

Press Release dated May 27, 2020

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# Trinity Biotech Announces Results for Q1, 2020

**DUBLIN, Ireland (May 27, 2020)...** 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 March 31, 2020.

### Quarter 1 Results

Total revenues for Q1, 2020 were \$21.2m which compares to \$22.0m in Q1, 2019, a decrease of \$0.8m and which were broken down as follows:

	2019	2020	Increase/
	Quarter 1	Quarter 1	(decrease)
	US\$'000	US\$'000	%
Point-of-Care	3,195	3,335	4.4%
Clinical Laboratory	18,831	17,842	(5.3%)
Total	22,026	21,177	(3.9%)

Point-of-Care revenues for Q1, 2020 increased from \$3.2m to \$3.3m when compared to Q1, 2019, an increase of 4.4%. This was due to a 19% increase in HIV revenues in Africa, which more than offset the decrease in USA revenues following the Company's decision to discontinue its USA HIV product in Q4, 2019.

Clinical Laboratory revenues decreased from \$18.8m to \$17.8m, which represents a decrease of 5.3% compared to Q1, 2019. This decrease was primarily due to lower Infectious Diseases revenues attributable to a reduction in sales to China due to Covid-19 and lower Lyme revenues. This was partially offset by growth in Autoimmune and Diabetes revenues, though the level of growth in both of these product lines was adversely impacted by the initial effects of Covid-19.

Gross profit for Q1, 2020 amounted to \$9.3m, representing a gross margin of 43.8%. This was higher than the 42.4% achieved in Q1, 2019 due to fewer instruments being placed (lower than average margin) and lower depreciation.

Research and Development expenses increased by \$0.1m to \$1.4m, whilst cost savings and lower depreciation resulted in a decrease in Selling, General and Administrative (SG&A) expenses from \$6.6m to \$6.1m when compared to Q1 2019.

Operating profit for the quarter was \$1.7m, which represents an increase on the \$1.3m achieved in Q1, 2019 and was attributable to a reduced level of indirect costs, though this was slightly offset by a lower gross profit.

Financial income for the quarter showed a reduction reflecting a lower level of cash deposits. Meanwhile, Financial Expenses amounted to \$1.2m which was in line with Q1, 2019. Of this, \$1.0m related to interest payable on the Company's Exchangeable Notes, with the remaining \$0.2m representing notional financing charges arising on leased assets (arising from IFRS16). A further non-cash expense of \$0.2m has been recognised separately for non-cash interest in relation to the Notes.

The profit after tax, before non-cash financial expenses & once-off items, for the quarter was \$0.5m in comparison to \$0.2m for the equivalent period last year. This was primarily due to the higher operating profit this quarter.

The basic EPS (excluding non-cash financial expenses & once-off items) for the quarter was 1.7 cents versus 0.5 cents in Q1, 2019. Unconstrained diluted EPS for the quarter amounted to 5.3 cents, which compares to 4.4 cents in the equivalent quarter in 2019.

Earnings before interest, tax, depreciation, amortisation and share option expense (EBITDASO) for the quarter was \$2.6m, and was made up as follows:

	\$ <i>m</i>
Operating Profit	1.7
Depreciation	0.4
Amortisation	0.4
Share Option Expense	0.1
EBITDASO	2.6

### **Carlsbad Closure Update**

In March, 2020 we announced that we would close our facility in Carlsbad, California which specialises in manufacturing Western Blot Lyme products, due to the on-going migration of Lyme confirmatory testing to alternative testing platforms. Closure remains on schedule for June 30, 2020. A charge of \$2.4m has been recognized in the Q1, 2020 income statement to cover the related closure costs. This primarily includes the write-off of inventory and redundancy costs and is mainly non-cash in nature.

# Covid-19 Update

# COVID-19 products

The Company is currently in the validation phase with its Covid-19 IgG ELISA antibody test. This test will determine which individuals within the population have been exposed to the SARS-CoV-2 virus. The transfer of the product into our facility at Jamestown, New York has been completed and we anticipate submitting the validation documentation to the FDA and gaining Emergency Use Authorization (EUA) by the end of June. As previously indicated, our ELISA production capability is very significant and the instrumentation platforms that perform this type of testing are available in virtually every laboratory in the world.

In addition, the Company is at an advanced stage in the development of a rapid point-of-care Covid-19 test to detect antibodies to the virus that can be run in 12 minutes using one drop of blood procured by finger prick. The utility of this test is similar to that outlined above for the ELISA antibody test. We expect to complete development and transfer to manufacturing of this rapid test over the coming months and again believe that we can avail of the FDA's EUA to expedite its approval.

The Company also sells an FDA approved transport medium product. This transport medium is a chemical formulation that stabilises the Covid-19 virus, whilst inhibiting bacterial contamination thereby providing an optimally preserved sample for laboratory analysis. The medium comes in prefilled tubes into which clinical swabs are placed at the point of collection, for transport to the clinical laboratory for testing.

# Impact on Revenues due to Covid-19

Covid-19 has had a limited impact on Q1, 2020 revenues, being largely confined to Diabetes (principally fewer instrument placements), Autoimmunity (lower reference laboratory testing towards the end of the quarter) and Infectious Diseases where sales to China were impacted by lockdown measures then in place.

However, the Company anticipates that the impact on revenues in Q2 will be more significant, principally due to:

- Lower diabetes testing volumes across all major markets as patients avoid or are prevented from having their A1c levels tested. This will result in lower Diabetes consumables revenues whilst instrument sales, which were already low in Q1, are expected to remain so.
- Lower autoimmune testing, reflecting the non-acute nature of this testing. This is particularly impacting our reference laboratory in Buffalo, but has also resulted in lower product sales in all major markets.
- The suspension or reduction of HIV testing programs in certain countries in Africa, in addition to a reduction in orders due to uncertainty surrounding what impact Covid-19 will have on healthcare services and local supply chains. These factors have also resulted in the temporary suspension of our TrinScreen clinical trials.

At the same time, the Company is benefitting from higher sales of Covid-19 transport medium (used for transporting Covid-19 patient samples in a stable environment) and higher sales of respiratory products for Legionnaire's Disease and Strep Pneumonia.

Taking these factors into account it is expected that Q2, 2020 revenues will be in the \$13m-15m range.

#### Covid-19 Expenditure Reduction Measures

In early Q2, 2020 we furloughed a large percentage of our work forces in the USA and Ireland in anticipation of the lower demand from customers. In the USA, the Company received loans totalling \$4.5m under the U.S. government's Paycheck Protection Program (PPP). Under the provisions of the PPP, these loans will be partially or totally forgiven, based on the extent to which a borrower's workforce returns to normal levels in the eight-week period immediately following the granting of the loans. Upon receipt of the loans Trinity ended the furloughing of staff in each of its U.S. plants and consequently we believe that a large percentage of these loans will be forgiven later in the year once the necessary verification has taken place. In Ireland, a significant level of furloughing remains in place, mainly due to the expected lower demand for HIV products for the African market. Trinity is also availing of economic supports being provided by the Irish Government. Meanwhile, in Brazil staff costs have also been significantly reduced.

In addition to the above, the Company has implemented a range of measures to reduce non-wage related costs principally in relation to the elimination of virtually all travel costs and significant reductions in discretionary SG&A expenditure.

# Comments

Commenting on the results Kevin Tansley, Chief Financial Officer stated "Operating profit increased this quarter from \$1.3m to \$1.7m. This was achieved with the aid of improved gross margin and lower indirect costs. However, the quarter did pre-date the most serious impact of Covid-19 and since then we have implemented a range of measures to safeguard the financial wellbeing of the company. In particular, we have availed of governmental supports provided by the U.S. and Irish governments. This included \$4.5m of loans from the USA government under its Paycheck Protection Program, most of which we expect to be forgiven in accordance with terms of that program. We have also furloughed a significant number of employees in response to lower demand and eliminated all non-essential expenditure."

Ronan O'Caoimh, Chief Executive Officer stated "Overall revenues held up reasonably well this quarter in the context of the initial effects of Covid-19. Clinical Laboratory revenues were down by 5% and this was due to a combination of lower Diabetes instrument placements as customers sought to defer such purchases due to onset of the pandemic. We also experienced a slowdown in Autoimmune testing at our reference laboratory in Buffalo. Meanwhile, Infectious Diseases revenues were impacted by lower sales to China, the first country to implement lockdown restrictions. As expected Lyme revenues were also lower this quarter due to the migration away from Western Blot testing. However, point-of-care revenues grew by 4.4% due to strong HIV revenues in Africa which more than outweighed the absence of USA HIV revenues following our recent withdrawal from that market.

Since the end of Q1, we have been seeing a much greater impact on revenues due to Covid-19. We have already seen a sharp reduction in diabetes and autoimmune testing as patients either feel reluctant to or unable to safely visit testing facilities. Meanwhile, HIV testing in Africa is also being impacted as some countries have temporarily suspended or downsized their testing programs. However, as Covid-19 related restrictions begin to ease we are now beginning to see revenues starting to rebound in some areas. We are also confident that once the pandemic passes business will revert to normality and that by its nature diagnostics will be largely protected from the worst economic impact of any economic downturn which may ensue.

Meanwhile, sales of our transport medium and sample collection device for Covid-19 are gaining traction. This FDA approved product is used to store the nasopharyngeal swab which contains the patient sample and stabilises it, prevents bacterial growth and maintains its integrity until such time as a test is run in the laboratory. Our product does not require refrigeration and is a key component in the identification of Covid-19 positives in the population. In addition, we are seeing an increase in sales of some of our respiratory products.

We are also aggressively executing our plans to develop new Covid-19 related tests. Our ELISA antibody test will be submitted to the FDA in the coming weeks and we expect to gain Emergency Use Authorization (EUA) by the end of June. This will then be followed by a rapid antibody test. With these tests we will be ideally positioned to participate in the surge in testing which will accompany the return to post-pandemic normality."

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: <u>www.trinitybiotech.com</u>.

# Trinity Biotech plc Consolidated Income Statements

(US\$000's except share data)	Three Months Ended Mar 31, 2020 (unaudited)	Three Months Ended Mar 31, 2019 (unaudited)
Revenues	21,177	22,026
Cost of sales	(11,901)	(12,688)
Gross profit Gross profit %	<b>9,276</b> 43.8%	<b>9,338</b> 42.4%
Other operating income	14	22
Research & development expenses Selling, general and administrative expenses Indirect share based payments	(1,378) (6,085) (134)	(1,311) (6,553) (176)
Operating profit	1,693	1,320
Financial income Financial expenses <b>Net financing expense</b>	31 (1,232) (1,201)	140 (1,243) (1,103)
Profit before tax, once-off & non-cash items	492	217
Income tax expense	(129)	(105)
Profit after tax before once-off & non-cash items	363	112
Non-cash financial expense	(160)	(323)
Once-off items	(2,425)	-
Loss after tax	(2,222)	(211)
Loss per ADR (US cents)	(10.6)	(1.0)
Earnings per ADR (US cents)**	1.7	0.5
Diluted (loss)/Earnings per ADR (US cents)	(4.2)*	4.4*
Diluted earnings per ADR (US cents)**	5.3*	4.4*
Weighted average no. of ADRs used in computing basic earnings per ADR	20,901,703	20,901,703
Weighted average no. of ADRs used in computing diluted earnings per ADR	25,467,516	25,467,516

\* Under IAS 33 Earnings per Share, diluted earnings per share cannot be anti-dilutive. In a reporting period where it is anti-dilutive, diluted earnings per ADR should be constrained to equal basic earnings per ADR. \*\* Excluding once-off charges & non-cash financial items.

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

	Mar 31, 2020 US\$ '000 (unaudited)	Dec 31, 2019 US\$ '000 (unaudited)
ASSETS		
Non-current assets	0.210	0.200
Property, plant and equipment	9,210	9,290 43,654
Goodwill and intangible assets Deferred tax assets	45,498 6,465	6,252
Other assets	485	485
Total non-current assets	61,658	59,681
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Current assets		
Inventories	32,671	32,021
Trade and other receivables	19,982	20,987
Income tax receivable	1,572	1,982
Cash, cash equivalents and deposits	13,244	16,400
Total current assets	67,469	71,390
TOTAL ASSETS	129,127	131,071
EQUITY AND LIABILITIES Equity attributable to the equity holders of the parent Share capital Share premium Accumulated surplus Treasury shares and other reserves Total equity	1,224 16,187 9,431 (26,074) 768	1,224 16,187 11,514 (24,212) 4,713
Current liabilities		
Income tax payable	374	48
Trade and other payables	21,639	19,351
Provisions	50	50
Total current liabilities	22,063	19,449
Non-current liabilities	82 185	82,025
Exchangeable senior note payable Other payables	82,185 17,039	17,745
Deferred tax liabilities	7,072	7,139
Total non-current liabilities	106,296	106,909
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TOTAL LIABILITIES	128,359	126,358
TOTAL EQUITY AND LIABILITIES	129,127	131,071

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# Trinity Biotech plc Consolidated Statement of Cash Flows

(US\$000's)	Three Months Ended Mar 31, 2020 (unaudited)	Three Months Ended Mar 31, 2019 (unaudited)
Cash and cash equivalents at beginning of period	16,400	30,277
Operating cash flows before changes in working capital Changes in working capital Cash generated from operations	2,467 (1,396) 1,071	3,208 (528) 2,680
Net Interest and Income taxes received	431	348
Capital Expenditure & Financing (net)	(2,756)	(3,114)
Payments for Leases (IFRS 16)	(790)	(758)
Free cash flow	(2,044)	(844)
Payment of HIV/2 License Fee	(1,112)	-
Cash and cash equivalents at end of period	13,244	29,433

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