



7 June 2019

**Surgical Innovations Group plc  
(the "Group" or the "Company")**

**Trading Update**

Surgical Innovations Group plc (AIM: SUN), the designer, manufacturer and distributor of innovative technology for minimally invasive surgery, provides an update on current trading.

Following the strong final quarter of 2018, trading in the first quarter ended 31 March 2019 was in line with the Board's expectations and showed modest growth in revenues compared with the equivalent period last year. This momentum has not carried into the second quarter, with orders in the UK and EU markets lower than expected. The disruption to order patterns by distributors and end users caused by Brexit uncertainties has made visibility of true demand more difficult than normal, and it is anticipated that this volatility is likely to continue until matters are resolved. Revenues in export markets elsewhere remain unaffected, especially the US where growth has been strong.

Demand in the UK market more generally continues to be muted by the level of activity in the NHS. Whilst a funding crisis was largely avoided last winter, hospitals continue to deliver a reduced level of elective procedures. The British Medical Association reported on 2 May 2019 that more than 20,000 elective cases were cancelled during the last quarter of 2018 (the latest quarter for which data was available), and that there were 4.3 million people waiting for treatment, including an increase in those waiting over 18 weeks by more than a fifth\*. Whilst our UK distribution business continues to have success in winning new accounts in the NHS, the overall volume of UK activity is a continuing concern, especially in the current political climate.

Sales of one of our key distribution product ranges, Cellis, have been slower to ramp up than expected following renewed regulatory approval being received in September 2018. Nevertheless, current trends in sales give us confidence in the potential for this key product range going forward and we are excited about the positive reception of new products in the range.

Surgical Innovations Limited underwent a comprehensive regulatory audit in May 2019, as a result of which we are able to proceed with recertification for ISO13485: 2016 and ISO9001: 2015. Importantly, certification for the Medical Device Single Audit Program (MDSAP) was also granted, streamlining market access in the US, Canada, Australia, Japan and Brazil. In addition, FDA approval for the core Elite range has been granted, which will enable a US market launch of these products later in the year.

Regulatory approvals are becoming increasingly challenging to achieve and provide a formidable barrier to prospective new entrants. They also place an increasing burden on operational and technical resources, and we continue to build a strong and expert team in this area. Recent redeployment of key personnel to support this activity has inevitably had a short-term impact on the introduction of new products, as well as line extensions of our current range. Delays in the regulatory approval process are symptomatic of the severe contraction in the number of approved regulatory bodies in Europe. In addition, extra resources will be put in place as we move towards Medical Device Regulation. This is likely to affect both the cost and timescale of introduction of new products across the industry.

Taking these factors into account, the Board considers that growth in revenues in the second half of the year is unlikely to fully counter the relatively weaker second quarter to date. Full year expectations for revenue will exceed those of the prior year by a more modest rate of growth than previously anticipated. Whilst margins are expected to remain in line, overheads will reflect the investment in additional resources

devoted to operational and regulatory matters. Accordingly, adjusted profit before tax is expected to be below the level achieved in 2018. The Group currently holds net cash and continues to be cash generative.

We continue to invest in operational excellence and innovative product development as the main drivers of organic growth, and to evaluate the potential for enhanced growth by acquisition. The directors recognise that the impact of the above external market factors on the Group is disappointing; however, as significant shareholders in the Group we continue to look to the future with confidence.

\* source: *British Medical Association: NHS Pressures - Winter 2018/19: A hidden crisis, 2 May 2019*

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014.

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