The Fiscal Year ending December 2017

Financial Results Presentation

February 9, 2018

Oncolys BioPharma Inc.

(TSE mothers: 4588)
Forward looking statements

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• This presentation material is a summary translation of the original published in Japanese. In case of any discrepancy, the Japanese original shall prevail.
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1. Financial results and future outlook
2. Telomelysin
3. TelomeScan
4. Message to investors
Our pipeline: oncolytic virotherapy platform

Oncolytic virotherapy platform

Early detection

Prognosis follow-up

Regional treatment

Systemic treatment

OBP-801

Telomelysin®

TelomeScan®

OBP-702

OBP-405
## FY2017 full year earnings results

<table>
<thead>
<tr>
<th></th>
<th>Sales</th>
<th>OP</th>
<th>CP</th>
<th>NP</th>
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<tbody>
<tr>
<td>FY2017 Full Year</td>
<td>229</td>
<td>△1,078</td>
<td>△1,087</td>
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<td>FY2016 Full Year</td>
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<td>△861</td>
<td>△864</td>
<td>△931</td>
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<td>YOY</td>
<td>+51</td>
<td>△217</td>
<td>△223</td>
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### Sales
1. License fee for Telomelysin from Hengrui
2. Co-development fund from Medigen
3. Sales of TelomeScan to Deciphera

### OP
1. Cost reduction efforts
2. Delay in R&D activities

### R&D costs
JPY 570 million

### Cash & equivalents
JPY 2.8 bn
## FY2017: achievements and status

### OBP-301

**Telomelysin®**

1. Melanoma P2 Started
2. Esophageal cancer P1 Started
3. HCC P1/2 Multiple administration (Cohort 5) in progress
4. Solid tumors, with PD-1 P1/2 Started
5. Esophageal cancer (USA) Scientific Advisory Board (SAB) meeting
6. 9 conference presentations, 4 publications

### OBP-801

**TelomelScan**

Cancer Diagnosis

1. PTC feasibility study for pancreatic cancer: IRB
2. Joint research agreement with Juntendo University
3. SAB for NSCLC
4. 9 conference presentations, 3 publications

### Others

**AI-004**

Novel HBV drug

1. Compound screening at Kagoshima University in progress

### Others

1. Completed 1.4 bn JPY financing by third-party allotment
Comparison: budget and actual expenses FY2017

 Planned budget | Results
---|---

**1.6bn**
- **7** Other SG&A
- **2** Patent
- **7** R&D

**1.23bn**
- **5.7** Other SG&A
- **0.6** Patent
- **6** R&D

**<Major factors>**

1. Delay in Telomelysin-related clinical trials
2. Reduced Telomelysin-related patent costs
3. Reduced TelomeScan joint research costs
### Financial year ending December 2018 full year forecast

#### Sales, OP, CP, NP (JPY: million)

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<th>OP</th>
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<td>△1,400</td>
<td>△1,400</td>
<td>△1,400</td>
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<tr>
<td>Results FY2017</td>
<td>229</td>
<td>△1,078</td>
<td>△1,087</td>
<td>△1,090</td>
</tr>
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</table>

| yoy       | +1  | -322 | -313 | -310 |

### R&D and SG&A

#### FY2016 (実) FY2017 (実) FY2018（予）

- **R&D:**
  - FY2016: 3.6 (JPY 100 million)
  - FY2017: 5.7 (JPY 100 million)
  - FY2018 (予): 12.3 (JPY 100 million)

- **SG&A:**
  - FY2016: 10.3 (JPY 100 million)
  - FY2017: 3.6 (JPY 100 million)
  - FY2018 (予): 0.7 (JPY 100 million)

### Notes

- （単位：百万円）

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### Pharmaceutical Business

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<th>Exploratory</th>
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<th>Phase II</th>
<th>Phase III</th>
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<td>Solid tumors</td>
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<td>Ophthalmic use</td>
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### Diagnostic Business

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</table>
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1. Financial results outline and future outlook
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3. TelomeScan
4. Message to investors
Telomelysin: oncolytic virotherapy

Ref.) The Lancet Oncology Vol. 3 Jan. 2002

Normal cell
(Telomerase activity –)
No replication
No cytophathy

Cancer cell
(Telomerase activity+)
Replication of Telomelysin
Induced cell death and diffusion of Telomelysin

Colorectal cancer
(15 days after administration)
Control group
Telomelysin

Lung cancer
Day 0
Day 14
Day 28
Control group
Telomelysin

<table>
<thead>
<tr>
<th>Tumor type</th>
<th>Treatment</th>
<th>Country</th>
<th>Pre-clinical</th>
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<td>Radiation Investigator initiated clinical trial</td>
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※Jiangsu Hengrui’s project is not included in this table.
Esophageal Cancer

“Cure without operation”
6 CR in 10 cases

Radiation therapy
5 times/week (Mon-Fri) x 6 weeks

Day 1
Day 4
Day 18
Day 32

Toshiyoshi Fujiwara, M.D., Ph.D.
Professor & Chairman
Department of Gastroenterological Surgery, Okayama University Graduate School of Medicine, Dentistry, and Pharmaceutical Sciences

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### Investigator initiated clinical research with radiation (2)

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<th>Age</th>
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<td>82</td>
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<td>CR</td>
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<td>002</td>
<td>85</td>
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<td>CR</td>
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<td></td>
<td>003</td>
<td>92</td>
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<td>004</td>
<td>68</td>
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<td>SD</td>
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<td>003</td>
<td>85</td>
<td>cStage I</td>
<td>CR</td>
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( * Level 1 005 dropped out as the enrollment was cancelled)

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**Cohort 3 completed**

**Data analysis**
1. Cohort 1 in progress

2. Cohort 2 to be completed within 2018

3. Start preparation for Phase II/III with radiation
   - Multicenter trial
   - Preliminary consultation with PMDA
   - Expected to start in 2019
Pembrolizumab combination therapy at NCCHE

- Patients with advanced or metastatic tumors
- Main endpoint: Safety and tolerability
Discussion on expanded indication of Telomelysin (20 Jan)

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<tr>
<th>Name</th>
<th>Specialty</th>
<th>Institution</th>
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<tr>
<td>Manish Shah, MD</td>
<td>Medical Oncology</td>
<td>Weill Cornell Medicine/ NewYork-Presbyterian</td>
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<tr>
<td>David Ilson, MD, PhD</td>
<td>Medical Oncology</td>
<td>Memorial Sloan Kettering Cancer Center</td>
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<tr>
<td>Khaldoun Almhanna, MD</td>
<td>Medical Oncology</td>
<td>Moffitt Cancer Center</td>
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<tr>
<td>Toshiyoshi Fujiwara, MD, PhD</td>
<td>Surgical Oncology</td>
<td>Okayama University</td>
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<td>Lawrence Kleinberg, MD</td>
<td>Radiation Oncology</td>
<td>Johns Hopkins</td>
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<td>Tanguy Seiwert, MD</td>
<td>Immunologist</td>
<td>U. Chicago</td>
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<td>Kenneth Wang, MD</td>
<td>Endoscope Specialist</td>
<td>Mayo Clinic</td>
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<td>Field Willingham, MD</td>
<td>Endoscope Specialist</td>
<td>Emory University</td>
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<Stomach and gastroesophageal cancer>

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<tr>
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<th>Stage</th>
<th>Combination</th>
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<tr>
<td>1</td>
<td>Stage IV</td>
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<tr>
<td>2</td>
<td>cStage II/III</td>
<td>Inoperable</td>
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<td>3</td>
<td>cStage II/III</td>
<td>Operable</td>
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# Tumor virotherapy: clinical trials

<table>
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<th>Indication</th>
<th># of clinical trials</th>
<th>Sponsors</th>
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<td>Melanoma</td>
<td>16</td>
<td>Amgen, Provectus, Takara Bio, Virttu, Viralytics, <em>Oncolys</em></td>
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<tr>
<td>Solid tumor</td>
<td>11</td>
<td>VBL, Silla Jen, Targovax, Remplimune, VCM</td>
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<tr>
<td>Brain tumor (incl. GBM)</td>
<td>10</td>
<td>VBL, DNAtrix, Virttu, VCN</td>
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<tr>
<td>HCC (incl. metastatic to liver)</td>
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<td>Amgen, Silla Jen, Virttu, <em>Oncolys</em></td>
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<td>Sarcoma &amp; myeloma</td>
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<td>SCCHN</td>
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<td>Bladder cancer</td>
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<td>Amgen</td>
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<td>Ovarian cancer</td>
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<td>Pancreatic cancer</td>
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<td>Mesothelioma</td>
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<td><strong>Esophageal Cancer</strong></td>
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<td>Others</td>
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<td><strong>Total</strong></td>
<td><strong>102</strong></td>
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Ref: data from ClinicalTrials.gov in Jan 2018
Esophageal cancer treatment perspectives

- Number of patients: approx. 31,000 in 2014
- Estimated incidence: approx. 22,000 between 2015 - 2019
  (Incidence worldwide: approx. 456,000 in 2012)
  (Incidence USA: approx. 17,000 in 2017)

Stage IV
Metastasis/operation inapplicable patients

Stage I ・ II ・ III
Operation applicable

Stage I ・ II
Operation/chemotherapy inapplicable patients

+ Radiation

ICI: pembrolizumab

Telomelysin®

Pre-operative chemotherapy/radiation

Melanoma

“Challenge to remote cancer”
Abscopal Effect observed in melanoma patients

Age: 54
Sex: Male
Race: Caucasian
Stage: IV
Cohort 1: $1 \times 10^{10}$ VP
Metastases: 5

Cytoreductive effect on administration/non-administration sites

1. axillary nodes (left)
2. axillary nodes (right)
3. Subpectoral node (left)
4. Breast (left)

1. Administration site
2. 28 days
3. 56 days

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Melanoma: 2 patients enrolled

- Total 4 clinical trial sites are open in the US so far
- Accelerating patient recruiting to realize an interim analysis

Unresectable or metastatic melanoma

4 x 10^{12} vp /multiple location

Efficacy, safety and immunological response

Trial sites
- Atlantic Health Systems (NJ)
- Huntsman Cancer Institute (UT)
- University of Iowa (IA)
- St. Luke's University Health Network Inc. (PA)
- Stanford University (CA)
“Challenge to refractory cancer”
HCC: Phase I/II in Taiwan and Korea

Moving on to PII after P I
→ monotherapy or combination with ICI?
Next Generation Telomelysin
Next Generation Telomelysin

Local therapy
- virotherapy

Next Generation Systemic therapy
- Virotherapy
- T lymphocyte therapy
- CP Inhibitors

Changing tumor microenvironment

OBP
- Telomelysin
- h4-1BBL
- hPD-1

A社
- E1A-E3
- h4-1BBL

B社
- E1A-E3
- hOX-40

Virus + Lymphocyte stimulation + CPI

+ anti-PD-1 Ab
Next Generation Telomelysin

NG Telomelysin

T Lymphocyte
Co-stimulate molecule

Virus particle

T cell

Cancer cell

Immunotherapy

CPI

Oncolytic virus

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Telomelysin project picture after 2020

<table>
<thead>
<tr>
<th>Tumor type</th>
<th>Treatment</th>
<th>Country</th>
<th>Pre-clinical</th>
<th>Phase I</th>
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(ICI: Immune Checkpoint Inhibitor)
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4. Message to investors
TelomeScan overview

TelomeScan is a gene-modified adenovirus which replicates and expresses GFP when infected to telomerase activity-positive tumor cells.
Tumor Metastasis and CTC Phenotype

1. Detection rate using tumor diagnostic markers currently available is around 30-40%.

2. PET and MRI only detect tumor cells bigger than 1cm

3. CTCs seep from tumor cells undetectable by PET and MRI
Joint research with Division of Respiratory Medicine, Juntendo University started in Nov. 2017 and promoted as a cross-sectional research project joined by medical doctors in wide range of oncology-related fields.

Juntendo University  
Oncolys Biopharma

Long term targets

1. Practical use in clinical settings across Japan for detection of early and recurrent tumors
2. Automation of tumor detection system
Future development

1. Differentiation from ctDNA/cfDNA
2. Precision Medicine
3. New CTC application
   → HPV detection
Comparison of Liquid Biopsy

<table>
<thead>
<tr>
<th></th>
<th>CTC</th>
<th>cfDNA</th>
<th>ctDNA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phenotyping</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Genotyping</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RNA</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>DNA</td>
<td>+/-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>Clinical Benefit</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early Detection</td>
<td>+/-</td>
<td>+</td>
<td>+/-</td>
</tr>
<tr>
<td>Longitudinal Monitoring</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Treatment Response</td>
<td>+</td>
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<td>+</td>
</tr>
</tbody>
</table>

Figure was modified from Wyatt AW and Gleave ME, EMBO Mol Med (2015)
## Challenge to Impossible for cf/ctDNA

### Phenotyping

**“PD-L1”**
- Lung Ca.
- Urothelial Ca.
- RCC
- Melanoma

### Genotyping

**“HPV/KRAS/BRAF/T790M”**
- Cervical Ca.
- SCCHN
- Vaginal Ca.
- Anal Ca.

### RNA

**“AR-V7”**
- Prostate Ca.
- Breast cancer

### Non-CTC

**“PTC”**
- Pancreatic Ca.
- Gastric Ca.

PTC : Peritoneal Tumor Cell
Application to precision medicine

NSCLC Project led by University of Pennsylvania

CTC CTC CTC CTC CTC CTC CTC CTC CTC CTC

Chemoradiation therapy (CRT)

5weeks

Treatment complete

Recurrence

Gene analysis
Selection of treatment

Follow-up

(CTC #)

(CTC #)
HPV is the cause of Cancer

HPV Detected in Cancer Cell

- Cervical Cancer: 1, 2
  ~100%

- Vaginal Cancer:
  1
  60~90%

- Head & Neck Cancer:
  2
  12~70%

HPV is NOT detected in Blood Stream, but in ONLY CTC

HPV Typing in CTCs

Cervical Cancer

< Sensitivity >

(≥1 cell/7.5ml of peripheral blood tested positive)

<table>
<thead>
<tr>
<th>CTC positive rate (%)</th>
<th>0</th>
<th>20</th>
<th>40</th>
<th>60</th>
<th>80</th>
<th>100</th>
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<tbody>
<tr>
<td>39.0%</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>39.0% (16/41)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
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< HPV Typing in CTCs >

<table>
<thead>
<tr>
<th>#</th>
<th>Stage</th>
<th>HPV type</th>
<th>CTC</th>
<th>Primary</th>
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<tr>
<td>2</td>
<td>IIA</td>
<td>16</td>
<td>16</td>
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<tr>
<td>4</td>
<td>recurrence</td>
<td>undetected</td>
<td>33</td>
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<tr>
<td>5</td>
<td>IB1</td>
<td>16</td>
<td>16</td>
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<tr>
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<td>IB1</td>
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<td>10</td>
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<td>16</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>IB1</td>
<td>16</td>
<td>16</td>
<td></td>
</tr>
</tbody>
</table>

Detected in 5/6 pts

Takakura et al., Cancer science (2017)
Table of Contents

1. Financial results and future outlook
2. Telomelysin
3. TelomeScan
4. Message to investors
Oncolys’ financial grounds in mid-long term

Further Growth & Business Expansion

**Stronger financial grounds**

- **New pipeline:** explore and develop

- **Current pipeline:** accelerate development

**New license agreements**

- More license agreements
  - New pipeline
  - Next generation Telomelysin

- Telomelysin
- TelomeScan

**Milestone fees & virus sales based on current license agreements**

Jiangsu Hengrui, Wonik Cube, Deciphera, etc.

**Steady income**

Co-development fund from Medigen

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Thank you!