



## ABIVAX – 2015 Half-Year Results €57.7 million raised on Euronext and Significant clinical progress on chronic Hepatitis B and HIV/AIDS

- €57.7 million raised, covering the company's net financial needs through the end of 2017
- Strong acceleration in the company's clinical development program with the launch in early 2015 of the ABVX203 pivotal trial (Phase IIb/III) to address chronic Hepatitis B, and the first phase IIa study on ABX464 for the treatment of HIV/AIDS
- Pioneering partnerships with Cuban life sciences organizations have been strengthened

**Paris, September 29th 2015** - ABIVAX (Euronext Paris : FR0012333284 – ABVX), a publicly traded, clinical stage biotech company developing and commercializing therapeutic anti-viral drugs and vaccines, today announced its financial results for the first half of 2015, ended June 30th 2015. The half-year financial report is available on the company's website. In compliance with regulations, the half-year financial results were reviewed, on a limited basis, by the company's statutory auditors and were approved by ABIVAX's Board of Directors on September 28th.

### HIGHLIGHTS OF THE FIRST-HALF OF 2015:

- In early 2015, launch of the pivotal study (Phase IIb/III) for ABX203, a therapeutic vaccine against chronic Hepatitis B; recruitment of 266 patients finalized in September 2015.
- In early 2015, initiation of a first phase IIa clinical study on ABX464, a small molecule to treat HIV/AIDS, stemming from an antiviral technological platform. Progress has been made within the anticipated timeframe (results of this study are expected before the end of 2015).
- ABIVAX's pioneering relationship with Cuban life sciences organizations has been strengthened.
- Identification of drug candidates for targeted viruses with significant unmet medical needs such as Dengue, Chikungunya and Ebola.
- Work on the selection of ABIVAX's commercial network in Asia and Latin America, enabling the likelihood of commercial activity in 2016.
- The company's Initial public offering on the regulated market of Euronext Paris, Compartment B, took place on June 26th, for total funds raised of €57.7 million (priced at the mid-point of the offer price range), in excess of the targeted amount, and a record-breaking sum for a biotechnology company in France.

*“The first half of 2015 constituted a key period for ABIVAX in its aim to become a global leader in the development and commercialization of therapeutic antiviral therapies and vaccines,” commented Prof. Hartmut Ehrlich, M.D., CEO of ABIVAX. “Since the beginning of the year, the company has successfully launched two clinical studies, including a pivotal study for a therapeutic vaccine against chronic Hepatitis B and a phase IIa study for a small anti-viral molecule against HIV/AIDS. In order to carry out its R&D program, the company has secured substantial funds thanks to the €57.7 million raised during the IPO. What we have accomplished in the first part of the year gives me confidence in our ability to reach*



our objectives and sign significant licensing agreements, as well as in our obtaining the first authorizations to market ABX203 in late 2017 or early 2018," continued Prof. Ehrlich.

## FINANCIAL HIGHLIGHTS OF THE FIRST HALF OF 2015

<b>PRINCIPAL ITEMS FROM THE P&amp;L STATEMENT</b> <i>in thousands of euros</i>	<b>30/06/2015</b> <b>COMPANY</b>	<b>30/06/2014</b> <b>PROFORMA</b>
Total operating revenue	310	241
Total operating expenses	<b>8,417</b>	<b>3,900</b>
of which Research & Development expenses	6,959	NA
of which administrative and general expenses	1,458	NA
<b>Operating Income</b>	<b>-8,107</b>	<b>-3,659</b>
Financial expense	-142	-59
<b>Pre-tax income</b>	<b>-8,250</b>	<b>-3,718</b>

Extraordinary income		
Income tax	-1,080	-720
<b>Net Income (loss)</b>	<b>-7,170</b>	<b>-2,998</b>

\*in order to facilitate the analysis of the half-year 2015 P&L, the latter has been compared to a pro-forma P&L statement at June 30, 2014, established on a comparable basis to the prevailing P&L at mid-year 2015 and incorporating the after the mergers/absorptions that took place in 2014.

<b>Balance sheet items</b> <i>In thousands of euros</i>	<b>30/06/2015</b> <b>Company</b>	<b>31/12/2014</b> <b>Company</b>
<b>Net cash position</b>	<b>51,553</b>	<b>835</b>
of which financial assets *	0	
of which time deposits (maturity > 1 year)	25,002	
of which marketable securities		1,703
of which available cash	28,673	1,221
(of which liabilities)	-2,122	-2,089
<b>Total Assets</b>	<b>89,538</b>	<b>37,966</b>
<b>Equity</b>	<b>80,737</b>	<b>33,935</b>
of which Shareholders' equity	77,543	30,653
of which conditional advances	3,194	3,282

\* Excluding items held in the liquidity contract (cash and treasury shares) and deposits and bonds



**ABIVAX's financial statements at mid-year 2015 reflect primarily:**

- **A prevalence of R&D expenses**

Research & development expenditures represent the lion's share of the company's operating expenses, accounting for 83% of the total, an increase compared to 72% of the total for the year ended 31 December 2014. The company maintains its strict policy regarding administrative expenses, while at the same time pursuing its priority cornerstone research programs and the initiation of its emerging R&D projects. These operating expenses encompass primarily R&D activities that are sub-contracted to private suppliers or assigned to public research institutions, particularly for the international clinical trials of ABX203 and ABX464, as well as the costs associated with the operations of the company's technological platforms at Montpellier and Evry.

In light of the ongoing R&D activity, the operating loss at mid-year 2015 was €8.107 million, compared to €3.659 million at mid-year 2014 on a pro-forma basis. This was partially offset by a research tax credit of €1.080 million at mid-year 2015, compared to a €720,000 research tax credit on a pro-forma basis for the first half of 2014.

- **Financial resources that ensure funding for the company through the end of 2017**

ABIVAX carried out an initial public offering of its shares on the regulated market of Euronext Paris on June 26th, 2015, through which it raised €57.7 million from institutional and individual investors. This transaction constituted the largest capital-raising ever carried out through an IPO by a biotechnology company in France.

The financial resources provided by the successful IPO should enable the company to cover its net financing needs through the end of 2017, particularly the costs of clinical development of its two cornerstone products, ABX464 and ABX203.

The company's net cash position at the end of June 2015 was €51.553 million compared to €835,000 at the end of June 2014.

The funds have been placed in time deposit and money market accounts with well-known banks in order to eliminate any tangible risk of capital loss.

## **MAIN OPERATING HIGHLIGHTS OF THE FIRST HALF OF 2015**

### **Update on R&D projects**

#### **ABX203, a therapeutic vaccine against chronic Hepatitis B (HBV):**

ABX203 is a therapeutic candidate vaccine, licensed from and developed in collaboration with the *Centro de Ingeniería Genética y Biotecnológica (CIGB-Cuba)*, targeting patients with chronic Hepatitis B, an infectious disease with one of the highest mortality rates in the world, which can evolve into cirrhosis or cancer of the liver. ABIVAX' therapeutic vaccine against HBV targets one of the primary unmet needs in infectious diseases at present.



A Phase IIb/III clinical trial that is pivotal for the registration process has recruited patients in seven countries in the Asia-Pacific region (Australia, New Zealand, Taiwan, Singapore, Hong-Kong, Thailand and South Korea). The positive reception of the study by researchers and patients in the countries where it is being conducted has enabled the rapid completion of recruitment, with a total of 266 patients.

The first results are expected during the fourth quarter of 2016. These results could pave the way for the first regulatory approvals in some countries in late 2017/early 2018.

**ABX 464, a novel anti-viral treatment against HIV/AIDS:**

ABIVAX has conceived ABX464 to offer a significant improvement in the treatment of HIV. ABX464 interferes with the biogenesis of viral RNA that is necessary for the replication of the HIV virus, a mechanism of action which had never been explored previously.

At year-end 2014, ABIVAX launched a pharmacokinetic study, with 48 volunteer patients, in order to evaluate the impact of food intake and the repeated administration of ABX464 on the pharmacokinetic properties as well as their biological safety. This study has been finalized and its results are currently being analyzed.

A first clinical study in patients with HIV (phase IIa) was launched in January 2015 in Mauritius and involves 80 naïve patients (who have never received antiretroviral treatment), divided in 10 groups of eight patients each (six patients per group receiving ABX464 and two patients per group receiving a placebo). The objective of this study is to evaluate the pharmacokinetic properties of ABX464, its biological safety, and its impact on the viral load of patients infected with HIV. The results of this study are expected before year-end 2015.

**The antiviral “splicing” technological platform:**

The platform, from which ABX464 is the first product to make it into the clinic, is based on thorough knowledge of the transformation process for viral RNA within the host human cells and the ability of the proprietary chemical compounds to interfere with the biogenesis of the viral RNA. ABIVAX had a pioneering role in the development of this new mechanism of action that blocks the replication of the virus. This platform and its chemical library have the potential to generate additional antiviral therapies, particularly against Dengue, Chikungunya and Ebola.

The evaluation of other drug candidates stemming from the antiviral “splicing” platform has been ongoing since the beginning of the year. The efforts have been focused on a small molecule which is active against Dengue and another small molecule that is active against Chikungunya. Other pre-clinical tests are planned to be conducted by year-end to confirm the potential of these two antivirals before they pass regulatory pre-clinical testing.

**Platform for the development of adjuvant vaccines based on iNKT agonists:**

ABIVAX is also developing a platform that may lead to a new class of adjuvants for therapeutic vaccines. This platform is based on a technology and the exclusive rights granted by The Scripps Research Institute, the University of Chicago, and Brigham Young University.

ABX196 is an innovative adjuvant candidate for vaccines based on NKT cell agonists. Since the beginning of the year, ABIVAX has tested new routes of administration for ABX196. The results are currently being evaluated.



### **Co-development with CIGB (Cuba) of a therapy against Dengue:**

On November 5th 2014, Heber Biotec (Cuba) also signed an exclusive licensing agreement with ABIVAX for a long-term co-development and collaboration to develop and commercialize an antiviral agent against Dengue. This compound is currently at the pre-clinical stage and is being evaluated in order to confirm its entry into the regulatory pre-clinical development phase.

### **Ebola Project:**

During the first half of 2015, discussions were held with The Scripps Research Institute for the acquisition of immunogenes (viral proteins, primarily GP1 proteins stemming from the Ebola virus) that will enable the development of polyclonal antibodies.

### **Work on the selection of a commercial network**

In 2014, the company signed three commercial distribution agreements with Vacunas Finlay, in Cuba. Per the terms of the agreements, ABIVAX has acquired exclusive and non-exclusive distribution rights, depending on the country, for three vaccines:

- vax-TyVi – targeting typhoid fever
- VA-MENGOCC-BC – targeting group B and C meningococcal
- x-SPIRAL - targeting leptospirosis

ABIVAX will commercialize these products in various countries across Asia and Latin America. In order to do this, ABIVAX is in the process of establishing the commercial contacts and agreements with distributors in those territories for a commercialization in 2016.

### **ABIVAX's initial public offering on the regulated market of Euronext Paris – Compartment B**

On June 26, 2015, ABIVAX was listed on the regulated market of Euronext Paris, which enabled the company to raise €57.7 million (gross proceeds), thus covering its financing needs through the end of 2017.

ABIVAX's IPO was carried out following the admission to trading of the 9,624,889 ordinary shares which comprise the company's share capital, of which 2,707,089 new shares were issued within the framework of a Global Offer, after the complete exercise of the extension clause and the over-allotment option.

The initial price per share was set at €21.30 the day of the IPO, for a total valuation of the company on its first trading day of €205 million.

Following this capital increase, ABIVAX's shareholding structure is as follows: 68.5% held by funds managed by Truffle Capital, 2.7% held by the Biotechnology Incubator Holding Fund, and 3.1% held by the company's management, its board members and scientific founders. The company's free float is currently 25.7% of the total shares issued.

### **EVENTS AFTER JUNE 30, 2015 AND OUTLOOK**

- On September 15 ABIVAX announced that Dr. Antonino Ligresti and Dr. Dominique Costantini had joined its Board of Directors.
- As of September 18 ABIVAX has been included in the CAC Small, CAC Mid & Small, and CAC All-Tradable indices of Euronext Paris.



- On September 23rd ABIVAX announced the appointment of Dr. Jean-Marc Steens to the position of Chief Medical Officer.
- On September 24th ABIVAX announced that it had finalized recruitment of 266 patients for the pivotal ABX203 study.
- The company expects to announce the results of the first Phase II clinical study for ABX464 before the end 2015.

## UPCOMING EVENTS

- October 7 - 8, 2015 Participation in the European Large and Midcap Event, Paris
- November 2-4, 2015 Presentation at the BIO Europe, Munich
- November 23-24, 2015 Presentation at the EigenKapital Forum, Frankfurt
- March 15, 2016 Press release on 2015 year-end results
- June 24, 2016 Annual General Meeting

## About ABIVAX

ABIVAX is an advanced clinical development biotech company focused on becoming a global leader in the discovery, development and commercialization of therapeutic anti-viral drugs and vaccines to treat some of the world's most life-threatening infectious diseases, including HIV/AIDS and chronic Hepatitis B.

ABIVAX has 2 compounds in clinical stage research: ABX464 a novel small molecule against HIV with a number of important potential competitive advantages, and ABX203, a therapeutic vaccine candidate that could be a cure for chronic Hepatitis B. The broader ABIVAX portfolio includes additional anti-viral compounds and therapeutic vaccines that may enter the clinical stage in the coming 18 months.

ABX464 has been developed using ABIVAX' anti-viral platform that allows the Company to address a broad range of viral targets involved in the production and management of viral RNA within the host cell. ABIVAX also has access to a number of cutting edge technologies including complex molecular protein/RNA-pro interactions to discover and develop proprietary breakthrough therapies to help patients' clear important pathogenic viruses.

Headquartered in Paris, France, ABIVAX conducts its research and development in Montpellier and Évry (France). In addition, ABIVAX benefits from long term partnerships with the Cuban Center for Genetic Engineering and Biotechnology (Havana, Cuba), The Finlay Institute (Havana, Cuba), the Molecular Genetics Institute of Montpellier (CNRS-Université de Montpellier, France), the Curie Institute (Paris, France), the Scripps Research Institute (La Jolla, CA, USA), the University of Chicago (Chicago, IL, USA), Brigham Young University (Provo, UT, USA), and the Institut Pasteur (Paris, France). ABIVAX intends to pursue further business development opportunities to access commercial products as part of its overall corporate strategy.

ABIVAX was founded by Dr. Philippe Pouletty, M.D., managing partner at Truffle Capital, the cornerstone investor in ABIVAX. The company is listed on the regulated market of Euronext Paris, compartment B (ISIN code: FR0012333284 – Ticker: ABVX). For more information, please visit [www.abivax.com](http://www.abivax.com). Follow us on Twitter @ABIVAX\_

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