SuperGen Reports 2009 Second Quarter Financial Results

DUBLIN, Calif.--(BUSINESS WIRE)--Jul. 27, 2009-- SuperGen, Inc. (NASDAQ:SUPG) today reported financial results for the second quarter and six months ended June 30, 2009.

Total revenues for the 2009 second quarter were $6.0 million, compared with $8.1 million for the same prior year period. Total revenues for the 2009 second quarter and same prior year period consisted entirely of royalty revenue. The decline in royalty revenue is primarily due to lower quarterly product sales reported by Eisai resulting from certain third party wholesalers adjusting their near-term inventory purchases. Royalty revenue is earned pursuant to the license agreement entered into with MGI PHARMA (acquired by Eisai Co., Ltd. in January 2008) during 2004, which granted MGI PHARMA exclusive rights to the development, manufacture, commercialization and distribution of *Dacogen*® (decitabine) for Injection. The Company recognizes royalty revenue when it is received.

SuperGen President & CEO, Dr. James S. J. Manuso, commented, “during the second quarter we continued to manage our cash conservatively, and we ended the quarter with $91.1 million in unrestricted cash, cash equivalents and current and non-current marketable securities. We remain debt-free, we will not access the public markets during 2009, and we project a basic non-GAAP cash burn in a range from $250,000 to $1.75 million for 2009. Our two clinical-stage drugs, MP-470, and SGI-1776, are advancing in Phase 1b and Phase I, respectively, and, on July 21, we hired a new Chief Medical Officer, Mohammad Azab, M.D., M.Sc., MBA, to lead our clinical and regulatory efforts.”

Excluding gain on sale of products, total operating expenses for the 2009 second quarter were $8.7 million, compared with $11.0 million for the same prior year period. The primary reasons for the decrease in operating expenses for the 2009 second quarter were lower research and development costs due to changes in the timing of costs incurred for product development activities and a reduction in general and administrative expenses due to lower general corporate expenses and the elimination of costs resulting from the cessation of our European operations in the prior year. Stock-based compensation expense, which is included in operating expenses, was $505,000 for the 2009 second quarter compared with $670,000 for the same prior year period.

There was no gain on sale of products in the 2009 second quarter. The reported gain on sale of products for the 2008 second quarter was $560,000 and primarily relates to the receipt of an additional milestone payment resulting from the sale in a prior year of the worldwide rights for *Nipent*® (pentostatin for injection) to Mayne Pharma (acquired by Hospira, Inc. in February 2007).

Loss from operations for the 2009 second quarter was $2.7 million compared with a loss from operations of $2.3 million for the same prior year period. The Company reported a net loss for the 2009 second quarter of $2.4 million, or $0.04 per basic and diluted share, compared with a net loss of $4.9 million, or $0.08 per basic and diluted share, for the same prior year period. The net loss for the 2008 second quarter includes a non-operating charge of $3.1 million that reflects an other than temporary decline in value in the Company’s equity investment in AVI BioPharma. There was no similar non-operating charge in the 2009 second quarter.

Total revenues for the six months ended June 30, 2009 were $18.9 million, compared with $16.3 million for the same prior year period. Total revenues for the six months ended June 30, 2009 and 2008 consisted entirely of royalty revenue. Royalty revenue is earned pursuant to the license agreement entered into with MGI PHARMA. The Company recognizes royalty revenue when it is received.

Excluding gain on sale of products, total operating expenses for the six months ended June 30, 2009 were $18.3 million, compared with $22.0 million for the same prior year period. The primary reasons for the decrease in operating expenses for the six months ended June 30, 2009 were lower research and development costs due to a shift in the timing of costs incurred for product development activities and a reduction in general and administrative expenses due to lower general corporate expenses and the elimination of costs resulting from the cessation of our European operations in the prior year. Stock-based compensation expense, which is included in operating expenses, was $1.1 million for the six months ended June 30, 2009, compared with $1.4 million for the same prior year period.

The reported gain on sale of products for the six months ended June 30, 2009 was $500,000 compared to $1.6 million for the same prior year period. The gain on sale of products for both periods primarily relate to the receipt of additional payments

resulting from the sale of the worldwide rights for *Nipent* to Mayne Pharma (acquired by Hospira, Inc. in February 2007) in a prior year.

Income from operations for the six months ended June 30, 2009 was $1.1 million compared with a loss from operations of $4.2 million for the same prior year period. The Company reported net income for the six months ended June 30, 2009 of $1.6 million, or $0.03 per basic and diluted share, compared with a net loss of $5.9 million, or $0.10 per basic and diluted share, for the same prior year period. The net loss for the six months ended June 30, 2008 included a non-operating charge of $3.1 million that reflects an other than temporary decline in value in the Company's equity investments. There was no similar non-operating charge for the six months ended June 30, 2009.

As of June 30, 2009, the Company had approximately $91.1 million in unrestricted cash, cash equivalents and current and non-current marketable securities compared to $91.8 million at March 31, 2009.

2009 Revised Financial Guidance

The revised annual financial guidance for 2009 is as follows:

- Anticipated royalty revenue remains unchanged from our prior guidance and is expected to be in a range from $38 million to $42 million.
- Research and development expenses have been revised downward from our prior guidance, to a range from $35 million to $37 million. Research and development expenses continue to be influenced by costs related to current and anticipated clinical trial programs, including MP-470 and SGI-1776, in addition to ongoing product development efforts.
- General and administrative expenses have been reduced further from our prior guidance to a range from $9.0 million to $9.5 million.
- During 2009, no additional gain on sale of products resulting from the previous sale of our commercial business is anticipated beyond the $500,000 already received during the 2009 first quarter.
- The revision to our financial guidance results in a further reduction to the anticipated annual net loss from our prior guidance and is now expected to be in a range from $3.0 million to $4.5 million.
- Included in total operating expenses are non-cash stock-based compensation expenses now estimated at $2.75 million. Excluding the non-cash expenses from the estimated net loss for 2009, the adjusted net loss results in a basic non-GAAP cash burn in a range from $250,000 to $1.75 million.
- The Company continues to remain debt-free and does not plan to access the capital markets for operational purposes during 2009.
- Average annual shares outstanding remain unchanged from our prior guidance and are expected to be approximately 59.2 million common shares.

Recent Corporate News:

April 2009: The Company highlighted data from several developmental programs at the 100th Annual Meeting of the American Association for Cancer Research (AACR) which took place April 18 – 22, 2009 in Denver, Colorado. Data concerning the PIM kinase inhibitor SGI-1776 was presented in oral and poster presentations as well as a poster presentation of the new, first-in-class inhibitors of Etk.

An oral presentation (Abstract No. 2013) held on Monday, April 20th, entitled *"Discovery of SGI-1776, a potent and selective PIM-1 kinase inhibitor,"* discussed SGI-1776 development strategies for potency and selectivity against the PIM-1 kinase, for which a first-in-human study was recently initiated in patients with hormone and docetaxel refractory prostate cancer and relapsed/refractory non-Hodgkin's lymphoma.

A poster presentation (Abstract No. 3743) entitled *"SGI-1776: A novel PIM kinase inhibitor with potent preclinical activity against Acute Myeloid Leukemia (AML)"* discussed preclinical results of low nanomolar concentrations of SGI-1776 potently diminishing cell viability in human AML cell lines. SGI-1776 inhibited tumor growth significantly more effectively in xenograft models than administration of standard of care agents cytarabine and daunorubicin. A follow on Phase I AML trial is planned to be initiated later this year, or early next year, after the first few cohorts of patients have been treated in the current Phase I lymphoma and prostate trial.

The Company also announced at AACR that it has identified a new class of small molecules which successfully inhibit Etk kinase in preclinical cancer models (Abstract No. 3745). Entitled *"Targeting Etk/Bmx kinase with small molecule inhibitors,"* the poster highlighted data indicating that our lead compounds in this class inhibit the autophosphorylation of Etk, the activation of

STAT3 downstream of EGF stimulation, and inhibit the colony formation of prostate and liver cancer cells lines in soft agar.

May 2009: The Company announced that Phase Ib data for MP-470, its multi-targeted, tyrosine kinase inhibitor and RAD51 suppressor, demonstrated an overall clinical benefit rate of 54 percent when the drug is given in combination with standard of care (SOC) anti-cancer therapies in patients with non-small cell lung cancer (NSCLC) and small-cell lung cancer (SCLC) who had previously failed other treatments. The data was presented at a poster session during May 2009 at the European Multidisciplinary Conference in Thoracic Oncology (EMCTO) in Lugano, Switzerland.

The Phase Ib dose escalation study enrolled thirteen poor prognosis patients: nine with NSCLC and four with SCLC as of August 31, 2008. Of eleven evaluable patients, only one showed progressive disease, five showed stable disease, and five showed partial response by RECIST criteria. MP-470 did not alter the pharmacokinetics of SOC agents.

The primary objectives were to estimate the maximum tolerated dose (MTD) in combination with SOC regimens, as well as define safety profiles of specific MP-470 combinations. Secondary objectives included estimating the therapeutic response rate by RECIST criteria, and defining the effect of MP-470 on the PK profile of SOC. MP-470 doses were started at 100 mg orally once per day, increasing to twice daily dosing based on the modified Fibonacci sequence. The MTDs have not been reached and no dose limiting toxicities have been identified.

July 2009: The Company announced the addition of Mohammad Azab, M.D., M Sc, MBA to the management team as Chief Medical Officer. With more than 20 years of experience in worldwide drug development, clinical research, and medical affairs, resulting in eight approved drugs, including six in oncology, Dr. Azab brings extensive international development and translational medicine expertise to SuperGen. Dr. Azab will manage SuperGen's clinical development strategy, clinical operations, regulatory affairs, quality, and safety departments to advance the Company's oncology product portfolio from discovery through clinical Proof of Concept.

Conference Call Information

SuperGen will host a conference call to discuss the results of the 2009 second quarter financial results today at 1:30 p.m. PT / 4:30 p.m. ET. A live webcast of the conference call is accessible via the investor relations section of the Company's web site at http://www.supergen.com. A webcast replay of the conference call will be available for 90 days.

About SuperGen

Based in Dublin, California, SuperGen is a pharmaceutical company dedicated to the discovery and development of novel cancer therapies. SuperGen is developing a number of therapeutic anticancer products focused on kinase and cell signaling inhibitors and DNA methyltransferase inhibitors. For more information about SuperGen, please visit http://www.supergen.com.

Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of Section 21A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created thereby. The actual results could differ materially from those projected in the forward-looking statements as a result of a number of risks and uncertainties. These forward-looking statements include statements regarding SuperGen's expectations regarding the various abilities of MP-470, including its Phase I and multi-arm Phase Ib clinical trial, expectations regarding the various abilities of SGI-1776, expectations about SuperGen's ability to remain debt-free and to avoid accessing the capital markets for fund-raising in this fiscal year, expectations about increases in royalty revenue, gains from sales of non-core assets, decreases in certain operating expenses, increases in research and development expenses, estimates of the 2009 net loss, expectations that SuperGen will receive the balance of the purchase price for *Nipent* from Mayne Pharma, as well as SuperGen's expectations and successful development of all its pipeline products. Important factors that could cause actual results to differ materially from the expectations reflected in the forward-looking statements include, but are not limited to, the ability of Eisai to generate global sales of *Dacogen*, risks and uncertainties related to the achievement of developmental milestones with respect to the compounds acquired in the Montigen acquisition, the research and development of MP-470 and SGI-1776, and the satisfaction of the contingencies related to the sale of the worldwide rights to *Nipent* to Mayne Pharma. In general, our future success is dependent upon numerous factors, including our ability to generate pre-clinical development candidates for selection into clinical testing, obtaining regulatory approval of product development programs, conducting and completing clinical trials and obtaining regulatory approval of our products and product candidates, and creating opportunities for future commercialization of compounds. Our future revenue and operating and net income or loss could be worse than anticipated if demand for our products is less than expected, or if the introduction of new products is delayed, for any reason, including regulatory delay. References made to the discussion of risk factors are detailed in the Company's filings with the Securities and Exchange Commission including reports on its most recently filed Form 10-K and Form 10-Q. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update or revise the information contained in any such forward-looking statements, whether as a result of new information, future events or otherwise.

Consolidated Statements of Operations and Balance Sheets to follow

SUPERGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six months ended June 30,	
	2009	**2008**	**2009**	**2008**
Revenues:				
Royalty revenue	$ 6,011	$ 8,133	$ 18,925	$ 16,271
Total revenues	6,011	8,133	18,925	16,271
Operating expenses:				
Research and development	6,756	7,740	14,091	15,687
General and administrative	1,984	3,273	4,209	6,350
Gain on sale of products	-	(560)	(500)	(1,560)
Total operating expenses	8,740	10,453	17,800	20,477
Income (loss) from operations	(2,729)	(2,320)	1,125	(4,206)
Interest income	187	497	458	1,303
Other than temporary decline in value of investments	-	(3,052)	-	(3,055)
Other income (expense)	-	(4)	-	9
Income (loss) before income tax benefit (provision)	(2,542)	(4,879)	1,583	(5,949)
Income tax benefit (provision)	115	-	(15)	-
Net income (loss)	$ (2,427)	$ (4,879)	$ 1,568	$ (5,949)
Net income (loss) per common share:				

Basic				
	$ (0.04)	$ (0.08)	$ 0.03	$ (0.10)
Diluted				
	$ (0.04)	$ (0.08)	$ 0.03	$ (0.10)
Weighted average shares outstanding:				
Basic				
	59,106	57,542	59,095	57,531
Diluted				
	59,106	57,542	59,102	57,531

SUPERGEN, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	June 30, 2009 (Unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,088	$ 48,908
Marketable securities	64,150	37,787
Prepaid expenses and other current assets	1,408	1,307
Total current assets	88,646	88,002
Marketable securities, non-current	3,893	1,617
Property, plant and equipment, net	4,652	4,437
Goodwill	731	731
Other intangibles, net	-	106
Restricted cash	2,268	2,367
Other assets	505	505
Total assets	$ 100,695	$ 97,765
LIABILITIES & STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable		
	$ 1,775	$ 2,614
Accrued liabilities	357	422
Payable to AVI BioPharma	565	565
Deferred gain on sale of products to Hospira, Inc.	125	125
Deferred rent	332	287
Accrued payroll and employee benefits		
	2,065	2,903
Total current liabilities	5,219	6,916
Deferred rent, non-current		
	176	358
Total liabilities	5,395	7,274
Total stockholders' equity		
	95,300	90,491
Total liabilities and stockholders' equity	$ 100,695	$ 97,765

Source: SuperGen, Inc.

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