Trinity Biotech Announces withdrawal of Troponin FDA 510(k) Submission

DUBLIN, Ireland, Oct. 04, 2016 — Trinity Biotech plc (Nasdaq:TRIB), a leading developer and manufacturer of diagnostic products for the point-of-care and clinical laboratory markets, announced today that it is withdrawing its 510(k) premarket notification submission for the Meritas Troponin-I Test and Meritas Point-of-Care Analyzer.

The company held a meeting with the FDA on Thursday 29 September, in order to obtain an update on the company's Meritas Troponin submission. At this meeting the FDA asked Trinity to consider withdrawing their submission, due to some concerns they have about the submission. Their primary concerns relate to the device's operating temperature range and that the Troponin-I clinical performance is not consistent with the clinical performance data presented by the most recently cleared laboratory Troponin device.

Whilst we believe that the Meritas product demonstrates excellent performance for a point-of-care product and is superior to all existing point-of-care Troponin products in the market, we decided yesterday to withdraw the submission. Over the coming weeks we will engage with the FDA to gain a better understanding of the nature of their concerns. However, it is our understanding that in order for any new point-of-care Troponin product to obtain clearance, the FDA will require it to demonstrate performance equivalent to the most recently cleared laboratory based device. Our decision to withdraw is based on the fact that, notwithstanding its excellent performance characteristics, we believe that there is no certainty that this level of performance can be achieved by the Meritas product even with the benefit of further development efforts.

We will now embark upon an internal process to determine the best future opportunity for this technically excellent platform, concentrating on which products and markets we should focus on, including establishing the optimal strategic outcome for Troponin. This process is expected to take between 9 and 12 months. In the meantime we have decided to move the technology from our Swedish facility in Uppsala to our facility in Bray, Ireland where it will be incorporated into our existing R&D and manufacturing infrastructure. This will result in the closure of the Uppsala facility, which will result in approximately 40 redundancies.

Consequently expenditure levels, which are currently running at an annualised rate of over $9m, will be reduced to approximately $1.5m per annum. There will however, be Swedish redundancy and closure costs which are currently in the process of being determined. The company will also recognise a non-cash write-off in excess of $50m, representing the costs incurred on the project, which will be recognised in our Q4 income statement.

Conference Call announcement

The Company has scheduled a conference call for today, Tuesday, October 4, 2016 at

11:00am ET (4:00pm BST) to discuss the matter further.

Interested parties can access the call by dialing:

USA:	1-844-861-5499
International:	1-412-317-6581
Conference ID #:	10094060

A simultaneous webcast of the call can be accessed at: https://www.webcaster4.com/Webcast/Page/1135/17597

A replay of the call can be accessed until October 11, 2016 by dialing:

USA:	1-877-344-7529
International:	1-412-317-0088
Conference ID #:	10094060

The webcast of the call will be available for 30 days at:
https://www.webcaster4.com/Webcast/Page/1135/17597

Forward-looking statements in this release are made pursuant to the "safe harbor" provision of the Private Securities 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.

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