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# Trinity Biotech Announces Quarter 3 Financial Results, Acquisition of Blood Bank Screening Business and FDA Approval of HIV-2 Claim

**DUBLIN, Ireland (October 17, 2013)….** Trinity Biotech plc (Nasdaq: TRIB), a leading developer and manufacturer of diagnostic products for the point-of-care and clinical laboratory markets, today announced results for the quarter ended September 30, 2013, the acquisition of the blood bank screening business of Lab 21 and FDA approval for a claim for HIV-2 on its Unigold rapid HIV product.

## Quarter 3 Results

Total revenues for Q3, 2013 were $24.1m which compares to $20.9m in Q3, 2012, an increase of 15.7%. However, this includes $1.8m of acquisition revenues. Excluding this impact, revenue growth for the quarter was 7%.

Point-of-Care revenues for Q3, 2013 increased by 11.9% when compared to Q3, 2012. This increase was mainly attributable to continued strong demand for HIV products in Africa.

Clinical Laboratory revenues increased from $16.1m to $18.8m, which represents an increase of 16.8% compared to Q3, 2012. Again excluding acquisition revenue, the increase during the quarter was approximately 6%. This growth was primarily driven by the continuing high level of Premier placements, 81 this quarter versus 54 in the equivalent quarter last year.

Revenues for Q3, 2013 were as follows:

| | **2012 Quarter 3** | **2013 Quarter 3** | **Increase** |
|---|---|---|---|
| | **US$'000** | **US$'000** | **%** |
| Point-of-Care | 4,751 | 5,315 | 11.9% |
| Clinical Laboratory | 16,100 | 18,806 | 16.8% |
| ***Total*** | ***20,851*** | ***24,121*** | ***15.7%*** |

Gross profit for Q3, 2013 amounted to $12.1m representing a gross margin of 50.3%, which is lower than the 51% achieved in Q3, 2012. This decrease is mainly due to the impact of lower margins on the higher level of Premier instrument sales achieved during the quarter.

Research and Development expenses have increased from $0.8m to $0.9m when compared to the equivalent quarter last year, whilst Selling, General and Administrative (SG&A) expenses have increased from $5.1m to $5.9m over the same period. In both cases this increase is due to the impact of the Immco acquisition.

Operating profit has increased from $4.3m to $4.9m for the quarter, an increase of 14%. Meanwhile operating margin for the quarter was 20.5%.

During the quarter the company recognised once off charges totalling $8.2m consisting of:

- a charge of $5.7m in relation to taking a HIV-2 licence, and
- a charge of $2.5m in relation to reorganisation, redundancy and acquisition costs associated with the blood bank business acquired from Lab 21.

Further information on each of these charges is given below.

Net financial income was approximately $0.2m and represents a decrease compared to $0.6m in Q3, 2012. This is due to lower prevailing deposit interest rates and a decrease in the level of funds on deposit, mainly due to the recent acquisition expenditure and dividend payment.

The tax charge for Q3, 2013 was $0.5m which represents an effective tax rate of 9.9% compared to 9.3% in Q3, 2012.

Profit After Tax before the Medical Device Excise Tax (MDET) and once off charges increased from $4.5m to $4.6m, an increase of 4%. EPS (excluding MDET and once off charges) for the quarter increased to 21.1 cents from 20.7 cents in Q3, 2012.

Earnings before interest, tax, depreciation, amortisation and share option expense for the quarter was $6.4m which compares to $5.6m in Q3, 2012.

**Blood Bank Screening Acquisition**

The Company is pleased to announce the acquisition of the blood bank business of UK based Lab 21 Ltd for $7.5m including acquisition costs. The acquired business generates annual revenues of approximately US$4m, of which US$3.5m is generated from syphilis products and the remainder from malaria products.

This business includes very high quality TPHA and ELISA products for blood bank screening. These products are best in class with an excellent balance between sensitivity and specificity and compete in a market which has limited competition. The syphilis products have a market share of over 75% of the syphilis blood bank markets in the UK, France, Germany, Netherlands, Switzerland, Austria and Belgium. Trinity plans to replicate the European success in other countries and more particularly in the USA, where it intends immediately submitting the products for FDA approval. We are confident of taking significant US market share with this excellent product offering through collaborative strategic partnerships.

The company's malaria test is now well positioned to avail of the increase in malaria blood bank testing in the developed world given the increased prevalence of malaria as a result of foreign travel.

Located in Cambridge and Newmarket in the United Kingdom, the business currently employs approximately 45 people between the two sites. Over the next 9 months, Trinity plans to transition the production activities of the business to its existing manufacturing facilities in Bray, Ireland and Jamestown, New York. This will result in significant operational synergies and efficiencies. A number of key employees, principally in sales and marketing, will be retained in the UK. The company is recognising a charge of $2.5m in the Q3 income statement mainly covering reorganisation and redundancy costs associated with the closure of the UK manufacturing operations.

Due to funding difficulties experienced by its former parent company, the business currently has very low inventory levels and a significant back order position. In the near term, Trinity will concentrate on increasing production and meeting customer demands as soon as possible. However, due to the lead times involved in acquiring raw materials and manufacturing finished product, revenues during Q4, 2013 are going to be limited with a return to normal sales levels being achieved in Q1, 2014.

**FDA Approval of Claim for HIV-2**

For the last two years, Trinity has put a major effort into obtaining a HIV-2 claim for its Uni-Gold™ Recombigen® HIV rapid product. This has included carrying out extensive comparative trials for incorporation into a detailed submission to the FDA. The Company is now delighted to announce FDA approval for this HIV-2 claim. The product has now been renamed Uni-Gold™ Recombigen® HIV 1 / 2. Previously, the product was approved for the detection of HIV-1 only, the predominant HIV strain in the USA. However, this had restricted the market size available to Trinity, as many public health bodies require a HIV-2 claim as a pre-qualifier for participation in their testing programs. Meanwhile, with regard to the hospital market, Trinity was at a competitive disadvantage due to the more favourable reimbursement rates paid in respect of HIV-1/2 testing versus HIV-1 only. Finally, the CDC has recently been informally recommending that testing is carried out for both HIV-1 and HIV-2, raising the possibility that in the near future, it will become a formal guideline that all rapid HIV tests detect both HIV-1 and HIV-2. Consequently, this approval for HIV-2 has safeguarded our existing sales of HIV in the USA, whilst at the same time expanding our US HIV sales potential, as Trinity can now participate in certain public health programs previously not open to us and compete more effectively in the hospital market. Over the past two years Trinity's HIV revenues have fallen by 5-6% p.a., due to lower federal and state funding for HIV testing. Management now believes that with HIV 1/2, it can reverse this decline and achieve double digit US HIV revenue growth in 2014.

As part of our strategy to commercialise the HIV-2 opportunity Trinity has negotiated a licence to a significant HIV-2 patent portfolio, which expires in 2021. In connection with this licence the Company is taking a once off charge in the third quarter for the license and associated legal costs in the amount of $5.7m. The licence fee will be paid in 5 equal annual installments commencing in Q4, 2013. The remaining terms of the licence agreement is subject to a confidentiality agreement.

**Other Recent Developments**

***Cardiac Update***

Our cardiac development programs continue to do well and are progressing according to plan. The new high sensitivity Troponin I test is nearing the conclusion of its CE marking trials and is exhibiting excellent results. These trials will be completed within the next number of weeks, and we confidently expect to announce CE marking of this product before year end. Meanwhile, planning for our FDA clinical trials continue to do well, with trials expected to commence at five US trial sites in early December. Our US trials will be conducted under the supervision of Dr. Fred Apple who has agreed to act as principle investigator for our Troponin clinical trials program.

We remain on target therefore for market launch of our point-of-care Troponin I test in Europe at the beginning of 2014 with the key US launch to follow approximately 12 months later, as soon as FDA approval has been obtained.

We are also making excellent progress on the development of our BNP test, which will run on the same platform. Initial clinical results indicate that our BNP product is exhibiting market leading performance characteristics with CE marking expected to take place in the first half of 2014 and FDA approval to follow in early 2015.

***Premier Sales***

Sales of our diabetes instrument, Premier, continue to perform strongly. During Q3, 81 instruments were sold which is similar to the number sold in Q 2, 2013 (80 instruments) and was in line with expectations. Third quarter sales tend to be impacted by the vacation period, particularly in continental Europe. On a cumulative basis sales of Premier instruments for the year to date are 228 which is 66% higher than the 137 instruments sold in the same period last year. Management remains confident of meeting its target of 320 instruments for the year as a whole.

***Immco Update***

Last quarter we announced the acquisition of Immco Diagnostics Inc., a company based in Buffalo, New York which specialises in autoimmune products. Even though it is less than 3 months since the company was acquired by Trinity, we are very pleased with the progress being made with its integration into the Trinity organisation. In particular, the integration of Immco's operations with Trinity's existing sales force in the USA is progressing very well and will begin to yield results in Q4, 2013. At the same time progress is also being made to integrate the respective international sales operations with a view to harnessing the many cross-selling opportunities which exist. Trinity remains excited about the growth drivers within the Immco business particularly with regard to its newly cleared Enhanced Cardiolipin Antibody ELISA product as well as the new tests for Sjögren's Syndome and Chronic Rhinosinusitus, both of which are being sold through Immco's reference laboratory.

During Q3, 2013 Immco contributed revenues of approximately $1.8m, and as had been indicated at the time of acquisition was neutral from an earnings perspective due to integration and acquisition related costs. Immco will be profitable and earnings enhancing from Q4, 2013 onwards.

**Comments**

Commenting on the results, Kevin Tansley, Chief Financial Officer, said

"Revenues this quarter increased by 15.7% to $24.1m. This was partly due to the impact of the Immco acquisition during the quarter but was also driven by higher HIV sales in Africa and the continued strong performance of Premier. We also performed well from a profitability perspective. Operating profits increased by 14% to $4.9m, representing an operating margin of over 20%. Meanwhile, EPS before MDET and once off charges increased from 20.7 cents to 21.1 cents. However, given that the fall in financial income, due to lower interest rates and funds on deposit, equated to approximately 2 cents per share, the underlying increase in EPS was over 2 cents per share or 13%."

Ronan O'Caoimh, CEO of Trinity said

"Over the past number of years Trinity has concentrated on growth, both in terms of our existing business and in developing new growth opportunities. This quarter we have achieved good revenue and underlying profitability growth. In this context, we are particularly pleased with the level of Premier sales which we have achieved so far this year. By the end of quarter 3, instrument sales for the year had reached 228 which represents a 66% increase over the same period last year.

In addition, we made good progress in developing and acquiring new growth opportunities for the company. Our new Troponin test is nearing the conclusion of its CE marking trials and is exhibiting excellent results. These trials will be completed within the next number of weeks, after which we expect to announce CE marking (i.e. regulatory approval in the EU). This will coincide with the commencement of our FDA trials at 5 trial sites in the USA. We remain on target for market launch of

the Troponin test in Europe at the start of 2014 with the key US launch to follow 12 months later, once FDA approval has been obtained. We are also making excellent progress on the development of our BNP test which will run on the same platform, with CE marking expected to take place in the first half of 2014 and FDA approval in early 2015.

Our recent acquisition of Immco Diagnostics also represents a significant growth prospect. With the combination of a best in class product range, a strongly growing market and excellent synergies with Trinity's infectious diseases business, we are expecting Immco to achieve revenue growth of 20% next year. To date the integration process has gone extremely well, in particular with regard to targeting the US market where Immco has virtually no presence.

This quarter we are pleased to announce two further growth opportunities. The acquisition of the Lab 21 blood bank business represents a perfect strategic fit for Trinity. Syphilis detection is an area in which we are already active and has long been identified as a key growth market for us. To date the Lab 21 business has concentrated on the European blood bank screening market, where through excellent product quality they have taken a dominant share in the larger markets such as the UK, France and Germany. Trinity will concentrate on leveraging this position to enter other markets whilst at the same time targeting the US market through strategic partner relationships. Although Trinity is in no way seeking acquisitions, the Lab 21 opportunity was compelling, given the price at which it was available, its significant growth history and prospects (particularly in the USA) and its excellent fit with Trinity's existing infectious diseases business.

We are also delighted to have obtained FDA approval for a claim for HIV-2 on our rapid HIV test, Uni-Gold. This is the culmination of over 24 months of hard work, including significant comparative trials and a detailed submission to the FDA. It will serve as a major boost to Uni-Gold sales in the USA. In fact, we believe it will reverse the recent decline in sales of this product, due to lower federal and state funding, and instead result in double digit percentage growth in 2014. As the product now has claims for both HIV-1 and HIV-2, it opens up the opportunity to participate in public health programs which require products to have claims for both strains and also enables us to compete more effectively in the hospital market, where higher reimbursements rates are available for tests able to detect both HIV-1 and HIV-2."

*Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties including, but not limited to, the results of research and development efforts, the effect of regulation by the United States Food and Drug Administration and other agencies, the impact of competitive products, product development commercialisation and technological difficulties, and other risks detailed in the Company's periodic reports filed with the Securities and Exchange Commission.*

Trinity Biotech develops, acquires, manufactures and markets diagnostic systems, including both reagents and instrumentation, for the point-of-care and clinical laboratory segments of the diagnostic market. The products are used to detect infectious diseases and to quantify the level of Haemoglobin A1c and other chemistry parameters in serum, plasma and whole blood. Trinity Biotech sells direct in the United States, Germany, France and the U.K. and through a network of international distributors and strategic partners in over 75 countries worldwide. For further information please see the Company's website: www.trinitybiotech.com.

## Trinity Biotech plc
## Consolidated Income Statements

| *(US$000's except share data)* | **Three Months Ended September 30, 2013 (unaudited)** | **Three Months Ended September 30, 2012 (unaudited)** | **Nine Months Ended September 30, 2013 (unaudited)** | **Nine Months Ended September 30, 2012 (unaudited)** |
|---|---|---|---|---|
| **Revenues** | **24,121** | **20,851** | **65,761** | **61,686** |
| Cost of sales | (11,988) | (10,213) | (32,669) | (29,967) |
| **Gross profit** | **12,133** | **10,638** | **33,092** | **31,719** |
| Gross profit % | *50.3%* | *51.0%* | *50.3%* | *51.4%* |
| Other operating income | 90 | 86 | 285 | 375 |
| Research & development expenses | (876) | (767) | (2,655) | (2,365) |
| Selling, general and administrative expenses | (5,885) | (5,147) | (16,420) | (15,591) |
| Indirect share based payments | (519) | (461) | (1,457) | (1,361) |
| **Operating profit** | **4,943** | **4,349** | **12,845** | **12,777** |
| Financial income | 226 | 597 | 1,169 | 1,748 |
| Financial expenses | (23) | (26) | (75) | (62) |
| **Net financing income** | 203 | 571 | 1,094 | 1,686 |
| **Profit before tax** | **5,146** | **4,920** | **13,939** | **14,463** |
| Income tax expense | (509) | (460) | (961) | (1,591) |
| **Profit for the period before MDET and once off charges** | **4,637** | **4,460** | **12,978** | **12,872** |
| Once off charges | (8,187) | - | (8,187) | - |
| Tax credit on once off charges | 716 | | 716 | |
| Medical device excise tax (MDET) | (155) | - | (500) | - |
| **Profit/(loss) for the period after MDET and once off charges** | **(2,989)** | **4,460** | **5,007** | **12,872** |
| Earnings per ADR (US cents) | (13.6) | 20.7 | 22.9 | 60.2 |
| Diluted earnings per ADR (US cents) | (12.8) | 19.8 | 21.8 | 57.5 |
| Earnings per ADR excluding MDET and once off charges (US cents) | 21.1 | 20.7 | 59.5 | 60.2 |
| Diluted earnings per ADR excluding MDET and once off charges (US cents) | 19.8 | 19.8 | 56.4 | 57.5 |
| Weighted average no. of ADRs used in computing basic earnings per ADR | 22,012,412 | 21,513,896 | 21,827,150 | 21,399,295 |
| Weighted average no. of ADRs used in computing diluted earnings per ADR | 23,369,678 | 22,488,295 | 23,007,085 | 22,382,750 |

*The above financial statements have been prepared in accordance with the principles of International Financial Reporting Standards and the Company's accounting policies but do not constitute an interim financial report as defined in IAS 34 (Interim Financial Reporting).*

# Trinity Biotech plc
## Consolidated Balance Sheets

| | September 30, 2013 US$ '000 (unaudited) | June 30, 2013 US$ '000 (unaudited) | March 31, 2013 US$ '000 (unaudited) | Dec 31, 2012 US$ '000 (audited) |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-current assets** | | | | |
| Property, plant and equipment | 12,090 | 10,189 | 9,331 | 8,883 |
| Goodwill and intangible assets | 126,324 | 80,489 | 76,748 | 73,046 |
| Deferred tax assets | 5,935 | 4,872 | 4,533 | 4,073 |
| Other assets | 1,011 | 1,065 | 945 | 908 |
| **Total non-current assets** | 145,360 | 96,615 | 91,557 | 86,910 |
| **Current assets** | | | | |
| Inventories | 27,387 | 22,923 | 23,110 | 20,757 |
| Trade and other receivables | 23,119 | 17,426 | 15,299 | 14,457 |
| Income tax receivable | 208 | 315 | 322 | 336 |
| Cash and cash equivalents | 26,806 | 66,164 | 73,095 | 74,947 |
| **Total current assets** | 77,520 | 106,828 | 111,826 | 110,497 |
| **TOTAL ASSETS** | 222,880 | 203,443 | 203,383 | 197,407 |
| **EQUITY AND LIABILITIES** | | | | |
| **Equity attributable to the equity holders of the parent** | | | | |
| Share capital | 1,169 | 1,158 | 1,143 | 1,134 |
| Share premium | 7,006 | 5,858 | 5,449 | 5,138 |
| Accumulated surplus | 163,039 | 163,338 | 163,886 | 158,973 |
| Other reserves | 3,916 | 4,463 | 4,128 | 4,135 |
| **Total equity** | 175,130 | 174,817 | 174,606 | 169,380 |
| **Current liabilities** | | | | |
| Income tax payable | 1,347 | 1,234 | 1,261 | 1,092 |
| Trade and other payables | 21,587 | 13,344 | 12,955 | 11,824 |
| Provisions | 50 | 50 | 50 | 50 |
| **Total current liabilities** | 22,984 | 14,628 | 14,266 | 12,966 |
| **Non-current liabilities** | | | | |
| Other payables | 5,959 | 2,325 | 3,344 | 4,318 |
| Deferred tax liabilities | 18,807 | 11,673 | 11,167 | 10,743 |
| **Total non-current liabilities** | 24,766 | 13,998 | 14,511 | 15,061 |
| **TOTAL LIABILITIES** | 47,750 | 28,626 | 28,777 | 28,027 |
| **TOTAL EQUITY AND LIABILITIES** | 222,880 | 203,443 | 203,383 | 197,407 |

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## Trinity Biotech plc
## Consolidated Statement of Cash Flows

| *(US$000's)* | **Three Months Ended September 30, 2013 (unaudited)** | **Three Months Ended September 30, 2012 (unaudited)** | **Nine Months Ended September 30, 2013 (unaudited)** | **Nine Months Ended September 30, 2012 (unaudited)** |
|---|---|---|---|---|
| **Cash and cash equivalents at beginning of period** | **66,164** | **73,605** | **74,947** | **71,085** |
| Operating cash flows before changes in working capital | 5,823 | 5,587 | 15,887 | 16,312 |
| Changes in working capital | (2,290) | (695) | (7,634) | (3,286) |
| Cash generated from operations | 3,533 | 4,892 | 8,253 | 13,026 |
| Net Interest and Income taxes received/(paid) | (125) | 554 | 673 | 1,055 |
| Capital Expenditure & Financing (net) | (4,641) | (3,527) | (14,569) | (8,684) |
| Free cash flow | (1,233) | 1,919 | (5,643) | 5,397 |
| Proceeds from sale of Coagulation product line | - | - | - | 11,250 |
| Cash paid to acquire Fiomi Diagnostics and Phoenix Biotech | - | - | - | (5,957) |
| Cash paid to acquire Immco and Blood Bank Screening Business | (39,217) | | (39,217) | |
| Net cash acquired on acquisition | 1,092 | | 1,092 | |
| Dividend payment | - | - | (4,373) | (3,223) |
| Repurchase of own company shares | - | (1,069) | - | (4,097) |
| **Cash and cash equivalents at end of period** | **26,806** | **74,455** | **26,806** | **74,455** |

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