

VIENNA Highlights

Fall & Winter 2019

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€ 60 million for early stage
drug development

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ABF is moving into new facilities in Vienna



Member of  GBA GROUP PHARMA

GBA Group Pharma offers GMP depot services, clinical trial supply, QP activities, preclinical testing, FDA certified testing labs as well as global central laboratory services under one roof in the EU. The new facilities in Vienna place the company in a unique position as EMA clearly states that GMP depots, QP release activities and GMP testing must be located in the EU.



Founded in 2004, ABF Pharmaceutical Services is a global specialist for clinical supply chains and commercials. It is also specialized in full service IMP/IND handling, import/export of IMPs and commercials, as well as GMP storage and GDP logistics of IMPs and commercials. In 2016, ABF became a member of GBA Group Pharma, one of Europe's largest and most experienced service groups in the pharmaceutical and biotech sector. GBA Group Pharma supports clients throughout the entire lifecycle of bringing drugs to patients – from early lead optimization and early preclinical stages to global clinical studies, regulatory, marketing authorization, PPV and QP batch release testing in addition to the logistics of commercials.

ABF focuses on complex clinical trial supply as well as commercials and offers a unique service through a global network including QP services. Its flexibility and personal approach differentiates ABF from its competitors and make it a trusted partner for many of the world's leading pharmaceutical and biotechnology companies and CROs.

New premises in Vienna

In response to the company's growth over the last few years and to prepare itself for a possible Brexit, ABF has decided to double the size of its facilities and to increase its capacities for import and release activities. The growth in size and service offerings will make ABF, in combination with the other GBA Group Pharma members, one of only a few companies able to offer a one-stop solution to the pharmaceutical industry. These state-of-the-art processing facilities will offer: 1,089 pallet spaces (948 at room temperature / 141 with cold storage), 5 packaging suites (primary & secondary packaging / cold chain) and a GMP warehouse for IMPs and commercials.

gba-pharma.com
abf-pharma.com

Facts & Figures

- 120+ active studies / day
- about 80% repeat business / year
- 1,000+ shipments / year

Members of GBA Group Pharma

- Pharmacelsus, Germany / Saarbrücken
- LKF Laboratory for Clinical Trials, Germany / Kiel
- ABF Pharmaceutical Services, Austria / Vienna
- GBA Pharma Labs, Germany / Martinsried, Gräfelfing and Ulm

Why Vienna?



Elisabeth Lackner,
CEO ABF & Global EVP GBA
Group Pharma

“With its unique position in the heart of Europe, Vienna is an important and respected hub for the global pharmaceutical and biotech industry. As a gateway between Eastern and Western Europe, it benefits from a well-developed infrastructure and highly qualified professionals. Furthermore, Vienna's life science community has also experienced a significant growth in recent years.”



The life science business is growing in Vienna. We are happy to see the start-up and scale-up community flourishing in the city. In addition, Boehringer Ingelheim's and Octapharma's new facilities are taking shape and ABF has doubled its facilities in the city.

To promote cutting-edge scientific research as well as assist life science companies at all stages of the value chain, Austria and the City of Vienna offer a 360-degree support network. Contact the LISAvienna team for tailor-made advice about the opportunities that will propel your company upward to the next level in Vienna. A new opportunity is available for drug discovery and development: Apply at wings4innovation to benefit from the €60 million KHAN-I fund.

In this Highlights edition, we will focus on hidden champions providing niche products for research and health care facilities worldwide and take a closer look at the medical device sector in Vienna. Learn more about a new Notified Body, high-risk medical devices and innovators in 3D printing of products meeting the needs of biomedicine, among others.

Of course, we also feature some major milestones achieved in biotech, including HOOKIPA's IPO at NASDAQ. As you probably are expecting, news from Marinomed, Themis and Valneva are also featured. Additional highlights are listed on our website.

Enjoy reading and do not hesitate to contact us via e-mail or telephone or in person at the trade shows and partnering meetings we plan to attend over the next few months.

Follow us on Twitter @lifesciencevie and sign up for our electronic newsletter to receive updates about life sciences in Vienna on a regular basis.

Peter Halwachs and Johannes Sarx
LISAvienna Executive Board

Meet us at trade shows & exhibitions

BIO-Europe 2019

Hamburg, November 11-13, 2019

HIMSS 2020

Orlando, March 9-13, 2020

MEDICA + COMPAMED 2019

Düsseldorf, November 18-21, 2019

BIO-Europe Spring 2020

Paris, March 23-25, 2020

Arab Health 2020

Dubai, January 27-30, 2020

BIO International Convention

San Diego, June 8-11, 2020

in cooperation with:



We reserve the right to make changes.

LISAvienna – Connecting Life Sciences

We offer core services at no charge

Joint life science platform for the advancement of life sciences in Vienna



Personalized support for innovative biotech, pharmaceutical and medical device companies

- in Vienna,
- that develop and market
- new products, services and processes

Connecting companies with development partners and key customers.

Contact us and benefit from our services



Information & Consulting:

Tips and contacts relating to sponsorship, private financing options, lab space in Vienna, development partners, leading customers and internationalization



Networking & Matching:

Contacts for an improved exchange of experiences and knowledge transfer as well as contact with development partners, leading customers and investors worldwide



Expertise:

Analyses, background information, reports and studies relating to life sciences in Vienna



Marketing:

Electronic and printed news items from the field of life sciences in Vienna

Newsletter & Tweets

Stay updated on the hottest news from the life science city Vienna!

Subscribe to our newsletter at [LISAvienna.at](https://www.lisavienna.at)

Follow us on Twitter @lifesciencevie



Need a lab for your start-up in Vienna? Please contact the LISAvienna team!

Life Sciences in Vienna

Are you familiar with the key facts and figures concerning biotechnology, the pharmaceutical industry and the medical device business sector in Vienna, the world's most livable city?



HOOKIPA Pharma: IPO at NASDAQ in April 2019 has raised \$84 million in gross proceeds



HOOKIPA Pharma Inc. (NASDAQ: HOOK; New York and Vienna) is a clinical stage biopharmaceutical company developing a new class of immunotherapeutics, targeting infectious diseases and cancers based on its proprietary arenavirus platform designed to reprogram the body's immune system.



- In July 2019, HOOKIPA announced FDA clearance of IND application for an HB-201 clinical trial to treat HPV-positive cancers. This will be HOOKIPA's first clinical trial in immuno-oncology.

- In May 2019, HOOKIPA achieved a \$2m research milestone for HBV by designing and delivering 10 research-grade vectors to Gilead Sciences, Inc., or Gilead, along with the characterization of these vectors and delivery of a data

package for the HBV program. These research vectors will be subject to further pre-clinical testing in order to validate a clinical candidate for novel combination therapies for the treatment of HBV. This follows the delivery of 14 research-grade vectors for the HIV program in January 2019.

- In April 2019, HOOKIPA completed its initial public offering, raising \$84 million in gross proceeds, and commenced trading on the Nasdaq Global Select Market under the ticker symbol "HOOK".

- In February 2019, HOOKIPA completed a \$37.4 million Series D Financing, led by Redmile Group with the participation of additional new investors Invus and Samsara BioCapital, as well as a number of current investors.

www.hookipapharma.com

Why Vienna?



Joern Aldag
CEO, Hookipa Pharma

“The Viennese biotech arena is an important and competitive hub at the center of Europe's biotech and life sciences sector. It provides a highly dynamic environment on an international scale and increases the industry's capacity to innovate. For HOOKIPA it offers an ideal breeding ground for advancing and delivering results so as to demonstrate the potential and uniqueness of our novel technology platform. Moreover, our people just love Vienna as a place to live.”

Start-up and grow your business in Vienna



The Federal Republic of Austria and the City of Vienna provide 360-degree support for start-ups, scale-ups and global players. Consult LISAvienna to learn more about opportunities that might fit your needs. We are pleased to introduce programs available at the Austrian Federal Promotional Bank, Austria Wirtschaftsservice (aws), and the Vienna Business Agency.

Startup Labs Vienna BioCenter

The Vienna Business Agency provides highly flexible co-working labs for young entrepreneurs at the Vienna BioCenter.

PreSeed

Up to €200,000 grant money for proof-of-principle or proof-of-concept studies by high-tech start-up projects in Austria is available at aws.

Seedfinancing

Apply for a conditionally repayable contribution of up to €800,000 to set up your high-tech businesses in Austria at aws.

Business R&D projects

Business R&D projects in Vienna are supported with up to €500,000 by the Vienna Business Agency. A €10,000 bonus is granted to projects managed by women.

Equity Funds, loans and guarantees

To support start-ups in Austria, aws operates

equity funds that invest or co-invest in high-tech companies and provides loans and guarantees.

Location Initiative

At the Vienna Business Agency, up to €500,000 of grant money is available for companies that are newly settling in Vienna, that are expanding their location or are relocating their business within Vienna.

www.aws.at
www.viennabusinessagency.at

Bulletin Board

Marinomed Biotech: Budesolv with a strongly decreased dose of the active ingredient compared to the marketed product Rhinocort Aqua already shows a pronounced efficacy after a first application – clinical validation of the Marinosolv® platform
www.marinomed.com

Austrian Life Sciences Directory

This online database allows you to identify partners in Austria's pharma, biotech & medtech landscape and research organizations. Browse profiles at www.lifesciencesdirectory.at!



Boehringer Ingelheim to invest € 700 million in new biopharmaceutical production facilities in Vienna

WORK, SHARE AND GROW

Startup Labs Vienna Biocenter

Opening in March 2020

1,100 m² of startup atmosphere

Basic equipment available

Move in and get to work

No minimum rental period

Lab space starting at € 300/month

Office space starting at € 250/month

www.viennabusinessagency.at

Valneva reports a strong operational performance and major corporate progress

- CEPI is awarding up to US\$23.4 million to Valneva for the late-stage development of a single-dose Chikungunya vaccine
- Valneva is initiating a Second Phase 2 Study for its Lyme Disease Vaccine Candidate VLA15

www.valneva.com

Themis Bioscience: Follow the journey to bring immune-modulation products to patients

- Themis raises €40 million in series D financing round backed by US/EU consortium to accelerate the company's pivotal Phase 3 clinical trial program for its Chikungunya vaccine and to expand the clinical pipeline
- Themis Bioscience to announce exclusive license and research collaboration agreement with MSD to develop vaccine candidates
- CEPI is awarding up to US\$21 million to Themis Bioscience for phase 3 Chikungunya vaccine development

www.themisbio.com

Participate in the Health Hub Vienna

The Health Hub Vienna runs an international 100-day acceleration program in Vienna. Corporate-ready start-ups with a verified business-model and a working prototype are invited to apply at INITS, Vienna's high-tech incubator. Topics include go-to-market strategies, regulatory affairs and certificates, stakeholder management regarding approval and reimbursement.

www.healthhubvienna.at

CEBINA GmbH launched in Vienna

The Central European Biotech Incubator and Accelerator provides state-of-the-art lab and office space, access to a highly experienced core R&D corporate and admin team, management mentoring and access to a private investor network. CEBINA is also active in developing a portfolio of in-house spin-out companies through project/technology in-licensing.

www.cebina.eu

Launch of KHAN-I fund: € 60 million for early stage drug development

KHAN-I

Austria Wirtschaftsservice invests in the KHAN Technology Transfer Fund I GmbH & Co KG (KHAN-I) to foster translational research in Austrian life sciences. LISAvienna spoke to Peter Nussbaumer, one of three managers of the newly established KHAN-I fund and managing director of the Vienna based wings4innovation GmbH. Read on to learn more about the future of drug discovery in the German-speaking region.

Why has the KHAN-I fund been raised?

Currently, basic research results are not applied efficiently to drive drug discovery and development, particularly also in the German-speaking region. Innovative findings are being used rather slowly for the benefit of patients. For industry, new ideas and hypotheses often are not mature and validated enough and considered as being too risky for in-house development. At the same time, academia is unable to perform the required additional development steps and validation. Usually, the publish-or-perish mode characterizing today's science leaves no room to follow the path of drug development. Neither the financial means, nor the required professional know-how and network are available at most of our basic research organizations. The KHAN-I fund will contribute to bridging the gap between labs and clinics and between academia and industry for the benefit of patients and all parties involved. A total of € 60 million is available for promising new drug discovery projects.

Who is investing in the fund?

The European Investment Fund contributes half the money, as its goal is to strengthen innovation and translation in Europe and also to tap the enormous economic potential of new inventions. In Austria, the Austria Wirtschaftsservice with funds provided by the Österreich-Fonds and the Federal Ministry for Digital and Economic Affairs, and the Max Planck Foundation in Germany, act as co-investors.

Which projects will be invested in?

The KHAN-I fund focuses on innovative projects that have a clear potential for creating new thera-



© LDC

Peter Nussbaumer is Managing Director at the Lead Discovery Center (LDC) since 2008 and, since recently, also at wings4innovation and Khanu. Before joining LDC, he managed the medicinal chemistry department and a broad range of drug discovery projects with Sandoz and Novartis at the research site in Vienna. The Austrian has more than 30 years of industry experience and holds a PhD in organic chemistry from TU Wien.

peutic modalities in indications with an unmet medical need. The results are prototypes of new drugs that have a high chance for further development and commercialization. Basic research undisputedly provides exciting new findings and hypotheses that need to undergo systematic and professional testing and validation. This is exactly the focus area of the projects that will be funded, managed, and commercialized by KHAN-I. Our team has long-standing expertise in drug discovery and development and such translational activities. Moreover, we maintain a top-quality network within both academia and industry. We talk to the best researchers and important decision makers in industry at eye level. This benefits the projects and increases the chances for success.

As of when and where to submit proposals for funding?

Proposals can be submitted as of now. In Austria, the newly founded wings4innovation GmbH, located in Vienna, is the contact point for questions and is in charge of evaluating project proposals. In Germany, you are invited to contact Khanu Management GmbH (Khanu), which is the managing entity of KHAN-I, in Dortmund. Both wings4innovation and Khanu evaluate and propose projects

for investment by the KHAN-I fund. We all are committed to keeping due diligence periods short and to effectively and efficiently fund the discovery and early development of potential future drugs. KHAN-I provides unique opportunities, particularly in the German-speaking region and we know that there is a great demand for this new financing vehicle.

How will projects be operationalized and who will benefit in case of success?

Researchers whose ideas and approaches are taken to the next level by KHAN-I will be on board as collaboration partners. Projects will be managed by the fund and the necessary experiments will be carried out in cooperation with partners such as the Lead Discovery Center and CROs. In case of positive results, drug candidates will be out-licensed or become the cornerstone of start-ups. Researchers and their home scientific institutions will have a share in the fund's proceeds. The biggest benefit however is with the patients: At the end of the day, our society will benefit much faster from research than is the case today.

KHAN-I: € 60 million for early stage drug development, both small molecules and biologics

Regional partners play a key role for making KHAN-I a true success story

Austria to foster translational research in the life sciences



in Austria

**WINGS4
INNOVATION**

www.w4i.org

in Germany

KHANU

www.khanu.de

austria
wirtschafts
service **aws**

**Federal Ministry
Republic of Austria
Digital and
Economic Affairs**

FTE NATIONALSTIFTUNG
FORSCHUNG | TECHNOLOGIE | ENTWICKLUNG

Hidden Champions in Vienna: Take note of these companies and business units

Vienna is home to several successful life science companies that provide worldwide customers with highly specialized niche products. When thinking about biotech and medtech in the city, you should definitely also have the following center-stage enterprises and business units in mind.

Research reagents, diagnostics and highly specialized logistics solutions for health care rarely hit the headlines of newspapers addressed to the general public. Nevertheless, biomedical research and human medicine would not prosper without all those companies that provide their products and services to customers around the globe.

At the forefront of transcriptome research

Lexogen GmbH, located at the Vienna BioCenter, provides unique proprietary expression-profiling technologies that enable transcriptome analysis. The company's web shop lists more than 10 product lines that serve scientists all over the world. New products include an RNA extraction kit for blood and a whole transcriptome library prep kit for Illumina.

Why Vienna?



Irene Rech-Weichselbraun
General Manager Vienna Operations,
Thermo Fisher Scientific - Life Science Solutions

“Thermo Fisher Scientific is steadily increasing its footprint in Vienna. Both the accumulated expertise and the excellent job market of highly educated people in the field of biotechnological research as well as development and operations combined with high economic, social and environmental security make the Vienna site attractive for the company to make further investments.”



Pneumatic tube systems

Ing. Sumetzberger GmbH is one of the leading manufacturers of pneumatic tube systems and conveyor technologies in the world. Sumetzberger's high-quality products allow for the fast, efficient and reliable on-demand transport of lab samples, pharmaceuticals, and documents, for example. Some 260 employees and a large number of partners worldwide enable the implementation of large projects while meeting tight timelines.

In-vitro diagnosis in hemostasis

Technoclone GmbH is a world-leading producer of superior quality test systems for in-vitro diagnostics in hemostasis and research. Technoclone is about to double its production capacities in Vienna. New products include a semiquantitative flow through assay to determine ADAMTS-13 activity levels, reagents for the accurate measurement of the oral direct Xa inhibitor Edoxaban and the first kit for fully automated thrombin generation.

Center of Excellence for Immunoassays

The Thermo Fisher Scientific site at the Vienna BioCenter is a Center of Excellence for Immunoassay technology, specialized in providing products for researchers in the areas of immunology, cell biology,

cancer biology / immuno-oncology, cardiovascular diseases, neurobiology and stem cell biology. The product portfolio comprises Invitrogen™ Immunoassay solutions for protein quantitation applying various simplex and multiplex technology platforms.

Your partner for complex genetic questions

ViennaLab Diagnostics GmbH develops, manufactures and distributes human in-vitro diagnostic tests globally through a strong network of distribution partners. Through the use of RealFast Assays (TaqMan-based real-time PCR assays) and StripAssays (reverse-hybridization based assays), ViennaLab tests cover the following therapeutic areas: inherited diseases, genetic predispositions, pharmacogenetics and oncology. ViennaLab provides customized solutions in addition to regular products.

www.lexogen.com
www.sumetzberger.at
www.technoclone.com
www.thermofisher.com
www.viennalab.com

Innovation made in Vienna: 3D printing in biomedicine

Vienna is home to pioneers in the additive manufacturing of medical objects. Fusing or depositing materials such as plastic, metal, ceramics, powders or liquids in layers has become a growing market. Benefits include the customization of medical devices, drugs and equipment.



Bioresorbable ceramics

Lithoz GmbH is a market leader for the additive manufacturing of high performance and bioresorbable ceramics. With 70 ceramic 3D printers installed worldwide, the Vienna-based company provides 3D printers, materials, software and custom developments to aerospace, industrial, medical and dental markets. The components produced meet the high levels of density, stability and precision required by the ceramics industry and ceramic research. For example, users are excited about the 3D printing of bone replacement material.

www.lithoz.com

High-resolution 3D printing

UpNano GmbH is a spin-off company of TU Wien and was founded in 2018. The company's business purpose is the development, production and commercialization of high-resolution 3D printing systems and associated materials. The printing process is based on 2-photon polymerization and enables new standards in micropart fabrication. The system has been developed to allow biocompatible printing with an unmatched throughput. Living cells can be mixed into the resin and printed directly or seeded on pre-fabricated structures.

www.upnano.at

Why Vienna?



© Hans Schubert

“Lithoz is the world market leader in the field of 3D printing of bone replacement material and has gained its position through a strong focus on industrial processes and leading edge research. Additionally, the partnerships in research and development are very important for a high-tech company such as Lithoz. Vienna is the ideal ecosystem for the incubation and the growth of leading-edge companies and offers a 360° service for entrepreneurs from funding, business advice and infrastructures to well educated people.”

Johannes Homa (CEO) and Johannes Benedikt (CTO)
Lithoz GmbH

A big challenge for inventors: High-risk medical devices

High-risk medical devices provide patients with a new quality of life. A number of start-ups have accepted the challenge of creating new implants and stents that meet requirements established by medical device regulations.

Advancing transcatheter mitral valve repair

AVVie GmbH is dedicated to the development of sophisticated treatment concepts for mitral valve repair. With the current lead product, the Mitral Butterfly implant, the company is concentrating on the minimally invasive intervention of mitral regurgitation, a condition that affects 2-3% of the world's population. Mitral Butterfly is in a preclinical testing stage. Angel Valve Vienna plans a Series A round starting in Q4/19 in an aim to collect €8 to 10 million.

www.angelvalve.com

Minimally invasive blood purification

CCORE Technology GmbH is looking into minimally invasive, intracorporeal blood-purification technologies. The company's lead product MILL, Minimally Invasive Liquid Lung, is a minimally invasive catheter used to eliminate CO₂ from the patient's bloodstream. It is based on the LiquiClear platform. Its technological core forms an intravascular membrane catheter with an integrated micro-pump drive to exchange substances with the patient's blood.

www.ccore.at

Valves and stents for minimally invasive surgery

P+F Products + Features GmbH is focusing on cardiac diseases. Products include a system of two self-expanding biological valves to treat patients with hemodynamically relevant tricuspid insufficiency, as well as self-expandable transcatheter valves and drug eluting biodegradable stents. Aortic balloon-expandable transcatheter valves, transcatheter pulmonary self-expandable valves, and transcatheter mitral balloon-expandable valves are also in the pipeline.

www.productsandfeatures.com



Major hub in the Austrian medical device industry

In 2017, more than 240 medical device companies were located in the city. With a workforce of 8,890 people, these companies generated around €3.4 billion in revenue. The Vienna Business Agency and aws are engaged in advancing the sector.

Most of Vienna's medical device companies, including most of the top 20 global players, are active in sales. Some of these companies were founded 40 years ago or more. **Ottobock**, for example, has been running its facilities in Vienna ever since 1969 and creates products in Vienna worth €123.5 million every year. In addition, Vienna hosts a growing start-up community in medtech with a strong focus on digital health solutions.

Digital health on the rise

In recent years, Vienna has become a leading city in the development of digital products and services for the health sector. **Agfa HealthCare**, for example, develops software in Vienna that serves the global healthcare market. The dynamics regarding the development of software solutions for the medical sector, including eHealth tools, are impressive: from seven companies in 2012 (2014: 10) the number grew to 20 companies in 2017, thus nearly tripling in only five years. Today, an estimated 30 companies focus on this business area. The diabetes care company **mySugr** is

just one of Vienna's success stories: Its acquisition by **Roche** is regarded as the biggest deal of its kind in Europe. Examples of newcomers include **contextflow**, **Image Biopsy Lab**, **piur imaging** and **SCARLETRED**. Contact LISAvienna for a more detailed overview.

New Notified Body in Vienna

In June 2019, newly-founded **QMD Services** submitted its application to the Austrian Federal Ministry of Labor, Social Affairs, Health and Consumer Protection to act as a Notified Body for Medical Devices. It is also preparing an application for in-vitro-diagnostics. The approval process, which involves the European Commission, is ongoing and is expected to take about 18 months. This new Notified Body should reduce the serious capacity problems that medical device companies are facing with Notified Bodies. Due to changes in the regulatory framework, many more products need to be analyzed by Notified Bodies. At the same time, standards for Notified Bodies have increased, causing some of them to close down. Brexit has made the situation even worse as

evaluations by UK-based Notified Bodies will no longer be valid for the EU market.

Smart money and business support

The **Vienna Business Agency** is dedicated to supporting Vienna's economy and strategically invests in the life sciences. Start-ups are invited to apply for a time slot at the accelerator program **Health Hub Vienna** to boost business. In addition, **PreSeed** and **Seedfinancing** is available from the Austrian federal promotional bank, **Austria Wirtschaftsservice**. In the matter of private equity, start-ups may, for example, turn to Apex Ventures, which is planning to invest €50 million in digital health start-ups, UNIQA Health Invest, which intends to invest €300 million in medical devices, diagnostics and other health-related matters, or Wellington Partners, which recently announced a €210 million fund to invest in European life science start-ups. Additional private equity partners are listed at www.LISAvienna.at.



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LISAvienna is a joint life science platform operated by **austria wirtschaftsservice** and the Vienna Business Agency. On behalf of the Austrian Federal Ministry for Digital and Economic Affairs and the City of Vienna, LISAvienna contributes to the advancement of life sciences in Vienna.