the public domain. Together with cost pressures in healthcare, this explains why roughly 50% of products sold by large pharmaceutical companies now come from external research.

Adocia’s model fits with this approach, with the added advantage of improving existing products. This approach also helps manage the medicinal product lifecycle by generating more efficient, patent-protected “second generation” agents for the companies that sell them.

Constrained global pharmaco-economic context

The growth and aging of the population, as well as increasing control of healthcare expenditure, adds to the pressure on the cost of treatments, especially for the so-called “mass” indications such as diabetes.

BioChaperone technology was designed to address these economic constraints by bringing therapeutic advances while controlling development and production costs of finished products. In this way BioChaperone provides an opportunity to achieve competitive and sustainable prices in the long term for healthcare systems.

Demand from emerging countries

Demand for pharmaceutical products in emerging markets is growing rapidly. For example, more than 116 million of the 463 million people living worldwide with diabetes live in China. Faced with this exponential growth, particularly in mass indications, these countries must rationalize healthcare costs.

By developing potential “best-in-class” products based on already available proteins, our strategy is particularly suitable for meeting the massive demand from emerging countries. This aligns with Adocia’s vision in developing “innovative medicine for everyone, everywhere.”
Over the last 14 years Adocia has become a world leader in the formulation of injectable products for the treatment of diabetes.

Two types of diabetes

Diabetes is a chronic disease in which patients suffer from high levels of sugar in the blood (hyperglycemia). With time, chronic hyperglycemia is responsible for serious long-term micro and macrovascular complications such as heart disease, strokes, kidney failure, retinopathy, neuropathy.

There are two main types of diabetes:

**Type 1:**

Auto-immune disease, most often diagnosed early. People with type 1 diabetes produce antibodies which attack the insulin-secreting beta-cells of the pancreas. When about 90% of these beta-cells have been destroyed, treatment with insulin is necessary for survival.

**Type 2:**

Progressive disease characterized by cellular resistance to insulin and the slow but relentless deterioration of beta cells, which eventually leads to a decrease in insulin production.

- 10 % of people with diabetes have type 1 diabetes
- 90 % of people with diabetes have type 2 diabetes
A complex hormonal imbalance

In a person without diabetes, glycemia is regulated by an array of metabolic hormones acting in synergy with each other to keep glycemia levels within a very precise range.

Four hormones, in particular, play a key role:

- Insulin and amylin are co-secreted by the beta cells with a peak during meals and act in synergy. Insulin helps cells capture glucides while amylin induces satiety, inhibits glucagon production, and slows down gastric emptying towards normal.

- GLP-1 is produced after a meal and works in synergy with insulin and amylin by stimulating insulin secretion, inhibiting glucagon secretion, promoting satiety and slowing gastric emptying.

- Glucagon is a hyperglycemic agent. It promotes the release of glucose into the bloodstream, particularly between meals and during physical or mental exertion.

Prandial hyperglycemia in the insulin-dependent diabetic has at least three causes:

- the secretion of glucagon, which leads to a release of sugars.

- accelerated gastric emptying, which leads to a rapid and massive supply of glucose.

- the absence of insulin, which does not allow the metabolism of these endogenous and exogenous sugars.

This may partly explain why the injection of insulin is not sufficient to completely control prandial hyperglycemia in a person with diabetes.

Schematic representation of the secretion patterns of four key metabolic hormones at mealtime.

Without diabetes

With type 1 diabetes (T1D)

Estimated change in the number of people with diabetes in the global population aged 20-79 between 2019 and 2045

- **North America and the Caribbean**
  - In 2019: 48 million
  - In 2045: 63 million (+33%)

- **Europe**
  - In 2019: 59 million
  - In 2045: 68 million (+15%)

- **Central and South America**
  - In 2019: 32 million
  - In 2045: 49 million (+55%)

- **Middle East and North Africa**
  - In 2019: 55 million
  - In 2045: 108 million (+96%)

- **Africa**
  - In 2019: 19 million
  - In 2045: 47 million (+143%)

- **Southeast Asia**
  - In 2019: 88 million
  - In 2045: 153 million (+74%)

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Source: International Federation of Diabetes

+51% increase in the number of diabetics predicted in 2025

**China and Western Pacific**

In 2025, an estimated 212 million people with diabetes
Insulin therapy

For all people with type 1 diabetes and around 25% of people with type 2 diabetes, insulin is a necessary treatment. There are three main types of insulin-based treatment products:

- **Basal insulins** (once a day) to manage glycemia throughout the day,
- **Prandial insulins** (taken before each meal) to prevent glycemic excursions occurring after meals,
- **Premixed insulins** (twice a day), which combine a basal component and a prandial component to reduce the number of daily injections,

Over time, insulin therapy has moved towards increasingly effective treatments, from purified animal insulin, to recombinant human insulin, to insulin analogues. These different “generations” co-exist on the global market. Insulin now represents 50% of the value of the global diabetes treatment market.
Our products
Our projects in clinical and preclinical development

In January 2019, Adocia aimed to extend its portfolio to new therapeutic indications that can benefit from BioChaperone® technology and the knowledge accumulated by the Company over the last 14 years.
Our portfolio is built around two axes:

- **“Biobetters”:** these products allow the development of products with strong medical benefits based on already approved therapeutic proteins.

- **Innovative bi-hormonal combinations:** by combining two hormones with complementary or synergistic effects, Adocia makes it possible to bring new medical benefits to people suffering from metabolic diseases with a simple treatment.

In the diabetes field, the Adocia portfolio of injectable products is one of the largest and most differentiated in the industry.

It has five products in the clinical phase and three in the preclinical phase:

### Pipeline

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BC: BioChaperone®; Lispro: insulin lispro; BC Combo: BC insulin glargine insulin lispro; M1: A21G insulin human; Pram: pramlintide; GLP-1: GLP-1 receptor agonist; Gla: insulin glargine; Glu: Glucagon
BioChaperone®
Lispro U100 & U200

Higher performance ultra-rapid insulins

9 Phase 1/2 clinical trials

Ultra-rapid insulin is an insulin whose absorption profile is faster and sometimes shorter than that of currently marketed insulin analogues.

Human insulin and prandial insulin analogues, so-called rapid-acting insulins should be injected 30 minutes (human insulin) or 15 minutes (insulin analogues) prior to the meals for optimal performance.

Acceleration of rapid insulin absorption is desirable as the vast majority of patients prefer to inject insulin at mealtime. There is no need to anticipate the time of injection and it is easier to define the optimal insulin dose. BioChaperone® Lispro when compared to Humalog® (commercial formulation of Lispro) has shown a very clear improvement in the control of blood sugar for a mealtime injection.

The other benefit of BioChaperone® Lispro with regards to insulin is its shorter absorption time, which would allow to reduce the risk of post prandial hypoglycemia.

During clinical studies conducted on individuals with type 1 diabetes, we were able to show a reduction in the number of hypoglycemic episodes with BioChaperone® Lispro.

Adocia has therefore developed two ultra-rapid insulin lispro formulations:

- BioChaperone® Lispro U100 (standard concentration of insulin, 100 IU/mL)
- BioChaperone® Lispro U200 (twice concentrated solution).

BioChaperone® Lispro insulins may offer a significant medical benefit to all prandial insulin users.

In particular, they could respond to specific needs:

- **Diabetic children:**
  It is difficult to predict exactly when and how a child is going to eat. To limit the risk of severe hypoglycemia, it is common to inject insulin to diabetic children at the time of the meal or preferably after the meal, but this can result in hyperglycemia. In clinical studies conducted on patients with type 1 diabetes, the administration of BioChaperone® Lispro 15 minutes after the start of the meal allows to achieve similar post prandial glycemic control to that observed with Humalog® injected before a meal.

- **Insulin pump users:**
  The development of an ultra-rapid insulin is a key element to facilitate the development of fully automated insulin pumps (also known as fully automated «artificial pancreas» or automated «insulin delivery system») that deliver insulin based on the patient’s blood sugar, in real-time. Concentrated ultra-rapid insulin (U200) could also facilitate the miniaturization of these devices and increase their autonomy.

- **People with high insulin needs:**
  BioChaperone® Lispro U200, an ultra-rapid concentrated insulin, could improve the glycemic control while limiting, while limiting the volume of each injection.

BioChaperone® Lispro insulins have been tested in 9 clinical studies (Phases 1/2) with positive results, in people with type 1 and 2 diabetes and healthy volunteers, using syringes or pumps.

They have consistently shown a more rapid profile than that of insulin analogues Humalog® and Novolog® and, in Phase 1 clinical trial, a profile at least as fast as the first ultra-rapid insulin Fiasp®. The acceleration of the end of the curve is specifically considered a key property to «close the loop» in the context of an artificial pancreas.
Next Steps for BioChaperone® Lispro

For the American, European and Japanese markets, search for a partner for entry into Phase 3 and product marketing.

Conduct a bridging study to show the comparability of Tonghua Dongbao’s lispro insulin with the lispro used in previous formulations of BioChaperone® Lispro (lispro Humalog®). This will allow all clinical results obtained on BioChaperone® Lispro to date to be included in the Phase 3 program.

>300

Type 1 and Type 2 patients have already been exposed to BioChaperone® Lispro, using different delivery devices.

Testimonial

Dr. Bruce Bode, M.D., Associate Professor at Emory University (USA)

Insulin pumps are used by approximately 40% of people with type 1 diabetes in the United States. For these people, the emergence of hybrid closed-loop delivery systems is a huge step towards better glycemic control and an improved quality of life.

In addition to its rapid onset of action, the faster-off effect observed with BioChaperone® Lispro (vs. Fiasp® & Novolog®) could be critical to optimize the effect of the algorithms used in these systems. For this reason, this product holds great promise for better disease management solutions.

Post-meal blood glucose after administration of BioChaperone® Lispro

Study in 38 subjects with type 1 diabetes (NCT#02213146).

**AUC0-2h:**

-61 %*

* LSM ratio. These results were the subject of an oral presentation by Dr. Tim Heise (Profil Neuss) during the 76th Scientific Sessions of the American Diabetes Association (June 2016).
BioChaperone®
Combo U200

An alternative to premixes for simple, safer and more effective insulin therapy

5 Phase 1/2 clinical trials
Type 2 diabetes is a progressive disease that requires increasing intensification of treatment. To reach the blood glucose target, it may be recommended to add prandial insulin to the treatment regimen or to replace basal insulin with premixed insulin.

Premixes are a fixed combination of a soluble and a precipitated fraction of a fast-acting prandial insulin analogue, usually injected twice daily. It is therefore a simpler regimen than multiple injections of insulin: a single product, twice a day at a fixed dose (rather than two products, four times a day at variable doses). But these products have a delayed and prolonged prandial action, with a higher risk of hypoglycemia, and an insufficiently constant basal action profile. To meet the medical requirement for a regimen as simple as a premix and as effective as a multiple injection regimen, Adocia has developed BioChaperone® Combo, a combination of insulin glargine (basal, Lantus®, Sanofi) and insulin lispro (prandial, Humalog®, Eli Lilly).

The BioChaperone® technology makes it possible to solubilize insulin glargine at neutral pH and make it compatible with a prandial insulin. BioChaperone® Combo represents an opportunity for significant improvement in patient treatment, particularly in countries where premixed insulins predominate, such as China.

To date, BioChaperone® Combo has been tested in five positive (Phase 1/2) clinical studies in more than 140 people with type 1 or type 2 diabetes. They consistently showed a faster profile than the Humalog® Mix premix and similar to that of a co-injection of Lantus® basal insulin and Humalog® prandial insulin.

Next Steps for BioChaperone® Combo
Adocia is actively looking for a partner to follow the development and commercialization of BioChaperone® Combo for the unlicensed territories in Tonghua Dongbao.

5 billion
global premix insulin market (2016)¹

1. Source: Adocia’s estimate is based on the annual reports of the major pharmaceutical companies

50%
of patients on basal insulin alone fail to achieve target blood glucose control²

2. Source: Sanofi communication de –Q3 Presentation, 2015

65%
of the volume of insulin sold in China is premixed insulin³

3. Source: IQVIA 2017 data
Testimonial

Olivier Soula, Deputy CEO and R&D Director

“Our collaboration with Tonghua Dongbao is effective and successful on both BC Lispro and BC Combo projects. BC Combo is now well mastered by our Chinese colleagues who are producing the first large-scale batches for clinical use. In parallel with technology transfer, we have worked closely together on the clinical and regulatory development plan.

BC Combo is the most important program of this collaboration because premixes are the most widely used insulins in Chinese patients suffering from type 2 but also type 1 diabetes, and Tonghua Dongbao is the second largest player in human insulin premixes in China. This is both a priority for our partner and for us.”

Postprandial blood glucose for type 1 diabetics

Study of 28 people with Type 1 diabetes (NCT#02514954); p=0.008*; p=0.003**

These results were presented by Dr. Steve Edelman (UCSD) at the 76th Scientific Sessions of the American Diabetes Association (June 2016).

AUC0-2h: area under the blood glucose curve over the 0 to 2 hour interval
BGmin: minimum blood glucose value

Individualized doses

Liquid Meal + Insulin subcutaneous injection
Focus 1

A privileged position vis-à-vis the Chinese market

China is not only the country with the highest population in the world, but also the country with the highest number of people with diabetes: it is estimated that approximately 116 million people live with the disease. Although only 30 million patients were treated in 2018, this number is expected to double by 2025 as a result of better diagnosis, improved access to care and more products being reimbursed, supporting an annual growth of more than 12% in diabetic treatment products.

Major global pharmaceutical companies, such as Novo Nordisk, which still retains a 47% market share, are now being challenged in China by local players such as Tonghua Dongbao (THDB) and Gan & Lee.

Tonghua Dongbao: a partner of choice

After two years of partnership, Adocia and the Chinese insulin leader Tonghua Dongbao (THDB) are launching a Phase 3 trial for BioChaperone® Lispro and a bridging study for BioChaperone® Combo.

In April 2018, Adocia and THDB announced a strategic partnership to enable THDB to develop and commercialize BioChaperone® Combo and BioChaperone® Lispro products in China and other territories in Asia and the Middle East. By collaborating with Adocia, Tonghua Dongbao intends to extend its product portfolio to the insulin analogues that are becoming standard in China, already reaching 50% of the market share, while immediately positioning itself on the latest generation of innovative formulations. Both products represent unique opportunities to compete directly with the world leaders and thus establish Tonghua Dongbao’s Chinese leadership:

- **BioChaperone® Combo**, which combines a basal insulin and a prandial insulin in a single product, is an asset to a Chinese market dominated by so-called «premix» insulins. It is also the only direct competitor to Ryzodeg®, the insulin combo launched on the Chinese market by global diabetes leader Novo Nordisk;

- **BioChaperone® Lispro** is the only ultra-rapid insulin capable of competing with the products developed by world leaders Novo Nordisk and Eli Lilly.

In China, Tonghua Dongbao has a strong reputation and is the leader in the production of high-quality insulins, which allows us to be competitive with the major players in the market.

YIKUI LI, Founder of Tonghua Dongbao
The licenses granted by Adocia to THDB for these two products included an upfront payment of $50 million (paid in April 2018), development milestone payments of up to $85 million and double-digit royalties on sales.

Additionally, in June 2018, Tonghua Dongbao agreed to produce and supply Adocia with the pharmaceutical ingredients insulin lispro and insulin glargine for the global market, except for China, to support the development of Adocia’s portfolio in these territories. The supply agreements signed with Tonghua Dongbao open up new partnership opportunities for Adocia, with companies that do not have an insulin production infrastructure but have a strong foothold in diabetes.

Source:
1. IDF, Diabetes Atlas, 2019
2. Presentation Novo Nordisk Market Capital Days 2017

Testimonial

Dr Chunsheng Leng,
Chairman and Chief Executive Officer
of Tonghua Dongbao

“The introduction of BioChaperone® Lispro and Bio-Chaperone® Combo represents the fourth generation of insulin, (...) and we are confident and have high expectations as to the future of these products. Every improvement in the insulin technology will greatly improve the quality of life for patients living with diabetes.”
Next steps for BioChaperone® Glucagon

Adocia has planned a second Phase 1/2 study in the second half of 2020. This study could be the last one before the program enters Phase 3. In parallel, Adocia has selected a high quality and easy-to-use autoinjector for BioChaperone® Glucagon.

1 Phase 1 clinical study

In a non-diabetic subject, glucagon is secreted during hypoglycemia or exercise to maintain normal blood glucose levels. In a diabetic subject, the production of endogenous glucagon does not allow an effective response to a hypoglycemic situation caused by excess insulin (see p.12). Human glucagon is therefore the only approved treatment for severe hypoglycemia, which can be fatal if left untreated.

Unfortunately, currently available products are very difficult to use in emergency situations, as they are presented as lyophilised human glucagon to be reconstituted just before injection. Recent studies evaluating the ease of use of these kits have shown that in 80% of cases, users fail to reconstitute properly and/or administer the recommended dose.

To respond to this need, Eli Lilly launched a glucagon in 2019 for the treatment of serum hypoglycemia by the nasal route (BaqsimTM) and Xeris launched a glucagon formulation injected subcutaneously (Glucagon Rescue Pen: G-VokeTM HypoPen).

BioChaperone® Glucagon is a ready-to-use, stable aqueous solution of human glucagon for the treatment of severe hypoglycemia, but also for chronic applications such as hyperinsulinism and the bi-hormonal artificial pancreas (insulin and glucagon). BioChaperone® Glucagon was successfully tested in a Phase 1 study in people with type 1 diabetes and showed a pharmacodynamic profile similar to the freshly reconstituted commercial product.

80% of failure when using glucagon1 commercial kits

1. Source: Locemia 2015
M1Pram and BC LisPram (Insulin Pramlintide)

Combination of two synergistic hormones for optimal prandial treatment

2 combined formulations

Adocia’s ambition is to make insulin therapy more physiological by combining insulin with pramlintide, a synergistic amylin analogue hormone. In healthy people, amylin is co-secreted with insulin by the β-cells of the islets of Langerhans in the pancreas to delay gastric emptying, inhibit glucagon secretion and trigger a satiety effect.

Combining these products is a challenge because insulin and pramlintide are not compatible in aqueous solution. Adocia has invented two types of stable liquid combinations. The first uses BioChaperone technology which allows pramlintide to be combined at pH7 with either human insulin (BC InsPram) or rapid-acting human insulin analogues: lispro (BC LisPram) or Aspart (BC AsPram). The second combines pramlintide with a human insulin analogue (M1) in a pH4 stable solution.

Pramlintide, an amylin analogue

Phase 3 clinical trials of pramlintide conducted by the company Amylin in the 2000s in patients with type 1 or type 2 diabetes showed that after 6 months, the addition of pramlintide to insulin therapy was associated with an improvement in HbA1c, a reduction in prandial insulin consumption and weight loss, compared to insulin therapy alone. However, since intensive insulin therapy requires multiple daily injections and frequent blood glucose control, the addition of three injections of pramlintide per day has proven to be problematic for patient adherence, monitoring and compliance (pramlintide is sold as Symlin® in the United States).

Insulin M1 is the major metabolite of the FDA-approved insulin analogue glargine (Lantus®). M1 has similar pharmacokinetic and pharmacodynamic profiles to human insulin. Both M1Pram and BC InsPram have been tested in Phase 1 clinical trials in patients with type 1 diabetes.

Among the possible combinations, Adocia chose to develop two, with different insulin PKs: one normal (M1Pram) and one rapid (BC LisPram). M1Pram is the most suitable combination for pen use with bolus injections at mealtime. BC LisPram should be best suited for pump use under algorithm control.

Adocia intends to develop the best combinations to meet first the needs of type 1 diabetic patients and then those of insulin-dependent type 2 diabetic patients.
2 Phase 1 clinical trials

In a first clinical study in people with type 1 diabetes, M1Pram showed a significant 85% reduction in glycemic excursion during the first two hours after a meal compared to Humalog® and simulated glycemic control with separate injections of Symlin® (pramlintide) and Ummeline® (human insulin) during the same period. All treatments were well tolerated.

In a second 24-day study, of which the main results were published in April 2020, the main therapeutic benefits expected from the combination of pramlintide and insulin were obtained with M1Pram:

- **100% reduction in glycemic excursion** during the first two hours after a meal compared to Novolog® in a test on day 24 (p=0.001).
- **70-minute increase** increase in average daily time spent in a «narrow» blood glucose range (p = 0.001) compared to Novolog® over the 24-day period.
- **Average weight loss of 0.7 kg** compared to the reference value (p = 0.012) after 24 days.
- **Good tolerance and safety of administration**

Post-meal blood glucose after M1Pram administration

Study in 21 subjects with type 1 diabetes (NCT#03981627).

![Graph](image)

**M1Pram**

**Aspart**

AUC0-4h:

-39 %*

Liquid meal + subcutaneous administration

* MMC ratio. These results are presented as a poster during the 80th Scientific Sessions of the American Diabetes Association (June 2020).

Sources:
5. Lantus® label, Section 12.3.

Comment

Pr. Thomas Pieber,
Professor of Medicine at the University of Graz Medical Clinic (Austria)

*In this clinical trial in people with type 1 diabetes, all known pharmacological effects of pramlintide were observed after only 3 weeks of treatment with M1Pram.*

This confirms the strong reduction in postprandial glycemic excursion already observed in a clinical trial with M1Pram. In addition, the ambulatory period showed an increase in the time spent in a target range of blood glucose without increasing the risk of hypoglycemia, as well as an improvement in weight control, two key benefits for type 1 diabetics.
Focus 2
Towards integrated diabetes management

In recent years, diabetes management technologies have evolved to enable better monitoring and management of the disease. In particular, Continuous Glucose Monitoring (CGM) is a key “facilitator” technology for insulin users. As the name suggests, these devices provide real-time monitoring of blood glucose levels, unlike older blood glucose monitoring (BGM) devices (see figure below).

By offering a visualization of “blood glucose trends”, rather than disconnected measuring points, CGMs allow patients to act on their blood glucose curve in anticipation (e.g. by eating if they are trending downwards or injecting insulin if they are trending upwards). The CGMs also allow to calculate the «Time in Range», i.e. the time spent in a target blood glucose range (generally between 70 and 180 mg/dL). This indicator is more precise than the quarterly measurement of glycated haemoglobin (HbA1c) and correlates well with the latter.

Indeed, for a person with diabetes, the time spent in hypo- or hyper-glycemia is extremely prejudicial at the time (fatigue, mood swings, even lethality for severe hypoglycemia) and can have serious consequences, in the short or long term. Maintaining their daily blood glucose levels in a target interval is therefore a major concern for patients.

Blood glucose and measurements for a patient using a BGM and then a CGM

With a BGM, the patient has only a partial knowledge of his or her blood glucose and its changes. He can neither see at 12:00 noon that his tendency is towards hyperglycemia, nor at 4:00 pm that he will soon be hypoglycemic.

With a CGM, he automatically measures his blood glucose every 5 minutes. He can then add a bolus to reduce hyperglycemia or eat a snack at 4:00 pm to avoid hypoglycemia.
Blood glucose and measurements for a patient using a BGM and then a CGM

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<table>
<thead>
<tr>
<th>Time (hour)</th>
<th>BGM</th>
<th>Prandial Insulin</th>
<th>Basal Insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>0:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>4:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>8:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>12:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>16:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>20:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>0:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
</tbody>
</table>

With a CGM, he automatically measures his blood glucose every 5 minutes. He can then add a bolus to reduce hyperglycemia or eat a snack at 4:00 pm to avoid hypoglycemia.

<table>
<thead>
<tr>
<th>Time (hour)</th>
<th>CGM</th>
<th>Prandial Insulin</th>
<th>Basal Insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>0:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>4:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>8:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>12:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>16:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>20:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>0:00</td>
<td>180</td>
<td>70</td>
<td>0</td>
</tr>
</tbody>
</table>

Artificial pancreas system

Recently, insulin dosing algorithms have been developed. They can be coupled with CGM data and possibly with injection devices («intelligent» pens and «automatic» pumps, also called artificial pancreas). In this context, Adocia’s products for the prandial treatment of diabetes are extremely well adapted to maximize the impact of these new technologies (and vice versa):

- **BC Lispro**, an ultra-fast insulin, could increase the responsiveness of algorithms to changes in blood glucose levels;
- **Insulin-Pram**, (M1Pram or BC LispPram) could eventually make it possible to achieve a fully functioning «closed-loop» pump (i.e. without human intervention), by restoring the physiological association between two complementary hormones and thus minimizing glycemic variations throughout the day.

Today, Adocia is considering the development of these two products in synergy with technological developments in the field.

BC Lispro has already demonstrated excellent clinical results in insulin pumps (vs. Novolog® and Fiasp®), which could be further improved by a specific algorithm. Adocia plans to test M1Pram in a clinical study in a pump, potentially controlled by an adapted algorithm.

Testimonial

Olivier Soula, Deputy CEO and R&D Director

*With CGM, physicians and patients have a remarkable tool to better control blood glucose levels. They can monitor blood glucose fluctuations 24/7.*

*This progress is an opportunity for Adocia which offers an improvement in the control of prandial blood glucose with a rapid-acting insulin BC Lispro and a combination of insulin and Pram. The use of CGMs is becoming more widespread and patients and their physicians will be able to appreciate the benefits of innovative insulins such as those that we are developing.*

Patient equipped with a continuous glucose monitoring system (CGM)

Testimonial

Olivier Soula, Deputy CEO and R&D Director

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Finance and governance
Adocia consolidates its cash position through a bond issue

The company’s cash position reached nearly 44 million euros at the end of December 2019 thanks to (i) the collection of $14.3 million, or €13 million, from Eli Lilly for the first part of the arbitration proceedings completed in September 2019, (ii) the subscription of a bond issue from IPF for a total of €15 million, (iii) a level of expenditure similar to that of last year, after restating expenses related to the legal proceedings against Eli Lilly.

The Company obtained a bond issue from IPF Fund II to finance its growth in October 2019. It consists in the issue, in two equal tranches, of a total number of 15 million bonds, to each of which is attached a share subscription warrant (BSA), for a maximum amount of bond issue in principal of €15 million. The first tranche (Tranche A), amounting to €7.5 million, was subscribed on October 11, 2019, at the signing of the contract. The second tranche (Tranche B) was subscribed on December 10, 2019. This loan generates interest payments of 8% (as well as 3% of capitalized interest) and is subject to various securities.

### Balance sheet (M€)

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-current assets</td>
<td>9.7</td>
<td>9.1</td>
</tr>
<tr>
<td>Current assets</td>
<td>8.6</td>
<td>21.1</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>43.7</td>
<td>39.8</td>
</tr>
<tr>
<td><strong>Total Actif</strong></td>
<td><strong>62.0</strong></td>
<td><strong>70.0</strong></td>
</tr>
<tr>
<td>Equity</td>
<td>28.0</td>
<td>45.8</td>
</tr>
<tr>
<td>Long-term provisions</td>
<td>3.1</td>
<td>2.8</td>
</tr>
<tr>
<td>Financial debt</td>
<td>21.2</td>
<td>7.1</td>
</tr>
<tr>
<td>Other current liabilities</td>
<td>7.8</td>
<td>10.3</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>1.9</td>
<td>4.0</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td><strong>62.0</strong></td>
<td><strong>70.0</strong></td>
</tr>
</tbody>
</table>
and continues its ambitious clinical development program

In 2019, the revenue of €2.1 million corresponds to the recognition, under the percentage of completion method, of a portion of the upfront payment related to the license agreements signed in 2018 with Tonghua Dongbao Pharmaceuticals.

This revenue relates to research and development services provided by Adocia to Tonghua Dongbao. Other operating income of €6 million consists mainly of the research tax credit generated on expenses for the year 2019.

Operating expenses for 2019, amounting to €30.2 million have significantly decreased compared to the previous year (minus €14 million). This is due to the conclusion of legal proceedings initiated against Eli Lilly & Company.

Research and Development expenses represents 75% of the operating expenses, when restated for these non-recurring legal expenses.

The activities carried out during the year 2019 mainly focused on supporting the Company’s Chinese partner for the development of the two products licensed in April 2018 and the development of the Company’s portfolio, in particular the clinical development of the M1Pram project (ADO09) with two clinical studies conducted during the year.

<table>
<thead>
<tr>
<th>Allocation of Operating Income</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research agreements and licencing revenues</td>
<td>2,1</td>
<td>47,4</td>
</tr>
<tr>
<td>Grants, research tax, credit and others</td>
<td>6,0</td>
<td>6,5</td>
</tr>
<tr>
<td>Total (M€)</td>
<td><strong>8,1</strong></td>
<td><strong>53,9</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Allocation of Operating expenses</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchased used in operations</td>
<td>1,7</td>
<td>2,2</td>
</tr>
<tr>
<td>Payroll expenses</td>
<td>13,9</td>
<td>14,9</td>
</tr>
<tr>
<td>External expenses</td>
<td>14,1</td>
<td>16,3</td>
</tr>
<tr>
<td>Legal fees</td>
<td>-1,0</td>
<td>9,2</td>
</tr>
<tr>
<td>Taxes and contribution</td>
<td>0,2</td>
<td>0,6</td>
</tr>
<tr>
<td>Depreciation, amortization and provisions</td>
<td>1,2</td>
<td>1,0</td>
</tr>
<tr>
<td>Total (M€)</td>
<td>30,2</td>
<td>44,2</td>
</tr>
</tbody>
</table>
The share price was impacted in August 2019 by the decision of the Arbitral Tribunal in the dispute with Eli Lilly: more than 560,000 shares were traded in two days, lowering the price from €20.50 to €12.84. The end of 2019 was marked by weak activity on the share, whose price stood at €9.90 on December 31, 2019. Volumes traded were higher in the first months of 2020 and the share price stands at €9.34 on May 12, 2020.

**Distribution of capital at the end of 2019**

- **Float**: 59.1%
- **Soulé Family**: 22.1%
- **BPI France (Public investment bank)**: 11.3%
- **SHAM (Public investment bank)**: 4.6%
- **Employees**: 1.6%
- **Oréo Finance**: 0.6%
- **Viveria**: 0.5%
- **Others**: 0.2%

**Adocia’s stock market year**

From 1st of January until 12th May 2020
Financial calendar 2020

May 28th
2020 Annual shareholders’ meeting

July 20th
Publication of mid-year financial statements as of June 30th, 2020

October 20th
Publication of revenue for Q3 2020
Executive committee

Gérard Soula
Chairman of the Board of Directors and Chief Executive Officer of Adocia since 2005, PhD in organic chemistry, graduate of IAD in Aix-Marseille and then MBA of IAE in Marseille. Co-author of more than 120 patents.

Olivier Soula
Deputy CEO and R&D Director, holder of a PhD in polymer physico-chemistry, graduate of ENSIC Mulhouse and graduate of the MBA of IAE Lyon. Co-author of 40 patents.

Valérie Danaguezian
Chief Financial Officer, graduate of ISC

Departure of Rémi Soula
Rémi Soula, co-founder of Adocia with Gérard and Olivier Soula, left the company in October 2019 to pursue new professionals objectives, after having contributed to the development of Adocia with talent and energy for fourteen years.
Board of directors

Gérard Soula
Chairman of the Board of Directors

Olivier Soula
Deputy CEO and R&D Director

Laurent Arthaud
Director, Representative of Bpifrance Investissement, President of the Remuneration Committee, Deputy Chief Executive Officer of Bpifrance Investissement

Olivier Martinez
Director, Member of the Audit Committee, Investment Director at Bpifrance Investissement

Dominique Takizawa
Independant Director, President of the Audit Committee, General Secretary of Institut Mérieux

Ekaterina Smirnyagina
Independant Director, Member of the Remuneration Committee, Investment Director at Capricorn Venture Partners (Belgium)
Human Resources Development
Human Resources Development

The objective of the human resources development policy implemented at Adocia is to provide and develop an international, highly qualified and multidisciplinary team of excellence, currently composed of 135 employees.

The Adocia team headcount remained stable in 2019.

Recruitment focused on key positions to move Adocia towards late stage development. This evolution of the team will continue in 2020 to meet the needs of projects ready to enter Phase 2 and Phase 3.

- 49% women
- 51% men

- 37 Average employee age
- 52 52 doctors, i.e. 39% of the workforce
- 80% of the workforce dedicated to R&D

24 January 2020, Chinese New Year’s Day at Adocia
Opening to the international market

The collaboration with the Chinese insulin leader Tonghua Dongbao gives us the opportunity to develop professional and cultural exchanges.

Thirteen team trips to THDB China took place in 2019. This experience is shared internally and encourages employee cohesion and motivation to cooperate remotely with the Chinese counterparts and to develop a 4th generation insulin-based treatment for Chinese diabetic patients.

"The development of each employee and the cohesion of all are the priorities for the success of our multidisciplinary and high technology projects which are being developed over several years within Adocia."

Géraldine Favre Soula, Human Ressources Director

Creation of an analysis laboratory and office space

In 2019, Adocia implemented a new 450 m² analysis laboratory, equipped with around twenty high-pressure liquid chromatography (HPLC) instruments, several gas chromatography (GC) systems, capillary electrophoresis (EC) and a new HIAC system for counting subvisible particles in formulations.

In this space, 22 offices have also been created to accommodate around 40 people, mainly from the Analysis department, but also from Quality Assurance, Regulatory Affairs, Pharmaceutical Operations and Human Resources Development.
Social ties at Adocia

Brand Identity Adocia

After 14 years of activity, in 2019 Adocia initiated internal workshops on its brand identity.

The aim of this project was to define all the essential attributes that made Adocia unique.

This work constitutes the foundation of our identity and allows everyone to communicate with the same voice thanks to the formalization of the «Adocia Brandbook». This document is shared internally with each Adocien and new collaborators.

Transmission mission

Throughout the year, Adocia welcomed students, future laboratory technicians and researchers. In 2019, 12 work-study students and 10 interns were trained at Adocia in their discipline (chemistry, physical chemistry, biology, PK/PD, law, BD, etc.).

Adocia is sponsoring the 135th class of the École Supérieure de Physique et de Chimie Industrielles de la Ville de Paris (ESPCI) and has been supporting students in their professionalization process for the past three years.

In 2019, Adocia initiated an eloquence competition at ESPCI Paris entitled «My industrial internship in 135 seconds!». 22 student-researchers presented their industrial internship work respecting the time constraint and presenting a slide.

A jury of Adociens awarded five prizes at the end of the event to reward the eloquence, originality, creativity, pedagogy and finally the humorous aspect of their presentation. The success of this experience has prompted ESPCI Paris to repeat the exercise each year!
An artistic initiative

Adocia is proposing a third edition of an internal photography competition that aims to reflect the image of employees, open to people and multiculturalism.

A garden in the city classified as LPO (League for the Protection of Birds) refuge.

At the initiative of several Adociens, a compost area in the Adocia garden was created in 2017 and in 2019 a vegetable garden was set up.

Tomatoes, aubergines, squash, strawberries, and basil were grown and distributed within the company, including «homemade» green tomato jams!
Main conferences in 2020

June 8-11
Bio Digital
SanDiego
USA

June 12-16
ADA, Virtual Experience
Chicago
USA

September 8-11
Congrès de la Société Francophone du diabète
Brussels
BELGIUM

September 21-25
EASD
Vienna
AUSTRIA

October 26 - 28
Bio Europe
Munich
GERMANY

To define
Biotech Agora
Paris
FRANCE

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This document contains certain forward-looking statements concerning Adocia and its business. Such forward-looking statements are based on assumptions that Adocia considers to be reasonable. However, there can be no assurance that the anticipated events in such forward-looking statements will occur. Forward-looking statements are subject to numerous risks and uncertainties including the risks described in the registration document of the company registered by the French Financial Markets Authority on April 22, 2020, and available on Adocia’s web site www.adocia.com and, in particular, to the uncertainties linked to research and development, future clinical data and analysis, and to the development of economic conditions, financial markets and the markets in which Adocia operates. The forward-looking statements contained in this document are also subject to risks not yet known to Adocia or not currently considered material by Adocia. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Adocia to be materially different from such forward looking statements. This document and the information it contains does not constitute an offer to sell or the solicitation of an offer to purchase or subscribe for Adocia shares in any country.

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Graphic design and layout: Yseult de Saint Louvent / www.yseultdesaintlouvent.com

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in 2021

January 11-14

JP Morgan
San Francisco
USA