

Biom'Up announces the filing of its *Document de base* within the framework of its planned IPO on the Euronext Paris regulated market

Saint-Priest, France, September 12, 2017 – Biom'Up, specialist of surgical hemostasis, announces that it filed its *Document de base* (source document) with the *Autorité des Marchés Financiers* (AMF, the French stock market authorities) on September 11, 2017 under the reference number I.17-064, within the framework of its planned IPO on the Euronext Paris regulated market.

The filing of the *Document de base* represents the first step in Biom'Up's planned IPO on the Euronext Paris regulated market, contingent on market conditions and regulatory prerequisites, and notably the granting of a visa by the AMF for the prospectus that has to be drawn up relative to this operation.

Biom'Up: the surgical hemostatis specialist

Thanks to a world-renowned medical team and its scientific expertise in the field of biopolymers, Biom'Up has developed HEMOBLAST™ Bellows, a **best in class hemostatic product that aims to control bleeding during surgical operations** (e.g., spine, heart, orthopedic or general surgeries) Bleeding leads to complications during surgery and lengthens the surgical procedure. Hemostatic products are crucial in surgical operations that present a significant risk of bleeding. Today these products represent a global growth market estimated at 2 billion dollars. The US and European markets already established (e.g., spine and cardiovascular surgeries) represent an opportunity of 1.2 billion dollars.

HEMOBLAST™ Bellows obtained the CE Mark in December 2016, and the PMA (Pre-Market Approval) application was submitted to the FDA (Food & Drug Administration) in July 2017 with a view to obtaining marketing approval in the United States in mid-2018.

HEMOBLAST™ Bellows has achieved **positive results for all primary and secondary endpoints of its pivotal study involving 412 patients in the United States** and aiming at obtaining PMA approval from the FDA.

"We have invested in unparalleled global clinical and scientific expertise in order to now be in a position to provide surgeons with the best hemostatic device in its category. This product has obtained exceptional clinical results enabling a PMA request to be filed in the United States. Within the framework of the Hemoblast study, Biom'up achieved an unparalleled level of clinical and regulatory requirements. Thanks to its clinically-proven efficacy acknowledged by leading surgeons, its ease of use and the absence of prep time, HEMOBLAST™ Bellows has been designed to become a benchmark on its market. The aim of our planned IPO is to provide Biom'Up with the necessary resources to strengthen its sales & marketing platform and to market Hemoblast in Europe and the United States as soon as it receives FDA clearance", said Etienne Binant, CEO of Biom'Up.

Biom'Up's key advantages

Hemostatic products represent a growing global market worth over 2 billion dollars

They enable bleeding on the operating table to be stopped or reduced, and aim to:

- cut operating times (1 minute in surgery can cost up to \$150),
- improve surgical performances in both complex and minimally invasive operations,
- reduce surgical complications, some of which can be linked to the mortality rate,
- reduce patients' average length of stay and recovery time.

Hemostatic products are used to enable surgeons to have better visibility and keep operating. When existing products require 4 to 18 minutes of prep time, HEMOBLAST™ Bellows is ready to use in just 20 seconds.

HEMOBLAST™ Bellows has demonstrated remarkable clinical results in an extensive pivotal study, and has been the subject of a clearance application in the United States within the framework of a PMA

HEMOBLAST™ Bellows is a hemostatic powder delivered via bellows. It was developed by a scientific, medical and clinical team unanimously recognized on the market. Indeed, the American cardiothoracic surgeon Professor William Spotnitz, Biom'up's Executive Vice President & Chief Medical Officer, is the world's most published author in the field of hemostasis.

HEMOBLAST™ Bellows has proven its efficacy within the framework of a pivotal clinical study enabling the Company to file a PMA application with the FDA (412 patients admitted to either cardiothoracic, abdominal or orthopedic surgery).

The pivotal study interim results confirm the following:

- 93% efficacy at 6 minutes,
- 74% efficacy for the control product.

All primary and secondary endpoints were met with very high statistical significance. Given the exceptional nature of these interim results, the members of the Independent Data Monitoring Committee (IDMC) unanimously recommended that the study be stopped prior to the initially-scheduled end of these trials, thus illustrating the efficacy of HEMOBLAST™ Bellows.

HEMOBLAST™ Bellows possesses efficacy and usage characteristics that could establish it as the best hemostatic product available on the market

HEMOBLAST™ Bellows has a number of advantages compared with existing hemostatic products:

- Ready to use in just a few seconds and unlike current hemostatic products that require 4 to 18 minutes prep time, HEMOBLAST™ Bellows requires no preparation giving it a major competitive advantage in terms of practicality and cost.
- Its powder formulation and its applicator allow HEMOBLAST™ Bellows to be used in most surgical procedures and situations.
- It can also be used in tricky from the outset surgeries such as minimally invasive and laparoscopic procedures ('keyhole' surgery) since it can be applied either to specific areas that are difficult to access or to broader areas.
- HEMOBLAST™ Bellows enjoys the support of 80 international opinion leaders in Europe and the United States, including Dr. Paul McAfee (spine surgeon, University of Maryland), Dr. Steven Colquhoun (director of the liver transplant program, USC), Prof. Abbas Ardehali (director of the heart and lung transplant program, UCLA), who is joining Biom'Up's Board of Directors as an independent member, and Dr. Alexandros Paraforos (cardiothoracic surgeon in Germany).

Biom'Up's commercial strategy in Europe and the United States is undertaken by an experienced team and is based on the optimization of direct sales and indirect sales through distributors

Biom'Up is sizing its direct sales teams in France and DACH countries (Germany, Austria and Switzerland). It will eventually comprise 25 staff in order to cover these countries' key hospitals. At the same time, the Company is engaged in active discussions with partners to distribute HEMOBLAST™ Bellows in Italy and Spain.

In the United States, the Company expects to receive FDA marketing clearance in mid-2018. Biom'Up will continue to invest in strengthening its sales & marketing teams in order to be ready to carry out the commercial launch of HEMOBLAST™ Bellows as soon as it is granted PMA.

The Company's goal is to directly cover the East and West coasts and to sign distribution agreements for the remainder of the country. Eventually, Biom'Up and its distributors should together have a total of around 70 sales staff and be able to target more than 500 of that country's 4,500 hospitals, by prioritizing the biggest users of hemostatic products and heart, spine and minimally invasive surgery.

A pipeline of clinical studies to position Hemoblast on new markets and which will result in sustained news flow in 2018

The Company intends to make the most of HEMOBLAST™ Bellows' advantages to extend its field of application to markets on which hemostatic products are rarely used or not used at all. Biom'Up is planning additional studies to demonstrate the benefits of its flagship product in the field of laparoscopy (443,000 surgical operations per year in the United States) and in preventing post-operative bleeding, in particular in cosmetic surgery and knee surgery (1.2 million and 919,000 operations in the United States, respectively).

The results of these various studies are expected during the final quarter of 2017 for laparoscopy in Europe, the first half of 2018 for cosmetic surgery and the second half of 2018 for knee surgery.

Biom'Up has the potential to create a global company with Hemoblast and target a long-term market share of 15%

Biom'Up is intending to eventually capture a market share of 15%, on a market estimated to about 1.2 billion \$ and to create, with Hemoblast, a truly global hemostatic company. To achieve this objective, the Group should initially rely on an increase of production capacity at its Saint-Priest site and, secondly, on the commissioning of a new production plant (potentially on the American continent). Hemoblast is a major innovation on the global hemostatic product market, and has the potential to be the best-in-class product in its category while capitalizing on market fragmentation to establish its leadership position.

Biom'Up's next phase of development will be undertaken by the same managerial team that has proven its execution ability by delivering a PMA study ahead of the initial schedule, by having already put in place – both in Europe and the United States – the leadership of a sales and marketing team and lastly by having shown its ability to develop production tools to cope with demand.

Biom'Up's managerial team is a highly international one and comprises successful scientific, commercial and transactional experience in hemostatic products in both Europe and the United States.

Bryan, Garnier & Co is acting as Sole Global-Coordinator and Joint-Bookrunner along with RBC Capital Markets who are acting as Joint-Bookrunner.

Availability of the *Document de base* – Biom'Up's *Document de base* is available for free on request from Biom'Up (8 Allée Irène Joliot-Curie, 69800 Saint-Priest), as well as on the Company's website (www.biomup.com) and AMF website (www.amf-france.org).

Risk factors - Biom'Up would like to draw your attention to Chapter 4, "Risk factors", of the *Document de base*, and in particular to the risk factors indicated in section 4.1 on business and product risks and 4.6.5 "Liquidity risk".

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About Biom'Up

Founded in 2005 and based in the Lyon suburb of Saint-Priest (France), Biom'Up designs, develops and markets innovative medical devices based on patented biopolymers that aim to simplify surgical procedures in numerous specialties (spine, cardiothoracic, general, orthopedic, plastic) and give patients a better quality of life. Its flagship product, HEMOBLAST™ Bellows, is a unique hemostatic solution that obtained the CE Mark in December 2016 and whose first sales were recorded in Europe in 2017. Developed by a world-renowned scientific team, HEMOBLAST™ Bellows has obtained positive results for all the primary and secondary endpoints of Phase III of its pivotal study involving 412 patients in the United States. Since its creation, Biom'Up has benefited from the support of prominent European investors such as Bpifrance, Innobio, GIMV, Lunbeckfond, Mérieux Participation, SHAM and ACG, as well as all the Company's managers, who have invested €2 million in equity.

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