



## PRESS RELEASE

### Advanced Accelerator Applications Reports 39% Sales Growth for Third Quarter 2017

#### ***\$3.9 Billion All Cash Proposed Tender Offer by Novartis***

#### ***European Approval of Lutetium Lu 177 Dotatate\* (Lutathera®) for GEP-NETs***

#### Recent Highlights:

- Sales for the third quarter of 2017 increased 39% compared to the third quarter of 2016
- NETSPOT® unit sales per month increased 14% (from 915 to 1040) from June to September 2017
- Entered into a Memorandum of Understanding with Novartis, pursuant to which Novartis proposes to make a \$3.9 billion cash tender offer to acquire all the outstanding shares of AAA
- European Commission approved marketing authorization for lutetium Lu 177 dotatate\* (Lutathera®) for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in adults
- Received Prescription Drug User Fee Act (PDUFA) action date of January 26, 2018 for lutetium Lu 177 dotatate\* (Lutathera®) New Drug Application (NDA) to the US Food and Drug Administration (FDA)
- FDA allowed an amendment to the protocol for the US Expanded Access Program (EAP) for lutetium Lu 177 dotatate\* (Lutathera®) expanding enrollment to patients with progressive, advanced, inoperable NETs arising at all sites
- FDA allowed production of EAP doses at Millburn, New Jersey site
- 226 patients and 30 centers in the US, and 1,857 patients and 67 centers in Europe were participating in the lutetium Lu 177 dotatate\* (Lutathera®) Expanded Access, compassionate use and named patient programs at October 31, 2017

**November 17, 2017, Saint-Genis-Pouilly, France - Advanced Accelerator Applications S.A. (NASDAQ:AAAP)** (AAA or the Company), a leader in nuclear medicine theragnostics, today announced its financial results for the third quarter ended September 30, 2017.

Stefano Buono, Chief Executive Officer of AAA, commented, *"The last few months have been truly transformative for AAA. With European Commission's approval of the marketing authorization for lutetium Lu 177 dotatate\* (Lutathera®), and the continued growth of NETSPOT® and SomaKit TOC®, we have achieved our vision of becoming the first radiopharmaceutical theragnostics platform in the global oncology marketplace. We are progressing with the commercial launch of lutetium Lu 177 dotatate\* (Lutathera®) in Europe, and are approaching the FDA PDUFA action date. The Novartis tender offer adds to this momentum, and we believe the proposed transaction will strategically position us to further accelerate development of our other theragnostic pipeline assets and maximize the impact of our platform on the oncology market."*



## Third Quarter 2017 Financial Results

Total sales for the third quarter of 2017 were €37.2 million (US\$43.9 million<sup>(1)</sup>), a 39% increase compared to €26.7 million (US\$31.5 million<sup>(1)</sup>) in the third quarter of 2016. The increase in sales was primarily driven by the PET product category, which increased by 72% to €27.0 million (US\$31.9 million<sup>(1)</sup>), compared to €15.8 million (US\$18.7 million<sup>(1)</sup>) in the prior year period. This includes €8.9 million (US\$10.5 million<sup>(1)</sup>) in US sales of NETSPOT<sup>®</sup> in the third quarter. Therapeutic sales for the third quarter were €5.4 million (US\$6.4 million<sup>(1)</sup>), compared to €5.4 million (US\$6.4 million<sup>(1)</sup>). SPECT sales for the third quarter were €2.1 million (US\$2.5 million<sup>(1)</sup>), compared to €2.3 million (US\$2.7 million<sup>(1)</sup>) for the third quarter of 2016. Third quarter sales of other products were €2.7 million (US\$3.2 million<sup>(1)</sup>), compared to €3.2 million (US\$3.8 million<sup>(1)</sup>) for the same period in 2016.

Operating loss for the third quarter was €3.7 million (US\$4.4 million<sup>(1)</sup>), compared to a loss of €5.1 million (US\$6.0 million<sup>(1)</sup>) for the prior year period. The Company experienced higher personnel costs and operating expenses during the third quarter of 2017, primarily related to the launch of new products and ongoing pipeline development; although these increases were partially offset by higher revenues.

Net loss for the quarter was €22.7 million (US\$26.8 million<sup>(1)</sup>), compared to a net loss of €6.2 million (US\$7.3 million<sup>(1)</sup>) for the third quarter of 2016. The increase in net loss was primarily the result of changes in fair value of contingent consideration for prior owners of a AAA subsidiary.

Adjusted EBITDA (see corresponding reconciliation exhibit below) for the quarter was a gain of €0.1 million (US\$0.1 million<sup>(1)</sup>) compared to a loss of €1.7 million (US\$2.0 million<sup>(1)</sup>) for the same period in 2016.

Cash, cash equivalents and short-term investments at September 30, 2017 were €192.7 million (US\$227.6 million<sup>(1)</sup>).

*(1) Translated solely for convenience into US\$ at the noon buying rate of €1.00 = \$1.1813 at September 30, 2017.*

## Recent Operational Updates

On October 30, the Company announced that it has entered into a Memorandum of Understanding with Novartis, pursuant to which Novartis proposes to make a cash tender offer to acquire all the outstanding shares of AAA, including shares represented by American Depositary Shares (the "ADSs"), for US\$41 per ordinary share and US\$82 per ADS (each representing 2 ordinary shares), in a transaction that is valued at approximately US\$3.9 billion. This represents a 47% premium to the 30 volume-weighted trading days prior to the unaffected share price on NASDAQ on September 27, 2017. The Memorandum of Understanding has been filed with the U.S. Securities and Exchange Commission.

On September 29, the Company announced that the European Commission has approved the marketing authorization of lutetium Lu 177 dotatate\* (Lutathera<sup>®</sup>) for "the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive GEP-NETs in adults". This approval allows for the marketing of lutetium Lu 177 dotatate\* (Lutathera<sup>®</sup>) in all 28 European Union member states, as well as Iceland, Norway and Liechtenstein.



The FDA allowed production of lutetium Lu 177 dotatate\* (Lutathera<sup>®</sup>) EAP doses at AAA's Millburn, New Jersey site.

On August 28, the Company announced that the FDA has acknowledged receipt and considered complete the resubmission of the NDA for lutetium Lu 177 dotatate\* (Lutathera<sup>®</sup>). The Agency provided a new PDUFA action date of January 26, 2018.

On September 6, the Company announced that the first patient was treated in a Phase I clinical study of lutetium Lu 177 dotatate\* (Lutathera<sup>®</sup>) in patients with inoperable, somatostatin receptor positive, progressive pancreatic, gastrointestinal, or pulmonary NETs in Japan. The primary objective of this open-label, uncontrolled, single-center, bridging study is to evaluate the safety, tolerability, pharmacokinetics, and dosimetry of lutetium Lu 177 dotatate\* (Lutathera<sup>®</sup>) in Japanese patients.

\* USAN: lutetium Lu 177 dotatate/INN: lutetium (<sup>177</sup>Lu) oxodotreotide

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#### **About USAN: lutetium Lu 177 dotatate / INN: lutetium (<sup>177</sup>Lu) oxodotreotide (Lutathera<sup>®</sup>)**

USAN: lutetium Lu 177 dotatate/INN: lutetium (<sup>177</sup>Lu) oxodotreotide (Lutathera<sup>®</sup>) is an investigational <sup>177</sup>Lu-labeled somatostatin analog peptide. USAN: lutetium Lu 177 dotatate/INN: lutetium (<sup>177</sup>Lu) oxodotreotide (Lutathera<sup>®</sup>) belongs to an emerging form of treatments called Peptide Receptor Radionuclide Therapy (PRRT), which involves targeting tumors with radiolabeled molecules that bind to specific receptors expressed by the tumor. The European Commission approved the marketing authorization of USAN: lutetium Lu 177 dotatate/INN: lutetium (<sup>177</sup>Lu) oxodotreotide (Lutathera<sup>®</sup>) for the treatment of unresectable or metastatic, progressive, well differentiated (G1 and G2), somatostatin receptor positive GEP-NETs in adults. An NDA submission to the US Food and Drug Administration (FDA) for lutetium Lu 177 dotatate (Lutathera<sup>®</sup>) is under review. The Prescription Drug User Fee Act (PDUFA) action date is January 26, 2018. This novel compound has received orphan drug designation from the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

#### **About Advanced Accelerator Applications S.A.**

Advanced Accelerator Applications (NASDAQ:AAAP) is an innovative radiopharmaceutical company developing, producing and commercializing molecular nuclear medicine theragnostics. AAA's theragnostic platform is based on radiolabeling a targeting molecule with either gallium Ga 68 for diagnostic use, or lutetium Lu 177 for therapy. AAA's first theragnostic pairing for neuroendocrine tumors includes diagnostic drugs NETSPOT<sup>®</sup> in the US and SomaKit TOC<sup>®</sup> in Europe; and therapeutic USAN: lutetium Lu 177 dotatate/INN: lutetium (<sup>177</sup>Lu) oxodotreotide (Lutathera<sup>®</sup>), which is approved for use in Europe and currently under review with the FDA. Additional theragnostics in development target gastrointestinal stromal tumors (GIST), and prostate and breast cancer. AAA is also an established leader in molecular nuclear diagnostic radiopharmaceuticals for PET and SPECT, mainly used in clinical oncology, cardiology and neurology. Headquartered in Saint-Genis-Pouilly, France, AAA currently has 21 production and R&D facilities, and more than 550 employees in 13 countries (France, Italy, the UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, the US and Canada). AAA is listed on the Nasdaq Global Select Market under the ticker "AAAP". For more information, please visit: [www.adacap.com](http://www.adacap.com).



## About Molecular Nuclear Medicine (“MNM”)

Molecular Nuclear Medicine is a medical specialty using trace amounts of active substances, called radiopharmaceuticals, to create images of organs and lesions, and to treat various diseases, like cancer. The technique works by injecting targeted radiopharmaceuticals into the patient’s body that accumulate in the organs or lesions and reveal specific biochemical processes. MNM can be divided in two branches: Molecular Nuclear Diagnostics and Molecular Nuclear Therapy. Molecular nuclear diagnostics employs a variety of imaging devices and radiopharmaceuticals. PET (Positron Emission Tomography) and SPECT (Single Photon Emission Computed Tomography) are highly sensitive imaging technologies that enable physicians to diagnose different types of cancer, cardiovascular diseases, neurological disorders and other diseases in their early stages. Molecular nuclear therapy uses radioactive sources (radionuclides) to treat a range of tumor types. Using short-range particles, this therapy can target tumors with little effect on normal tissues.

## Reconciliation of adjusted EBITDA to net loss for the period from continuing operations for the three and nine months ended September 30, 2017 and 2016

	Nine months		Three months		Nine months	
	September 30, 2017	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016	
	in USD thousands <sup>(1)</sup>	In € thousands		In € thousands		
<b>Net loss for the period from continuing operations</b>	<b>(51,898)</b>	<b>(22,741)</b>	<b>(6,243)</b>	<b>(43,933)</b>	<b>(10,651)</b>	
<b>Adjustments</b>						
Finance income (including changes in fair value of contingent consideration)	(10,098)	(1,214)	(427)	(8,548)	(812)	
Finance costs (including changes in fair value of contingent consideration)	40,930	19,577	1,502	34,648	4,659	
Income taxes	1,977	689	25	1,674	(422)	
Depreciation and amortization	13,273	3,817	3,411	11,236	9,838	
<b>Adjusted EBITDA</b>	<b>(5,816)</b>	<b>128</b>	<b>(1,732)</b>	<b>(4,923)</b>	<b>2,612</b>	
<b>Sales</b>	125,702	37,245	26,723	106,410	81,282	
<b>Adjusted EBITDA margin</b>	<b>-4.63%</b>	<b>0.34%</b>	<b>-6.48%</b>	<b>-4.63%</b>	<b>3.21%</b>	

(1) Translated solely for convenience into dollars at the noon buying rate of EUR 1.00 = USD 1.1813 at September 29, 2017.

## Additional Information

This press release is neither an offer to purchase nor a solicitation of an offer to sell securities. The tender offer for the outstanding ordinary shares and American Depositary Shares of AAA described in this press release has not commenced. At the time the tender offer is commenced, Novartis and an indirect wholly owned subsidiary of Novartis (“Purchaser”) will file, or will cause to be filed, a Schedule TO Tender Offer Statement with the U.S. Securities and Exchange Commission (the “SEC”) and AAA will file a Schedule 14D-9 Solicitation/Recommendation Statement with the SEC, in each case with respect to the tender offer. The Schedule TO Tender Offer Statement (including an offer to purchase, a related letter of transmittal and other offer documents) and the Schedule 14D-9 Solicitation/Recommendation Statement will contain important information that should be read



carefully before any decision is made with respect to the tender offer. Those materials and all other documents filed by, or caused to be filed by, Novartis and Purchaser with the SEC will be available at no charge on the SEC's website at [www.sec.gov](http://www.sec.gov). The Schedule TO Tender Offer Statement and related materials may be obtained for free under the "Investors – Financial Data" section of Novartis website at <https://www.novartis.com/investors/financial-data/sec-filings>. The Schedule 14D-9 Solicitation/Recommendation Statement and such other documents may be obtained for free from the Company under the "Investor Relations" section of the Company's website at <http://investorrelations.adacap.com/>.

### **Cautionary Statement Regarding Forward-Looking Statements**

This press release contains forward-looking statements. All statements, other than statements of historical facts, contained in this press release, including statements regarding the Company's strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements that appear in a number of places in this press release include the Company's current expectation regarding future events and various matters, including expected timing of filings with the FDA, approval dates and expansion of NETSPOT<sup>®</sup>. These forward-looking statements involve risks and uncertainties that may cause actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such factors include, but are not limited to, changing market conditions, the successful and timely completion of clinical studies, the timing of our submission of applications for regulatory approvals, FDA and other regulatory approvals for our product candidates, the occurrence of side effects or serious adverse events caused by or associated with our products and product candidates; our ability to procure adequate quantities of necessary supplies and raw materials for USAN: lutetium Lu 177 dotatate/INN: lutetium (<sup>177</sup>Lu) oxodotreotide (Lutathera<sup>®</sup>) and other chemical compounds acceptable for use in our manufacturing processes from our suppliers; our ability to organize timely and safe delivery of our products or product candidates by third parties; any problems with the manufacture, quality or performance of our products or product candidates; the rate and degree of market acceptance and the clinical utility of USAN: lutetium Lu 177 dotatate/INN: lutetium (<sup>177</sup>Lu) oxodotreotide (Lutathera<sup>®</sup>) and our other products or product candidates; our estimates regarding the market opportunity for USAN: lutetium Lu 177 dotatate/INN: lutetium (<sup>177</sup>Lu) oxodotreotide (Lutathera<sup>®</sup>), our other product candidates and our existing products; our anticipation that we will generate higher sales as we diversify our products; our ability to implement our growth strategy including expansion in the US; our ability to sustain and create additional sales, marketing and distribution capabilities; our intellectual property and licensing position; legislation or regulation in countries where we sell our products that affect product pricing, taxation, reimbursement, access or distribution channels; regulatory actions or litigation; and general economic, political, demographic and business conditions in Europe, the US and elsewhere. Except as required by applicable securities laws, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.



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## CONDENSED CONSOLIDATED STATEMENTS OF INCOME

THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016

In € thousands	Three months		Nine months	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Sales	37,245	26,723	106,410	81,282
Raw materials and consumables used	(9,416)	(6,072)	(26,248)	(17,268)
Personnel costs	(14,213)	(10,789)	(40,747)	(29,716)
Other operating expenses	(14,813)	(12,277)	(47,912)	(35,190)
Other operating income	1,325	683	3,574	3,504
Depreciation and amortization	(3,817)	(3,411)	(11,236)	(9,838)
<b>Operating loss</b>	<b>(3,689)</b>	<b>(5,143)</b>	<b>(16,159)</b>	<b>(7,226)</b>
Finance income (including changes in fair value of contingent consideration)	1,214	427	8,548	812
Finance costs (including changes in fair value of contingent consideration)	(19,577)	(1,502)	(34,648)	(4,659)
<b>Net finance loss</b>	<b>(18,363)</b>	<b>(1,075)</b>	<b>(26,100)</b>	<b>(3,847)</b>
<b>Loss before income taxes</b>	<b>(22,052)</b>	<b>(6,218)</b>	<b>(42,259)</b>	<b>(11,073)</b>
Income taxes	(689)	(25)	(1,674)	422
<b>Loss for the period</b>	<b>(22,741)</b>	<b>(6,243)</b>	<b>(43,933)</b>	<b>(10,651)</b>
<b>Attributable to:</b>				
Owners of the Company	(22,741)	(6,243)	(43,933)	(10,651)
<b>Loss per share</b>				
Basic (€ per share)	(0.26)	(0.08)	(0.50)	(0.14)
Diluted (€ per share)	(0.26)	(0.08)	(0.50)	(0.14)

Some non-significant figures in the nine-month period ended September 30, 2016 were reclassified for comparison purposes, without impact to net results.



## CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

THREE AND NINE MONTHS ENDED SEPTEMBER 2017 AND 2016

In € thousands	Three months		Nine months	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
<b>Loss for the period</b>	<b>(22,741)</b>	<b>(6,243)</b>	<b>(43,933)</b>	<b>(10,651)</b>
<b>Other comprehensive income / (expense):</b>				
<b>Items that may be reclassified subsequent to profit or loss</b>				
Exchange differences on translating foreign operations	(690)	25	(56)	(374)
<b>Items that will never be reclassified subsequent to profit or loss</b>				
Remeasurement of defined benefit liability	(13)	9	2	(34)
<b>Other comprehensive income / (expense) net of tax <sup>(1)</sup></b>	<b>(703)</b>	<b>34</b>	<b>(54)</b>	<b>(408)</b>
<b>Total comprehensive loss for the year</b>	<b>(23,444)</b>	<b>(6,209)</b>	<b>(43,987)</b>	<b>(11,059)</b>
<b>Total comprehensive loss attributable to:</b>				
Owners of the Company	(23,444)	(6,209)	(43,987)	(11,059)

(1) Negative tax effect of €8,000 for the three months ended September 30, 2017 and negative tax effect of €5,000 for the three months ended September 30, 2016.

Negative tax effect of €19,000 for the nine months ended September 30, 2017 and positive tax effect of €17,000 for the nine months ended September 30, 2016.

## CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

AT SEPTEMBER 30, 2017 AND DECEMBER 31, 2016

ASSETS (in € thousands)	September 30, 2017	December 31, 2016
<b>Non-current assets</b>	<b>140,067</b>	<b>149,695</b>
Goodwill	33,384	34,070
Other intangible assets	40,332	45,027
Property, plant and equipment	58,338	63,915
Financial assets	1,748	2,187
Other non-current assets	5,650	3,941
Deferred Tax assets	615	555
<b>Current assets</b>	<b>251,277</b>	<b>269,048</b>
Inventories	12,514	8,100
Trade and other receivables	37,882	31,079
Other current assets	8,202	7,789
Short-term investment	22,000	-
Cash and cash equivalents	170,679	222,080
<b>TOTAL ASSETS</b>	<b>391,344</b>	<b>418,743</b>
<b>EQUITY AND LIABILITIES (in € thousands)</b>	<b>September 30, 2017</b>	<b>December 31, 2016</b>
<b>Equity attributable to owners of the Company</b>	<b>266,622</b>	<b>299,461</b>
Share capital	8,833	8,795
Share premium	361,708	360,085
Reserves and retained earnings	(59,986)	(44,125)
Net loss for the period/year	(43,933)	(25,294)
<b>Total equity</b>	<b>266,622</b>	<b>299,461</b>
<b>Non-current liabilities</b>	<b>78,939</b>	<b>79,540</b>
Non-current provisions	11,265	12,725
Non-current financial liabilities	10,161	12,302
Deferred tax liabilities	3,726	4,649
Other non-current liabilities	53,787	49,864
<b>Current liabilities</b>	<b>45,783</b>	<b>39,742</b>
Current provisions	4,745	1,135
Current financial liabilities	3,371	4,017
Trade and other payables	19,913	20,119
Other current liabilities	17,754	14,471
<b>Total liabilities</b>	<b>124,722</b>	<b>119,282</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>391,344</b>	<b>418,743</b>



## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016

In € thousands	Nine months	
	September 30, 2017	September 30, 2016
<b>Cash flows from operating activities</b>		
Net loss for the period	(43,933)	(10,651)
<u>Adjustments:</u>		
Depreciation, amortization and impairment of non-current assets	11,236	9,838
Share based payment expense	9,487	4,220
(Gain) / Loss on disposal of property, plant and equipment	(33)	265
Financial result	26,100	3,847
Income tax expense	1,674	(422)
Negative goodwill	-	(127)
Subsidies income	(298)	-
<b>Subtotal</b>	<b>4,233</b>	<b>6,970</b>
Increase in inventories	(4,566)	(2,140)
Increase in trade receivables	(7,465)	(4,836)
Increase in trade payables	287	1,900
Change in other receivables and payables	(648)	(5,259)
Increase in provisions	1,843	864
<b>Change in working capital</b>	<b>(10,549)</b>	<b>(9,471)</b>
Income tax paid	(1,549)	(1,821)
<b>Net cash used in operating activities</b>	<b>(7,865)</b>	<b>(4,322)</b>
<b>Cash flows from investing activities</b>		
Acquisition of property, plant and equipment	(3,496)	(10,234)
Acquisition of intangible assets	(520)	(1,241)
Acquisition of financial assets	(71)	(62)
Repayment of financial assets	454	383
Acquisition of short-term investment	(22,000)	-
Interest received	1,153	389
Proceeds from disposal of property, plant and equipment	66	86
Net proceeds from government grants	440	37
Acquisition of subsidiaries, net of cash acquired	-	(22,453)
<b>Net cash used in investing activities</b>	<b>(23,974)</b>	<b>(33,095)</b>
<b>Cash flows from financing activities</b>		
Payment of deferred and contingent liabilities to former owners of acquired subsidiaries	(3,581)	(2,878)
Exercise and subscription of warrants	1,661	-
Proceeds from borrowings	333	-
Repayment of borrowings	(3,147)	(4,397)
Interest paid	(311)	(405)
Other finance costs payments	(172)	-
<b>Net cash used in financing activities</b>	<b>(5,217)</b>	<b>(7,680)</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(37,056)</b>	<b>(45,097)</b>
Cash and cash equivalents at the beginning of the year	222,080	118,886
Effect of exchange rate changes on cash and cash equivalents	(14,345)	(912)
<b>Cash and cash equivalents at the end of the period</b>	<b>170,679</b>	<b>72,877</b>