

TRINITY BIOTECH PLC
Form 20-F
April 05, 2013
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SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 20-F

.. REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
OR

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2012

OR

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

.. SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Date of event requiring this shell company report

Commission file number: 0-22320

Trinity Biotech plc

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(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)

Ireland

(Jurisdiction of incorporation or organization)

IDA Business Park, Bray, Co. Wicklow, Ireland

(Address of principal executive offices)

Kevin Tansley

Chief Financial Officer

Tel: +353 1276 9800

Fax: +353 1276 9888

IDA Business Park, Bray, Co. Wicklow, Ireland

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
None	None

Securities registered or to be registered pursuant to Section 12(g) of the Act:

American Depositary Shares (each representing 4 A Ordinary Shares, par value US\$0.0109)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

88,994,069 Class A Ordinary Shares

(as of December 31, 2012)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued

Other

by the International Accounting Standards Board

If Other has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow: Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes No

This Annual Report on Form 20-F is incorporated by reference into our Registration Statements on Form S-8 File No. 33-76384, 333-220, 333-5532, 333-7762, 333-124384 and 333-166590.

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General

As used herein, references to we, us, Trinity Biotech or the Group in this form 20-F shall mean Trinity Biotech plc and its world-wide subsidiaries, collectively. References to the Company in this annual report shall mean Trinity Biotech plc.

Our financial statements are presented in US Dollars and are prepared in accordance with International Financial Reporting Standards (IFRS) both as issued by the International Accounting Standards Board (IASB) and as adopted by the European Union (EU). The IFRS applied are those effective for accounting periods beginning on or after 1 January 2012. Consolidated financial statements are required by Irish law to comply with IFRS as adopted by the EU which differ in certain respects from IFRS as issued by the IASB. These differences predominantly relate to the timing of adoption of new standards by the EU. However, as none of the differences are relevant in the context of Trinity Biotech, the consolidated financial statements for the periods presented comply with IFRS both as issued by the IASB and as adopted by the EU. All references in this annual report to Dollars and \$ are to US Dollars, and all references to Euro or are to European Union Euro. Except as otherwise stated herein, all monetary amounts in this annual report have been presented in US Dollars. For presentation purposes all financial information, including comparative figures from prior periods, have been stated in round thousands.

Forward-Looking Statements

This Annual Report on Form 20-F contains 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 versions 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 risk factors in Item 3 for a more comprehensive outline of these risks and the threats which they pose to the Company and its results.

Item 1 Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2 Offer Statistics and Expected Timetable

Not applicable.

Item 3 Selected Consolidated Financial Data

The following selected consolidated financial data of Trinity Biotech as at December 31, 2012 and 2011 and for each of the years ended December 31, 2012, 2011 and 2010 have been derived from, and should be read in conjunction with, the audited consolidated financial statements and notes thereto set forth in Item 18 of this annual report. The selected consolidated financial data as at December 31, 2010, 2009 and 2008 and for the years ended December 31, 2009 and December 31, 2008 are derived from the audited consolidated financial statements not appearing in this Annual Report. This data should be read in conjunction with the financial statements, related notes and other financial information included elsewhere herein.

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	<i>Year ended December, 31</i>				
	2012	2011	2010	2009	2008
	<i>Total</i>	<i>Total</i>	<i>Total</i>	<i>Total</i>	<i>Total</i>
	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>	<i>US\$ 000</i>
Revenues	82,510	77,948	89,635	125,907	140,139
Cost of sales	(40,257)	(37,820)	(45,690)	(68,891)	(77,645)
Gross profit	42,253	40,128	43,945	57,016	62,494
Other operating income	468	910	1,616	437	1,173
Research and development expenses	(3,130)	(3,206)	(4,603)	(7,341)	(7,544)
Total research and development expenses	(3,130)	(3,206)	(4,603)	(7,341)	(7,544)
Selling, general and administrative expenses	(22,425)	(22,048)	(26,929)	(36,013)	(47,816)
Selling, general and administrative impairment charges and restructuring expenses					(87,882)
Total selling, general and administrative expenses	(22,425)	(22,048)	(26,929)	(36,013)	(135,698)
Net gain on divestment of business and restructuring expenses			46,474		
Operating profit/(loss)	17,166	15,784	60,503	14,099	(79,575)
Financial income	2,280	2,428	1,352	8	65
Financial expenses	(88)	(12)	(495)	(1,192)	(2,160)
Net financing income/(costs)	2,192	2,416	857	(1,184)	(2,095)
Profit/(loss) before tax	19,358	18,200	61,360	12,915	(81,670)
Income tax (expense)/ credit	(2,017)	(2,607)	(942)	(1,091)	3,892
Profit/(loss) for the year (all attributable to owners of the parent)	17,341	15,593	60,418	11,824	(77,778)
Basic earnings/(loss) per ADS (US Dollars)	0.81	0.73	2.85	0.57	(3.82)
Diluted earnings/(loss) per ADS (US Dollars)	0.77	0.70	2.79	0.57	(3.82)
Basic earnings/(loss) per A ordinary share (US Dollars)	0.20	0.18	0.71	0.14	(0.96)
Diluted earnings/(loss) per A ordinary share (US Dollars)	0.19	0.18	0.70	0.14	(0.96)
Weighted average number of shares used in computing basic EPS per A ordinary share	85,675,284	85,171,494	84,734,378	83,737,884	81,394,075
Weighted average number of shares used in computing diluted EPS per A ordinary share	89,773,616	88,912,596	86,661,535	83,772,094	81,394,075

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	December 31, 2012	December 31, 2011	December 31, 2010	December 31, 2009	December 31, 2008
	US\$ 000	US\$ 000	US\$ 000	US\$ 000	US\$ 000
Net current assets (current assets less current liabilities)	97,531	101,684	89,068	42,835	39,494
Non-current liabilities	(15,061)	(6,838)	(7,331)	(27,500)	(27,897)
Total assets	197,407	171,499	160,874	132,445	129,509
Capital stock	1,134	1,106	1,092	1,080	1,070
Shareholders' equity	169,380	151,332	141,287	79,344	65,905

No dividends were declared in either of the periods ended December 31, 2008 or December 31, 2009. A final dividend of 15 cents per ADS was paid in 2012 in respect of the financial year 2011 (10 cents per ADS paid in 2011 in respect of the financial year 2010). The dividend payable in respect of the 2012 financial year will be proposed by the Directors prior to the next AGM, to be held in May 2013.

Risk Factors

You should carefully consider all of the information set forth in this Form 20-F, including the following risk factors, when investing in our securities. The risks described below are not the only ones that we face. Additional risks not currently known to us or that we presently deem immaterial may also impair our business operations. We could be materially adversely affected by any of these risks.

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. We are committed to significant expenditure on R&D. However, there is no certainty that this investment in research and development will yield technically feasible or commercially viable products. Development of new diagnostic tests is subject to very stringent regulatory control and very significant costs in research, development and marketing. Failure to introduce new products could significantly slow our growth and adversely affect our market share.

Technological advances in the industry could render our products obsolete.

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), Alere Inc. (Determine , Wampole , Athena), Arkray (HA-8180), Bio-Rad (ELISA, WB, 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, Enzygno®), Siemens Bayer (Centaur), Siemens DPC (Immulite), Thermo Fisher (Konelab) and Tosoh (G8).

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

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.

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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. 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. If found to infringe, we may attempt to obtain a license to such intellectual property; however, we may be unable to do so on favorable terms, or at all. Additionally, if our products are found to infringe on third-party intellectual property, we may be required to pay damages for past infringement and lose the ability to sell certain products, causing our revenues to decrease. Any substantial loss resulting from such a claim could 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.

Our business is heavily regulated and non-compliance with applicable regulations could reduce revenues and profitability.

Our manufacturing and marketing of diagnostic test kits are subject to government regulation in the United States of America by the Food and Drug Administration (FDA), and by comparable regulatory authorities in other jurisdictions. The approval process for our products, while variable across countries, is generally lengthy, time consuming, detailed and expensive. Our continued success is dependent on our ability to develop and market new products, some of which are currently awaiting approval from these regulatory authorities. There is no certainty that such approval will be granted or, even once granted, will not be revoked during the continuing review and monitoring process.

We are required to comply with extensive post market regulatory requirements. Non-compliance with applicable regulatory requirements of the FDA or comparable foreign regulatory bodies can result in enforcement action which may include recalling products, ceasing product marketing, paying significant fines and penalties, and similar actions that could limit product sales, delay product shipment, and adversely affect profitability.

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. Changes in the healthcare industry delivery system have resulted in major consolidation among reference laboratories and in 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.

Future acquisitions may be less successful than expected, 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. There can be no guarantees that recent or future acquisitions can be successfully assimilated or that projected growth in revenues or synergies in operating costs can be achieved. Our ability to integrate future acquisitions may also be adversely affected by inexperience in dealing with new technologies, and changes in regulatory or competitive environments. Additionally, even during a successful integration, the investment of management's time and resources in the new enterprise may be detrimental to the consolidation and growth of our existing business.

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

Trinity Biotech currently distributes its product portfolio through di