TRINITY BIOTECH PLC
Form F-3/A
April 26, 2017

Registration No. 333-203555
As filed with the Securities and Exchange Commission on April 26, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Amendment No. 1
to
FORM F-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933
TRINITY BIOTECH PLC
(Exact name of registrant as specified in its charter)

Republic of Ireland	Not Applicable
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.C. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.C. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act .

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information contained in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated April 26, 2017

P R O S P E C T U S

TRINITY BIOTECH PLC
$200,000,000
'A' Ordinary Shares
Warrants
Debt Securities
Subscription Rights
Units

We may offer to the public from time to time in one or more series or issuances:

· 'A' Ordinary Shares;

· warrants to purchase 'A' Ordinary Shares or debt securities;

· debt securities (including convertible debt securities);

· subscription rights;

or any combination of the above, separately or as units.

We refer to the 'A' Ordinary Shares, warrants and debt securities, subscription rights and units collectively as "securities" in this prospectus. American Depositary Shares (each representing 4 'A' Ordinary Shares, par value $0.0109 per share) (our "ADSs") are listed on the NASDAQ Global Market under the symbol "TRIB." On April 25, 2017, the last reported sale price of an ADS of our company on the NASDAQ Global Market was $5.87.

The securities will have a total public offering price not to exceed $200,000,000. This prospectus provides a general description of the securities we may offer. Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update, or change information contained in this prospectus. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement. You should read both this prospectus and any prospectus supplement together with additional information described under the heading "Where You Can Find More Information" and the documents incorporated or deemed to be incorporated by reference carefully before you make your investment decision.

We will sell these securities directly to our shareholders or to purchasers or through agents on our behalf or through underwriters or dealers as designated from time to time. If any agents or underwriters are involved in the sale of any of these securities, the applicable prospectus supplement will provide the names of the agents or underwriters and any applicable fees, commissions, or discounts. The prospectus supplement for each offering of securities will describe in detail the plan of distribution for that offering. For general information about the distribution of securities offered, please see "Plan of Distribution" in this prospectus on page 26.

Investing in these securities involves certain risks. Please carefully consider the "Risk Factors" beginning on page 2 of this prospectus, and in any applicable prospectus supplement, for a discussion of the factors you should consider carefully before deciding to purchase these securities.

Neither the Securities and Exchange Commission (the "Commission") nor any state securities commission has approved or disapproved of the securities being offered by this prospectus, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is

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You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operation and prospects may have changed since that date.

In this prospectus, references to "we", "us", "Trinity Biotech" or the "Group" shall mean Trinity Biotech plc and its world-wide subsidiaries, collectively. References to the "Company" shall mean Trinity Biotech plc.

All references to "dollars" or "$" in this prospectus are to U.S. dollars, and all references to "Euro" or "€" are to European Union Euro.

PROSPECTUS SUMMARY

We develop, acquire, manufacture and market medical diagnostic products for the clinical laboratory and point-of-care segments of the diagnostic market. These products are used to detect autoimmune, infectious and sexually transmitted diseases, diabetes and disorders of the liver and intestine. We are also a significant provider of raw materials to the life sciences and research industries globally.

We market our portfolio of almost 850 products to customers in approximately 100 countries around the world through its own sales force and a network of international distributors and strategic partners.

We were incorporated as a public limited company ("plc") registered in Ireland in 1992. The Company commenced operations in 1992 and, in October 1992, completed an initial public offering of its securities in the US. The principal offices of the Group are located at IDA Business Park, Bray, Co Wicklow, Ireland. The Group has expanded its product base through internal development and acquisitions.

RISK FACTORS

An investment in our securities is speculative and involves a high degree of risk. You should carefully consider the following factors as well as the other information contained in this prospectus and in the other reports that we file with the SEC and that we incorporate by reference into this prospectus before deciding to invest in our securities. This prospectus and statements that we may make from time to time may contain forward-looking information. There can be no assurance that actual results will not differ materially from our expectations, statements or projections. Factors that could cause actual results to differ from our expectations, statements or projections include the risks and uncertainties relating to our business described below. The information in this prospectus is complete and accurate as of the date of this prospectus, but the information may change thereafter.

Risks Related to our Business

Our long-term success depends upon the successful development and commercialization of new products.

- Our long-term viability and growth will depend upon the successful discovery, development and commercialization of other products from our research and development ("R&D") activities. In order to remain competitive, we are committed to significant expenditures on R&D and the commercialization of new or enhanced products. The R&D process generally takes a significant amount of time from product inception to commercial launch. However, there is no certainty that this investment in research and development will yield technically feasible or commercially viable products. We may have to abandon a new or enhanced product or a product during its development phase in which we have invested substantial time and money. During the fiscal years ended December 31 2016, 2015 and 2014, we incurred US$17.4 million, US$19.7 million and US$20.3 million, respectively, in capitalized R&D expenses. We expect to continue to incur significant costs related to our research and development activities.

- Successful products require significant development and investment, including testing to demonstrate their performance capabilities, cost-effectiveness or other benefits prior to commercialization. In addition, unless exempt, regulatory clearance or approval must be obtained before our medical device products may be sold. Additional development efforts on these products may be required before we are ready to submit applications for marketing authorisation to any regulatory authority. Regulatory authorities may not clear or approve these products for commercial sale or may substantially delay or condition clearance or approval. In addition, even if a product is successfully developed and all applicable regulatory clearances or approvals are obtained, there may be little or no market for the product. Accordingly, if we fail to develop and gain commercial acceptance for our products, or if we have to abandon a new product during its development phase, or if competitors develop more effective products or a greater number of successful new products, customers may decide to use products developed by our competitors.

This would result in a loss of revenues and adversely affect our results of operations, cash flow and business.

- Our future growth in the United States is dependent in part on Food and Drug Administration ("FDA") clearance of products. If FDA clearance is delayed or not achieved for these products, it could have a material impact on the future growth of our business. Similarly, future growth outside of USA is dependent on clearance of products by the relevant regulatory authorities in those countries.

Our ability to sell products could be adversely affected by competition from new and existing diagnostic products.

- We have invested in research and development but there can be no guarantees that our R&D programmes will not be rendered technologically obsolete or financially non-viable by the technological advances of our competitors, which would also adversely affect our existing product lines and inventory. The main competitors of Trinity Biotech (and their principal products with which Trinity Biotech competes) include: Abbott Diagnostics (AxSYM™, IMx™, i-STAT®, Determine™, Wampole™, Athena™, Biosite Triag®), Arkray (HA-8180), Bio-Rad (Bioplex™, Variant II, Turbo and D10™ Diasorin Inc. (Liasion™, ETIMAX™), Johnson & Johnson – Ortho Clinical Diagnostics (Vitros™), OraSure Technologies, Inc. (OraQuick®), Roche Diagnostics (COBAS AMPLICOR™, Ampliscreen™, Accutrend™, Tina Quant™), Siemens – Beckman Coulter (Uni-Cel), Siemens – Dade-Behring (BEP 2000, Enzygnost®), Siemens – Bayer (Centaur™), Siemens – DPC (Immulite™), Thermo Fisher (Konelab™) and Tosoh (G8™).

- The diagnostics industry is focused on the testing of biological specimens in a laboratory or at the point-of-care and is highly competitive and rapidly changing. As new products enter the market, our products may become obsolete or a competitor's products may be more effective or more effectively marketed and sold than ours. If we fail to maintain and enhance our competitive position, our customers may decide to use products developed by competitors which could result in a loss of revenues.

- We may in certain instances also face competition from products that are sold at a lower price. Where this occurs, customers may choose to buy lower cost products from third parties or we may be forced to sell our products at a lower price, both of which could result in a loss of revenues or a lower gross margin contribution from the sale of our products. We may also be required to increase our marketing efforts in order to compete effectively, which would increase our costs.

- Our tests compete with products made by our competitors. Multiple competitors are making investments in competing technologies and products, and a number of our competitors may have a competitive advantage because of their greater financial, technical, research and other resources. Some competitors offer broader product lines and may have greater market presence or name recognition than we have. If we receive FDA clearance, and in order to achieve market acceptance, we and/or our distributors will likely be required to undertake substantial marketing efforts and spend significant funds to inform potential customers and the public of the existence and perceived benefits of our products. Our marketing efforts for these products may not be successful. As such, there can be no assurance that these products will obtain significant market acceptance and fill the market needs that are perceived to exist on a timely basis, or at all.

If we fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, regulatory clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

- Our medical device products and operations are subject to rigorous government regulation in the United States by the FDA, and numerous other federal, state and foreign governmental authorities, as well as and by comparable regulatory authorities in other jurisdictions such as the Health Products Regulatory Authority ("HPRA") in Ireland and the Medicines and Healthcare products Regulatory Agency ("MHRA") in the UK . In particular, we are subject to strict governmental controls on the development, manufacture, labelling, storage, testing, advertising, promotion, marketing, distribution and import and export of our products. In addition, we or our distributors are often required to register with and/or obtain clearances or approvals from foreign governments or regulatory bodies before we can import and sell our products in foreign countries. The clearance and approval process for our products, while variable across countries, is generally lengthy, time consuming, detailed and expensive.

- The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under

Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), or is the subject of an approved premarket approval application ("PMA") unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other 510(k)-cleared products. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA.

The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. The 510(k) clearance process usually takes from three to 12 months, but it can take longer. The process of obtaining PMA approval is much more costly and uncertain than the 510(k) clearance process. It generally takes from one to three years, or even longer, from the time the PMA application is submitted to the FDA, until an approval is obtained. There is no assurance that we will be able to obtain FDA clearance or approval for any of our new products on a timely basis, or at all.

- In the United States, the majority of our currently commercialized products have received pre-market clearance under Section 510(k) of the FDCA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or cancelled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process. Although we currently market only one device pursuant to an approved PMA, the FDA may demand that we obtain a PMA prior to marketing certain of our future products.

- The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:
- our ability to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended users;
- insufficient data from our pre-clinical studies and clinical trials to support clearance or approval, where required; and
- the failure of the manufacturing process or facilities we use to meet applicable requirements.

- In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. FDA's review of its 510(k) clearance process could result in additional changes to regulatory requirements or guidance documents which could increase the costs of compliance, or restrict our ability to maintain current clearances. In addition, as part of the Food and Drug Administration Safety and Innovation Act ("FDASIA"), Congress reauthorised the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval.

- Our continued success is dependent on our ability to develop and market new products, some of which are currently awaiting clearance or approval from the applicable regulatory authorities. There is no certainty that such clearance or approval will be granted or, even once granted, will not be revoked during the continuing review and monitoring process. Further, regulatory authorities, including the FDA, may not approve or clear our future products for the indications that are necessary or desirable for successful commercialization. A regulatory authority may impose requirements as a condition to granting a marketing authorisation, may include significant restrictions or limitations as part of a marketing authorisation it grants and may delay or refuse to authorise a product for marketing, even though a product has been authorised for marketing without restrictions or limitations in another country or by another agency. Failure to receive clearance or approval for our new products, or commercially undesirable limitations on our clearances or approvals, would have an adverse effect on our ability to expand our business.

Clinical trials necessary to support future premarket submissions will be expensive and will require enrollment of suitable patients who may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

- Initiating and completing clinical trials necessary to support approval of future products under development, is time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

- Conducting successful clinical studies will require the enrollment of patients who may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, and the availability of appropriate clinical trial investigators. Patients may not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

- Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Any challenges to patient enrollment may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

- Our facility and our clinical investigational sites operate under procedures that govern the conduct and management of FDA-regulated clinical studies under 21 CFR Parts 50, 56 and 812, and Good Clinical Practices. Although the majority of our in-vitro diagnostic ("IVD") clinical studies meet the definition of exempted investigations under 21 Part 812 and are exempt from the Investigational Device Exemption ("IDE") regulations in 21 CFR Part 812, we are still required to meet the requirements of 21 CFR Parts 50 and 56 for informed consent and Institutional Review Board ("IRB") approval. FDA may conduct Bioresearch Monitoring ("BiMo") inspections of us and/or our clinical sites to assess compliance with FDA regulations, our procedures, and the clinical protocol. If the FDA were to find that we or our clinical investigators are not operating in compliance with applicable regulations, we could be subject to the above FDA enforcement action as well as refusal to accept all or part of our data in support of a 510(k) or PMA and/or we may need to conduct additional studies.

If the third parties on which we rely to conduct our pre-clinical studies and clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

- We may not have the ability to independently conduct our pre-clinical studies and clinical trials for our products and we may rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our pre-clinical or clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

The results of our clinical trials may not support our product candidate claims.

- Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues.

Failure to comply with FDA or other regulatory requirements may require us to suspend production of our products or institute a recall which could result in higher costs and a loss of revenues.

- Even after we obtain clearance or approval for our medical devices, we are still subject to ongoing and extensive post market regulatory requirements. Regulation by the FDA and other federal, state and foreign regulatory agencies, such as the HPRA in E.U., impacts many aspects of our operations, and the operations of our suppliers and distributors, including manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, marketing, record keeping, import and export. For example, the manufacture of medical devices must comply with the FDA's Quality System Regulation ("QSR"), which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. Our manufacturing facilities and those of our suppliers and distributors are, or can be, subject to periodic regulatory inspections by the FDA to assess compliance with the QSR and other regulations, and by other comparable foreign regulatory authorities with respect to similar requirements in other jurisdictions. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the performance of approved products or place conditions on any product clearances or approvals that could restrict the commercial applications of those products. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Other regulatory authorities have similar sanctions in their respective jurisdictions.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

- Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

- In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or

frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

In the ordinary course of business, we must frequently make subjective judgments with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with the manner in which we have sought to comply with these regulations, we could be subjected to substantial civil and criminal penalties, as well as product recall, seizure or injunction with respect to the sale of our products. The assessment of any civil and criminal penalties against us could severely impair our reputation within the industry and any limitation on our ability to manufacture and market our products could have a material adverse effect on our business.

- In addition to the FDA and other regulations described above, laws and regulations in some countries may restrict our ability to sell products in those countries. While we intend to comply with any applicable restrictions, there is no guarantee we will be successful in these efforts.

- We must also comply with numerous laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, disposal of hazardous substances and labour or employment practices. Compliance with these laws or any new or changed laws regulating our business could result in substantial costs. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of these requirements. To the extent the costs and procedures associated with complying with these laws and requirements are substantial or it is determined that we do not comply, our business and results of operations could be adversely affected.

Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

- Manufacturers may, on their own initiative, initiate actions, including a non-reportable market withdrawal or a reportable product recall, for the purpose of correcting a material deficiency, improving device performance, or for other reasons. Additionally, the FDA and similar foreign health or governmental authorities have the authority to require an involuntary recall of commercialized products in the event of material deficiencies or defects in design, manufacturing or labeling or in the event that a product poses an unacceptable risk to health. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated.

- Companies are required to maintain certain records of post-market actions, even if they determine such actions are not reportable to the FDA. If we determine that certain actions do not require notification of the FDA, the FDA may disagree with our determinations and require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted or failing to timely report or initiate a reportable product action. Further, depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

- We are also required to comply with the FDA's Medical Device Reporting ("MDR"), requirements in the United States and comparable regulations worldwide, such as the HPRA. For example, under the FDA's MDR regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in European Union markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the Competent Authority in whose jurisdiction the incident occurred.

Were this to happen to us, the relevant Competent Authority would file an initial report, and there would then be a further inspection or assessment if there are particular issues. This would be carried out either by the Competent

Authority or it could require that Trinity Biotech's Notified Body, carry out the inspection or assessment.

- We have reported MDRs in the past, and we anticipate that in the future it is likely that we may experience events that would require reporting to the FDA pursuant to the MDR regulations. Any adverse event involving our products could result in future voluntary corrective actions, or agency actions, such as inspection, mandatory recall or other enforcement action.

- Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Modifications to our products, if cleared or approved, may require new 510(k) clearances or pre-market approvals, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

- Any modification to a 510(k)-cleared device in the United States that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary.

If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to previously cleared products for which we conclude that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.

- For example, we obtained 510(k) clearance for our Primus Variant System for the separation and quantification of normal and abnormal haemoglobin species as an aid in the diagnosis of haemoglobinopathies. The sample type used by this system was blood tubes. We subsequently introduced two systems based on the original Primus Variant System and they were named as ultra² GeneSys Variant System and ultra² Resolution Variant System. The primary focus of the GeneSys was on newborn screening using Dried Blood Spots as the sample type, while the Resolution was intended for confirmatory testing on the adult population using blood tubes as the sample type. We determined that these modifications to the indications for use were within our existing clearance and did not require the submission of a new 510(k) notification. The FDA stated that the use of Dried Blood Spots was not part of the original submission and represented a new modified Intended Use. The FDA informed us that it disagreed with our decision not to seek new 510(k) clearances for these modifications, and we have agreed to file new 510(k) notifications to obtain clearance for these indications. We have filed the 510(k) submission and are awaiting FDA approval. . Although the FDA has informed us that we may continue marketing these products pending clearance of new 510(k) notifications, there is no guarantee that we will be able to obtain new 510(k) clearances on a timely basis, or at all or that the FDA will not withdraw its authorisation to continue marketing the products pending new 510(k) clearance. If we are not able to obtain new 510(k) clearances, or if the FDA withdraws its authorisation, we may be required to cease marketing for the currently-marketed indications and remove these products from U.S. commercial distribution.

- Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to any products for which we obtain clearance, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) notification for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. For example, in accordance with FDASIA, the FDA was obligated to prepare a report for Congress on the FDA's approach for determining when a new 510(k) clearance will be required for modifications or changes to a previously cleared device. The FDA issued this report and indicated that manufacturers should continue to adhere to the FDA's 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) clearance is required for a change or modification to a device. However, the practical impact of the FDA's continuing scrutiny of the 510(k) program remains unclear.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses.

- Our promotional materials must comply with FDA and other applicable laws and regulations. We believe that the specific uses for which our products are marketed fall within the scope of the indications for use that have been cleared or approved by the FDA. However, the FDA could disagree and require us to stop promoting our products for those specific uses until we obtain FDA clearance or approval for them. In addition, if the FDA determines that our promotional materials constitutes promotion of an unapproved use, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties.

It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

If the FDA were to modify its policy of enforcement discretion with respect to our laboratory developed tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or other approvals.

- Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to laboratory developed tests ("LDTs"), although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to FDA regulation. The FDA defines the term "laboratory developed test" as an IVD test that is intended for clinical use and designed, manufactured and used within a single laboratory. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug, and Cosmetic Act, or FDA Act, with respect to LDTs. In July 2014, due to the increased proliferation of LDTs for complex diagnostic testing and concerns with several high-risk LDTs related to lack of evidentiary support for claims and erroneous results, the FDA issued guidance that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. As part of this developing framework, FDA issued draft guidance in October 2014, informing Congress and manufacturers of LDTs of its intent to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. The FDA will use this information to classify LDTs and to prioritize enforcement of premarket review requirements for categories of LDTs based on risk, using a public process. Specifically, the FDA plans to use advisory panels to provide recommendations to the agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate.

- We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for any of our LDTs, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our current LDTs or to develop and introduce new LDTs. We cannot predict the timing or content of future legislation enacted, regulations promulgated or guidance issued regarding LDTs, or how it will affect our business.

- If FDA premarket review, including clearance or approval, is required for our current or future LDTs (either alone or together with sample collection devices), products or services we may develop, or we decide to voluntarily pursue FDA clearance or approval, we may be forced to stop selling our LDTs while we work to obtain such FDA clearance or approval. Our business would be negatively affected until such review was completed and clearance to market or approval was obtained. The regulatory process may involve, among other things, successfully completing additional clinical studies and submitting premarket notification or filing a premarket approval application with the FDA. If premarket review is required by the FDA or if we decide to voluntarily pursue FDA premarket review of our LDTs, there can be no assurance that any tests, products or services we may develop in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of for our LDTs. If our LDTs are allowed to remain on the market but there is uncertainty in the marketplace about our tests, if we are required by the FDA to label them investigational and we cannot offer the LDTs for diagnostic purposes, or if labeling claims the FDA allows us to make are limited, orders may decline.

- Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

We are also subject to various federal and state laws targeting fraud and abuse in the healthcare industry.

If we fail to comply with federal and state health care laws, including fraud and abuse, false claims, physician payment transparency and privacy and security laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected. We are subject to anti-kickback laws, self-referral laws, false claims laws, and laws constraining the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements we may enter into with physicians, hospitals, laboratories and other potential purchasers of our products. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and wilfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the Physician Self-Referral Law, also known as the "Stark Law", which provides for strict liability for referrals by physicians to entities with which they or their immediate family members have a financial arrangement for certain designated health services, including clinical laboratory services provided by our CLIA-certified laboratory owned and operated by Immco Diagnostics Inc., that are reimbursable by federal healthcare programs, unless an exception applies. Penalties for violating the Stark Law include denial of payment, civil monetary penalties of up to fifteen thousand dollars per claim submitted, and exclusion from federal health care programs, as well as a penalty of up to one-hundred thousand dollars for attempts to circumvent the law;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers", may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments or other "transfers of value" made to physicians (defined to

include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. Manufacturers are required to submit reports to CMS by the 90th day of each calendar year. We cannot assure you that we have and will successfully report all transfers of value by us, and any failure to comply could result in significant fines and penalties. Failure to submit the required information may result in civil monetary penalties up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations;

- federal and state laws governing the certification and licensing of clinical laboratories, including operational, personnel and quality requirements designed to ensure that testing services are accurate and timely, and federal and state laws governing the health and safety of clinical laboratory employees;

- the U.S. Foreign Corrupt Practices Act, or the FCPA, which prohibits corporations and individuals from paying, offering to pay or authorising the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; the UK Bribery Act, which prohibits both domestic and international bribery, as well as bribery across both public and private sectors; and bribery provisions contained in the German Criminal Code, which makes the corruption and corruptibility of physicians in private practice and other healthcare professionals a criminal offense; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbours available under such laws, it is possible that some of our business activities, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase and/or order our tests, our sales and marketing efforts and certain arrangements with customers, including those where we provide our instrumentation for free in exchange for minimum purchase requirements of our reagents, and our billing and claims processing practices, could be subject to challenge under one or more of such laws. By way of example, some of our consulting arrangements with physicians do not meet all of the criteria of the personal services safe harbour under the federal Anti-Kickback Statute. Accordingly, they do not qualify for safe harbour protection from government prosecution. A business arrangement that does not substantially comply with a safe harbour, however, is not necessarily illegal under the Anti-Kickback Statute, but may be subject to additional scrutiny by the government. We are also exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and distributors may engage in fraudulent or other illegal activity. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

To enforce compliance with the federal laws, the U.S. Department of Justice ("DOJ"), has recently increased its scrutiny of interactions between health care companies and health care providers, which has led to a number of investigations, prosecutions, convictions and settlements in the health care industry. Dealing with investigations can be time and resource consuming and can divert management's attention from the business. In addition, settlements with the DOJ or other law enforcement agencies have forced healthcare providers to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Many of the existing requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. In addition, changes in or evolving interpretations of these laws, regulations, or administrative or judicial interpretations, may require us to change our business practices or subject our business practices to legal challenges, which could have a material adverse effect on our business, financial condition and results of operations.

- We have not yet developed a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we are or may become subject. Although the development and implementation of such compliance programs can mitigate the risk of investigation, prosecution, and penalties assessed for violations of these laws, or any other laws that may apply to us, the risks cannot be entirely eliminated.

If our operations are found to be in violation of any of the laws described above or any other laws and regulations that apply to us, we could receive adverse publicity, face enforcement action and be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

Our business could be adversely affected by changing conditions in the diagnostic market.

- The diagnostics industry is in transition with a number of changes that affect the market for diagnostic test products. The diagnostics industry has experienced considerable consolidation through mergers and acquisitions in the past several years. For example, major consolidation among reference laboratories and the formation of multi-hospital alliances, reducing the number of institutional customers for diagnostic test products. There can be no assurance that we will be able to enter into and/or sustain contractual or other marketing or distribution arrangements on a satisfactory commercial basis with these institutional customers. Further, this consolidation trend may result in the remaining companies having greater financial resources and technological capabilities, thereby intensifying competition in the industry, which could have a material adverse effect on our business.

Future acquisitions may be less successful than expected, not generate the expected benefits, disrupt our ongoing business, distract our management, increase our expenses and adversely affect our business, and therefore, growth may be limited.

- Trinity Biotech has historically grown organically and through the acquisition of, and investment in, other companies, product lines and technologies. We may enter into strategic acquisitions or investments as a way to expand our business. These activities, and their impact on our business, are subject to many risks, including the following:

- Suitable acquisitions or investments may not be found or consummated on terms or schedules that are satisfactory to us or consistent with our objectives;

- The benefits expected to be derived from an acquisition may not materialize and could be affected by numerous factors, such as regulatory developments, insurance reimbursement, general economic conditions and increased competition;

- We may be unable to successfully integrate an acquired company’s personnel, assets, management systems, products and/or technology into our business;

- Worse than expected performance of an acquired business may result in the impairment of intangible assets;

- Acquisitions may require substantial expense and management time and could disrupt our business;

- We may not be able to accurately forecast the performance or ultimate impact of an acquired business;

- An acquisition and subsequent integration activities may require greater capital and other resources than originally anticipated at the time of acquisition;

- An acquisition may result in the incurrence of unexpected expenses, the dilution of our earnings or our existing stockholders’ percentage ownership, or potential losses from undiscovered liabilities not covered by an indemnification from the seller(s) of the acquired business;

- An acquisition may result in the loss of our or the acquired company’s key personnel, customers, distributors or suppliers;

- An acquisition of a foreign business may involve additional risks, including, but not limited to, foreign currency exposure, liability or restrictions under foreign laws or regulations, and our inability to successfully assimilate differences in foreign business practices or overcome language or cultural barriers; and

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Our ability to integrate future acquisitions may be adversely affected by inexperience in dealing with new technologies.

The occurrence of one or more of the above or other factors may prevent us from achieving all or a significant part of the benefits expected from an acquisition or investment. This may adversely affect our financial condition, results of operations and ability to grow our business or otherwise achieve our financial and strategic objectives.

Our revenues are highly dependent on a network of distributors worldwide.

- Trinity Biotech currently distributes its product portfolio through distributors in approximately 100 countries worldwide. Our continuing economic success and financial security is dependent on our ability to secure effective channels of distribution on favourable trading terms with suitable distributors.

- The loss or termination of our relationship with these key distributors could significantly disrupt our business unless suitable alternatives were timely found or lost sales to one distributor are absorbed by another distributor. Finding a suitable alternative to a lost or terminated distributor may pose challenges in our industry's competitive environment, and another suitable distributor may not be found on satisfactory terms, if at all. For instance, some distributors already have exclusive arrangements with our competitors, and others do not have the same level of penetration into our target markets as our existing distributors. If total revenue from these or any of our other significant distributors were to decrease in any material amount in the future or we are not successful in timely transitioning business to new distributors, our business, operating results and financial condition could be materially and adversely affected.

Reductions in government funding to agencies and organizations we work with could adversely affect our business and financial results.

- We sell our products into the public health market, which consists of state, county and other governmental public health agencies, community based organizations, service organizations and similar entities. Many of these customers depend to a significant degree on grants or funding provided by governments or governmental agencies to run their operations, including programs that use our products, such as our HIV testing products. In international markets, we often sell our products to parties funded by such agencies. The level of available government grants or funding is unpredictable, and certain organizations may not have their contracts renewed for funding. Available funding may be affected by various factors including future economic conditions, legislative and regulatory developments, political changes, civil unrest and changing priorities for research and development activities. Any reduction or delay in government funding or change in organizational contracts could cause our customers to delay, reduce or forego purchases of our products or cause short term or long term fluctuations in our product revenues through these channels.

Trinity Biotech may be subject to liability resulting from its products or services.

- Trinity Biotech may be subject to claims for personal injuries or other damages if any of our products, or any product which is made with the use or incorporation of any of our technologies, causes injury of any type or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or usage. There is no assurance that we would be successful in defending any product liability lawsuits brought against us. Regardless of merit or eventual outcome, product liability claims could result in:

- Decreased demand for our products;
- Lost revenues;
- Damage to our image or reputation;
- Costs related to litigation;
- Diversion of management time and attention; and
- Incurrence of damages payable to plaintiffs.

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Trinity Biotech has global product liability insurance in place for its manufacturing subsidiaries up to a maximum of €6,500,000 (US$6,841,000) for any one accident, limited to a maximum of €6,500,000 (US$6,841,000) in any one year period of insurance. A deductible of €5,000 ($5,300) for each claim and every claim increasing to US$25,000 in respect of USA/Canada is applicable to each insurance event that may arise. There can be no assurance that our product liability insurance is sufficient to protect us against liability that could have a material adverse effect on our business. In addition, although we believe that we will be able to continue to obtain adequate coverage in the future, there is no assurance that we will be able to do so at acceptable costs.

Significant interruptions in production at our principal manufacturing facilities and/or third-party manufacturing facilities would adversely affect our business and operating results.

- Products manufactured at our facilities in Bray, Ireland, Jamestown and Buffalo, New York, Kansas City, Missouri and Carlsbad, California comprised approximately 84% of revenues during the fiscal year ended December 31, 2016. Our global supply of these products and services is dependent on the uninterrupted and efficient operation of these facilities. In addition, we currently rely on a small number of third-party manufacturers to produce certain of our diagnostic products and product components.

- If we do not negotiate long-term contracts, our suppliers will likely not be required to provide us with any guaranteed minimum production levels. As a result, we cannot assure you that we will be able to obtain sufficient quantities of product in the future. In addition, our reliance on third-party suppliers involves a number of risks, including, among other things:

  - contract manufacturers or suppliers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the efficacy or safety of our products or cause delays in shipments of our products;

  - we or our contract manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our suppliers may have excess or inadequate inventory of materials and components;

  - we or our contract manufacturers and suppliers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;

  - we or our contract manufacturers and suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems;

  - we may experience delays in delivery by our contract manufacturers and suppliers due to changes in demand from us or their other customers;

  - fluctuations in demand for products that our contract manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;

  - our suppliers or those of our contract manufacturer may wish to discontinue supplying components or services to us for risk management reasons;

  - we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and

  - our contract manufacturers and suppliers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

- The operations of our facilities or these third-party manufacturing facilities could be adversely affected by fire, power failures, natural or other disasters, such as earthquakes, floods, or terrorist threats. Although we carry insurance to protect against certain business interruptions at our facilities, some pieces of manufacturing equipment are difficult to replace and could require substantial replacement lead-time. There can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all.

- If any of these risks materialize, it could significantly increase our costs and impact our ability to meet demand for our products. If we are unable to satisfy commercial demand for our products in a timely manner, our ability to

generate revenue would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use our competitors' products. In addition, we could be forced to secure new or alternative contract manufacturers or suppliers. Securing a replacement contract manufacturer or supplier could be difficult. The introduction of new or alternative manufacturers or suppliers also may require design changes to our products that are subject to FDA and other regulatory clearances or approvals.

We may also be required to assess the new manufacturer's compliance with all applicable regulations and guidelines, which could further impede our ability to manufacture our products in a timely manner. As a result, we could incur increased production costs, experience delays in deliveries of our products, suffer damage to our reputation, and experience an adverse effect on our business and financial results. Any significant interruption in the Group's or third-party manufacturing capabilities could materially and adversely affect our operating results.

We are highly dependent on our senior management team and other key employees, and the loss of one or more of these employees or the inability to attract and retain qualified personnel as necessary could adversely affect our operations.

- Trinity Biotech's success is dependent to a large extent upon the contributions of certain key management personnel. Our key employees at December 31, 2016 were Ronan O'Caoimh, our CEO and Chairman, Jim Walsh, Executive Director, and Kevin Tansley, our CFO/Executive Director. We may not be able to attract or retain a sufficient number of qualified employees in the future due to the intense competition for qualified personnel among medical products and other life science businesses.

- If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to effectively manufacture, sell and market our products, to meet the demands of our strategic partners in a timely fashion, or to support research, development and clinical programs. Although we believe we will be successful in attracting and retaining qualified personnel, competition for experienced scientists and other personnel from numerous companies and academic and other research institutions may limit our ability to do so on acceptable terms.

We are dependent on third-party suppliers for certain critical components and the primary raw materials required for our test kits.

- The primary raw materials required for Trinity Biotech's test kits consist of antibodies, antigens or other reagents, glass fibre and packaging materials which are acquired from third parties. If our third-party suppliers are unable or unwilling to supply or manufacture a required component or product or if they make changes to a component, product or manufacturing process or do not supply materials meeting our specifications, we may need to find another source and/or manufacturer. This could require that we perform additional development work.

- Some of our products, which we acquire from third parties, are highly technical and are required to meet exacting specifications, and any quality control problems that we experience with respect to the products supplied by third-party vendors could adversely and materially affect our reputation, our attempts to complete our clinical trials or commercialization of our products and adversely and materially affect our business, operating results and prospects. We may also need to obtain FDA or other regulatory authorisations for the use of an alternative component or for certain changes to our products or manufacturing process. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including, warning letters, product recalls, termination of distribution, product seizures, or civil penalties. Completing that development and obtaining such authorisations could require significant time and expense and we may not obtain such authorisations on a timely basis, or at all. The availability of critical components and products from other third parties could also reduce our control over pricing, quality and timely delivery. These events could either disrupt our ability to manufacture and sell certain of our products into one or more markets or completely prevent us from doing so, and could increase our costs. Any such event could have a material adverse effect on our results of operations, cash flow and business. Furthermore, since some of these suppliers are located outside of the United States, we are subject to foreign export laws and United States import and customs regulations, which complicate and could delay shipments of components to us.

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Although Trinity Biotech does not expect to be dependent upon any one source for these critical components or raw materials, alternative sources of antibodies with the characteristics and quality desired by Trinity Biotech may not be available. Such unavailability could affect the quality of our products and our ability to meet orders for specific products.

Global economic conditions may have a material adverse impact on our results.

- We currently generate significant operating cash flows, which combined with access to the credit markets provides us with discretionary funding capacity for research and development and other strategic activities. Uncertainty in global economic conditions may continue for the foreseeable future and intensify. This uncertainty poses a risk to the overall economy that could impact demand for our products, as well as our ability to manage normal commercial relationships with our customers, suppliers and creditors, including financial institutions. Volatile economic conditions have adversely affected and could continue to adversely affect our financial performance and condition or those of our customers and suppliers. These circumstances could adversely affect our access to liquidity needed to conduct or expand our business or conduct future acquisitions or make other discretionary investments. Many of our customers rely on public funding provided by federal, state and local governments, and this funding has been and may continue to be reduced or deferred as a result of economic conditions.

- If global economic conditions deteriorate significantly, our business could be negatively impacted, including such areas as reduced demand for our products from a slow-down in the general economy, supplier or customer disruptions resulting from tighter credit markets and/or temporary interruptions in our ability to conduct day-to-day transactions through our financial intermediaries involving the payment to or collection of funds from our customers, vendors and suppliers. These circumstances may adversely impact our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. Even with the improvement of economic conditions, it may take time for our customers and suppliers to establish new budgets and return to normal purchasing and shipping patterns. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery.

We face risks relating to our international sales and business operations, including regulatory risks, which could impact our current business operations and growth strategy.

- Our international sales and operations are subject to various United States and foreign laws and regulations relating to export controls (including, without limitation, the U.S. Commerce Department's Export Administration Regulations), economic sanctions (including, without limitation, various sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control), and anti-corruption (including, without limitation, the United States Foreign Corrupt Practice Act). Failure to comply with such applicable laws and regulations could subject us to civil or criminal penalties, government investigations, debarment from export privileges, and reputational harm, which could have a material adverse effect on our business.

Our sales and operations are subject to the risks of fluctuations in currency exchange rates.

- A substantial portion of our operations is based in Ireland and Europe is one of our main sales territories. As a result, changes in the exchange rate between the U.S. Dollar and the Euro can have significant effects on our results of operations. In addition, in markets where we invoice in U.S. Dollars but where the local currency has weakened, we have been required to reduce our pricing in order to preserve our competiveness. The Group has an exposure to the Canadian Dollar through its two Canadian entities (Nova Century Scientific and Phoenix Biotech) and to the Brazilian Real through its Brazilian entity. Since the acquisition of Fiomi Diagnostics AB in 2012 and the blood bank screening business of Lab21 Ltd in 2013, the Group also has a currency exposure to the Swedish Kroner and Sterling.

- In the future, we may enter into hedging instruments to manage our currency exchange rate risk. However, our attempts to hedge against these risks may not be successful. If we are unable to successfully hedge against unfavourable foreign currency exchange rate movements, our consolidated financial results may be adversely impacted.

The conversion of our outstanding employee share options would dilute the ownership interest of existing shareholders.

- The total share options exercisable at December 31, 2016 are convertible into American Depository Shares (ADSs), 1 ADS representing 4 “A” Ordinary Shares. The exercise of the share options exercisable will likely occur only when the conversion price is below the trading price of our ADSs and will dilute the ownership interests of existing shareholders. For instance, should the options of the 5,838,851 “A” Ordinary Shares (1,459,713 ADSs) exercisable at December 31, 2016 be exercised, Trinity Biotech would have to issue 5,838,851 additional “A” Ordinary Shares (1,459,713 ADSs). On the basis of 96,162,410 “A” Ordinary Shares outstanding at December 31, 2016, this would effectively dilute the ownership interest of the existing shareholders by approximately 6%.

It could be difficult for US holders of ADSs to enforce any securities laws claims against Trinity Biotech, its officers or directors in Irish Courts.

- At present, no treaty exists between the United States and Ireland for the reciprocal enforcement of foreign judgments. The laws of Ireland do however, as a general rule, provide that the judgments of the courts of the United States have in Ireland the same validity as if rendered by Irish Courts. Certain important requirements must be satisfied before the Irish Courts will recognize the United States judgment. The originating court must have been a court of competent jurisdiction, the judgment may not be recognized if it is based on public policy, was obtained by fraud or its recognition would be contrary to Irish public policy. Any judgment obtained in contravention of the rules of natural justice will not be enforced in Ireland.

Our inability to manufacture products in accordance with applicable specifications, performance standards or quality requirements could adversely affect our business.

- The materials and processes used to manufacture our products must meet detailed specifications, performance standards and quality requirements to ensure our products will perform in accordance with their label claims, our customers' expectations and applicable regulatory requirements.

- As a result, our products and the materials used in their manufacture or assembly undergo regular inspections and quality testing. Factors such as defective materials or processes, mechanical failures, human errors, environmental conditions, changes in materials or production methods by our vendors, and other events or conditions could cause our products or the materials used to produce or assemble our products to fail inspections and quality testing or otherwise not perform in accordance with our label claims or the expectations of our customers.

- Any failure or delay in our ability to meet the applicable specifications, performance standards, quality requirements or customer expectations could adversely affect our ability to manufacture and sell our products or comply with regulatory requirements. These events could, in turn, adversely affect our revenues and results of operations.

Compliance with regulations governing public company corporate governance and reporting is complex and expensive.

- Many laws and regulations impose obligations on public companies, which have increased the scope, complexity and cost of corporate governance, reporting and disclosure practices. Our implementation of certain aspects of these laws and regulations has required and will continue to require substantial management time and oversight and may require us to incur significant additional accounting and legal costs. We continually evaluate and monitor developments with respect to new and proposed rules and cannot predict or estimate the ultimate amount of additional costs we may incur or the timing of such costs. These laws and regulations are also subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Although we are committed to maintaining high standards of corporate governance and public disclosure, if we fail to comply with any of these requirements, legal proceedings may be initiated against us, which may adversely affect our business.

Failure to achieve our financial and strategic objectives could have a material adverse impact on our business prospects.

- As a result of any number of risk factors identified herein, no assurance can be given that we will be successful in implementing our financial and strategic objectives. In addition, the funds for research, clinical development and other projects have in the past come primarily from our business operations. If our business slows and we have less money available to fund research and development and clinical programs, we will have to decide at that time which programs to cut, and by how much. Similarly, if adequate financial, personnel, equipment or other resources are not

available, we may be required to delay or scale back our business. Our operations will be adversely affected if our total revenue and gross profits do not correspondingly increase or if our technology, product, clinical and market development efforts are unsuccessful or delayed.

- Furthermore, our failure to successfully introduce new or enhanced products and develop new markets could have a material adverse effect on our business and prospects.

We may require future additional capital.

- Our future liquidity and ability to meet our future capital requirements will depend on numerous factors, including, but not limited to, the following:
- The costs and timing of expansion of sales and marketing activities;
- The timing and success of the commercial launch of new products;
- The extent to which we gain or expand market acceptance for existing, new or enhanced products;
- The costs and timing of the expansion of our manufacturing capacity;
- The success of our research and product development efforts;
- The time, cost and degree of success of conducting clinical trials and obtaining regulatory approvals;
- The magnitude of capital expenditures;
- Changes in existing and potential relationships with distributors and other business partners;
- The costs involved in obtaining and enforcing patents, proprietary rights and necessary licenses;
- The costs and liability associated with patent infringement or other types of litigation;
- Competing technological and market developments; and
- The scope and timing of strategic acquisitions.

- If additional financing is needed, we may seek to raise funds through the sale of equity or other securities or through bank borrowings. There can be no assurance that financing through the sale of securities, bank borrowings or otherwise will be available to us on satisfactory terms, or at all.

Investor confidence and share value may be adversely impacted if we and/or our independent registered public accounting firm conclude that our internal control over financial reporting is not effective.

- As directed by the Sarbanes-Oxley Act of 2002, we are required to include a report in our Annual Reports on Form 20-F that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, our independent registered public accounting firm must report on the effectiveness of these internal controls.

- We expect that our internal controls will continue to evolve as our business activities change. Although we seek to diligently and vigorously review our internal control over financial reporting in an effort to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. In addition, the overall quality of our internal controls may be affected by the internal control over financial reporting implemented by any business we acquire and our ability to assess and successfully integrate the internal controls of any such business.

- If, during any year, our independent registered public accounting firm is not satisfied with our internal control over financial reporting or the level at which our controls are documented, designed, operated, tested or assessed, then it may issue a report that is adverse. We also could conclude that our internal control over financial reporting is not effective. These events could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements and effectiveness of our internal controls, which ultimately could negatively impact the market price of our common stock.

Our success depends on our ability to service and support our products directly or in collaboration with our strategic partners.

- To the extent that we or our strategic partners fail to maintain a high quality level of service and support for diagnostic products, there is a risk that the perceived quality of our products will be diminished in the marketplace. Likewise, we may fail to provide the level, quantity or quality of service expected by the marketplace. This could

result in slower adoption rates and lower than anticipated utilisation of our products which could have a material adverse effect on our business, financial condition and results of operations.

Consolidation of our customers or the formation of group purchasing organisations could result in increased pricing pressure that could adversely affect our operating results.

- The health care industry has undergone significant consolidation resulting in increased purchasing leverage for customers and consequently increased pricing pressures on our business. Additionally, some of our customers have become affiliated with group purchasing organisations. Group purchasing organisations typically offer members price discounts on laboratory supplies and equipment if they purchase a bundled group of one supplier's products, which results in a reduction in the number of manufacturers selected to supply products to the group purchasing organization and increases the group purchasing organization's ability to influence its members' buying decisions. Further consolidation among customers or their continued affiliation with group purchasing organizations may result in significant pricing pressures and correspondingly reduce the gross margins of our business or may cause our customers to reduce their purchases of our products, thereby adversely affecting our business, prospects, operating results or financial condition.

We may be unable to protect or obtain proprietary rights that we utilise or intend to utilise.

- In developing and manufacturing our products, we employ a variety of proprietary and patented technologies. In addition, we have licensed, and expect to continue to license, various complementary technologies and methods from academic institutions and public and private companies. We cannot provide any assurance that the technologies that we own or license provide protection from competitive threats or from challenges to our intellectual property. In addition, we cannot provide any assurances that we will be successful in obtaining licenses or proprietary or patented technologies in the future, or that licenses granted to us by third parties will not be granted to other third parties who could potentially compete with us.

- Filing, prosecuting and defending patents covering our current and future products throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

The scope of the patent protection we obtain may not be sufficiently broad to compete effectively in our markets; our patent applications could be rejected or the existing patents could be challenged; and trade secrets and confidential know-how could be obtained by competitors.

- Trinity Biotech currently owns 8 U.S. patents with remaining patent lives varying from nine months to 16 years.

- We may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current products or any future products in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application.

- We can provide no assurance that third parties will not challenge the validity, enforceability or scope of the patents Trinity Biotech may apply for, or obtain, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any products covered by those patents.

Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We can provide no assurance that our patents will continue to be commercially valuable.

- Trade secrets and confidential know-how are important to our scientific and commercial success. Although we seek to protect our proprietary information through confidentiality agreements and other contracts, we can provide no assurance that others will not independently develop the same or similar information or gain access to our proprietary information.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

- Periodic maintenance fees on any issued patent are due to be paid to the United States Patent and Trademark Organization ("USPTO") and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalise and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our current or future products, our competitors might be able to enter the market, which would have an adverse effect on our business.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

- Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future.

- For example, the United States has enacted and implemented wide-ranging patent reform legislation, which could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents, all of which could have an adverse effect on our business and financial condition.

- Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

Product infringement claims by other companies could result in costly disputes and could limit our ability to sell our products.

- Litigation over intellectual property rights is prevalent in the diagnostic industry, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter party review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions.

As the market for diagnostics continues to grow and the number of participants in the market increases, we may increasingly be subject to patent infringement claims. It is possible that a third-party may claim infringement against

us. For example, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products may infringe. Defence of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of managerial and financial resources from our business. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialise one or more of our products. The pendency of any litigation may cause our distributors and customers to reduce or terminate purchases of our products. If found to infringe, we may have to pay substantial damages, including treble damages and attorneys' fees for wilful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. Any substantial loss resulting from such a claim could cause our revenues to decrease and have a material adverse affect on our profitability, and the damage to our reputation in the industry could have a material adverse affect on our business.

- If we need to obtain a license as a result of litigation, we cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialisation of our products. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialise one or more of our products, which could harm our business significantly.

We may be involved in lawsuits to enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.

- Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorised use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defence proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte re-examinations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

- We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defence of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future products. Such a loss of patent protection could harm our business.

- We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

- Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our ordinary shares.

Our ability to protect our information systems and electronic transmissions of sensitive data from data corruption, cyber-based attacks, security breaches or privacy violations is critical to the success of our business.

- We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store electronic information, including personal information of our customers. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, malware attacks by hackers and similar breaches, can cause all or portions of our websites to be unavailable, create system disruptions, shutdowns, erasure of critical data and software or unauthorised disclosure of confidential information. We invest in security technology to protect our data against risks of data security breaches and cyber-attacks and we have implemented solutions, processes, and procedures to help mitigate these risks, such as encryption, virus protection, security firewalls and comprehensive information security and privacy policies. However, despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. The age of our information technology systems, as well as the level of our protection and business continuity or disaster recovery capability, varies from site to site, and there can be no guarantee that any such plans, to the extent they are in place, will be effective. In addition, a security breach or privacy violation that leads to disclosure of consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent further security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, we may be subject to legal claims or proceedings, or we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data, which could have a material adverse impact on our business, financial condition and results of operations. While we currently expend resources to protect against cyber-attacks and security breaches, hackers and other cyber criminals are using increasingly sophisticated and constantly evolving techniques, and we may need to expend additional resources to continue to protect against potential security breaches or to address problems caused by such attacks or any breach of our safeguards. In addition, a data security breach could distract management or other key personnel from performing their primary operational duties.

- In addition, the interpretation and application of consumer and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices. If so, this could result in government-imposed fines or orders requiring that we change our data practices, which could have an adverse effect on our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

Reductions in government funding and research budgets could adversely affect our business and financial results

- We sell our products into the public health market, which consists of state, county and other governmental public health agencies, community based organisations, service organisations and similar entities. Many of these customers depend to a significant degree on grants or funding provided by governmental agencies to run their operations including programs that use our products. In international markets, we often sell our products to parties funded by such agencies. The level of available government grants or funding is unpredictable and may be affected by various factors including future economic conditions, legislative and regulatory developments, political changes, civil unrest and changing priorities for research and development activities. Any reduction or delay in government funding could cause our customers to delay, reduce or forego purchases of our products.

Risks Related to Government Regulation

We could be adversely affected by healthcare reform legislation and other changes in coverage and reimbursement for our tests by third-party payors.

- The results of the 2016 Presidential election in USA have generated uncertainty with respect to, and could result in, significant changes in legislation, regulation and government policy that could significantly impact our business. While it is not possible to predict whether and when any such changes will occur or what form any such changes may take (including through the use of Executive Orders), specific proposals discussed during and after the election that could have a material adverse effect on our business, liquidity and results of operations include, but are not limited to, the repeal of all or part of the Affordable Care Act ('ACA') and other significant changes to health care system legislation as well as changes with respect to tax and trade policies, tariffs and other government regulations affecting trade between the United States and other countries. The repeal of all or part of the ACA, significant changes to Medicaid funding or even significant destabilization of the Health Insurance Marketplaces could impact the number of Americans with health insurance. Even if ACA remains, significant provisions of ACA have not yet been finalized (e.g., non-discrimination in health programs and activities, excise tax on high-cost employer-sponsored health coverage) and it is uncertain whether or in what form these provisions will be finalized. We cannot predict the effect, if any, a repeal of all or part of ACA, the implementation or failure to implement the outstanding provisions of ACA, or the enactment of new health care system legislation to replace current legislation may have on our business.

- In the USA, there are continued efforts of health maintenance organizations, managed care organizations, government entities, and other third party payors to reduce reimbursement rates for diagnostic testing services. In addition, during the past several years, the USA health care industry has been subject to an increase in governmental regulation and audits at both the federal and state levels. Efforts to control health care costs are continuing at the federal and state government levels. Changing political, economic and regulatory influences may significantly affect health care financing and reimbursement practices. For example, we anticipate that federal and state governments will continue to review and assess alternative health care delivery systems, payment methodologies and operational requirements for health care providers. Any action taken to repeal or replace all or significant parts of healthcare legislation could also impact our profitability, though it is unclear at this time what the full effects will be.

- Furthermore, comprehensive tax reform in USA is likely to be considered in the current political environment. We expect that U.S. tax reform, if enacted, could have a significant impact on the Company. Current proposals aim to lower the U.S. corporate tax rate from 35% to as low as 15% or 20%, but generally broaden the base to which the lower tax rate would apply. Many aspects of tax reform plans remain unknown though, and no proposed legislation has been filed. We cannot say with certainty if tax reform will be enacted, or how it would impact the Company.

Our laboratory business could be harmed from the loss or suspension of a license or imposition of a fine or penalties under, or future changes in, the law or regulations of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), or those of other state or local agencies.

- Our laboratory operated by Immco Diagnostics Inc. is subject to CLIA, which is administered by CMS and extends federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally-approved accreditation agency. CLIA is designed to ensure the quality and reliability of clinical laboratories by, among other things, mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Laboratories must undergo on-site surveys at least every two years, which may be conducted by the Federal CLIA program or by a private CMS approved accrediting agency such as the College of American Pathologists, among others. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties.

- We are also subject to regulation of laboratory operations under state clinical laboratory laws of New York and of certain other states from where we accept specimens. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. For example, California requires that we maintain a license to conduct testing in California, and California law establishes standards for our day-to-day laboratory operations, including the training and skill required of laboratory personnel and quality control. In some respects, notably with respect to qualifications of testing personnel, California's clinical laboratory laws impose more rigorous standards than does CLIA. Certain other states, including Florida, Maryland, New York and Pennsylvania, require that we hold licenses to test specimens from patients residing in those states, and additional states may require similar licenses in the future. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorisations, which could adversely affect our business and results of operations.

FORWARD LOOKING STATEMENTS

This prospectus and the documents incorporated in it by reference contain forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements accompanied by meaningful cautionary statements. Except for historical information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, which may be identified by words such as "estimates", "anticipates", "projects", "plans", "seeks", "may", "will", "expects", "intends", "believes", "should" and similar expressions or the negative thereof and which also may be identified by their context. Such statements, whether expressed or implied, are based upon current expectations of the company and speak only as of the date made. The company assumes no obligation to publicly update or revise any forward-looking statements even if experience or future changes make it clear that any projected results expressed or implied therein will not be realized. These statements are subject to various risks, uncertainties and other factors – please refer to the matters described under the caption "Risk Factors" for a comprehensive outline of these risks and the threats which they pose to the company and its results, as well as certain other matters discussed in this prospectus, the documents incorporated by reference in this prospectus, and other publicly available sources. Such factors and many other factors beyond the control of our management could cause

our actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by the forward-looking statements any future results, performance or achievements that may be expressed or implied by the forward-looking statements.

RATIO OF EARNINGS TO FIXED CHARGES

The following table shows our ratio of earnings to fixed charges:

	Year Ended December 31,				
	2012	2013	2014	2015	2016
Ratio of earnings to fixed charges	-	-	-	6.51	(21.88)

CAPITALIZATION AND INDEBTEDNESS

The table below sets forth our capitalization as of December 31, 2016.

	As of December 31, 2016 (dollars in thousands)
Short-term debt (including current maturities of long term loans and debt)	-
Long-term loans	115,000
Total shareholders' equity	108,727
Total liabilities and shareholders' equity	249,592

MARKET FOR OUR AMERICAN DEPOSITARY SHARES

Our ADSs are quoted on the NASDAQ Global Market under the symbol “TRIB”. On April 25, 2017, the last reported sale price of our ADSs on the NASDAQ Global Market was $5.87.

Annual Share Price Information

The following table sets forth, each of the years indicated, the high and low market prices of our ADSs on the NASDAQ Global Market.

	NASDAQ	
Year	High	Low
2012	$15.75	$8.81
2013	$25.63	$14.30
2014	$28.06	$14.00
2015	$20.24	$10.74
2016	$13.68	$5.76

Quarterly Share Price Information

The following table sets forth, for each of the full financial quarters in the years indicated the high and low market prices of our ADSs on the NASDAQ Global Market:

	NASDAQ	
	High	Low
2015		
First quarter	$20.24	$17.00
Second quarter	$19.35	$15.43
Third quarter	$19.03	$11.00
Fourth quarter	$13.28	$10.74
2016		
First quarter	$12.02	$9.20
Second quarter	$12.17	$10.37
Third quarter	$13.68	$10.51
Fourth quarter	$13.15	$5.76
2017		
First quarter	$7.20	$5.20

Monthly Share Price Information

The following table sets forth, for the most recent six months, the high and low market prices of our ADSs on the NASDAQ Global Market:

	NASDAQ	
	High	Low
October 2016	$13.15	$5.76

November 2016	$7.40	$6.52
December 2016	$7.27	$6.64
January 2017	$7.20	$6.28
February 2017	$6.86	$6.02
March 2017	$6.33	$5.20

USE OF PROCEEDS

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities covered by this prospectus for potential future acquisitions and for general corporate purposes, which may include continued product development and commercialization. Additional information on the use of net proceeds from the sale of securities covered by this prospectus may be set forth in the prospectus supplement relating to the specific offering.

PLAN OF DISTRIBUTION

We may sell the securities being offered hereby in any one or more of the following methods from time to time:

- to or through one or more underwriters on a firm commitment or best efforts basis;
- to or through dealers, who may act as agents or principals, including a block trade (which may involve crosses) in which a broker or dealer so engaged will attempt to sell as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- through agents;
- through privately negotiated transactions;
- directly to purchasers, including our affiliates;
- purchases by a broker or dealer as principal and resale by such broker or dealer for its own account pursuant to this prospectus;
- exchange distributions and/or secondary distributions;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- to one or more underwriters for resale to the public or to investors;
- in “at the market offerings,” to or through a market maker or into an existing trading market, on an exchange or otherwise;
- transactions not involving market makers or established trading markets, including direct sales or privately negotiated transactions;
- transactions in options, swaps or other derivatives that may or may not be listed on an exchange or
- in any combination of these methods of sale.

The prospectus supplement with respect to any offering of our securities will set forth the terms of the offering, including:

- the name or names and addresses of any underwriters, dealers or agents;
- the purchase price of the securities and the proceeds to us from the sale;

- any underwriting discounts and commissions or agency fees and other items constituting underwriters' or agents' compensation;

- the public offering price;

·any discounts or concessions allowed or reallowed or paid to dealers;

·any securities exchanges or markets on which such securities may be listed. and

·any delayed delivery arrangements.

The distribution of the securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices, or in a combination of any of the above noted pricing methods.

If securities are sold by means of an underwritten offering, we will execute an underwriting agreement with an underwriter or underwriters, and the names of the specific managing underwriter or underwriters, as well as any other underwriters, and the terms of the transaction, including commissions, discounts and any other compensation of the underwriters and dealers, if any, will be set forth in the prospectus supplement which will be used by the underwriters to sell the securities. If underwriters are utilized in the sale of the securities, the securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at fixed public offering prices or at varying prices determined by the underwriters at the time of sale. Maximum compensation to any underwriters, dealers or agents will not exceed any applicable Financial Industry Regulatory Authority, or FINRA, limitations. In particular, in compliance with the guidelines of FINRA, the aggregate maximum fees or other items of value to be received by any FINRA member or independent broker-dealer will not exceed 8% of the gross proceeds of any offering pursuant to this registration statement.

Our securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by the managing underwriters. If any underwriter or underwriters are utilized in the sale of the securities, unless otherwise indicated in the prospectus supplement, the underwriting agreement will provide that the obligations of the underwriters are subject to conditions precedent and that the underwriters with respect to a sale of securities will be obligated to purchase all of those securities if they purchase any of those securities.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price with additional underwriting discounts or commissions. If we grant any over-allotment option, the terms of any over-allotment option will be set forth in the prospectus supplement relating to those securities.

If a dealer is utilized in the sales of securities in respect of which this prospectus is delivered, we will sell those securities to the dealer as principal. The dealer may then resell those securities to the public at varying prices to be determined by the dealer at the time of resale. Any reselling dealer may be deemed to be an underwriter, as the term is defined in the Securities Act of the securities so offered and sold. The name of the dealer and the terms of the transaction will be set forth in the related prospectus supplement.

Offers to purchase securities may be solicited by agents designated by us from time to time. Any agent involved in the offer or sale of the securities in respect of which this prospectus is delivered will be named, and any commissions payable by us to the agent will be set forth, in the applicable prospectus supplement. Unless otherwise indicated in the prospectus supplement, any agent will be acting on a reasonable best efforts basis for the period of its appointment. Any agent may be deemed to be an underwriter, as that term is defined in the Securities Act of the securities so offered and sold.

Offers to purchase securities may be solicited directly by us and the sale of those securities may be made by us directly to institutional investors or others, who may be deemed to be underwriters within the meaning of the Securities Act with respect to any resale of those securities. The terms of any sales of this type will be described in the related prospectus supplement.

We also may sell directly to investors through subscription rights distributed to our shareholders on a pro rata basis. In connection with any distribution of subscription rights to shareholders, if all of the underlying securities are not subscribed for, we may sell the unsubscribed securities directly to third parties or may engage the services of one or more underwriters, dealers or agents, including standby underwriters, to sell the unsubscribed securities to third parties.

Underwriters, dealers, agents and remarketing firms may be entitled under relevant agreements entered into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act"), that may arise from any untrue statement or alleged untrue statement of a material fact or any omission or alleged omission to state a material fact in this prospectus, any supplement or amendment hereto, or in the registration statement of which this prospectus forms a part, or to contribution with respect to payments which the agents, underwriters or dealers may be required to make. We may use underwriters, dealers, agents and remarketing firms with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, dealers, agents and/or remarketing firm and the nature of any such relationship.

If so indicated in the prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by institutions to purchase securities from us pursuant to contracts providing for payments and delivery on a future date. Institutions with which contracts of this type may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and others, but in all cases those institutions must be approved by us. The obligations of any purchaser under any contract of this type will be subject to the condition that the purchase of the securities shall not at the time of delivery be prohibited under the laws of the jurisdiction to which the purchaser is subject. The underwriters and other persons acting as our agents will not have any responsibility in respect of the validity or performance of those contracts.

One or more firms, referred to as “remarketing firms,” may also offer or sell the securities, if the prospectus supplement so indicates, in connection with a remarketing arrangement upon their purchase. Remarketing firms will act as principals for their own accounts or as agents for the company or any of its subsidiaries. These remarketing firms will offer or sell the securities in accordance with a redemption or repayment pursuant to the terms of the securities.

The prospectus supplement will identify any remarketing firm and the terms of its agreement, if any, with the company or any of its subsidiaries and will describe the remarketing firm's compensation. Remarketing firms may be deemed to be underwriters in connection with the securities they remarket. Remarketing firms may be entitled under agreements that may be entered into with the company or any of its subsidiaries to indemnification by the company or any of its subsidiaries against certain civil liabilities, including liabilities under the Securities Act, and may engage in transactions with or perform services for the company or any of its subsidiaries in the ordinary course of business.

Disclosure in the prospectus supplement of our use of delayed delivery contracts will include the commission that underwriters and agents soliciting purchases of the securities under delayed contracts will be entitled to receive in addition to the date when we will demand payment and delivery of the securities under the delayed delivery contracts. These delayed delivery contracts will be subject only to the conditions that we describe in the prospectus supplement.

In connection with the offering of securities, persons participating in the offering, such as any underwriters, may purchase and sell securities in the open market. These transactions may include over-allotment and stabilizing transactions and purchases to cover syndicate short positions created in connection with the offering. Stabilizing transactions consist of bids or purchases for the purpose of preventing or retarding a decline in the market price of the securities, and syndicate short positions involve the sale by underwriters of a greater number of securities than they are required to purchase from any issuer in the offering. Underwriters also may impose a penalty bid, whereby selling concessions allowed to syndicate members or other broker-dealers in respect of the securities sold in the offering for their account may be reclaimed by the syndicate if the securities are repurchased by the syndicate in stabilizing or covering transactions. These activities may stabilize, maintain or otherwise affect the market price of the securities, which may be higher than the price that might prevail in the open market, and these activities, if commenced, may be discontinued at any time.

An underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934. Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriter to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. These activities may cause the price of our securities to be higher than it would otherwise be on the open market. The underwriter may discontinue any of these activities at any time.

All securities we offer will be new issues of securities, with no established trading market (other than ‘A’ Ordinary Shares, which are traded via our ADSs). Underwriters may make a market in these securities, but will not be obligated to do so and may discontinue market making at any time without notice. We cannot guarantee the liquidity of the

trading markets for any securities.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to the ‘A’ Ordinary Shares for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution.

DESCRIPTION OF ‘A’ ORDINARY SHARES

Capital Structure

Our authorized share capital consists of 200,700,000 ‘A’ Ordinary Shares, par value $0.0109 per share. Our ‘A’ Ordinary Shares are represented by American Depository Receipts or ADRs. An ADR is a receipt for the shares of a foreign corporation held in the vault of a U.S. bank and entitling the holder to all dividends and capital gains. Instead of buying shares of foreign-based companies in overseas markets, U.S. persons can buy shares in the United States in the form of an ADR. An American Depositary Share or ADS is the share issued under a depositary agreement representing the underlying ‘A’ Ordinary Share. Technically, ADS is the instrument that actually is traded, whereas the ADR is the certificate that represents a number of ADSs.

The Bank of New York acts as the depositary for Trinity’s ADSs pursuant to an amended and restated deposit agreement which is an exhibit to the Form F-6 registration statement filed by Trinity on January 15, 2004, registration no. 333-111946. The depositary’s offices are located at 101 Barclay Street, New York, NY 10286. Holders of ADSs do not have the same rights as holders of ‘A’ Ordinary Shares and may only exercise the voting rights with respect to the underlying ‘A’ Ordinary Shares in accordance with the provisions of the deposit agreement.

As of April 26, 2017 we had outstanding 96,162,410 ‘A’ Ordinary Shares and 9,780,183 ‘A’ Ordinary Shares were subject to outstanding options. We may issue shares subject to the maximum prescribed by our authorized share capital contained in our memorandum of association. The authorized share capital may be increased or reduced by way of an ordinary resolution of our shareholders.

As a matter of Irish company law, the directors of a company may issue new shares without shareholder approval once authorized to do so by the Articles of Association of the company or by an ordinary resolution adopted by the shareholders at a general meeting. An ordinary resolution requires over 50% of the votes of a company's shareholders cast at a general meeting. The authority conferred can be granted for a maximum period of five years, at which point it must be renewed by the shareholders of the company by an ordinary resolution. Because of this requirement of Irish law, the board of directors is authorized to issue new shares up to the current authorized share capital limit without shareholder approval for a period of five years from the date of an ordinary resolution passed by the shareholders of our company on May 25, 2012. We plan to seek shareholder approval to renew this authority at our Annual General Meeting in 2017.

The rights and restrictions to which the ‘A’ Ordinary Shares are subject are prescribed in our Articles of Association.

Irish law does not recognize fractional shares held of record; accordingly, our Articles of Association does not provide for the issuance of fractional shares, and our official Irish register does not reflect any fractional shares.

Where a shareholder or person who appears to be interested in shares fails to comply with a request for information from us in relation to the capacity in which such shares or interest are held, who is interested in them or whether there are any voting arrangements, that shareholder or person may be disenfranchised and thereby restricted from transferring the shares and voting or receiving any sums in respect thereof (except in the case of a liquidation). In addition, if cheques in respect of the last three dividends paid to a shareholder remain uncashed, we are, subject to compliance with the procedure set out in our Articles of Association, entitled to sell the shares of that shareholder.

Preemption Rights, Share Warrants and Share Options

Under Irish law, certain statutory pre-emption rights apply automatically in favor of shareholders where shares are to be issued for cash. However, we have opted out of these pre-emption rights as permitted under Irish law. Irish law provides that this opt-out expires every five years unless renewed by special resolution (approval by not less than 75% of the votes cast at a general meeting). If the opt-out is not renewed, shares issued for cash must be offered to existing shareholders on a pro rata basis to their existing shareholding before the shares may be issued to any new shareholders. The statutory pre-emption rights do not apply (i) where shares are issued for non-cash consideration (such as in a stock-for-stock acquisition), (ii) to the issue of non-equity shares (that is, shares that have the right to participate only up to a specified amount in any income or capital distribution) or (iii) where shares are issued pursuant to an employee stock option or similar equity plan.

Our Articles of Association provide that the board of directors is authorised to grant options to purchase shares and to cause warrants to be issued. The Irish Companies Act 2014 (the "Irish Companies Act") provides that directors may issue share warrants or options without shareholder approval once authorized to do so by the Articles of Association or an ordinary resolution of shareholders. The board may issue shares upon exercise of warrants or options without further shareholder approval or authorization.

Dividends

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves generally means accumulated realized profits less accumulated realized losses and includes reserves created by way of capital reduction. In addition, no distribution or dividend may be made unless our net assets are equal to, or in excess of, the aggregate of its called up share capital plus undistributable reserves and the distribution does not reduce its net assets below such aggregate. Undistributable reserves include the share premium account, the capital redemption reserve fund and net unrealized profits.

The determination as to whether or not we have sufficient distributable reserves to fund a dividend must be made by reference to our “relevant entity financial statements”. The “relevant entity financial statements” are either the last set of unconsolidated annual audited financial statements or other financial statements properly prepared in accordance with the Irish Companies Act (not in accordance with U.S. GAAP), which give a “true and fair view” of our unconsolidated financial position and accord with accepted accounting practice. The relevant accounts must be filed in the Companies Registration Office (the official public registry in Ireland).

Our Articles of Association authorize our directors to declare dividends without shareholder approval to the extent they appear justified by profits lawfully available for distribution. Our board of directors may also recommend a dividend to be approved and declared by the shareholders at a general meeting. The board of directors may direct that the payment be made by distribution of assets, shares or cash, and no dividend issued may exceed the amount recommended by the directors. The dividends declared by the shareholders may be paid in the form of cash or non-cash assets. The board of directors may deduct from any dividend payable to any shareholder any amounts payable by such shareholder to us in relation to its shares.

Share Repurchases

Subject to the Irish Companies Act, other provisions of our Articles of Association and to any rights conferred on the holders of any class of shares, Article 14 of our Articles of Association allows us to purchase any of our own shares and may cancel any shares so purchased or hold them as treasury shares with liberty to re-issue any such shares or shares of any class or classes provided that we have obtained shareholder consent to do so by way of special resolution under Section 1074 of the Irish Companies Act.

We will not exercise any authority granted under Section 1074 of the Irish Companies Act to make market purchases of our own shares unless the authority required by such section shall have been granted by special resolution. Any such special resolution must (i) specify the date on which the authority will expire and cannot be later than 5 years after the date on which the special resolution is passed (ii) specify the maximum number of shares authorised to be acquired and (iii) specify the maximum and minimum price to be paid for such shares. We are under no obligation to select the shares to be purchased on a pro rata basis or in any particular manner as between shareholders of the same or different classes of share.

Repurchased and redeemed shares may be cancelled or held as treasury shares. While we hold treasury shares, we cannot exercise any voting rights in respect of those shares. Treasury shares may be cancelled by us or re-issued subject to certain conditions.

Under Irish law, a company may issue redeemable shares and redeem them out of distributable profits (which are described in "—Dividends") or the proceeds of a new issue of shares for that purpose. Redeemable shares may only be issued if the nominal value of the issued share capital that is not redeemable is not less than 10% of the nominal value of the total issued share capital. All redeemable shares must be fully paid and the terms of redemption of the shares must provide for payment on redemption. Redeemable shares may, upon redemption, be cancelled or held in treasury. Based on the provision of our Articles, shareholder approval will not be required to redeem our shares.

Bonus Shares

Under our Articles of Association, we may by ordinary resolution, on the recommendation of our board of directors, resolve to capitalize any undivided profits of our company. Accordingly, the board of directors are authorised to apply such sums either for the issuance to shareholders of shares as fully paid bonus shares or towards paying up amounts unpaid on any shares or debentures held by such members. However, any share premium account or capital redemption reserve fund or capital surplus arising on the revaluation of unrealised fixed assets may only be applied in paying up of unissued shares to be issued to members as fully paid.

Consolidation and Division

Under our Articles of Association, we may by ordinary resolution consolidate and divide all or any of our share capital into shares of larger amount than our existing shares.

Reduction of Share Capital

We may, by special resolution, reduce our share capital, any capital redemption reserve fund and any share premium account in any manner authorised by the Irish Companies Act. We may also, by special resolution and subject to confirmation by the Irish High Court, reduce or cancel our issued share capital in any way permitted by the Irish Companies Act.

General Meetings of Shareholders

We must hold a general meeting each year. Not more than 15 months can elapse between annual general meetings. The annual general meetings are held at such time and place as the directors determine and all other general meetings are called extraordinary general meetings. A general meeting or an extraordinary general meeting of the company may be held inside or outside the Republic of Ireland. The directors may at any time call an extraordinary general meeting and such meetings may also be convened on such requisition, or in default may be convened by such requisitions, as is provided by the Irish Companies Acts. In the case of an annual general meeting or a meeting at which a special resolution (a resolution approved by not less than 75% of the votes cast at a general meeting, in person or by proxy, of the Company's shareholders) is proposed, 21 clear days' notice of the meeting is required and in any other case it is 14 clear days' notice. Notice must be given in writing to all members and to the auditors and must state the details specified in our Articles of Association. A general meeting (other than one at which a special resolution is to be proposed) may be called on shorter notice subject to the agreement of the auditors and all members entitled to attend and vote at it. In certain circumstances provided in the Irish Companies Acts, extended notice is required. These include removal of a director.

Shareholders are entitled to call a meeting by way of a requisition. The requisition must be signed by ordinary shareholders holding not less than one tenth of the paid up capital of our company carrying the right of voting at general meetings of our company.

No business may be transacted at a general meeting unless a quorum is present. Five members present in person or by proxy (not being less than five individuals) representing not less than 40% of the 'A' Ordinary Shares shall be a quorum. There are no limitations in our Articles of Association or under Irish law restricting the rights of non-resident or foreign shareholders to hold or exercise voting rights on the shares in our company.

At a general meeting, on a show of hands, every shareholder who is present in person or by proxy and entitled to vote shall have one vote (so, however, that no individual shall have more than one vote) and upon a poll, every shareholder present in person or by proxy shall have one vote for every share. In the case of joint holders, the vote of the senior (being the first person named in the register of members in respect of the joint holding) who tendered a vote, whether in person or by proxy, shall be accepted to the exclusion of votes of the other joint holders. Our Articles of

Association permit shareholders to approve corporate matters in writing provided that a written consent is signed by all the members for the time being entitled to vote and attend at general meeting.

One third of the directors other than an executive director or, if their number is not three or a multiple of three, then the number nearest to but not exceeding one third, shall retire from office at each annual general meeting. If, however, the number of directors subject to retirement by rotation is two, one of such directors shall retire. If the number is one, that director shall retire. The directors to retire at each annual general meeting shall be the ones who have been longest in office since their last appointment. Where directors are of equal seniority, the directors to retire shall, in the absence of agreement, be selected by lot. A retiring director shall be eligible for re-appointment and shall act as director throughout the meeting at which he retires. A separate motion must be put to a meeting in respect of each director to be appointed unless the meeting itself has first agreed that a single resolution is acceptable without any vote being given against it.

We may, subject to the provisions of the Irish Companies Acts, issue any share on the terms that it is to be redeemed on such terms and in such manner as we may determine by special resolution. Before recommending a dividend, the directors may reserve out of our profits such sums as they think proper which shall be applicable for any purpose to which our profits may properly be applied and, pending such application, may be either employed in our business or be invested in such investments (other than shares of the Company or of its holding company (if any)) as the directors may from time to time think fit.

Subject to any conditions of allotment, the directors may from time to time make calls on members in respect of monies unpaid on their shares. At least 14 days' notice must be given of each call. A call shall be deemed to have been made at the time when the directors resolve to authorize such call.

Our Articles of Association do not contain any provisions discriminating against any existing or prospective holder of securities as a result of such shareholder owning a substantial number of shares. Any shareholder who complains that the affairs of our company are being conducted or that the powers of the directors of our company are being exercised in a manner oppressive to him or any of the shareholders (including himself), or in disregard of his or their interests as shareholders, may apply to the Irish courts for relief. Shareholders have no right to maintain proceedings in respect of wrongs done to our company save in limited circumstances (addressed below in the paragraph entitled "Shareholder Suits").

Variation of Rights Attaching to a Class or Series of Shares

In order to change the rights attaching to any class of shares a special resolution passed at a class meeting of the holders of such shares is required. The provisions in relation to general meetings apply to such meetings except the quorum shall be two persons holding or representing by proxy at least one third in nominal amount of the issued shares of that class. In addition, in order to amend any provisions of our Articles of Association in relation to rights attaching to shares, including 'A' Ordinary Shares, a special resolution of the shareholders as a whole is required.

Shareholder Proposals

Under Irish law, there is no general right for a shareholder of a NASDAQ-listed company to put items on the agenda of an annual general meeting. Our Articles of Association provide that shareholders duly qualified to be present and vote at a meeting of our company may nominate persons to be elected as directors at such general meetings. Our Articles of Association specify requirements for notices with respect to members' director nominations at general meetings.

Shareholders' Suits

In Ireland, the decision to institute proceedings on behalf of a company is generally taken by the company's board of directors. In certain limited circumstances, a shareholder may be entitled to bring a derivative action on our company's behalf. A central question at issue in deciding whether a minority shareholder may be permitted to bring a derivative action is whether, unless the action is brought, a wrong committed against us would otherwise go unredressed. The

cause of action may be against a director, another person or both.

A shareholder may also be permitted to bring proceedings against our company in his or her own name where the shareholder's rights as such have been infringed or where the Company's affairs are being conducted, or the powers of the board of directors are being exercised, in a manner oppressive (connotes conduct that is burdensome, harsh or wrongful) to any shareholder or shareholders or in disregard of their interests as shareholders. This is an Irish statutory remedy under Chapter 8 (Protection for Minorities) of the Irish Companies Act and the court can grant any order it sees fit, including providing for the purchase or transfer of the shares of any shareholder.

Inspection of Books and Records

Pursuant to Irish law, we must maintain a register of our shareholders. This register is open to inspection by shareholders free of charge and to any member of the public on payment of a small fee. The books containing the minutes of proceedings of any general meeting of our company are required to be kept at the registered office of our company and are open to the inspection of any member without charge. Minutes of meetings of the Board of Directors are not open to scrutiny by shareholders. We are obliged to keep Proper Books of Account. The shareholders have no statutory right to inspect the books of account. The only financial records, which are open to the shareholders, are the financial statements, which are sent to shareholders with the annual report. Irish law also obliges us to file information relating to certain events within our company (new share capital issues, changes to share rights, changes to the Board of Directors). This information is filed with the Companies Registration Office in Dublin and is open to public inspection.

Directors' Duties

Ordinarily, our directors owe their duties only to our company and not its shareholders. The duties of directors are twofold, fiduciary duties and duties of care and skill. Fiduciary duties are owed by the directors individually and owed to our company. The Irish Companies Act, which came into effect on June 1, 2015 has codified the law in Ireland on directors' duties. Section 228 of the Irish Companies Act specifies eight relevant fiduciary duties which apply to directors of Irish Companies (i) to act in good faith and in the best interests of the company (ii) to act honestly and responsibly in relation to the company's affairs (iii) to act in accordance with the company's Articles of Associational documents and to exercise powers only for lawful purposes; (iv) not to misuse the company's property information and/or opportunity; (v) not to fetter independent judgment; (vi) to avoid conflicts of interest; (vii) to exercise care, skill and due diligence; and (viii) to have regard to interests of the company's shareholders.

The Irish Companies Act also specifies a number of general duties for directors of Irish companies: (i) ensure compliance with the Irish Companies Act and Irish tax legislation; (ii) ensure that the company secretary of the company is suitably qualified; (iii) acknowledge the existence of their duties by signing a declaration to that effect; (iv) take in account the interest of the shareholders of the company and have regard to the interests of the employees; (v) disclose any interests in contracts made by the Company; and (vi) notify the company of any interests in shares in the company, its parent or its subsidiaries (no obligation arises if the shares held represent less than 1% or the shares are non-voting).

A director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. When directors, as agents in transactions, make contracts on behalf of our company, they generally incur no personal liability under these contracts. It is our company, as principal, which will be liable under them, as long as the directors have acted within our company's objects and within their own authority. A director who commits a breach of his fiduciary duties shall be liable to our company for any profit made by him or for any damage suffered by our company as a result of the breach. In addition to the above, a breach by a director of his duties may lead to a sanction from a Court including damages of compensation, summary dismissal of the director, a requirement to account to our company for profit made and restriction of the director from acting as a director in the future.

Conflicts of Interest

As a matter of Irish law unless released from the obligation in the company's Articles of Association, a director is under a general fiduciary duty to avoid conflicts of interest. Irish law and our Articles of Association provide that (1) a director may be a director of or otherwise interested in a company relating to us and will not be accountable to us for any remuneration or other benefits received as a result, unless we otherwise direct; (2) a director or a director's firm may act for us in a professional capacity other than as auditor; and (3) a director may hold an office or place of profit in us and will not be disqualified from contracting with us. If a director has a personal interest in an actual or proposed

contract with us, the director must declare the nature of his or her interest and we are required to maintain a register of such declared interests that must be available for inspection by the shareholders. Such a director may not vote on any resolution of the board of directors in respect of such a contract.

Indemnification of Directors and Officers

Our Articles of Association confer an indemnity on our directors and officers. However, this indemnity is limited by the Irish Companies Act, which prescribe that an advance commitment to indemnify only permits a company to pay the costs or discharge the liability of a director or corporate secretary where judgment is given in favor of the director or corporate secretary in any civil or criminal action in respect of such costs or liability where the director or corporate secretary is acquitted, or where an Irish court grants relief because the director or corporate secretary acted honestly and reasonably and ought fairly to be excused. Any provision whereby an Irish company seeks to commit in advance to indemnify its directors or corporate secretary over and above the limitations imposed by the Irish Companies Act will be void under Irish law, whether contained in its Articles of Association or any contract between the company and the director or corporate secretary. This restriction does not apply to our executives who are not directors, the corporate secretary or other persons who would be considered “officers” within the meaning of that term under the Irish Companies Act.

Directors' Borrowing Powers

The directors may exercise all the powers of our company to borrow money, to mortgage or charge its undertaking, property and uncalled capital and subject to the Irish Companies Act to issue debentures and other securities, whether outright or as collateral security for any debt, liability or obligation of our company or of any third party.

Irish Competition Law

Under Irish Competition Act 2002 (as amended), the Irish Competition and Consumer Protection Commission ("CCPC") must be notified of a merger or acquisition before it is put into effect if certain financial thresholds are satisfied. Failure to notify the CCPC of a mandatorily notifiable merger or acquisition is an offence and will result in the voiding of the transaction, as well as the potential imposition of fines. A merger or acquisition that does not meet the relevant criteria but which may give rise to competition concerns, though not legally required, may be notified voluntarily to the CCPC in order to seek legal comfort that the merger or acquisition will not be reviewed by the CCPC under its residual powers of investigation.

Acquisitions

An Irish public limited company may be acquired in a number of ways, including:

- a court-approved scheme of arrangement under the Irish Companies Act. A scheme of arrangement with shareholders requires a court order from the Irish High Court and the approval of a majority in number representing 75% in value of the shareholders present and voting in person or by proxy at a meeting called to approve the scheme;

- through a tender or takeover offer by a third party for all of a company's shares. Where the holders of 80% or more of a company's shares have accepted an offer for their shares, the remaining shareholders may also be statutorily required to transfer their shares, and if the bidder does not exercise its "squeeze out" right, then the non-accepting shareholders also have a statutory right to require the bidder to acquire their shares on the same terms. If a company's shares were to be listed on the main securities market of the Irish Stock Exchange or another regulated stock exchange in the European Union, this threshold would be increased to 90%; and

- by way of a merger with an European Economic Area (the European Economic Area includes all member states of the European Union and Norway, Iceland and Liechtenstein) company under the EU Cross-Border Mergers Directive 2005/56/EC. Such a merger must be approved by a special resolution (i.e. 75% of shareholders for an Irish company) and by the Irish Courts.

Irish law does not generally require shareholder approval for a sale, lease or exchange of all or substantially all of a company's property and assets, unless the company is listed on a regulated stock exchange in the European Union.

Our Articles of Association do not contain any provisions:

- which would have an effect of delaying, deferring or preventing a change in control of our company and which would operate only with respect to a merger, acquisition or corporate restructuring involving our company (or any of its subsidiaries); or

- governing the ownership threshold above which a shareholder ownership must be disclosed; or

- imposing conditions governing changes in the capital which are more stringent than is required by Irish law.

We incorporate by reference all other information concerning our Articles of Association from our Registration Statement on Form F-1 dated June 12, 1992

Appraisal Rights

Generally, under Irish law, shareholders of an Irish company do not have dissenters' or appraisal rights. Under the European Communities (Cross-Border Mergers) Regulations 2008 governing the merger of an Irish company limited by shares such as our company and a company incorporated in the European Economic Area, a shareholder (i) who voted against the special resolution approving the merger or (ii) of a company in which 90% of the shares are held by the other party to the merger, has the right to request that the company acquire its shares for cash at a price determined in accordance with the share exchange ratio set out in the merger agreement.

Disclosure of Interests in Shares

Under the Irish Companies Act, subject to certain limited exceptions, a person must notify our company (but not the public) if, as a result of a transaction, such person will become interested in three percent or more of our company's voting shares, or if as a result of a transaction a shareholder who was interested in more than three percent of our voting shares ceases to be so interested. Where any person is interested in more than three percent of our voting shares, such person must notify us of any alteration of his or her interest that brings his or her total holding through the nearest whole percentage number, whether an increase or a reduction. The relevant percentage figure is calculated by reference to the aggregate nominal value of the voting shares in which the person is interested as a proportion of the entire nominal value of our issued share capital (or any such class of share capital in issue). Where the percentage level of the person's interest does not amount to a whole percentage, this figure may be rounded down to the next whole number. We must be notified within five business days of the transaction or alteration of the person's interests that gave rise to the notification requirement. If a person fails to comply with these notification requirements, such person's rights in respect of any of our shares he or she holds will not be enforceable, either directly or indirectly. However, such person may apply to the court to have the rights attaching to such shares reinstated.

In addition to these disclosure requirements, we, under the Irish Companies Act, may, by notice in writing, require a person whom we know or have reasonable cause to believe to be, or at any time during the three years immediately preceding the date on which such notice is issued to have been, interested in shares comprised in our relevant share capital to: (i) indicate whether or not it is the case; and (ii) where such person holds or has during that time held an interest in our shares, to provide additional information, including the person's own past or present interests in our company's shares. If the recipient of the notice fails to respond within the reasonable time period specified in the notice, we may apply to a court for an order directing that the affected shares be subject to certain restrictions, as prescribed by the Irish Companies Act, as follows:

- any transfer of those shares or, in the case of unissued shares, any transfer of the right to be issued with shares and any issue of shares, shall be void;
- no voting rights shall be exercisable in respect of those shares;
- no further shares shall be issued in right of those shares or in pursuance of any offer made to the holder of those shares; and
- no payment shall be made of any sums due from us on those shares, whether in respect of capital or otherwise.

The court may also order that shares subject to any of these restrictions be sold with the restrictions terminating upon the completion of the sale.

In the event we are in an offer period pursuant to the Irish takeover rules, as defined below, accelerated disclosure provisions apply for persons holding an interest in our securities of one percent or more.

Anti-Takeover Provisions

Irish Takeover Rules and Substantial Acquisition Rules

A transaction in which a third party seeks to acquire 30% or more of the voting rights of our company and certain other acquisitions of our company‘s securities are governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules made thereunder, which are referred to in this offering circular as the “Irish takeover rules,” and are regulated by the Irish Takeover Panel. The “General Principles” of the Irish takeover rules and certain important aspects of the Irish takeover rules are described below.

General Principles

The Irish takeover rules are built on the following general principles which will apply to any transaction regulated by the Irish Takeover Panel:

- in the event of an offer, all holders of securities of the target company must be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;
- the holders of securities in the target company must have sufficient time and information to enable them to reach a properly informed decision on the offer; where it advises the holders of securities, the board of directors of the target company must give its views on the effects of the implementation of the offer on employment, employment conditions and the locations of the target company's place of business;
- a target company's board of directors must act in the interests of the company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;
- false markets must not be created in the securities of the target company, the bidder or any other company concerned by the offer in such a way that the rise or fall of the prices of the securities becomes artificial and the normal functioning of the markets is distorted;
- a bidder can only announce an offer after ensuring that he or she can pay in full the consideration offered, if such is offered, and after taking all reasonable measures to secure the implementation of any other type of consideration;
- a target company may not be hindered in the conduct of its affairs longer than is reasonable by an offer for its securities (this is a recognition that an offer will disrupt the day-to-day running of a target company, particularly if the offer is hostile and the board of directors of the target company must direct its attention to resisting the offer); and
- an acquisition of securities (whether such acquisition is to be effected by one transaction or a series of transactions) shall take place only at an acceptable speed and shall be subject to adequate and timely disclosure. Specifically, the acquisition of 10% or more of the issued voting shares within a seven day period that would take a shareholder's holding to or above 15% of the issued voting shares (but less than 30%) is prohibited, subject to certain exemptions.

Mandatory Bid

Under certain circumstances, a person who acquires ‘A’ Ordinary Shares or ADSs, or other of our voting securities, may be required under the Irish takeover rules to make a mandatory cash offer for the remaining issued and outstanding voting securities at a price not less than the highest price paid for the securities by the acquirer, or any parties acting in concert with the acquirer, during the previous 12 months. This mandatory bid requirement is triggered if an acquisition of securities would increase the aggregate holding of an acquirer, including the holdings of

any parties acting in concert with the acquirer, to securities representing 30% or more of the voting rights in our company, unless the Irish Takeover Panel otherwise consents. An acquisition of securities by a person holding, together with its concert parties, securities representing between 30% and 50% of the voting rights in our company would also trigger the mandatory bid requirement if, after giving effect to the acquisition, the percentage of the voting rights held by that person (together with its concert parties) would increase by 0.05% within a 12-month period. Any person (excluding any parties acting in concert with the holder) holding securities representing more than 50% of the voting rights of a company is not subject to these mandatory offer requirements in purchasing additional securities.

Voluntary bid; Requirements to Make a Cash Offer and Minimum Price Requirements

If a person makes a voluntary offer to acquire the issued and outstanding 'A' Ordinary Shares or ADSs of our company and the bidder acquired 'A' Ordinary Shares or ADSs in the three-month period prior to the commencement of the offer period, the offer price must not be less than the highest price paid for 'A' Ordinary Shares or ADSs by the bidder or its concert parties during that period. The Irish Takeover Panel has the power to extend the "look back" period to 12 months if the Irish Takeover Panel, taking into account the General Principles, believes it is appropriate to do so.

If the bidder or any of its concert parties has acquired more than 10% of the issued and outstanding 'A' Ordinary Shares or ADSs (i) during the period of 12 months prior to the commencement of the offer period or (ii) at any time after the commencement of the offer period, the offer must be in cash (or accompanied by a full cash alternative) and the price per ordinary share must not be less than the highest price paid by the bidder or its concert parties during, in the case of (i), the 12-month period prior to the commencement of the offer period or, in the case of (ii), the offer period. The Irish Takeover Panel may apply this rule to a bidder who, together with its concert parties, has acquired less than 10% of the total 'A' Ordinary Shares or ADSs in the 12-month period prior to the commencement of the offer period if the Irish Takeover Panel, taking into account the General Principles, considers it just and proper to do so.

An offer period will generally commence on the date of the first announcement of the offer or proposed offer.

Substantial Acquisition Rules

The Irish takeover rules also contain rules governing substantial acquisitions of shares and other voting securities which restrict the speed at which a person may increase his or her holding of shares and rights over shares to an aggregate of between 15% and 30% of the voting rights of our company. Except in certain circumstances, an acquisition or series of acquisitions of shares or rights over shares representing 10% or more of the voting rights of our company is prohibited, if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of the voting rights of our company and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of acquisitions of shares or rights over shares relating to such holdings.

Frustrating Action

Under the Irish takeover rules, our board of directors is not permitted to take any action that might frustrate an offer for our shares once the board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (i) the issue of shares, options or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our company's board of directors has reason to believe an offer is or may be imminent. Exceptions to this prohibition are available where:

· the action is approved by our shareholders at a general meeting; or

· the Irish Takeover Panel has given its consent, where:

o it is satisfied the action would not constitute frustrating action;

o our shareholders holding more than 50% of the voting rights state in writing that they approve the proposed action and would vote in favour of it at a general meeting;

o

the action is taken in accordance with a contract entered into prior to the announcement of the offer (or any earlier time at which our company's board of directors considered the offer to be imminent); or

- the decision to take such action was made before the announcement of the offer and either has been at least partially implemented or is in the ordinary course of business.

Certain other provisions of Irish law or our company's Articles of Association may be considered to have anti-takeover effects, including advance notice requirements for director nominations and other shareholder proposals.

Corporate Governance

Our Articles of Association allocate authority over the management of our company to the board of directors. The board of directors may then delegate management to committees of the board, executives or to a management team, but regardless, the directors will remain responsible, as a matter of Irish law, for the proper management of the affairs of our company. The board of directors has currently established, audit, remuneration and compensation committees. We have adopted a code of ethics that applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and all organisation employees.

Legal Name; Formation; Fiscal Year; Registered Office

The legal and commercial name of our company, an Irish company, is Trinity Biotech Public Limited Company. Trinity Biotech plc was incorporated in Ireland, as a private limited company on January 22, 1992 with company registration number 183476. We re-registered as a public limited company on July 16, 1992. We operate and report financial results on a fiscal year ending on December 31. Our registered address is IDA Business Park, Bray, Co. Wicklow, Ireland.

Duration; Dissolution; Rights upon Liquidation

Our company’s duration is unlimited. We may be dissolved at any time by way of either a shareholders' voluntary winding up or a creditors' voluntary winding up. In the case of a shareholders' voluntary winding up, the consent of not less than 75% of the shareholders of our company is required. We may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure where our company has failed to file certain returns.

The rights of the shareholders to a return of our company’s assets on dissolution or winding up, following the settlement of all claims of creditors, may be prescribed in its Articles of Association or the terms of any preferred shares issued by the directors from time to time. The holders of preferred shares in particular may have the right to priority in a dissolution or winding up of our company. If the Articles of Association contain no specific provisions in respect of a dissolution or winding up then, subject to the priorities or any creditors, the assets will be distributed to shareholders in proportion to the paid-up par value of the shares held. Our Articles of Association provide that the ‘A’ ordinary shareholders of our company are entitled to participate pro rata in a winding up, but their right to do so may be subject to the rights of any preferred shareholders to participate under the terms of any series or class of preferred shares.

Certificated Shares

Every person whose name is entered as a member in our register of members shall be entitled, without payment, to one certificate for all his shares of each class and, if he transfers part of his holding, to one certificate for the balance. Upon payment of such sum, not exceeding €0.32 for every certificate after the first, as the Directors shall from time to time determine, he shall also be entitled to several certificates, each for one or more of his shares.

If any certificates become worn out, defaced, destroyed or lost, they may be renewed on such evidence being produced as the board of directors shall require, and, in case of wearing out or defacement, on delivery up of the old certificate and, in case of destruction or loss, on execution of such indemnity (if any) as the board of directors may from time to time require. In case of destruction or loss, the members to whom such renewed certificate is given shall also bear and pay to us all expenses incidental to the investigation by us of the evidence of such destruction or loss to such indemnity.

No Sinking Fund

Our ‘A’ Ordinary Shares have no sinking fund provisions.

No Liability for Further Calls or Assessments

Our ‘A’ Ordinary Shares are not liable to further calls and assessments beyond any consideration required in connection with their initial issuance or vesting.

Transfer and Registration of ‘A’ Ordinary Shares

Our ‘A’ Ordinary Share register is maintained by Computershare and registration in the share register for our ‘A’ Ordinary Shares is determinative of membership in us. Any of our shareholders who hold ADSs will not be the holder of record of the underlying ‘A’ Ordinary Shares.

Our depositary, the Bank of New York, is the holder of record of the ‘A’ Ordinary Shares underlying our ADSs. Accordingly, a transfer of ADSs from a person who holds ADSs to a person who will also hold such ADSs will not be registered in our official share register.

A written instrument of transfer will be required under Irish law in order to register on our official share register any transfer of ‘A’ Ordinary Shares from a person who holds such shares directly to any other person. Our Articles grant our board of directors general discretion, without giving a reason, to decline to register any transfer of ‘A’ Ordinary Shares that is not fully paid. Furthermore, our Articles of Association allow our company to delegate any person the authority to execute an instrument of transfer on behalf of a transferring party.

DESCRIPTION OF WARRANTS

We may issue warrants to purchase ‘A’ Ordinary Shares and/or debt securities in one or more series together with other securities or separately, as described in the applicable prospectus supplement. Below is a description of certain general terms and provisions of the warrants that we may offer. Particular terms of the warrants will be described in the warrant agreements and the prospectus supplement for the warrants.

The applicable prospectus supplement will contain, where applicable, the following terms of and other information relating to the warrants:

- the specific designation and aggregate number of, and the price at which we will issue, the warrants;
- the currency or currency units in which the offering price, if any, and the exercise price are payable;
- the designation, amount, and terms of the securities purchasable upon exercise of the warrants;
- if applicable, the exercise price for ‘A’ Ordinary Shares and the number of ‘A’ Ordinary Shares to be received upon exercise of the warrants;
- if applicable, the exercise price for our debt securities, the amount of debt securities to be received upon exercise, and a description of that series of debt securities;
- the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;
- whether the warrants will be issued in fully registered form or bearer form, in definitive or global form, or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security included in that unit;
- any applicable material U.S. federal income tax consequences;

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the identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars, or other agents;

- the proposed listing, if any, of the warrants or any securities purchasable upon exercise of the warrants on any securities exchange;

- if applicable, the date from and after which the warrants and the 'A' Ordinary Shares and/or debt securities will be separately transferable;

- if applicable, the minimum or maximum amount of the warrants that may be exercised at any other time;
- information with respect to book-entry procedures, if any;
- the anti-dilution provisions of the warrants, if any;
- any redemption or call provisions;
- whether the warrants are to be sold separately or with other securities as parts of units; and
- any additional terms of the warrants, including terms, procedures, and limitations relating to the exchange and exercise of the warrants.

DESCRIPTION OF DEBT SECURITIES

We may issue debt securities together with other securities or separately, as described in the applicable prospectus supplement, under an indenture to be entered into between us and the trustee identified in the applicable prospectus supplement. The terms of the debt securities will include those stated in the indenture and those made part of the indenture by reference to the Trust Indenture Act of 1939, as in effect on the date of the indenture. The indenture will be subject to and governed by the terms of the Trust Indenture Act of 1939.

We may issue the debt securities in one or more series with the same or various maturities, at par, at a premium, or at a discount. We will describe the particular terms of each series of debt securities in a prospectus supplement relating to that series, which we will file with the SEC.

The prospectus supplement will set forth, to the extent required, the following terms of the debt securities in respect of which the prospectus supplement is delivered:

- the title of the series;
- the aggregate principal amount;
- the issue price or prices, expressed as a percentage of the aggregate principal amount of the debt securities;
- any limit on the aggregate principal amount;
- the date or dates on which principal is payable;
- the interest rate or rates (which may be fixed or variable) or, if applicable, the method used to determine such rate or rates;
- the date or dates from which interest, if any, will be payable and any regular record date for the interest payable;
- the place or places where principal and, if applicable, premium and interest, is payable;
- the terms and conditions upon which we may, or the holders may require us to, redeem or repurchase the debt securities;
- the denominations in which such debt securities may be issuable, if other than denomination of $1,000, or any integral multiple of that number;

· whether the debt securities are to be issuable in the form of certificated debt securities or global debt securities;

- the portion of principal amount that will be payable upon declaration of acceleration of the maturity date if other than the principal amount of the debt securities;

- the currency of denomination;

- the designation of the currency, currencies or currency units in which payment of principal and, if applicable, premium and interest, will be made;

- if payments of principal and, if applicable, premium or interest, on the debt securities are to be made in one or more currencies or currency units other than the currency of denominations, the manner in which exchange rate with respect to such payments will be determined;

- if amounts of principal and, if applicable, premium and interest may be determined by reference to an index based on a currency or currencies, or by reference to a commodity, commodity index, stock exchange index, or financial index, then the manner in which such amounts will be determined;

- the provisions, if any, relating to any collateral provided for such debt securities;

- any events of default;

- the terms and conditions, if any, for conversion into or exchange for 'A' Ordinary Shares;

- any depositaries, interest rate calculation agents, exchange rate calculation agents, or other agents; and

- the terms and conditions, if any, upon which the debt securities shall be subordinated in right of payment to other indebtedness of our company.

One or more debt securities may be sold at a substantial discount below their stated principal amount. We may also issue debt securities in bearer form, with or without coupons. If we issue discount debt securities or debt securities in bearer form, we will describe material U.S. federal income tax considerations and other material special considerations which apply to these debt securities in the applicable prospectus supplement.

We may issue debt securities denominated in or payable in a foreign currency or currencies or a foreign currency unit or units. If we do, we will describe the restrictions, elections, and general tax considerations relating to the debt securities and the foreign currency or currencies or foreign currency unit or units in the applicable prospectus supplement.

The debt securities of a series may be issued in whole or in part in the form of one or more global securities that will be deposited with, or on behalf of, a depositary identified in the prospectus supplement. Global securities will be issued in registered form and in either temporary or definitive form. Unless and until it is exchanged in whole or in part for individual debt securities, a global security may not be transferred except as a whole by the depositary for such global security to a nominee of such depositary or by a nominee of such depositary to such depositary or another nominee of such depositary or by such depositary or any such nominee to a successor of such depositary or a nominee of such successor. The specific terms of the depositary arrangement with respect to any debt securities of a series and the rights of and limitations upon owners of beneficial interests in a global security will be described in the applicable prospectus supplement.

DESCRIPTION OF SUBSCRIPTION RIGHTS

We may issue subscription rights to purchase our ‘A’ Ordinary Shares. These subscription rights may be issued independently or together with any other security offered hereby and may or may not be transferable by the shareholder receiving the subscription rights in such offering. In connection with any offering of subscription rights, we may enter into a standby arrangement with one or more underwriters or other purchasers pursuant to which the underwriters or other purchasers may be required to purchase any securities remaining unsubscribed for after such offering.

The prospectus supplement relating to any subscription rights we offer, if any, will, to the extent applicable, include specific terms relating to the offering, including some or all of the following:

- the price, if any, for the subscription rights;
- the exercise price payable for each ordinary share upon the exercise of the subscription rights;
- the number of subscription rights to be issued to each shareholder;
- the number and terms of the shares 'A' Ordinary Shares which may be purchased per each subscription right;
- the extent to which the subscription rights are transferable;
- any other terms of the subscription rights, including the terms, procedures and limitations relating to the exchange and exercise of the subscription rights;
- the date on which the right to exercise the subscription rights shall commence, and the date on which the subscription rights shall expire;
- the extent to which the subscription rights may include an over-subscription privilege with respect to unsubscribed securities; and
- if applicable, the material terms of any standby underwriting or purchase arrangement which may be entered into by us in connection with the offering of subscription rights.

The description in the applicable prospectus supplement of any subscription rights we offer will not necessarily be complete and will be qualified in its entirety by reference to the applicable subscription right agreement, which will be filed with the Commission if we offer subscription rights. For more information on how you can obtain copies of the applicable subscription right agreement if we offer subscription rights, see the sections entitled "Where You Can Find More Information" and "Incorporation of Information by Reference". We urge you to read the applicable subscription right agreement and any applicable prospectus supplement in their entirety.

DESCRIPTION OF UNITS

We may, from time to time, issue units comprised of one or more of the other securities that may be offered under this prospectus, in any combination.

Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately at any time, or at any time before a specified date.

Any applicable prospectus supplement will describe:

- the material terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any material provisions relating to the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- any material provisions of the governing unit agreement that differ from those described above.

The description in the applicable prospectus supplement of any units we offer will not necessarily be complete and will be qualified in its entirety by reference to the applicable unit agreement, which will be filed with the Commission if we offer units. For more information on how you can obtain copies of the applicable unit agreement if we offer warrants, see the sections entitled “Where You Can Find More Information” and “Incorporation of Information by Reference”. We urge you to read the applicable unit agreement and any applicable prospectus supplement in their entirety.

AUTHORIZED REPRESENTATIVE

Our authorized representative in the United States for this offering as required pursuant to Section 6(a) of the Securities Act of 1933, is Denis Burger, a director of our company.

OFFERING EXPENSES

The following is a statement of expenses in connection with the distribution of the securities registered. All amounts shown are estimates except the Commission registration fee. The estimates do not include expenses related to offerings of particular securities. Each prospectus supplement describing an offering of securities will reflect the estimated expenses related to the offering of securities under that prospectus supplement.

Securities and Exchange Commission registration fee	$23,240
Legal fees and expenses	$25,000
Accountants' fees and expenses	$9,000
Printing fees	$3,000
Miscellaneous	-
Total	$60,240

*Reflects the registration fee attributable to the $200 million of securities registered on this registration statement.

LEGAL MATTERS

Carter Ledyard & Milburn LLP, New York, New York, will be passing upon matters of United States law for us with respect to securities offered by this prospectus and any accompanying prospectus supplement. The validity of the securities offered hereunder was passed upon for us by William Fry, Dublin, Ireland on April 22, 2015.

EXPERTS

The consolidated financial statements and management's assessment of the effectiveness of internal control over financial reporting incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the reports of Grant Thornton, independent registered public accountants, upon the authority of such firm as experts in accounting and auditing.

MATERIAL CHANGES

Except as otherwise described in our Annual Report on Form 20-F for the fiscal year ended December 31, 2016 and in our Reports on Form 6-K filed or submitted under the Exchange Act and incorporated by reference herein, no reportable material changes have occurred since December 31, 2016.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is a part of a registration statement on Form F-3 that we filed on April 22, 2015 and a Form F-3/A filed on April 26, 2017, with the Commission under the Securities Act of 1933. We refer you to this registration statement, for further information about us and the securities offered hereby.

We file annual and special reports and other information with the Securities and Exchange Commission (Commission File Number 000-22320). These filings contain important information that does not appear in this prospectus. For further information about us, you may read and copy these filings at the Commission's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549-0102. You may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330, and may obtain copies of our filings from the public

reference room by calling (202) 551-8090. Our Securities and Exchange Commission filings are also available on the Commission's Internet site at http://www.sec.gov, which contains periodic reports and other information regarding issuers that file electronically.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

We file annual and special reports and other information with the Commission (File Number 000-22320). These filings contain important information which does not appear in this prospectus. The Commission allows us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to other documents which we have filed or will file with the Commission. We are incorporating by reference in this prospectus the documents listed below and all amendments or supplements we may file to such documents, as well as any future filings we may make with the Commission on Form 20-F under the Exchange Act before the time that all of the securities offered by this prospectus have been sold or de-registered.

- Our Annual Report on Form 20-F for the fiscal year ended December 31, 2016, filed with the Commission on April 24, 2017.

In addition, we may incorporate by reference into this prospectus our reports on Form 6-K filed after the date of this prospectus (and before the time that all of the securities offered by this prospectus have been sold or de-registered) if we identify in the report that it is being incorporated by reference in this prospectus.

Certain statements in and portions of this prospectus update and replace information in the above listed documents incorporated by reference. Likewise, statements in or portions of a future document incorporated by reference in this prospectus may update and replace statements in and portions of this prospectus or the above listed documents.

We will provide you without charge, upon your written or oral request, a copy of any of the documents incorporated by reference in this prospectus, other than exhibits to such documents which are not specifically incorporated by reference into such documents. Please direct your written or telephone requests to Trinity Biotech Plc, IDA Business Park, Bray, Co Wicklow, Ireland., Attn: Corporate Secretary, telephone number +(353) 1 276 9800. You may also obtain information about us by visiting our website at www.trinitybiotech.com. Information contained in our website is not part of this prospectus.

We are an Irish company and are a "foreign private issuer" as defined in Rule 3b-4 under the Securities Exchange Act of 1934, or Exchange Act. As a result, (i) our proxy solicitations are not subject to the disclosure and procedural requirements of Regulation 14A under the Exchange Act, (ii) transactions in our equity securities by our officers, directors and principal shareholders are exempt from Section 16 of the Exchange Act; and (iii) we are not required under the Exchange Act to file periodic reports and financial statements as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

ENFORCEABILITY OF CIVIL LIABILITIES

Service of process upon us and upon our directors and officers and the Irish experts named in this prospectus, most of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because substantially all of our assets and substantially all of our directors and officers are located outside the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States.

We have been advised by counsel that the United States currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

A judgment of the U.S. courts will be enforced by the Irish courts if the following general requirements are met: (i) the procedural rules of the U.S. court must have been observed and the U.S. court must have had jurisdiction in relation to the particular defendant according to Irish conflict of law rules (the submission to jurisdiction by the

defendant would satisfy this rule); and (ii) the judgment must be final and conclusive and the decree must be final and unalterable in the court which pronounces it. A judgment can be final and conclusive even if it is subject to appeal or even if an appeal is pending. Where however, the effect of lodging an appeal under the applicable law is to stay execution of the judgment, it is possible that, in the meantime, the judgment should not be actionable in Ireland. It remains to be determined whether final judgment given in default of appearance is final and conclusive. However, the Irish courts may refuse to enforce a judgment of the U.S. courts which meets the above requirements for one of the following reasons: (a) if the judgment is not for a debt or a definite sum of money; (b) if the judgment was obtained or alleged to have been obtained by fraud; (c) if the process and decision of the U.S. Courts were contrary to natural or constitutional justice under the laws of Ireland and if the enforcement of the judgment in Ireland would be contrary to natural or constitutional justice; (d) if the judgment is contrary to Irish public policy or involves certain United States laws which will not be enforced in Ireland or constitute the enforcement of a judgment of a penal or taxation nature; (e) if jurisdiction cannot be obtained by the Irish courts over the judgment debtors in the enforcement proceedings by personal service in Ireland or outside Ireland under Order 11 of the Irish Superior Courts Rules; (f) there is no practical benefit to the party in whose favor the foreign judgment is made in seeking to have that judgment enforced in Ireland, or (g) if the judgment is not consistent with a judgment of an Irish court in respect of the same matter.

TRINITY BIOTECH PLC

‘A’ Ordinary Shares
Warrants
Debt Securities
Subscription Rights
Units

_____

PROSPECTUS

_____

You should rely only on the information incorporated by reference or provided in this prospectus and in any accompanying prospectus supplement. We have not authorized anyone to provide you with different information. We are not making any offer to sell or buy any of the securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date that appears below.

, 2017

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 15. Exemption, Indemnification and Insurance of Directors and Officers.

Trinity Biotech's Articles of Association provide that every Director, Managing Director, agent secretary or other officer of Trinity Biotech shall be entitled to be indemnified out of the assets of Trinity Biotech against all losses or liabilities which he may sustain or incur in or about the execution of the duties of his office or otherwise in relation thereto, including any liability incurred by him in defending any proceeding, whether civil or criminal, in which judgment is given in his favor or in which he is acquitted, and no Director or other officer shall be liable for any loss, damage or misfortune which may happen to or be incurred by Trinity Biotech in the execution of the duties of his office or in relation thereto.

Item 16. Exhibits.

The index to exhibits appears below on the page immediately following the signature pages of this Registration Statement.

Item 17. Undertakings.

(1) The undersigned registrant hereby undertakes:

(a) to file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933 (the "Securities Act");

(ii) to reflect in the prospectus any facts or events arising after the effective date of this Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the ''Calculation of Registration Fee'' table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in this Registration Statement; provided, however, that paragraphs (i), (ii) and (iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") that are incorporated by reference in this Registration Statement or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the Registration Statement.

(b) that, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(d) that, for the purpose of determining any liability under the Securities Act to any purchaser:

(i) each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be a part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which the prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(e) that, for the purpose of determining liability of a registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) any preliminary prospectus or prospectus of the undersigned registrant to the offering required to be filed pursuant to Rule 424;

(ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by an undersigned registrant;

(iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(2) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan’s annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this Registration Statement shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions referred to in Item 15, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a

director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(4) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(5) The undersigned registrant hereby undertakes that, for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(6) The undersigned registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of section 310 of the Trust Indenture Act ("Act") in accordance with the rules and regulations prescribed by the Commission under section 305(b)2 of the Act.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant certifies that it has reasonable grounds to believe that it complies with all of the requirements for filing on Form F-3/A and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Dublin, Ireland, on April 26, 2017.

TRINITY BIOTECH PLC

By: /s/ Ronan O'Caoimh
Ronan O'Caoimh
Chairman and Chief Executive Officer

Pursuant to the requirements of the Securities Act, this registration statement has been signed below by the following persons in the capacities indicated on April 26, 2017.

Signature	Title
/s/ Ronan O'Caoimh Ronan O'Caoimh	Chairman, Chief Executive Officer and Director (Principal Executive Officer)
* Jim Walsh	Chief Scientific Officer and Director
/s/ Kevin Tansley Kevin Tansley	Chief Financial Officer, Company Secretary, and Director
* Denis Burger	Non-executive Director (Authorized U.S. Representative)
* Peter Coyne	Non-executive Director
* Clint Severson	Non-executive Director
* James D. Merselis	Non-executive Director

*: /s/ Kevin Tansley
Attorney-in-fact

Exhibit No.	Description of Exhibit
4.1	Memorandum and Articles of Association of Trinity Biotech plc. *
4.2	Form of Deposit Agreement dated as of October 21, 1992, as amended and restated, among Trinity Biotech plc, The Bank of New York as Depositary, and all Owners and holders from time to time of American Depositary Receipts issued thereunder. [2]
4.3	Indenture, dated April 9, 2015, among Trinity Biotech Investment Limited, Trinity Biotech plc and Wilmington Trust, National Association, as trustee. [3]
4.4	Indenture relating to the issuances of debentures, notes, bonds or other evidences of indebtedness *
4.5	Form of Warrant or Warrant Certificate [4]
4.6	Form of Unit [4]
5.1	Opinion of William Fry *
5.2	Opinion of Carter Ledyard & Milburn LLP*
23.1	Consent of Grant Thornton
23.2	Consent of William Fry (contained in Exhibit 5.1) *
23.2	Consent of Carter Ledyard & Milburn LLP (contained in Exhibit 5.2) *
24.1	Power of Attorney (included in the signature page to the Registration Statement) *

(*) Previously Filed on Form F-3 (File No. 333-203555)

(1) Incorporated by reference to Exhibit 1 to our Annual Report on Form 20-F (File No. 000-22320), filed with the SEC on March 31, 2006.

(2) Incorporated by reference to Exhibit 1 to our Form F-6 (File No. 333-111946), filed with the Commission on January 15, 2004)

(3) Incorporated by reference to Exhibit 99.2 to our Form 6-K (File No. 000-22320), filed with the Commission on April 9, 2015)

(4) Incorporated by reference, if necessary, to a corresponding exhibit to a Current Report on Form 6-K in connection with an offering of securities.