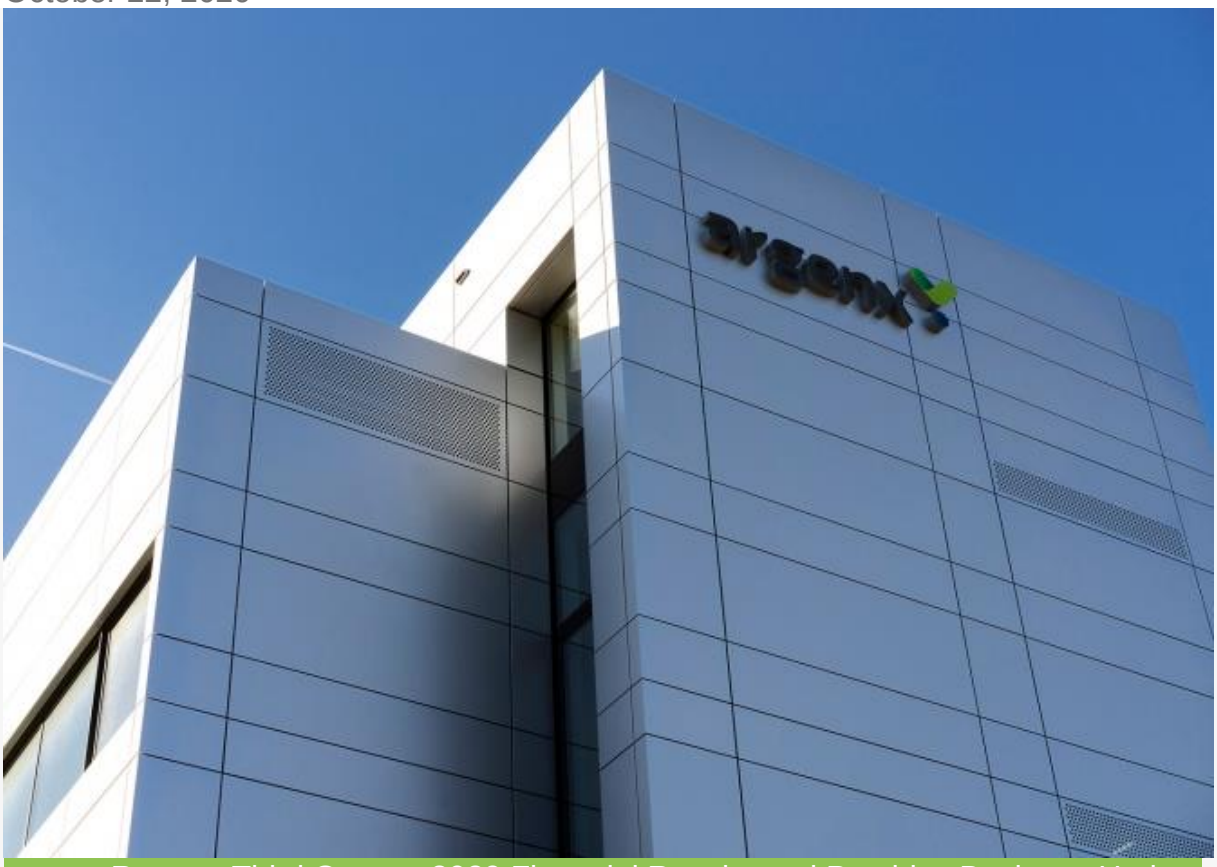
argenx Reports Third Quarter 2020 Financial Results and Provides Business Update

News
October 22, 2020



argenx Reports Third Quarter 2020 Financial Results and Provides Business Update

Breda, the Netherlands / Ghent, Belgium

- Biologics License Application (BLA) for efgartigimod in generalized myasthenia gravis (gMG) on track to be submitted to U.S. Food and Drug Administration (FDA) by end of 2020
- Global Phase 3 ADDRESS trial evaluating subcutaneous (SC) efgartigimod in pemphigus patients on track to initiate by end of 2020
- Decision to continue ADHERE trial beyond first 30 patients in chronic inflammatory demyelinating polyneuropathy (CIDP) now expected in first half of 2021
- Management to host conference call today at 2:30 pm CEST (8:30 am ET)

argenx (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer, today announced its financial results for the third quarter ended September 30, 2020 and provided a business update.

“It has been an important year for argenx, marked by a number of significant achievements that position us to file our first BLA for efgartigimod as a new treatment for gMG by year-end. We remain focused on both the BLA filing and commercial preparations as we work to bring efgartigimod to patients as soon as possible,” said Tim Van Hauwermeiren, CEO of argenx. “We have built an exceptional team, established our global supply chain and connected with physicians, payors and patient advocacy groups – all critical elements for a successful commercial launch.”

“We are building a broad FcRn antagonist program by leveraging the potential of efgartigimod across a number of important indications where there is a high unmet need for innovation. Our global Phase 3 ADDRESS trial in pemphigus is on track to start soon and, as we did with the ADAPT trial in MG, we have carefully designed the trial alongside patients and physicians to best address the complex challenges presented by this serious disease. We continue to ground our pipeline expansion strategy in biology, working from the science to address severe autoimmune diseases and advance our ‘argenx 2021’ vision across our emerging franchises,” continued Mr. Van Hauwermeiren.

THIRD QUARTER 2020 AND RECENT BUSINESS UPDATE

Preparations underway to support potential approval and launch of FcRn antagonist, efgartigimod, in gMG in U.S., Japan and EU

- BLA on track to be filed with the FDA by the end of 2020 with an expected U.S. commercial launch in 2021
- Japanese Marketing Authorization Application (J-MAA) expected to be filed with the Pharmaceuticals and Medical Devices Agency (PMDA) in the first half of 2021 with an anticipated Japan commercial launch in 2022
- Regulatory filing in the EU to follow filing in Japan
- Pre-commercial launch activities underway, including global supply chain creation, and physician, payor and patient advocacy engagement

Presented supportive data from global Phase 3 ADAPT trial of efgartigimod in gMG at recent medical meetings, showing rapid and clinically meaningful responses to efgartigimod and a safety profile comparable to placebo

- Results from Phase 3 ADAPT trial presented at Myasthenia Gravis Foundation of America (MGFA) 2020 Virtual Scientific Session and American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) 2020 Virtual Annual Meeting were consistent with previously announced positive topline results

- New data analyses presented on significant magnitude and repeatability of response, clinical benefit in antibody-negative patients and validation of proposed mechanism of action, with notable reductions in total IgG and pathogenic autoantibody levels

Broad efgartigimod development plan progressing with Phase 2 trial of fifth indication expected to start in mid-2021

- Within neuromuscular franchise, efgartigimod is being developed for gMG and CIDP
    - FDA discussions to occur by end of 2020 to inform bridging strategy for SC efgartigimod for the treatment of gMG
        - Path forward to be communicated after alignment with FDA
    - Phase 2 ADHERE trial of SC efgartigimod for the treatment of CIDP is ongoing
        - Decision to expand trial after analysis of first 30 patients now expected in first half of 2021 due to enrollment delays caused by COVID-19
- Within hematology franchise, efgartigimod is being developed for primary immune thrombocytopenia (ITP)
    - Communication with FDA planned to discuss development of SC efgartigimod
    - Updated plan for registration program to include two trials to run concurrently
        - ADVANCE trial ongoing in up to 156 patients treated with IV efgartigimod
        - ADVANCE-SC trial expected to start by end of 2020 in up to 156 patients treated with SC efgartigimod
- argenx is advancing development of efgartigimod for pemphigus (vulgaris and foliaceus)

    - Global Phase 3 ADDRESS trial evaluating SC efgartigimod in up to 150 pemphigus patients to initiate by end of 2020

    - Trial to evaluate efficacy and safety, including potential to drive fast onset of disease control and complete remission and the ability to taper corticosteroids

- Preparations underway to initiate Phase 2 trial in fifth rare disease indication by mid-2021

    - Indication details, including on biology rationale, Phase 2 trial design and commercial opportunity, to be shared during investor event in first half of 2021

Development of cusatuzumab ongoing as potential treatment for acute myeloid leukemia (AML) and higher-risk myelodysplastic syndromes (MDS) as part of global collaboration and licensing agreement with Cilag GmbH International, an affiliate of Janssen

- Ongoing trials under collaboration include:

    - Phase 2 CULMINATE trial of cusatuzumab in combination with azacitidine in newly diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy

    - Phase 1b ELEVATE trial of cusatuzumab in combination with venetoclax +/- azacitidine in newly diagnosed, elderly patients with AML who are ineligible for intensive chemotherapy

    - Phase 1 trial in Japan of cusatuzumab in combination with azacitidine evaluating newly diagnosed, elderly AML patients who are ineligible for intensive chemotherapy

- Topline data from CULMINATE trial are anticipated to be reported in early 2021

Initiated Phase 1 healthy volunteer study of IV and SC ARGX-117 targeting complement C2

- Data from Phase 1 healthy volunteer study expected in mid-2021

- Following analysis of Phase 1 data, argenx plans to launch Phase 2 proof-of-concept trials in severe autoimmune diseases, including multifocal motor neuropathy (MMN)

- Single-center Phase 1 trial remains open for enrollment to evaluate ARGX-117 as a potential treatment for acute respiratory distress syndrome (ARDS), a frequent and serious complication associated with COVID-19

Continued investment in Immunology Innovation Program to build pipeline of first-in-class antibodies against immunologic targets

- New partnerships announced with Chugai and the Clayton Foundation to expand argenx's access to innovative antibody engineering technologies and to enhance its capabilities to build future antibody candidates with sweeping and half-life extending characteristics

- Collaboration with Halozyme for ENHANZE® drug delivery technology expanded to include three additional exclusive targets upon nomination bringing the total to six potential targets

Q3 2020 FINANCIAL RESULTS

	Nine Months Ended September 30,		
(in thousands of € except for shares and EPS)	**2020**	**2019**	**Variance**
Revenue	€ 30,062	€ 52,264	€ (22,202)
Other operating income	12,524	8,914	3,610
Total operating income	**42,586**	**61,178**	**(18,592)**
Research and development expenses	(246,284)	(122,800)	(123,484)
Selling, general and administrative expenses	(100,380)	(41,734)	(58,646)
Total operating expenses	**(346,664)**	**(164,534)**	**(182,130)**
Change in fair value on non-current financial assets	1,076	—	1,076
Operating loss	**€ (303,002)**	**€ (103,356)**	**€ (199,646)**
Financial income/(expenses)	(1,683)	10,789	(12,472)

Exchange gain/(losses)	(55,896)	26,943	(82,838)
Loss before taxes	**€ (360,581)**	**€ (65,624)**	**€ (294,956)**
Income taxes	€ (2,715)	€ (4,433)	€ 1,718
Loss for the period and total comprehensive loss	**€ (363,296)**	**€ (70,057)**	**€ (293,238)**
Weighted average number of shares outstanding	44,717,568	37,882,282	
Basic and diluted profit/(loss) per share (in €)	(8.12)	(1.85)	
Net increase in cash, cash equivalents and current financial assets compared to year-end 2019	468,223	358,679	
Cash, cash equivalents and current financial assets at the end of the period	1,804,043	923,248	

DETAILS OF THE FINANCIAL RESULTS

Cash, cash equivalents and current financial assets totaled €1,804.0 million on September 30, 2020, compared to €1,335.8 million on December 31, 2019. The increase in cash and cash equivalents and current financial assets resulted primarily from the closing of a global offering, including a U.S. offering and a European private placement, which resulted in the receipt of €730.7 million in net proceeds in June 2020, and net cash flows used in operating activities.

Total operating income decreased by €18.6 million for the nine months ended September 30, 2020 to €42.6 million, compared to €61.2 million for the nine months ended September 30, 2019. The decrease was due to the milestone payments following the first-in-human clinical trial with ABBV-115 under the AbbVie collaboration which was achieved in the nine months ended September 30, 2019. This was partly offset by higher revenue recognition of the transaction price related to the Janssen collaboration and the increase in other income driven by higher payroll tax rebates for employing certain research and development personnel.

Research and development expenses increased by €123.5 million for the nine months ended September 30, 2020 to €246.3 million, compared to €122.8 million for the nine months ended September 30, 2019. The increase in the first nine months of 2020 resulted primarily from higher external research and development expenses, primarily related to the efgartigimod program in various indications, the cusatuzumab program and other clinical and preclinical programs. Furthermore, the personnel expenses increased due to a planned increase in headcount.

Selling, general and administrative expenses totaled €100.4 million for the nine months ended September 30, 2020, compared to €41.7 million for the nine months ended September 30, 2019. The increase resulted primarily from higher personnel expenses and consulting fees related to the preparation of a possible future commercialization of argenx's lead product candidate efgartigimod.

For the nine months ended September 30, 2020, financial expenses, which primarily relate to interest received and changes in fair value of current financial assets, amounted to €1.7 million, compared to a financial income of €10.8 million for the nine months ended September 30, 2019. Financial expenses corresponded mainly to a decrease in net asset value of current financial assets following the impact of the COVID-19 outbreak on the financial markets.

Exchange losses totaled €55.9 million for the nine months ended September 30, 2020, compared to an exchange gain of €26.9 million for the nine months ended September 30, 2019. The change is mainly attributable to unrealized exchange rate losses on the cash, cash equivalents and current financial asset position in U.S. dollars.

EXPECTED 2021 FINANCIAL CALENDAR:

- March 4, 2021: FY 2020 financial results and business update
- May 13, 2021: Q1 2021 financial results and business update
- July 29, 2021: HY 2021 financial results and business update
- October 28, 2021: Q3 2021 financial results and business update

CONFERENCE CALL DETAILS

The third quarter 2020 results and business update will be discussed during a conference call and webcast presentation today at 2:30 pm CEST/8:30 am ET. A webcast of the live call may be accessed on the Investors section of the argenx website at argenx.com/investors. A replay of the webcast will be available on the argenx website.

Dial-in numbers:
Please dial in 15 minutes prior to the live call.

Belgium	0800 389 13
France	0805 102 319
Netherlands	0800 949 4506
United Kingdom	0800 279 9489
United States	1 866 270 1533

International 1 412 317 0797

About argenx

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases and cancer. Partnering with leading academic researchers through its Immunology Innovation Program (IIP), argenx aims to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. argenx is evaluating efgartigimod in multiple serious autoimmune diseases, and cusatuzumab in hematological cancers in collaboration with Janssen. argenx is also advancing several earlier stage experimental medicines within its therapeutic franchises. argenx has offices in Belgium, the United States, and Japan. For more information, visit www.argenx.com and follow us on LinkedIn at https://www.linkedin.com/company/argenx/.

For further information, please contact:

Beth DelGiacco, Vice President, Corporate Communications & Investor Relations
+1 518 424 4980
bdelgiacco@argenx.com

Joke Comijn, Director Corporate Communications & Investor Relations (EU)
+32 (0)477 77 29 44
+32 (0)9 310 34 19
jcomijn@argenx.com

Forward-looking Statements

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements." These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "intends," "may," "will," or "should" and include statements argenx makes concerning its 2020 business and financial

outlook and related plans; the therapeutic potential of its product candidates; the intended results of its strategy and argenx's, and its collaboration partners', advancement of, and anticipated clinical development, data readouts and regulatory milestones and plans, including the timing of planned clinical trials and expected data readouts; the design of future clinical trials and the timing and outcome of regulatory filings and regulatory approvals. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including the effects of the COVID-19 pandemic, argenx's expectations regarding its the inherent uncertainties associated with competitive

developments, preclinical and clinical trial and product development activities and regulatory approval requirements; argenx's reliance on collaborations with third parties; estimating the commercial potential of argenx's product candidates; argenx's ability to obtain and maintain protection of intellectual property for its technologies and drugs; argenx's limited operating history; and argenx's ability to obtain additional funding for operations and to complete the development and commercialization of its product candidates. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.