

## **Update for the Quarter Ending 31 December 2018**

**Brisbane, Australia, 29 January 2019** – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to provide an update on the company's activities during the second quarter of the financial year, ending 31 December 2018.

"Submitting the ResAppDx-EU CE Mark Technical File at the end of the quarter represented significant progress towards becoming the world's first company to obtain regulatory approval for a smartphone application to diagnose acute respiratory disease," said Tony Keating, CEO and Managing Director of ResApp Health. "Two key clinical studies also delivered positive results during the quarter. The US SMARTCOUGH-C-2 clinical study showed our algorithms were able to accurately diagnose the most commercially important indications – upper and lower respiratory tract disease and asthma/reactive airway disease in paediatric patients, while our prospective sleep apnoea study confirmed our proof-of-concept results for identifying obstructive sleep apnoea using a smartphone placed on a bedside table. As we enter the third financial quarter, we are looking forward towards submitting a De Novo application to the US FDA for our paediatric acute respiratory disease diagnostic tool, completing clinical adjudication in our Australian adult study and further progressing our sleep apnoea program."

### **Recent Highlights and Outlook**

- Filed CE Mark Technical File for ResAppDx-EU with European Notified Body. In late December, ResApp submitted its CE Mark Technical File for ResAppDx-EU, a mobile software application to be used by clinicians for the diagnosis of lower respiratory tract disease, croup, pneumonia, asthma/reactive airway disease and bronchiolitis in infants and children. CE Marking will enable the commercial sale of ResAppDx-EU in the European Economic Area and facilitate commercialisation in other markets such as Australia, Canada and Singapore. ResApp also achieved ISO 13485:2016 compliance during the quarter, confirming that ResApp's quality systems meet the ISO requirements for a comprehensive quality management system for the design and manufacture of medical devices, an essential step in obtaining European CE Mark and Australian TGA approval.
- Positive top-line results from US SMARTCOUGH-C-2 study. SMARTCOUGH-C-2 is a multisite, prospective, double-blind study evaluating the efficacy of the ResAppDx smartphone application in the diagnosis of childhood acute respiratory disease using cough sounds. A total of 1,470 patients were recruited at three hospital sites in the US from which 1,251 patients completed the study and were analysable. ResApp announced in October that ResAppDx achieved a positive percent agreement between 73% and 78% and a negative percent agreement between 71% and 86% when compared to a clinical diagnosis for lower



respiratory tract disease, asthma/reactive airway disease and primary upper respiratory tract disease. Results for pneumonia and bronchiolitis were less than 70% prompting the company to pursue further investigation of these indications in the US. A technical issue delayed clinical adjudication for croup, however this has since been solved with adjudication progressing towards completion in the first quarter of this calendar year.

- Positive results from double-blind, prospective obstructive sleep apnoea (OSA) study. In October, ResApp announced that its smartphone-based algorithms achieved 84% sensitivity and 83% specificity for identifying patients with an apnoea hypopnea index (AHI) greater than or equal to 5/h (patients with mild, moderate or severe OSA) compared to simultaneous in-laboratory polysomnography in a double-blind, prospective study. The algorithms were similarly able to identify patients with an AHI greater than or equal to 15/h (moderate or severe OSA) and an AHI greater than or equal to 30/h (severe OSA). During the quarter the study investigators presented a poster on earlier proof-of-concept OSA results at Sleep DownUnder 2018, the 30<sup>th</sup> Annual Scientific Meeting of the Australasian Sleep Association and the Australasian Sleep Technologists Association. Recruitment in an at-home study, with simultaneous smartphone diagnosis and AASM Type II home sleep testing is nearly complete with results being the next major milestone for this program.
- Continued progress on US regulatory submission. ResApp is working closely with its US and Australian-based consultants on a De Novo premarket submission for its acute paediatric respiratory disease diagnostic smartphone application and plans to file this with the US Food and Drug Administration (FDA) in the first quarter of this calendar year.
- **Building evidence for European commercialisation.** ResApp continues to work with a German private hospital network on a pilot study planned to commence during the European winter. The finalisation of a study protocol, including measures of success such as a reduction in time to diagnosis, improved patient flow and reduced diagnostic testing costs, is underway.
- Advancement of DARPA WASH program. ResApp received initial funding from Lockheed Martin during the quarter and continues to work on the Defense Advanced Research Projects Agency (DARPA) Warfighter Analytics using Smartphones for Health (WASH) program.
- Strong balance sheet to advance ResApp through multiple value inflection points. The Company held cash of \$6.8m as of December 31, 2018 and is well-funded to execute its clinical and commercialisation strategy. A large portion of ResApp's expenditure has been on research and development and is expected to be eligible under the Australian Federal Government's R&D Tax Incentive program which provides a cash refund on eligible research and development activities.

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### About ResApp Health Limited

ResApp Health Limited (ASX: RAP) is a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease. ResApp's machine learning algorithms use sound to diagnose and measure the severity of respiratory conditions without the need for additional hardware. Clinical studies at leading hospitals in Australia and the United States have demonstrated accurate diagnosis of lower respiratory tract disease, upper respiratory tract infections, asthma/reactive airway disease, pneumonia, bronchiolitis, croup, chronic obstructive pulmonary disease and obstructive sleep apnoea. Potential customers of ResApp's products include healthcare providers in telehealth, emergency department, urgent care and primary care settings as well as humanitarian organisations in the developing world. For more information, please visit <a href="https://www.resapphealth.com.au">www.resapphealth.com.au</a>.

#### **Contacts**

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+Rule 4.7B

# **Appendix 4C**

# Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

### Name of entity

| ResApp Health Limited |                |                                   |  |
|-----------------------|----------------|-----------------------------------|--|
| ABN                   |                | Quarter ended ("current quarter") |  |
|                       | 51 094 468 318 | 31 December 2018                  |  |

| Consolidated statement of cash flows |   | Current quarter<br>\$A'000 | Year to date<br>(6 months)<br>\$A'000 |
|--------------------------------------|---|----------------------------|---------------------------------------|
| 1.                                   | Cash flows from operating activities                            |                            |                                       |
| 1.1                                  | Receipts from customers   | 48                         | 48                                    |
| 1.2                                  | Payments for  |                            |                                       |
|                                      | (a) research and development                                    | (804)                      | (1,974)                               |
|                                      | <ul><li>(b) product manufacturing and operating costs</li></ul> | -                          | -                                     |
|                                      | (c) advertising and marketing (see note 4)                      | -                          | (1)                                   |
|                                      | (d) leased assets   | -                          | -                                     |
|                                      | (e) staff costs   | (525)                      | (997)                                 |
|                                      | (f) administration and corporate costs                          | (224)                      | (660)                                 |
| 1.3                                  | Dividends received (see note 3)                                 | -                          | -                                     |
| 1.4                                  | Interest received   | 30                         | 35                                    |
| 1.5                                  | Interest and other costs of finance paid                        | (2)                        | (3)                                   |
| 1.6                                  | Income taxes paid   | -                          | -                                     |
| 1.7                                  | Government grants and tax incentives                            | -                          | -                                     |
| 1.8                                  | Other – R&D rebate  | -                          | -                                     |
| 1.9                                  | Net cash from / (used in) operating activities                  | (1,477)                    | (3,552)                               |

| 2.  | Cash flows from investing activities |      |      |
|-----|--------------------------------------|------|------|
| 2.1 | Payments to acquire:                 |      |      |
|     | (a) property, plant and equipment    | (16) | (16) |
|     | (b) businesses (see item 10)         | -    | -    |
|     | (c) investments                      | -    | -    |

<sup>+</sup> See chapter 19 for defined terms

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| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date<br>(6 months)<br>\$A'000 |
|-----|--|----------------------------|---------------------------------------|
|     | (d) intellectual property                      | -                          | -                                     |
|     | (e) other non-current assets                   | -                          | -                                     |
| 2.2 | Proceeds from disposal of:                     |                            |                                       |
|     | (a) property, plant and equipment              | -                          | -                                     |
|     | (b) businesses (see item 10)                   | -                          | -                                     |
|     | (c) investments                                | -                          | -                                     |
|     | (d) intellectual property                      | -                          | -                                     |
|     | (e) other non-current assets                   | -                          | -                                     |
| 2.3 | Cash flows from loans to other entities        | -                          | -                                     |
| 2.4 | Dividends received (see note 3)                | -                          | -                                     |
| 2.5 | Other (provide details if material)            | -                          | -                                     |
| 2.6 | Net cash from / (used in) investing activities | (16)                       | (16)                                  |

| 3.   | Cash flows from financing activities  |     |       |
|------|---|-----|-------|
| 3.1  | Proceeds from issues of shares  | -   | 7,500 |
| 3.2  | Proceeds from issue of convertible notes                                    | -   | -     |
| 3.3  | Proceeds from exercise of share options                                     | -   | -     |
| 3.4  | Transaction costs related to issues of shares, convertible notes or options | (1) | (494) |
| 3.5  | Proceeds from borrowings  | -   | -     |
| 3.6  | Repayment of borrowings   | -   | -     |
| 3.7  | Transaction costs related to loans and borrowings                           | -   | -     |
| 3.8  | Dividends paid  | -   | -     |
| 3.9  | Other (provide details if material)   | -   | -     |
| 3.10 | Net cash from / (used in) financing activities                              | (1) | 7,006 |

| 4.  | Net increase / (decrease) in cash and cash equivalents for the period |         |         |
|-----|---|---------|---------|
| 4.1 | Cash and cash equivalents at beginning of quarter/year to date        | 8,330   | 3,398   |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above)       | (1,477) | (3,552) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above)       | (16)    | (16)    |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above)      | (1)     | 7,006   |

<sup>+</sup> See chapter 19 for defined terms 1 September 2016

| Con | solidated statement of cash flows                 | Current quarter<br>\$A'000 | Year to date<br>(6 months)<br>\$A'000 |
|-----|---|----------------------------|---------------------------------------|
| 4.5 | Effect of movement in exchange rates on cash held | -                          | -                                     |
| 4.6 | Cash and cash equivalents at end of quarter       | 6,836                      | 6,836                                 |

| 5.  | Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts | Current quarter<br>\$A'000 | Previous quarter<br>\$A'000 |
|-----|---|----------------------------|-----------------------------|
| 5.1 | Bank balances   | 6,836                      | 8,330                       |
| 5.2 | Call deposits   | -                          | -                           |
| 5.3 | Bank overdrafts   | -                          | -                           |
| 5.4 | Other (provide details)   | -                          | -                           |
| 5.5 | Cash and cash equivalents at end of quarter (should equal item 4.6 above)   | 6,836                      | 8,330                       |

| 6.  | Payments to directors of the entity and their associates                       | Current quarter<br>\$A'000 |
|-----|--|----------------------------|
| 6.1 | Aggregate amount of payments to these parties included in item 1.2             | 135                        |
| 6.2 | Aggregate amount of cash flow from loans to these parties included in item 2.3 |                            |
| 0.0 |  |                            |

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

| 1. C | irector | fees, | salary | and | super; | and |
|------|---------|-------|--------|-----|--------|-----|
|------|---------|-------|--------|-----|--------|-----|

2. Consultancy fees.

| 7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3                  | 7.  | Payments to related entities of the entity and their associates    | Current quarter<br>\$A'000 |
|---|-----|--|----------------------------|
| in item 2.3  7.3 Include below any explanation necessary to understand the transactions included in | 7.1 | Aggregate amount of payments to these parties included in item 1.2 |                            |
| ,,,,,   | 7.2 |  |                            |
|   | 7.3 |  | ns included in             |
|   |     |  |                            |

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<sup>+</sup> See chapter 19 for defined terms

| 8.  | Financing facilities available Add notes as necessary for an understanding of the position   | Total facility amount at quarter end \$A'000 | Amount drawn at<br>quarter end<br>\$A'000 |  |  |
|-----|--|--|---|--|--|
| 8.1 | Loan facilities  | -  | -   |  |  |
| 8.2 | Credit standby arrangements  | -  | -   |  |  |
| 8.3 | Other (please specify)   | -  | -   |  |  |
| 8.4 | Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well. |  |   |  |  |
|     |  |  |   |  |  |

| 9.  | Estimated cash outflows for next quarter  | \$A'000 |
|-----|---|---------|
| 9.1 | Research and development                  | (753)   |
| 9.2 | Product manufacturing and operating costs | -       |
| 9.3 | Advertising and marketing                 | -       |
| 9.4 | Leased assets                             | -       |
| 9.5 | Staff costs                               | (632)   |
| 9.6 | Administration and corporate costs        | (223)   |
| 9.7 | Other (provide details if material)       | -       |
| 9.8 | Total estimated cash outflows             | (1,608) |

| 10.  | Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above) | Acquisitions | Disposals |
|------|---|--------------|-----------|
| 10.1 | Name of entity  | -            | -         |
| 10.2 | Place of incorporation or registration  | -            | -         |
| 10.3 | Consideration for acquisition or disposal                                       | -            | -         |
| 10.4 | Total net assets  | -            | -         |
| 10.5 | Nature of business  | -            | -         |

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### **Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Sign here: Date: 29 January 2019

Print name: Tony Keating

#### **Notes**

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
- If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

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<sup>+</sup> See chapter 19 for defined terms