

INTERIM REPORT

JANUARY 2019 - JUNE 2019

Q2

INCREASE SURGICAL PRECISION STARTING
BY LIGHTING UP THE CANCER

2019

FluoGuide's innovative solution reduces suffering for the cancer patients and increases the likelihood of cure, as well as reducing costs for the health care system

FluoGuide

FluoGuide A/S | email : info@fluoguide.com | Phone: +45 31 3143 73 | www.fluoguide.com

"I am very pleased that promising data on the benefit of FG001 in glioblastoma and pancreatic cancer have been selected for presentation at WMIC, an important society within molecular imaging and surgical guidance. Optical targeting of uPAR is likely to become of benefit to patients and surgeons in several cancer indications and this presentation is an important event to highlight the technology's potential."



Andreas Kjær

Responsible for research, FluoGuide A/S

TABLE OF CONTENT

Summary	3
CEO has the floor	4
FluoGuide	5
Financial development	8
Miscellaneous	9
Submission of Q2 report	10
Income statement	11
Balance sheet	12
Change in equity	13
Cash flow analysis	14

SUMMARY

The Board of Directors and CEO of FluoGuide hereby publish the Q2 report of 2019

In this interim report, the following definitions apply, unless stated otherwise: The “Company” or “FluoGuide” refers to FluoGuide A/S with CVR number 39296438. The Company is not part of a group and does not have any subsidiaries. FluoGuide was formed on 30 January 2018 but had very limited business activities during its first fiscal year 2018. Amounts within brackets corresponds to comparable period in the previous year.

FluoGuide did not have any revenue for the reported period, and the Company had a negative result. This follows the plan outlined in the IPO prospectus and is conventional from an early stage life science company. The financial result is as expected, and it is the Board’s opinion that FluoGuide has a relatively short time to market compared to many other life science companies. The Company is continuing its work on preparing FG001 for the first clinical study to be able to improve the outcome for patients with cancer undergoing surgery.

Summary	Q2 2019	Q2 2018	H1 2019	H1 2018
	01/Apr/19	01/Apr/18	01/Jan/19	30/Jan/18
(KDKK)	30/Jun/19	30/Jun/18	30/Jun/19	30/Jun/18
Net Revenue	0	0	0	0
Operating result	-1,343	0	-1,785	0
Net result	-1,540	0	-2,493	0
Cash and bank	11,259	1	11,259	1
<i>Result per share (DKK) *)</i>	-0.23	0.00	-0.44	0.00
<i>Solidity (%) **)</i>	94%	100%	94%	100%

***) Result per share (DKK per share):** Operating result divided by the average number of shares during the period. Total number of shares as of 30 June 2019, amounted to 7,224,274 shares (105,500). The total number of shares at the beginning of the period amounted to 4,000,000 shares (105,500). The average number of shares for the second quarter 2019 was 6,651,070 (105,500). The Company was converted to a public company and increased its shares in Q2 2019.

****) Solidity:** Total equity divided by total capital and liability.

HIGHLIGHTS DURING Q2

- FluoGuide conducts a successful IPO that initially provides the Company approx. DKK 15.9 million and more than 1,000 new shareholders.
- The trading in FluoGuide’s shares and warrants commences at Spotlight Stock Market.
- FluoGuide announces registration of ownership to the key patent family, which was acquired by the Company prior to its IPO in April/May 2019. The patent family was issued nationally in the USA in 2018 and is valid until 2034.

HIGHLIGHTS AFTER Q2

- The Company announces that new data confirms FG001’s potential in guiding surgical removal of glioblastoma. The data will be presented at the World Molecular Imaging Congress 2019 (WMIC) in Montreal, on September 4-7.
- FluoGuide announces that data, confirming FG001’s potential in also guiding surgical removal of pancreatic cancer, will be presented at the World Molecular Imaging Congress 2019 (WMIC) in Montreal, on September 4-7.

CEO HAS THE FLOOR

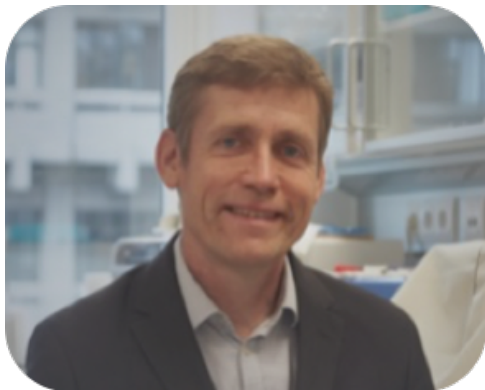
We are continuing our journey to transform cancer treatment, by developing surgical solutions that are expected to reduce the suffering of patients and increase the likelihood of cure. This first half-year of 2019 has offered many important events, and I would like to take this opportunity to comment on some of these.

During the second quarter we conducted a share issue of units prior to our listing on Spotlight Stock Market. As you may know, the IPO was significantly oversubscribed with a total subscription ratio of approx. 244 percent. We value the trust that we have been shown and we work hard on delivering on the milestones, advancing our first product FG001 towards the market and a broad clinical use.

Before FG001 can be tested in humans, its safety has to be established in non-clinical toxicity studies to the satisfaction of both FluoGuide and health care authorities. The required non-clinical safety studies are typically conducted by specialized contract laboratories, which is supported by a large share of the proceeds from the IPO. It is a stepwise process that was initiated in Q2 2019. We have worked very diligently to design the non-clinical safety studies, which has provided two avenues for establishing the safety of FG001. One avenue will be as outlined in our plans and the other avenue will result in a delay of one quarter to deliver the first result from the first clinical study with FG001, assuming slots are available at our vendors. A study guiding us to decide which of the two avenues to select is ongoing. The result is known to us in Q4 2019 and we can then confirm or update the anticipated timing for presenting the first result of the clinical study with FG001. Should we decide to proceed with the alternative avenue, I believe it is important to emphasize that no other milestones will be affected, including but not limited to, partnering, compassionate use sales or anticipated approval of FG001 for broad commercial sales.

Consultation with health authorities is being prepared in order to secure their feedback is taken into consideration prior to the submission of the application for the first clinical study with FG001.

We are pleased to have fulfilled all set targets for H1 2019. We have initiated the process to manufacture FG001 in a quality that is satisfying FluoGuide for use in the first clinical – the proof-of-concept phase I/IIa study. It is, like the non-clinical safety studies, a step-wise process where first a small amount of material is produced, then analyzed and documented before it is scaled up to larger quantities.



The manufacturing of FG001 requires very large infrastructure investment of highly specialized equipment, why this is also typically out-sourced to specialized companies. We are pleased to have identified good quality partners preparing FG001 for human use, in line with our CMC targets.

FG001 is a product with significant potential for the health care industry, since the product is not limited to a single cancer indication. The initial priority indication for FG001 is glioblastoma. Good preclinical results are also available in head & neck cancer and pancreatic cancer. FG001 was tested again in a glioblastoma animal model with human cancer that repeatedly demonstrated that FG001 binds to and lights up glioblastoma brain cancer. We believe FG001 has the potential to improve the surgical outcome of several different types of cancer providing the potential to help thousands of patients with cancer. Two abstracts were submitted for presentation at the World Molecular Imaging Congress 2019 (WMIC) and after end of Q2 they were also accepted. One of the presentations will highlight FG001's potential for guiding glioblastoma surgery, whereas the other presentation will demonstrate the benefits of using it in pancreatic cancer surgery.

Another target that we fulfilled was initiation of partnering discussions, in order to release FG001's full potential and secure commercial validation of the product. It is our ambition to establish our first commercial partnership with FG001 in H2-2020 following the phase I/II result. However, in order to be able to achieve this aim we need to establish a dialogue much earlier. We have received contacts from potential partners and have started to reach out to others in order to prepare this target in H2 2020.

Our participation in the Grand Solution research grant is also progressing accordingly to plans – initiate formal development of a second product no later than at completion of the phase I/IIa study with FG001.

Cancer is a severe disease that affects everyone, directly or indirectly, and we feel very proud that FluoGuide is dedicated to contributing to transform cancer surgery – potentially improving the life for patients with cancer, while as well reducing health care costs. I would like to thank all shareholders for their trust and all others for their hard work in improving the precision in cancer surgery to the benefit of patients and society. We are very excited about the journey ahead.

“We are very pleased with the successful IPO and to see that the potential of uPAR as target for guiding cancer surgery is unfolding earlier than expected as exemplified with the two presentations at WMIC”

Morten Albrechtsen - CEO, FluoGuide A/S

FG001

FluoGuide provides solutions for maximizing surgical outcome through intelligent targeting.

FluoGuide A/S (Spotlight Stock Market: FLUO) provides solutions for maximizing surgical outcome through intelligent targeting. FluoGuide's first product, FG001, improves precision in cancer surgery by lighting up the cancer and its invasive growth into the surrounding tissue. FG001 is made of a cancer targeting molecule linked to a fluorophore. FluoGuide's products are expected to reduce the suffering of patients and increase the likelihood of cure. They can also reduce costs for the health care system and thus benefit society. Currently, FluoGuide focuses on demonstrating the effect of FG001 in patients by conducting a human proof-of-concept clinical study.

FG001

FG001, FluoGuide's first product, lights up the cancer and its invasive growth into the surrounding tissue. It helps the surgeon remove the entire tumor during surgery and increases the chance for complete cure of the patient. The task for the surgeon is simply to "turn the lights on and see the entire tumor". The solution helps surgeons remove a minimal amount of normal tissue while also reducing the risk of leaving cancer tissue behind. This reduces the suffering of the patient and increases the likelihood of cure, and also reduces costs for the health care system. FG001 is currently prepared for a proof-of-concept clinical study (Phase I/IIa).

FG001 is an innovative and patentable product that lights up the cancer and its invasive growth into the surrounding tissue.

How it works

FG001 is made of a cancer targeting molecule linked to a fluorophore. The targeting molecules bind to the urokinase-type plasminogen activator receptor ("uPAR"), which is extensively expressed by cancer cells. FluoGuide utilizes this fact in the development of FG001 – a fluorescing molecule that binds to uPAR on the cancer cells.

Fits into current work flow

FG001 is injected into a vein of the patient during anesthesia, and therefore fits into the hospital workflow when surgery is performed. Furthermore, the use of FG001 is equipment independent, which means that surgeons are not restricted by available equipment; the present equipment in the surgical operating room remains available and is compatible with FG001.

A product with significant potential

FluoGuide's focus for the initial clinical development of FG001 is glioblastoma (aggressive form of brain cancer) even though the potential of the product goes beyond a single indication. Glioblastoma has high priority due to its large unmet medical need. Essentially every patient with glioblastoma has a cancer expressing uPAR.

Preclinical studies have confirmed the effect of FG001 in glioblastoma, pancreatic cancer and head and neck cancer. However, as uPAR is extensively expressed in most aggressive cancer types, also including breast cancer and colorectal cancer, FG001 has the potential to demonstrate a clinical benefit in more indications than those mentioned.

FG001's route to the market

Active fluorescent targeting products require that the national health authorities approve the documentation of safety and efficacy. Broad commercialization of FluoGuide's products is contingent on such approval, which in USA and Europe is granted by FDA and EMA, respectively. Active fluorescent targeting products are regulated by guidelines for pharmaceutical drugs (Medicinal Products).

Although both the targeting molecule and the fluorophore have demonstrated to be well tolerated in humans, FluoGuide has initiated the production of high quality FG001 in a step vice process and in parallel initiated the documentation of the safety of before administering it to humans in a clinical study.

Early commercialization is important for patients

FluoGuide's ambition for FG001 is to initiate compassionate use sales (a treatment option where a not yet approved medicine is allowed to be used under strict conditions because withholding it would be considered unethical) by the end of 2020, provided that a positive result is obtained from the proof-of-concept clinical study with FG001. FluoGuide considers early commercialization to be of utmost importance, since FG001 has the potential of improving the surgical outcome for thousands of patients with cancer every year.

Patent protection

The patent family protecting FG001 is owned by FluoGuide and is issued in the USA. The protection will last until 2034.

PATENT NAME: uPAR targeting peptide for use in peroperative optical imaging of invasive cancer
PATENT NUMBER: WO/2016/041558A1
TYPE: Issued in USA and pending in EU.
FILED: 17/Sep/2014
EXPIRES: 16/Sep/2034
OWNER: FluoGuide A/S

The market for FG001

FluoGuide is initially focusing on glioblastoma (an aggressive form of brain cancer). A total of 60,000 patients are diagnosed with glioblastoma annually in the EU and USA, and approximately 8-12% of the patients are children. The prognosis for individuals with glioblastoma is very poor. Approximately 50% of the patients die within 14 months, and only 5% are alive five years after the diagnosis. Precise removal of glioblastoma tumors is very difficult and local recurrence is frequent.

Since uPAR is also extensively expressed in other solid cancers, FluoGuide has the ambition to expand its business to other solid cancers. Several malignant cancers are treated primarily with surgical tumor resections, and in e.g. the UK approximately 45% of all patients undergo surgery as primary treatment. This underlines the significant potential of FG001, as its potential goes far beyond glioblastoma. FG001 could be used for other types of cancer indications as well, enhancing the effectiveness of surgery for cancer indications such as breast or colorectal cancer which to a high degree are treated with surgical tumor resections. FluoGuide sees a huge potential for FG001 in improving the lives of patients with cancer.

FluoGuide

FluoGuide A/S provides solutions for maximizing surgical outcome through intelligent targeting. FG001 is the lead product of FluoGuide but the potential of FluoGuide goes beyond FG001 and cancer surgery.

uPAR – broadly expressed, highly selective and perfectly delineating cancer.

Robust scientific foundation on uPAR - a perfect target to guide surgical removal of cancer

uPAR is a perfect target to delineate cancer from normal tissue. It is a protein present on the surface of cancer cells. uPAR is directly correlated to the aggressiveness of the cancer. More importantly, uPAR is particularly expressed in the aggressive invasive front of the cancer – the more uPAR, the more invasive the cancer. This means that lighting up cells expressing uPAR is a perfect help for the surgeon to delineate the cancer from normal tissue.

uPAR is extensively expressed in most solid cancers, including glioblastoma, breast, colorectal and lung cancer. uPAR is a highly relevant target for more than 50% of all cancers undergoing surgical removal, and it is therefore an attractive target for guiding the surgeons in removal of several types of cancer, maximizing the surgical outcome for patients and society.

Pipeline

The Innovation Fund Denmark has awarded a Grand Solution grant with the title: “FluoGuide: optical probe to guide cancer surgeons”. FluoGuide’s Head of Scientific Advisory Board, Andreas Kjaer, is the project leader of the grant which will run until the end of 2021, with a total of EUR 1.39 million being allocated to the project. FluoGuide has a first right to new inventions arising from the project within its field.

Partnerships

In parallel with the development of FG001, FluoGuide will explore commercial partnerships to accelerate its value creation. FluoGuide will finance the development of FG001 until completion of the proof-of-concept clinical study. The Company thereafter plans to enter into a commercial partnership securing, at least partly, funding for further development and to unfold the full potential of FG001. Partnerships are also being investigated to explore new uses of FG001, new products, and commercialization in selected geographic regions.

Market for maximizing surgical outcome

The market for surgery is huge and surgical costs account for more than 5% of the GDP (Gross Domestic Product) in the USA and Europe. FluoGuide’s products will be used in hospitals and paid for by patients’ insurance and/or by governments through hospitals, as well as by patients themselves. FluoGuide’s customers are hospitals and surgeons. The customers are highly concentrated and therefore provide an opportunity to be served directly by FluoGuide for selected geographic regions.

The team

FluoGuide has a strong management team representing the entire value chain, from discovery of imaging products and development of health care products to international commercialization of health care solutions.

FluoGuide has an experienced Board of Directors representing diverse skill sets and networks to guide FluoGuide’s ambitious value creation.

Outlook for FluoGuide

FluoGuide’s first product – FG001 – can help 60,000 patients with glioblastoma in USA and Europe alone.

uPAR targeted products for guiding cancer surgery can help many patients with cancer undergoing surgery every year. Realizing this huge potential, FluoGuide works on accelerating the development of FG001 in indications beyond glioblastoma as well as developing even brighter and more selective products targeting uPAR, in order to develop FluoGuide into a leading position in guiding cancer surgery.

uPAR targeting – a potential help for a significant share of patients undergoing surgery for removal of cancer.

FINANCIAL DEVELOPMENT

Operating income and operating results Net revenue amounted to DKK 0 (0) and the operating result was KDKK -1,540 (0) in Q2 2019. The operating result was as expected as the Company is currently conducting development activities.

Balance sheet and solidity

The total equity at 30 June 2019 was KDKK 12,422 (1) as the operating result exceeded share capital The solidity as per 30 June 2019 was 94% (100).

Cash flow and investments

The cashflow and investments were as expected. The total cash flow was KDKK 6,543 (1). There were no investments during the period.

The share

The shares in FluoGuide were listed at Spotlight Stock Market on 7 May 2019. The ticker is FLUO and the ISIN code is DK0061123312. The total number of shares as per 1 April 2019, amounted to 4,000,000 (105,500). During Q2 2019, FluoGuide converted the bridge loan and raised capital in the IPO resulting in 7,224,274 (105,500) shares by 30 June 2019. The average number of shares during Q2 2019 amounted to 6,651,070 (105,500). Every share equals the same rights to the Company's assets and results.

Warrants

The warrants of series TO 1 in FluoGuide were listed at Spotlight Stock Market on 7 May 2019. The ticker is FLUO TO1 and the ISIN code is DK0061138773. In total, there is a total of 1,074,758 outstanding warrants. Each warrant entitles the holder the right to subscribe for one (1) new share in FluoGuide at a subscription price of DKK 5.95 per share during the exercise period 16 April – 7 May 2020. The warrants can provide the Company a total of DKK 6,394,810.10 if all warrants are exercised.

MISCELLANEOUS

Shareholders after the IPO (Shares)	Number of shares	Votes and capital
Life Science IVS *	2,124,891	29.4%
Wexotec ApS **	1,487,394	20.6%
Grethe Nørskov Rasmussen ***	254,218	3.5%
Arne Ferstad ****	254,218	3.5%
PME Holding ApS *****	112,577	1.6%
Micaela Sjøkvist ****	57,678	0.8%
Shomit Ghose ****	39,810	0.6%
Others shareholders	2,893,488	40.1%
TOTAL	7,224,274	100.0%

* *Life Science IVS is a wholly owned company by Board Member and Head of the Scientific Advisory Board Andreas Kjaer.*

** *Wexotec ApS is a wholly owned company by CEO Morten Albrechtsen.*

*** *Management.*

**** *Member of the Board of Directors.*

***** *PME Holding Aps is a wholly owned company by Board member Peter Mørch Eriksen.*

FINANCIAL CALENDER

January - September 2019 (Q3): 30 November 2019

Year-end report 2019: 28 February 2020

ACCOUNTING POLICY

The financial statements for 2018 of FluoGuide are prepared in accordance with International Financial Reporting Standards as adopted by the EU and further requirements in the Danish Financial Statements Act for annual reports of class B companies. For further information on accounting policies, please see the Annual Report of 2018.

This interim report has been prepared using unchanged accounting policies for recognition and measurement as the Annual Report for 2018.

OPERATIONAL RISKS AND UNCERTAINTIES

The risks and uncertainties that FluoGuide's operations are exposed to are summary related to factors such as development, competition, permissions, capital requirements, customers, suppliers/manufacturers, currencies and interest rates. During the current period, no significant changes in risk factors or uncertainties have occurred. For more detailed description of risks and uncertainties, refer to the prospectus published in April 2019. The prospectus is available on FluoGuide's website: www.fluoguide.com

AUDITOR'S REVIEW

The Q2 report has not been reviewed or audited by FluoGuide's auditor.

SUBMISSION OF Q2 REPORT

The Board of Directors hereby certify that the Q2 report provides a true and fair view of the Company's business.

Copenhagen
30 August 2019
The Board of Directors

INCOME STATEMENT

Income Statement ('000 DKK)	Q2 2019		Q2 2018		H1 2019		H1 2018		2018	
	01/Apr/19	30/Jun/19	01/Apr/18	30/Jun/18	01/Jan/19	30/Jun/19	30/Jan/18	30/Jun/18	30/Jan/18	31/Dec/18
Revenue	0	0	0	0	0	0	0	0	0	0
Other operating income	0	0	0	0	0	0	0	0	0	0
Other operating expenses	-792	-792	0	0	-1,785	-1,785	0	0	0	-52
Staff expenses	-552	-552	0	0	-919	-919	0	0	0	0
Operating loss before net financials	-1,343	-1,343	0	0	-1,785	-1,785	0	0	0	-52
Financial costs	-506	-506	0	0	-1,018	-1,018	0	0	0	-1
Loss before tax	-1,850	-1,850	0	0	-2,803	-2,803	0	0	0	-53
Tax on loss for the period	310	310	0	0	310	310	0	0	0	0
Net loss for the period	-1,540	-1,540	0	0	-2,493	-2,493	0	0	0	-53
Other comprehensive income for the period, net of	0	0	0	0	0	0	0	0	0	0
Total comprehensive income	-1,540	-1,540	0	0	-2,493	-2,493	0	0	0	-53

BALANCE SHEET

Balance Sheet (‘000 DKK)	Q2 2019 30/Jun/19	Q2 2018 30/Jun/18	H1 2019 30/Jun/19	H1 2018 30/Jun/18	2018 31/Dec/18
Assets					
Total non-current assets			12	0	0
Tax receivables			310	0	0
Other receivables			74	0	0
Prepayments			768	0	17
Cash at bank			11,259	1	59
Total current assets			12,411	1	75
Total assets			12,422	1	75
Equity and liabilities					
Equity					
Share capital			722	0	50
Share premium			13,516	1	0
Retained earnings			-2,536	0	-43
Total equity			11,702	1	7
Liabilities					
Total long term liabilities			0	0	0
Convertible loan			0	0	0
Trade payables			538	0	68
Other payables			182	0	0
Total current liabilities (short-term)			720	0	68
Total liabilities			720	0	68
Total equity and liabilities			12,422	1	75

The figures for Q2 are identical with the figures for H1 and therefore not shown.

CHANGE IN EQUITY

Change in Equity: Q2 2019 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Apr/19	400	50	-997	-547
				0
Paid in capital	206	9,993		10,199
Capital contribution	116	5,645		5,761
Costs relating to contribution		-2,172		-2,172
Net result Q2			-1,540	-1,540
30/Jun/19	722	13,516	-2,536	11,702

Change in Equity: Q2 2018 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Apr/18	1	0	0	1
				0
Paid in capital	0	0		0
Capital contribution				0
Costs relating to contribution		0		0
Net result Q2			0	0
30/Jun/18	1	0	0	1

Change in Equity: H1 2019 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
01/Jan/19	50	0	-43	7
Paid in capital	556	10,043		10,599
Capital contribution	116	5,645		5,761
Costs relating to contribution		-2,172		-2,172
Net result H1			-2,493	-2,493
30/Jun/19	722	13,516	-2,536	11,702

Change in Equity: H1 2018 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
30/Jan/18	0	0	0	0
Paid in capital	1			1
Capital contribution				0
Costs relating to contribution		0		0
Net result H1			0	0
30/Jun/18	1	0	0	1

Change in Equity: 2018 (KDKK)	Share-capital	Share Premium	Retained earnings	Shareholders equity
30/Jan/18	0	0	0	0
Paid in capital	50			50
Capital contribution	0		15	15
Costs relating to contribution			-5	-5
Net result 2018			-53	-53
31/Dec/18	50	0	-43	7

CASH FLOW ANALYSIS

Cash flow (‘000 DKK)	Q2 2019	Q2 2018	H1 2019	H1 2018	2018
	01/Apr/19 30/Jun/19	01/Apr/18 30/Jun/18	01/Jan/19 30/Jun/19	30/Jan/18 30/Jun/18	30/Jan/18 31/Dec/18
Loss before tax	-1,850	0	-2,803	0	-53
Financial expenses, reversed	506	0	1,018	0	1
Change in working capital	-103		-173		52
Cash flow from operating activities before net	-1,447	0	-1,959	0	0
Financial expenses paid	-26		-58		-1
Cash flow from operating activities	-1,473	0	-2,016	0	-1
Cash flow from investing activities	-12		-12		
Cash capital increase	10,199	0	10,599	1	1
Contribution					64
Convertible loan			4,801		
Transaction cost, cash capital increase	-2,172		-2,172		-5
Cash flow from financing activities	8,027	0	13,228	1	60
Total cash flow from the period	6,543	0	11,200	1	59
Cash, beginning of the period	4,717	1	59	0	
Cash, end of the period	11,259	1	11,259	1	59



FluGuide

www.fluguide.com