Non-consolidated Financial Results for the Six Months Ended June 30, 2018 [Japanese GAAP]

August 3, 2018

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
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Scheduled date of filing quarterly securities report: August 3, 2018
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on quarterly financial results: No
Schedule of quarterly financial results briefing session: Scheduled (for analysts)

(Amounts of less than one million yen are rounded down.)

1. Financial Results for the Six Months Ended June 30, 2018 (January 1, 2018 to June 30, 2018)

(1) Operating Results (% indicates changes from the previous corresponding period.)

	Net sales		Operating profit		Ordinary profit		Profit	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
June 30, 2018	90	354.4	(643)	-	(639)	-	(641)	-
June 30, 2017	19	(55.5)	(509)	-	(517)	-	(518)	-

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2018	(57.89)	-
June 30, 2017	(53.89)	-

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of June 30, 2018	2,808	2,290	81.2
As of December 31, 2017	3,526	2,931	82.9

(Reference) Equity: As of June 30, 2018: ¥2,279 million
As of December 31, 2017: ¥2,921 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2017	-	0.00	-	0.00	0.00
Fiscal year ending December 31, 2018	-	0.00			
Fiscal year ending December 31, 2018 (Forecast)			-	0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Financial Results Forecast for the Fiscal Year Ending December 31, 2018 (January 1, 2018 to December 31, 2018)

(% indicates changes from the previous corresponding period for the full year.)

	Net sales		Operating profit		Ordinary profit		Profit		Basic earnings per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Full year	230	0.4	(1,400)	-	(1,400)	-	(1,400)	-	(126.29)

(Note) Revision to the financial results forecast announced most recently: No

*** Notes:**

(1) Accounting policies adopted specially for the preparation of quarterly financial statements: No

(2) Changes in accounting policies, changes in accounting estimates and retrospective restatement
1) Changes in accounting policies due to the revision of accounting standards: Yes
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No

Notes on changes in accounting policies

(3) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
June 30, 2018: 11,086,000 shares
December 31, 2017: 11,086,000 shares

2) Total number of treasury shares at the end of the period:
June 30, 2018: - shares
December 31, 2017: - shares

3) Average number of shares during the period:
Six months ended June 30, 2018: 11,086,000 shares
Six months ended June 30, 2017: 9,625,018 shares

* These quarterly financial results are outside the scope of quarterly review by certified public accountants or an audit corporation.

* Explanation of the proper use of financial results forecast and other notes

(Note regarding forward-looking statements, etc.)

The earnings forecasts and other forward-looking statements herein are based on information available to the Company at the time of the release of these materials and certain assumptions deemed reasonable, and do not represent a commitment from the Company that they will be achieved. In addition, actual financial results, etc. may differ significantly due to a wide range of factors. For the assumptions used in forecasting financial results and notes regarding the use of financial forecasts, please see "1. Qualitative Information on Quarterly Financial Results for the Period Under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information" on page 3 of the supplementary material.

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1. Qualitative Information on Quarterly Financial Results for the Period Under Review

(1) Explanation of Business Results

The Japanese economy during the six months ended June 30, 2018 trended toward moderate recovery, backed by improvements in corporate earnings and the employment environment and other factors, but the economic outlook remains uncertain, with instability in share prices and exchange rates, etc., owing partly to external factors such as the sluggish growth of wages and the risk of trade friction between the U.S. and China, caused by the U.S. Trump administration's policies.

Amid these circumstances, the Company endeavored to make management more efficient, and actively expanded its research, development, and licensing activities.

In the pharmaceutical business, the Company promoted research, development and licensing activities, centered on Telomelysin® (OBP-301) virotherapy for cancer and OBP-801. In addition, in the diagnostic business, the Company promoted research, development and licensing activities, centered on TelomeScan (OBP-401/1101). For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

As a result, for the six months ended June 30, 2018, net sales were ¥90,445 thousand (¥19,904 thousand in the same period of the previous year), and operating loss was ¥643,722 thousand (operating loss of ¥509,662 thousand in the same period of the previous year). In addition, the Company recorded interest income of ¥9,116 thousand and other items as non-operating income, and foreign exchange losses of ¥3,942 thousand and other items as non-operating expenses. As a result, ordinary loss was ¥639,994 thousand (ordinary loss of ¥517,038 thousand in the same period of the previous year), and loss was ¥641,822 thousand (loss of ¥518,662 thousand in the same period of the previous year).

Financial results by segment were as follows.

1) Pharmaceutical business

In the pharmaceutical business, the Company recorded joint development revenue from Medigen Biotechnology Corp. (Taiwan; hereinafter "Medigen") in relation to Telomelysin® (OBP-301) virotherapy for cancer and other revenues, and as a result, net sales were ¥86,011 thousand (zero net sales in the same period of the previous year), and operating loss was ¥265,224 thousand (operating loss of ¥211,272 thousand in the same period of the previous year).

2) Diagnostic business

In the diagnostic business, in addition to sales of TelomeScan, a drug for detecting circulating tumor cells (CTCs) in blood, research-related contracted testing revenue was generated from academia, and as a result, net sales were ¥4,434 thousand (net sales of ¥19,904 thousand in the same period of the previous year), and operating loss was ¥93,421 thousand (operating loss of ¥54,125 thousand in the same period of the previous year).

(2) Explanation of Financial Position

Status of Assets Liabilities and Net Assets

Assets at the end of the second quarter of the fiscal year under review were ¥2,808,451 thousand (20.4% decline compared with the end of the previous fiscal year), owing partly to a decline in cash and deposits. Liabilities were ¥518,289 thousand (12.8% decline compared with the end of the previous fiscal year), owing partly to a decline in accounts payable – other. Net assets were ¥2,290,161 thousand (21.9% decline compared with the end of the previous fiscal year), owing to loss incurred and other factors.

(3) Explanation of Financial Results Forecast and Other Forward-looking Information

No revisions have been made to the full year financial results forecasts released on February 9, 2018.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2017	As of June 30, 2018
Assets		
Current assets		
Cash and deposits	2,867,512	1,852,162
Accounts receivable - trade	88,736	52,291
Finished goods	11,807	10,140
Work in process	4,931	5,137
Supplies	1,842	1,447
Advance payments - other	12,645	1,080
Prepaid expenses	51,011	45,098
Accounts receivable - other	6,822	15,843
Consumption taxes receivable	26,116	14,652
Other	285	151
Total current assets	3,071,713	1,998,004
Non-current assets		
Property, plant and equipment		
Buildings	2,794	2,794
Accumulated depreciation	(2,794)	(2,794)
Buildings, net	—	—
Tools, furniture and fixtures	67,313	68,259
Accumulated depreciation	(64,807)	(65,544)
Tools, furniture and fixtures, net	2,506	2,714
Total property, plant and equipment	2,506	2,714
Investments and other assets		
Investment securities	400,194	665,614
Shares of subsidiaries and associates	10,173	101,153
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	11,079	11,045
Lease and guarantee deposits	29,212	28,756
Long-term prepaid expenses	1,223	1,044
Other	19	19
Total investments and other assets	452,002	807,732
Total non-current assets	454,508	810,446
Total assets	3,526,222	2,808,451

(Thousand yen)

	As of December 31, 2017	As of June 30, 2018
Liabilities		
Current liabilities		
Short-term loans payable	93,336	83,336
Lease obligations	9,822	8,270
Accounts payable – other	88,740	48,572
Accrued expenses	10,959	10,991
Income taxes payable	32,826	26,036
Deposits received	3,351	6,492
Total current liabilities	239,035	183,698
Non-current liabilities		
Long-term loans payable	344,440	327,772
Lease obligations	7,140	3,288
Provision for retirement benefits	3,712	3,530
Total non-current liabilities	355,293	334,590
Total liabilities	594,328	518,289
Net assets		
Shareholders' equity		
Capital stock	5,802,444	5,802,444
Capital surplus		
Legal capital surplus	5,794,944	5,794,944
Total capital surpluses	5,794,944	5,794,944
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(8,660,016)	(9,301,839)
Total retained earnings	(8,660,016)	(9,301,839)
Total shareholders' equity	2,937,371	2,295,548
Valuation and translation adjustments		
Valuation difference on available-for-sale securities	(15,786)	(15,696)
Total valuation and translation adjustments	(15,786)	(15,696)
Share acquisition rights	10,309	10,309
Total net assets	2,931,893	2,290,161
Total liabilities and net assets	3,526,222	2,808,451

(2) Quarterly Statements of Income

Six Months Ended June 30

(Thousand yen)

	For the six months ended June 30, 2017	For the six months ended June 30, 2018
Net sales	19,904	90,445
Cost of sales	7	70,009
Gross profit	19,896	20,435
Selling, general and administrative expenses	529,559	664,158
Operating loss	(509,662)	(643,722)
Non-operating income		
Interest income	1,969	9,116
Dividend income	4	4
Other	29	30
Total non-operating income	2,002	9,150
Non-operating expenses		
Interest expenses	1,596	1,480
Foreign exchange losses	7,780	3,942
Total non-operating expenses	9,377	5,422
Ordinary loss	(517,038)	(639,994)
Loss before income taxes	(517,038)	(639,994)
Income taxes - current	1,623	1,828
Total income taxes	1,623	1,828
Loss	(518,662)	(641,822)

(3) Quarterly Statements of Cash Flows

(Thousands of Yen)

	For the six months ended June 30, 2017	For the six months ended June 30, 2018
Cash flows from operating activities		
Loss before income taxes	(517,038)	(639,994)
Depreciation	401	737
Increase (decrease) in provision for retirement benefits	470	(182)
Interest and dividend income	(1,973)	(9,120)
Interest expenses	1,596	1,480
Foreign exchange losses (gains)	7,478	8,972
Decrease (increase) in notes and accounts receivable - trade	61,872	36,445
Decrease (increase) in inventories	2,619	1,857
Decrease (increase) in accounts receivable - other	(7,057)	(42)
Decrease (increase) in advance payments - other	(15,974)	11,565
Increase (decrease) in accounts payable - other	(44,389)	(40,148)
Other, net	(3,054)	16,591
Subtotal	(515,048)	(611,836)
Interest and dividend income received	427	142
Interest expenses paid	(1,653)	(1,502)
Income taxes paid	(3,186)	(3,703)
Net cash provided by (used in) operating activities	(519,460)	(616,900)
Cash flows from investing activities		
Proceeds from withdrawal of time deposits	400,000	600,000
Purchase of investment securities	(55,670)	(356,310)
Purchase of property, plant and equipment	(965)	(1,129)
Payments of long-term loans receivable	—	—
Payments for lease and guarantee deposits	(1,105)	—
Proceeds from collection of lease and guarantee deposits	960	—
Net cash provided by (used in) investing activities	343,218	242,560
Cash flows from financing activities		
Net increase (decrease) in short-term loans payable	—	(10,000)
Proceeds from long-term loans payable	100,000	—
Repayments of long-term loans payable	(11,536)	(16,668)
Repayments of lease obligations	(5,330)	(5,403)
Proceeds from issuance of common shares	955,637	—
Proceeds from issuance of share acquisition rights	3,248	—
Net cash provided by (used in) financing activities	1,042,018	(32,071)
Effect of exchange rate change on cash and cash equivalents	(7,478)	(8,938)
Net increase (decrease) in cash and cash equivalents	858,298	(415,350)
Cash and cash equivalents at beginning of year	1,418,993	1,922,454
Cash and cash equivalents at end of period	2,277,291	1,507,104

(4) Notes to Quarterly Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Notes in the case of significant changes in shareholders' equity)

There is no relevant information.

(Changes in accounting policies)

The "Practical Solution on Transactions Granting Employees and Others Stock Acquisition Rights, which Involve Considerations, with Vesting Conditions" (Practical Issues Task Force No. 36, January 12, 2018; hereinafter "PITF No. 36") and other guidelines have been applied since April 1, 2018 and transactions granting employees and others stock acquisition rights which involve consideration with vesting conditions are accounted for in accordance with the "Accounting Standard for Share-based Payment" (ASBJ Statement No. 8, December 27, 2005), etc.

However, the Company adopts PITF No. 36 in accordance with the transitional treatment specified in Article 10 (3) thereof and continually uses the previous accounting treatment for transactions granting employees and others stock acquisition rights which involve consideration with vesting conditions before the day on which PITF No. 36 was applied.

(Segment information, etc.)

[Segment information]

I. For six months ended June 30, 2017

1. Information on net sales and profit (loss) by reportable segment

(Thousand yen)

	Reportable segment			Adjustment (Note 1)	Amount recorded in Quarterly Financial Statements (Note 2)
	Pharmaceutical Business	Diagnostic Business	Total		
Net sales					
Net sales to outside customers	—	19,904	19,904	—	19,904
Inter-segment net sales or transfers	—	—	—	—	—
Total	—	19,904	19,904	—	19,904
Segment loss	(211,272)	(54,125)	(265,397)	(244,264)	(509,662)

(Notes) 1. The adjustment to segment loss is a corporate expense that has not been allocated to reportable segments, and is mainly expenses related to administrative departments that do not belong to any reportable segment.

2. Segment loss has been adjusted with operating loss in quarterly financial statements.

2. Information on impairment loss of non-current assets or goodwill for each reportable segment, etc.

There is no relevant information.

II. For six months ended June 30, 2018

1. Information on net sales and profit (loss) by reportable segment

(Thousand yen)

	Reportable segment			Adjustment (Note 1)	Amount recorded in Quarterly Financial Statements (Note 2)
	Pharmaceutical Business	Diagnostic Business	Total		
Net sales					
Net sales to outside customers	86,011	4,434	90,445	—	90,445
Inter-segment net sales or transfers	—	—	—	—	—
Total	86,011	4,434	90,445	—	90,445
Segment loss	(265,224)	(93,421)	(358,645)	(285,076)	(643,722)

(Notes) 1. The adjustment to segment loss is a corporate expense that has not been allocated to reportable segments, and is mainly expenses related to administrative departments that do not belong to any reportable segment.

2. Segment loss has been adjusted with operating loss in quarterly financial statements.

2. Information on impairment loss of non-current assets or goodwill, etc., for each reportable segment

There is no relevant information.

(Significant subsequent events)

1. Following the resolution by the board of the Company on 29 June, 2018, the 17th Series Stock Acquisition Rights by third party allotment were issued on 17 July, 2018.

2. During the period from 1 July 2018 to 31 July 2018, capital stock and legal capital surplus increased by ¥220,139 thousand, to ¥6,022,583 thousand and ¥6,015,083 thousand respectively, due to the new share issues upon the exercise of the 17th Series Stock Acquisition Rights.

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the six months ended June 30, 2018 totaled ¥308,810 thousand, including ¥216,843 thousand for the pharmaceutical business, ¥80,855 thousand for the diagnostic business, and ¥11,111 thousand shared by both segments. Furthermore, the status of research and development activities during the fiscal year under review is as follows.

(1) Research and development structure

As of June 30, 2018, 13 persons belonged to research and development departments, equivalent to 40.6% of the total number of employees.

(2) Research and development and business activities

The Company promoted research and development, and business activities centered on the following projects.

(a) Pharmaceutical business

1) Activities related to Telomelysin® (OBP-301) virotherapy for cancer

Five clinical trials are simultaneously in progress for Telomelysin® (OBP-301) virotherapy for cancer: i) investigator-initiated clinical study in combination with radiation therapy for esophageal cancer; ii) Phase I sponsor-initiated clinical trial in combination with radiation therapy for esophageal cancer; iii) investigator-initiated clinical trial in combination with pembrolizumab, an anti-PD-1 antibody, for solid tumors; iv) Phase II for melanoma; and v) Phase I/II for hepatocellular cancer.

In the above i) "investigator-initiated clinical study in combination with radiation therapy for esophageal cancer" where the safety and efficacy of Telomelysin® in combination with radiation therapy are evaluated for esophageal cancer patients refractory to resection through surgery and definitive chemoradiotherapy, enrollment has been completed with a total of 13 patients. At a meeting of the Japanese Society of Medical Oncology held in July 2018, Dr. Toshiyoshi Fujiwara of the Department of Gastroenterological Surgery Transplant and Surgical Oncology, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences gave a presentation that "treatment effect on the primary tumor was complete response (CR) in 8 among 13 patients and serious adverse events have not been reported."

Regarding ii) "Phase I sponsor-initiated clinical trial in combination with radiation therapy for esophageal cancer" whose target population is similar to those for "investigator-initiated clinical study in combination with radiation therapy for esophageal cancer," in March 2018, the Company received a report from the Data and Safety Monitoring Committee confirming the safety of Telomelysin® in the low-dose administration patient cohort and began to administer it to the higher-dose patient cohort. This trial is being conducted at Okayama University Hospital and National Cancer Center Hospital East, and the Company intends to administer it to up to 12 patients.

This Phase I clinical trial is scheduled to complete in 2018 and the Company started discussion about a policy and implementation guidelines of the Phase II/III clinical trials with the Pharmaceuticals and Medical Devices Agency (PMDA), an advisory body to the Ministry of Health, Labour and Welfare. In July 2018, the Company held a workshop for closely discussing implementation details of the Phase II/III clinical trials with domestic esophageal cancer specialists. Furthermore, the Company established a cooperative structure with the Japan Esophageal Society and is steadily preparing to begin the Phase II/III clinical trials.

Regarding iii) "investigator-initiated clinical trial in combination with an anti-PD-1 antibody for various types of solid tumors" where combination with anti-PD-1 immune checkpoint inhibitor pembrolizumab is evaluated for various types of solid tumors centered on esophageal cancer, administration to patients began in December 2017 and up to 28 patients will be administered in the future. In addition, at the American Society of Clinical Oncology (ASCO) meeting held in Chicago, the U.S. in June 2018, the protocol of this clinical trial was presented by the Department of Experimental Therapeutics, National Cancer Center Hospital East.

Regarding iv) "Phase II clinical trial for melanoma," administration to unresectable or metastatic melanoma patients began in July 2017. This trial will be conducted at multiple facilities in the U.S., including the Atlantic Health System, and the Company plans to conduct the trial with up to 50 patients.

Regarding v) Phase I/II clinical trial for hepatocellular cancer, the results of single-dose study in 12 patients in cohorts 1 to 4 which was completed at Pusan National University (South Korea) and National Taiwan University (Taiwan) as trial sites have been compiled and the study for cohort 5 involving repeated administration is being conducted. The Company plans to complete the Phase I clinical trial in 2018.

In addition to the above, preparation for investigator-initiated clinical trials in combination with an anti-PD-1 antibody for advanced esophageal cancers is underway, centered on Cornell University in the U.S. Furthermore, Jiangsu Hengrui Medicine Co., Ltd. (China), a licensee of Telomelysin in China, is preparing to apply to the Chinese government to conduct clinical trials.

From the perspective of intellectual property rights, in May 2018, the Company entered into a license agreement with Stabilitech Biopharma Limited (head office: U.K.; hereinafter "Stabilitech") in the U.K. for the purpose of introducing storage and stability formulation technology to improve the usability of Telomelysin®. The Company aims to realize easier and simpler handling of Telomelysin® by using Stabilitech's virus stability platform technology which was not possible in the past and formulation patent of Telomelysin® will be extended to up to March 2031.

Also in the future, the Company will further and widely accumulate clinical data of Telomelysin® in the field of esophageal cancer in Japan and the U.S. to differentiate its target diseases from those for other "oncolytic virus therapies" and thereby intends to obtain a license agreement with major pharmaceutical companies.

2) Other activities related to the pharmaceutical business

Phase I clinical trials are underway in the U.S. for OBP-801, a novel epigenetic anticancer drug licensed from Astellas Pharma, for patients with advanced solid tumors that show resistance to other forms of treatment. However, dose limiting toxicity was observed in two of six patients in cohort 3 and thus study enrollment of new patients was stopped. The Company is currently considering a change of protocol including the possibility of combination with other drugs. Furthermore, the Company is conducting joint research with a research group from the Ophthalmology Department of the Kyoto Prefectural University of Medicine in the ophthalmic field as a new area of indication and in July 2018, applied for a patent regarding the indication of OBP-801 in the ophthalmic field.

The Company has lowered the development priority of the novel anti-HIV drug, OBP-601 (Censavudine), taking into consideration the current status of the anti-HIV drug market, and is currently looking for development partners.

In addition to the above, the Company is also actively focusing on joint research with academia and information exchange with pharmaceutical companies, in order to create pipeline products from new pharmaceutical development seeds, including a novel drug for treating hepatitis B, and a next-generation Telomelysin candidate. In addition, in February 2018, the Company made an investment in Unleash Immuno Oncolytics, Inc. (the U.S.; hereinafter "Unleash"), a U.S. biotech venture specializing in the development of novel oncolytic adenoviruses, and also received common shares of Precision Virologics Inc. (the U.S.) held by Unleash. The Company intends to expand its future business opportunities by strengthening its relationship with these two companies, which have a pipeline of genetically modified adenoviruses and world-leading technology, expanding its platform for "cancer virotherapy utilizing genetically-modified adenoviruses," led by Telomelysin®, which the Company is researching and developing in Japan and overseas, and promoting a pipeline of products for "cancer and serious infectious diseases."

The status of clinical trials in the Pharmaceutical Business is as follows.

Development code	Trademark or name	Indication	Development region	Development stage
OBP-301	Telomelysin® (Virotherapy for cancer)	Esophageal cancer In combination with radiation therapy	Japan	Phase I
		Melanoma (skin cancer)	U.S.	Phase II
		Hepatocellular cancer	South Korea and Taiwan	Phase I/II
		Various types of solid tumor In combination with anti-PD-1 antibody	Japan	Phase I
		Esophageal cancer In combination with radiation therapy	Japan	Clinical study
OBP-801	Epigenetic anticancer drug	Various types of solid tumor	U.S.	Phase I
OBP-601	Censavudine (anti-HIV drug)	HIV infection	Europe, America and others	Phase IIb (complete)

(b) Diagnostic business

Regarding TelomeScan, a drug for detecting cancer, the Company and Juntendo University is continuing joint research in the field of circulating tumor cells (CTC) in the blood from November 2017, in order to automate the CTC detection system and expand the range of clinical indications. This research is being conducted as a cross-departmental research project at cancer-related departments of Juntendo University. In addition, the Company entered into a joint research agreement with Shimane University regarding the field of female-specific cancer under which the CTC inspection system with higher sensitivity and specificity will be established through detection of genes of human papillomavirus from CTCs in cervical cancer patients. As such, by offering a service that can detect cervical cancer from blood alone, the Company aims to commercialize a cancer detection system with lower psychological stress in patients. Liquid Biotech USA, Inc. (the U.S.), to which rights were granted in the North American territory, has begun preparing for clinical trials using the CTC detection technology in the field of lung cancer, centered on the University of Pennsylvania. Furthermore, Wonik Cube Corp. (South Korea) is preparing for virus manufacturing of TelomeScan, as it aims to obtain CTC detection approval in South Korea. Furthermore, in July 2018, the patent application in relation to OBP-1101 (TelomeScan F35) was registered in Europe. In the future, the Company plans to continue actively proposing the utilization of TelomeScan in liquid biopsy for identifying cancer cells to operating companies and academia, and expanding new license agreements and sales of the cancer detection drug TelomeScan.