# ANNUAL REPORT 2016 SUMMARY







# **CONTENTS**

## About the summary

This summary for 2016 contains key messages and selected figures from the statutory audited annual report for 2016.

The summary does not replace the annual report, which is published in English only and can be downloaded from the Company's website: www.bavarian-nordic.com.

Annual report 2016 – summary	
Strong pipeline progress – letter from the CEO & chairman	
Vaccines for a better world	;
Our vaccine pipeline	10
Competitive advantages	13
Cancer immunotherapy	1-
The time is now for cancer vaccines	1
Infectious diseases	2
The Bavarian Nordic share	2
Consolidated key figures	2
Financial results for 2016	2.
Outlook for 2017	2.

# STRONG PIPELINE PROGRESS LETTER FROM THE CEO & CHAIRMAN



Gerard van Odijk Chairman of the Board of Directors



Paul Chaplin
President & CEO

2016 was an important year for Bavarian Nordic, both in the advancement and diversification of our clinical pipeline, and from a financial perspective as well.

The year has seen the initiation of six clinical trials, positive data from our first clinical study in RSV, and the expansion of our partnerships. Financially we continue to see revenues from our core businesses, providing us with yet another breakeven result, and additional capital inflows from both new and existing investors which has allowed us to triple our cash preparedness over the past three years. We are happy to report that the company we present to you today is a stronger and more capable company than we have ever known, and while we are proud of all we have accomplished, we remain steadfast in our belief that the best is yet to come.

Operationally, the company has expanded its expertise and capabilities with the appointment of key personnel. The hiring of Dr. Christopher Heery as Chief Medical Officer and the addition of Henrik Birk to our executive management team as Chief Operating Officer have been extremely valuable additions. Chris brings with him a wealth of knowledge from his time at the National Cancer Institute (NCI), both from a clinical and research perspective. Henrik has been a dedicated member of the Bavarian Nordic team, who has worked his way up through positions of increasing responsibility,

and his vision and counsel are a welcome addition to executive management. Along with the hiring of Chris, management and the Board decided to utilize this opportunity to consolidate the U.S. operations of the company on the east coast, opening a new facility in the famed Research Triangle area of North Carolina. This move strategically places our U.S. operations in close proximity to our partners both in the U.S. Government and the pharmaceutical industry.

We furthermore strengthened the Board with the election of Dr. Frank Verwiel at the annual general meeting. Having served as an observer to the Board since 2015, Frank's extensive international experience from biotech companies, particularly in the U.S., is a valuable addition to the Board.

Clearly a large focus remains on the readout of PROSPECT, our global phase 3 study of PROSTVAC in metastatic prostate cancer. We are all anticipating these data and are confident in the potential of our platform and the likelihood of a successful outcome. We have already seen the conclusion of two interim analyses, and anticipate the third is likely to occur in the middle of 2017, with final overall survival data toward the end of the year. All efforts are

4 SUMMARY ANNUAL REPORT 2016

# For the fifth consecutive year, we have generated more than **DKK 1 billion** in revenues

ongoing to ensure we have a timely submission for approval, and if approved, that the product is available as soon as possible to the benefit of patients. While our belief in a positive outcome is as strong as ever, we know that success can never be guaranteed. It is with this in mind that we have built a complete company with multiple value-creating assets and a platform designed to differentiate us from the traditional binary nature that many biotech companies encounter.

The U.S. Government continue to support us with the initiation of new studies, not only with NCI in the exploration of PROSTVAC in earlier stages of prostate cancer, but also with other government agencies as they explore the potential of our vaccine candidates in new disease targets. The order of USD 100 million worth of bulk IMVAMUNE received in May 2016 means that we will have manufactured and stored a total of USD 233 million worth of bulk IMVAMUNE which the U.S. Government has highlighted will be finished as freeze-dried IMVAMUNE. It is our expectation that a tender process will be initiated this year, which could

allow us to continue to supply IMVAMUNE to the U.S. Government for years to come. As we await the future orders it is important not to forget the phase 3 liquid-frozen IMVAMUNE study which will report data in the second half of 2017. The successful conclusion of this study will allow us to file for approval of IMVAMUNE in the U.S. Along with the approval of IMVAMUNE, we would be eligible for receipt of a Priority Review Voucher, which is a transferable voucher allowing for faster review with the FDA.

With our partners in the pharma industry we are making great progress. We continue to work with Janssen to advance a path forward for Ebola, our commercial collaboration continues to take shape as we lay the foundation for an HPV study, and we have now supplied the remaining undisclosed commercial candidates for evaluation. With Bristol-Myers Squibb, we continue to have active dialogue as we both prepare for final PROSTVAC data and the potential submission of a Biologics License Application. We have also seen the initiation of the first of two combination studies of PROSTVAC with checkpoint inhibitors from

Bristol-Myers Squibb, with the second to begin shortly, and they continue to see the possibility of our platform by agreeing to provide us with OPDIVO®, at no cost, for our new combination study of CV301 in lung cancer. Similarly, we have recently entered an agreement with Roche to supply Tecentriq® for a combination study in bladder cancer, and we are looking forward to exploring the potential synergistic effect of CV301 in multiple indications as part of our strategy to grow a broad cancer immunotherapy pipeline.

The advancement of our infectious disease pipeline continues as well with the announcement of positive phase 1 data from our RSV program. MVA-BN RSV is highly differentiated compared to other RSV vaccine candidates and was shown to induce strong and broad immune responses against RSV in an elderly population. The ongoing phase 2 study, which is fully recruited, will report data in the middle of 2017. These data will not only provide us with additional safety data and dosing information, but also with a mechanistic proof of concept. As we progress our pipeline and platform, our ability and desire to make

innovative therapies only become stronger. As we continue making new discoveries, we expect to further expand our pipeline in the near-term with existing development projects.

We would like to thank our employees, partners, patient volunteers, and investors in Bavarian Nordic. Your collective support has helped to create the company you see today.

**Paul Chaplin** 

President & CEO

Gerard van Odiik

Chairman of the Board of Directors

**SUMMARY ANNUAL REPORT 2016** 



# OUR VACCINE PIPELINE

Product	Indication	Commercial Rights	Status		
Infectious diseases			Phase 1	Phase 2	Phase 3
IMVAMUNE liquid-frozen*	Smallpox	Bavarian Nordic	T		
IMVAMUNE freeze-dried	Smallpox	Bavarian Nordic			
MVA-BN Filo monovalent**	Ebola	Janssen			l
MVA-BN Filo multivalent	Ebola/Marburg	Janssen			
MVA-BN RSV	Respiratory Syncytial Virus	Bavarian Nordic			
MVA-BN HPV	Chronic HPV Infection	Janssen			
Cancer Immunotherapy					
PROSTVAC monotherapy	Prostate cancer (mCRPC)	Bristol-Myers Squibb			
PROSTVAC combinations***	Prostate cancer (localized and metastatic)	Bristol-Myers Squibb			
CV301 + nivolumab	Lung cancer (NSCLC)	Bavarian Nordic			
MVA-BN Brachyury	Solid Tumors	Bavarian Nordic			

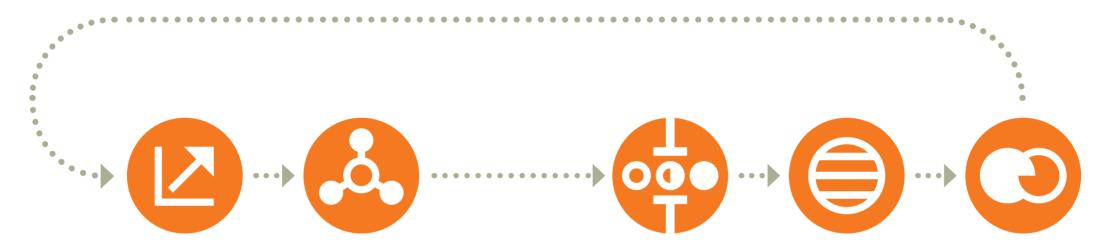
<sup>\*</sup> Approved in Canada and the European Union (marketed as IMVANEX® in the EU). Phase 3 ongoing in the U.S.

<sup>\*\*</sup> Multiple Janssen-sponsored Phase 1, 2 and 3 clinical studies ongoing

<sup>\*\*\*</sup> Multiple NCI-sponsored Phase 2 clinical studies ongoing

# **COMPETITIVE ADVANTAGES**

As a fully integrated biotechnology company, we have several key competitive advantages in developing, producing and commercializing live virus vaccines.



# Existing revenue generation advances our growth

Our existing revenue generation from our research and development, supply contracts, and commercial partnerships can be used to invest in the advancement of our clinical pipeline.

# Modular and proprietary vaccine technology

Our vaccine platform takes a modular approach to live virus vaccine development and is based on the use of different types of poxviruses, notably our MVA-BN viral vector with a favorable safety profile. These viruses can be used in various combinations for both the prime and booster applications in both cancer and infectious diseases.

### Commercialscale cGMP production facility

Our ability to effectively and efficiently produce our live virus vaccines has been demonstrated by our production of more than 28 million doses of IMVAMUNE smallpox vaccine and more than 2 million doses of our MVA-BN Filo product candidate for Ebola to date, as well as production of all clinical materials.

# Ongoing relationships with government agencies

We have entered into research and development contracts with the U.S. Government worth more than USD 1.2 billion in revenue. Contract partners include HHS, NIH, BARDA, NCI, DOD, and the DHS, spanning multiple disease areas and biological threats.

# Collaborations with Bristol-Myers Squibb and Janssen

We have a global commercialization agreement for PROSTVAC with Bristol-Myers Squibb. In addition, we have a partnership with Janssen, under which we have outlicensed our MVA-BN vaccine technology for Ebola and HPV vaccines.

# CANCER IMMUNO-THERAPY

Targeted active immunotherapy candidates for the treatment of cancer are part of a promising field of research, which harnesses the power of the immune system to fight cancer. By eliciting a robust and broad anticancer immune response, immunotherapies aim to decrease the tumor growth rate, potentially resulting in a prolonged overall survival while maintaining a favorable risk-benefit profile.

# OUR STRATEGY FOR CANCER IMMUNOTHERAPY

## Maximize PROSTVAC's commercial potential as monotherapy and in combination regimens

We believe that PROSTVAC has significant commercial potential as both a monotherapy and as part of a combination regimen in multiple stages of prostate cancer. We therefore seek to maximize this potential through our collaborations with Bristol-Myers Squibb and NCI.

### Next steps

- Report Phase 3 interim #3 and top-line results for PROSTVAC (2017)
- Bristol-Myers Squibb to decide on PROSTVAC license
- Initiation of Phase 2 combination study of PROSTVAC, ipilimumab and nivolumab (2017)
- · Results from ongoing Phase 2 trials with NCI

# Establish a broad and deep cancer immunotherapy franchise

We intend to expand and advance our pipeline by demonstrating that our vaccine candidates, CV301 and MVA-BN Brachyury, can be synergistic with other cancer immunotherapies.

### Next steps

- Complete initial safety component and initiate randomized enrollment of Phase 2 combination trial of CV301 and nivolumab in lung cancer (2017)
- Initiation of Phase 2 combination study of CV301 and atezolizumab in bladder cancer
- Initiation of investigator-sponsored Phase 2 combination trials of CV301 and other immune-modulating agents in additional cancer indications
- Initiation of NCI-sponsored Phase 2 trials of MVA-BN Brachyury (2017)



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He built his career at the National Cancer Institute (NCI) and has played a key role in the clinical development of PROSTVAC, CV301 and MVA-BN Brachyury as well as other novel immunotherapies.

ANNUAL REPORT 2016

# THE TIME IS NOW FOR CANCER VACCINES – continued

His broad experience in immuno-oncology and relationship with multiple scientists, companies and institutions had left him in high demand, and for Christopher Heery, already planning a career move, it was an excellent opportunity to focus his research, and essentially a matter of choosing the right path. He joined Bavarian Nordic as new Chief Medical Officer in 2016.

- I had been approached by many potential industry jobs, but when Paul (Chaplin) called and offered the opportunity to focus in on the work around Bavarian Nordic's vaccine platform, I saw the opportunity as too good to pass up.

Bavarian Nordic is an established company with a unique platform technology and excellent growth. It is science-driven and the products we make are likely going to directly impact the quality of patients' lives over the next few years and beyond, Chris says.

### **Collaboration is key**

While he enjoys the responsibility and the ability to work in a more strategic and focused direction at Bavarian Nordic, Chris appreciates his time with NCI and knows the importance of this relationship.

Our collaboration with the NCI is one of our most treasured resources at Bavarian Nordic. The colleagues at NCI offer valuable insight on strategy decisions, connections to investigators, and the ability for us to do clinical trials in rare or specific patient populations that would otherwise be very costly and/or logistically difficult for a company our size. And our oncology platform started based on the exceptional work of the team at NCI. It is our job now to ensure that, together, we

can demonstrate the utility of the platform in patients, he says.

### The time is now for cancer vaccines

In his new role as CMO, Chris is also leading the company's development in infectious disease vaccines, and this has added a new dimension to his work, which he highly appreciates. However he still has a heartfelt interest in the oncology field and his extensive knowledge in this field will be key over coming years.

- The field of immuno-oncology is moving rapidly, which is definitely a good thing for patients with cancer, but we still have a lot of work to do to decide how agents will best be used for a given patient at a given stage of a certain disease. This complexity can seem neverending. It is our job to, first, show we have some level of efficacy with our vaccines and then, second, identify the patients most likely to benefit, and then, third, learn how we can use our vaccines in combination with other agents to help the most patients possible. The good news, this type of work is already happening and is

becoming more standard. We plan to be a part of that rapid development in the near future and beyond, he says.

For years, vaccines for oncology were unlikely to cause tumor regression in advanced cancers for a number of reasons. In the last few years, checkpoint inhibitors have demonstrated that there is a role for the immune system in causing tumor regression, resulting in increased interest and funding for trials involving the immune response.

- We have known for years that we can generate the type of immune responses in patients that can kill tumor cells in vitro (in a dish), but that has not resulted in tumors shrinking frequently enough in patients to merit rapid vaccine development through regulatory pathways. Now, with the rise of interest and the number of potential agents that may unleash the effects of vaccines, we stand at an inflection point where we can demonstrate, definitively, that vaccines can improve the lives of patients with advanced cancer, he ends.

# INFECTIOUS DISEASES

We have leveraged our live virus vaccine platform to create a commercial smallpox vaccine and a pipeline of infectious disease vaccine candidates. While most of the development is sponsored by the U.S. Government or our partner Janssen, we have initiated our own program for the development of an RSV vaccine, which we believe represents a significant opportunity.

# OUR STRATEGY FOR INFECTIOUS DISEASES

# Maintain the global leadership of our smallpox vaccine franchise

We intend to maximize the value of this franchise by developing a longer lasting freeze-dried formulation of our IMVAMUNE smallpox vaccine, potentially expanding the addressable patient population in the United States. Furthermore we intend to expand the end market to include other countries and governments across the world, most notably in Europe.

### Next steps

- Award of contract for freeze-dried IMVAMUNE from the U.S. Government
- Report results from Phase 3 non-inferiority study of IMVAMUNE and file for approval of liquid-frozen formulation
- Receipt of Priority Review Voucher from the FDA (post IMVAMUNE approval)

# Rapidly advance our pipeline of infectious disease programs

We intend to utilize our proprietary vaccine platforms to expand the infectious disease vaccine pipeline to meet high unmet medical needs as we have with RSV. We also intend to achieve global leadership in Ebola preparedness through our collaboration with Janssen, with whom we will also continue to explore our MVA-BN technology, initially focusing on a therapeutic HPV vaccine.

### next steps

- Report Phase 2 results for MVA-BN RSV (2017)
- Determine appropriate clinical pathway to approval of MVA-BN RSV
- Finalize clinical development of primeboost Ebola
- Initiate Phase 1 study of MVA-BN HPV with Janssen
- Potential license agreement with Janssen for MVA-BN in two additional infectious diseases

# THE BAVARIAN NORDIC SHARE

Bavarian Nordic is listed on the Nasdaq Copenhagen exchange under the symbol BAVA. The Company's share capital was DKK 313,538,460 by year-end 2016, comprising 31,353,846 shares with a nominal value of DKK 10 each. Each share carries one vote.

Bavarian Nordic has established a sponsored Level 1 American Depositary Receipt (ADR) program. The ADRs are available for trading in the US over-the-counter (OTC) market, where three ADRs represent one Bavarian Nordic share. The ADR ticker symbol is BVNRY.

### **Ownership**

As of December 31, 2016, Bavarian Nordic had 38,370 registered shareholders owning

27,099,503 shares. The following shareholders had publicly informed Bavarian Nordic that they own five per cent or more of the Company's shares: ATP Group, Hillerød, Denmark.

Bavarian Nordic holds 11,144 own shares as treasury shares, corresponding to 0.04% of the share capital. The shares were purchased in May 2016 to hedge obligations under incentive scheme for the Company's executive management. See note 28 in the consolidated financial statements.

### **Analysts**

Bavarian Nordic is covered by a dozen domestic and international financial analysts who regularly make research comments and recommendations based on the Company's performance and factors

### Share price development



that may influence its business and future development of the share price. A list of analysts can be found on the Company's website.

### **Investor relations**

The Company seeks to maintain an active dialogue with shareholders, analysts, prospective investors and other stakeholders by providing open, honest and accessible information to ensure that they have the requisite knowledge to assess the Company. The Company seeks to do so by, among other things, ensuring timely and correct communication about relevant strategic, economic, financial, operational and scientific affairs of the Company, subject to due observance of the Company's investor relations policy.

### Services for shareholders

Registered shareholders are offered a range of electronic information services through the shareholder portal, which can be accessed from the Company's website. The portal also offers the opportunity to request admission cards and/or vote by proxy for the general meetings.

Shareholders are encouraged to have their shares registered with the Company; registration must be through the holder's custodian bank.

### Annual general meeting

The annual general meeting will be held at 4 pm CET on Tuesday, April 25, 2017, at the Comwell Borupgaard, Nørrevej 80, DK-3070 Snekkersten, Denmark.

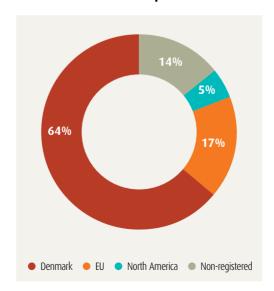
### **Contact investor relations**

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- **Seth Lewis**, Vice President, Investor Relations & Communications (U.S.) Phone: +1 978 341 5271

### Read more

Visit the investor relations section on our website to gain access to financial reports, releases, investor presentations, and much more: www.bavarian-nordic.com/investor

### Distribution of share capital



### Financial calendar 2017

April 25, 2017
Annual General Meeting

### May 4, 2017

Financial Statements for the first quarter of 2017 (Q1)

### August 25, 2017

Financial Statements for the first half of 2017 (Q2)

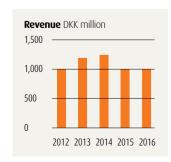
### November 8, 2017

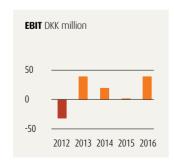
Financial Statements for the first nine months of 2017 (Q3)

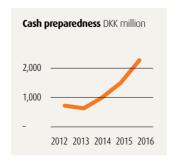
### CONSOLIDATED KEY FIGURES

DKK million	2016	2015	2014	2013	2012
Income statement					
Revenue	1,006.7	1,020.6	1,216.8	1,212.5	1,016.6
Production costs	297.8	415.1	495.1	484.7	513.6
Research and development costs	463.2	386.8	478.9	496.6	340.1
Distribution and administrative costs	212.8	217.1	226.1	197.8	194.6
Income before interest and tax (EBIT)	33.0	1.6	16.7	33.4	(31.7)
Net profit for the year	30.6	59.4	25.9	(46.7)	(240.0)
Balance sheet					
Total non-current assets	541.1	585.0	568.1	551.8	644.3
Total current assets	2,282.6	1,404.3	1,319.1	900.4	894.9
Total assets	2,823.7	1,989.3	1,887.3	1,452.2	1,539.2
Equity	2,017.2	1,342.5	1,252.1	976.3	999.7
Non-current liabilities	54.7	56.6	51.9	86.7	54.2
Current liabilities	751.8	590.2	583.3	389.3	485.3
Cash flow statement					
Securities, cash and cash equivalents	1,899.9	1,058.2	979.7	532.1	549.9
Cash flow from operating activities	267.6	105.3	338.7	147.1	20.1
Cash flow from investment activities	(448.2)	(178.1)	(503.7)	(146.5)	71.0
- of which investment in securities	(358.3)	(119.3)	(397.8)	7.2	116.4
Cash flow from financing activities	657.2	26.6	216.2	(7.1)	(9.6)
Financial ratios (in DKK) 1)					
Earnings (basic) per share of DKK 10	1.0	2.1	1.0	(1.8)	(9.2)
Net asset value per share	64.3	47.9	45.2	37.4	38.3
Share price at year-end	249	358	198	89	50
Share price/Net asset value per share	3.9	7.5	4.4	2.4	1.3
Number of outstanding shares at year-end (thousand units)	31,354	28,020	27,671	26,094	26,094
Equity share	71%	67%	66%	67%	65%
Number of employees, converted to full-time, at year-end	437	409	422	426	450

<sup>&</sup>lt;sup>1)</sup> Earnings per share (EPS) is calculated in accordance with IAS 33 "Earning per share". Other financial ratios have been calculated in accordance with "Anbefalinger og Nøgletal 2015" (Recommendations and Financial Ratios 2015)







### FINANCIAL RESULTS FOR 2016

We met our financial guidance for 2016 with revenues of DKK 1,007 million and a profit before interest and tax (EBIT) of DKK 33 million.

Cash preparedness at December 31, 2016 was DKK 2,292 million. Our expectations to the cash

preparedness were upgraded in April 2016 to DKK 1,900 million after successfully raising DKK 665 million in a private placement, and again in January 2017 to DKK 2,300 million, primarily as a result of payments for IMVAMUNE deliveries, which were received earlier than expected.

	2016	2016	2017
DKK million	guidance	actual	guidance
Revenue	1,000	1,007	1,300
Income before interest and tax (EBIT)	-	33	350
Cash preparedness, year-end	2,300	2,292	2,400

### **OUTLOOK FOR 2017**

In 2017, we expect revenue of approximately DKK 1,300 million and a profit before interest and tax (EBIT) of approximately DKK 350 million.

Revenue of DKK 399 million is expected from recognition of the upfront payment received from Bristol Myers Squibb (BMS) as part of the global license option for PROSTVAC. This is based upon the assumption that we provide BMS with top-line PROSPECT (Phase 3) data in the second half of 2017.

Revenues of approximately DKK 800 million are expected from the production of bulk material of IMVAMUNE for the U.S. Government, as well as from delivery of doses of IMVAMUNE to the Public Health Agency of Canada.

Additional revenues of approximately DKK 100 million are expected from ongoing research and development contracts.

The cash preparedness at the end of the year is expected to increase to approximately DKK 2,400 million. Cash preparedness includes cash and cash equivalents, investments in securities and the aggregate amount of undrawn credit lines. This includes a EUR 50 million unsecured loan from the European Investment Bank, which the Company anticipates drawing on.

As of the reporting date, all known external USD exposure is hedged.

Total research and development costs of approximately DKK 425 million are expected, primarily related to the conclusion of the PROSPECT study, the ongoing RSV Phase 2 study, finalization of the IMVAMUNE liquid-frozen Phase 3 study, and the CV301 proof of concept study in lung cancer.

# Our mission is to make significant contributions to improve public health through the discovery and development of novel therapies that could help to protect or sustain people's lives. SUMMARY

### Disclaimer

This summary contains forward looking statements. The words "believe", "expect", "anticipate", "intend" and "plan" and similar expressions identify forward looking statements. Actual results or performance may differ materially from any future results or performance expressed or implied by such statements. The important factors that could cause our actual results or performance to differ materially include, among others, risks associated with product discovery and development, uncertainties related to the outcome and conduct of clinical trials including unforeseen safety issues, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products obsolete, and other factors. For a further discussion of these risks, please refer to the section "Risk Management" in the annual report for 2016. Bavarian Nordic does not undertake any obligation to update or revise forward looking statements in this annual report nor to confirm such statements in relation to actual results, unless required by law.

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### www.bavarian-nordic.com

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